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## Part II

### Department of Health and Human Services

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Food and Drug Administration

21 CFR Parts 1, 11, and 111

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Final Rule

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 1, 11, and 111

[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:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is adopting a regulation on foreign supplier verification programs (FSVPs) for importers of food for humans and animals. The regulation requires importers to verify that food they import into the United States is produced in compliance with the hazard analysis and risk-based preventive controls and standards for produce safety provisions 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 issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA). The regulation will help ensure the safety of imported food.

**DATES:** This rule is effective January 26, 2016. For the applicable compliance dates, see “Effective and Compliance Dates” in the **SUPPLEMENTARY INFORMATION** section of this document.

**ADDRESSES:** 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 final rule 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.

**FOR FURTHER INFORMATION CONTACT:** Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4614; or Domenic Veneziano, Office of Enforcement and Import Operations (ELEM-3108), Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, 301-796-6673.

#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

Executive Summary  
Purpose and Coverage of the Rule

- Summary of the Major Provisions of the Final Rule
- Modified Provisions for Certain Types of Importers
- Costs and Benefits
- I. Background
  - A. FDA Food Safety Modernization Act
  - B. Stages in the FSVP Rulemaking
  - C. Summary of the Major Provisions of the Proposed Rule
  - D. Public Comments
- II. Legal Authority
- III. Comments on the Proposed Rule and Supplemental Notice of Proposed Rulemaking
  - A. Definitions (§ 1.500)
  - B. Applicability and Exemptions (§ 1.501)
  - C. Purpose and Scope of FSVPs (§ 1.502)
  - D. Personnel Developing and Performing FSVP Activities (§ 1.503)
  - E. Hazard Analysis (§ 1.504)
  - F. Evaluation for Foreign Supplier Approval and Verification (§ 1.505)
  - G. Foreign Supplier Verification Activities (§ 1.506)
  - H. Foods That Cannot Be Consumed Without Control of Hazards and Foods Whose Hazards Are Controlled After Importation (§ 1.507)
  - I. Corrective Actions and Investigations Into FSVP Adequacy (§ 1.508)
  - J. Identification of Importer at Entry (§ 1.509)
  - K. Records (§ 1.510)
  - L. Dietary Supplements and Dietary Supplement Components (§ 1.511)
  - M. Very Small Importers and Importers of Food From Certain Small Foreign Suppliers (§ 1.512)
  - N. Importing a Food From a Foreign Supplier in a Country With an Officially Recognized or Equivalent Food Safety System (§ 1.513)
  - O. Consequences of Failure To Comply With FSVP Requirements (§ 1.514)
  - P. Other Issues
- IV. Effective and Compliance Dates
  - A. Effective Date
  - B. Compliance Dates
- V. Executive Order 13175
- VI. Economic Analysis of Impacts
- VII. Analysis of Environmental Impact
- VIII. Paperwork Reduction Act of 1995
- IX. Federalism
- X. References

#### Executive Summary

##### Purpose and Coverage of the Rule

This rule is part of FDA’s implementation of the FDA Food Safety Modernization Act (FSMA), which intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This rule adopts provisions concerning FSVPs that importers must create and follow to help ensure the safety of imported food. The regulation is designed to be flexible based on risk, and the requirements 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 rule requires importers to implement FSVPs to 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.

This rule is the result of significant stakeholder engagement. We took this approach to help ensure that the rule achieves its public health goal, reflects industry practice, and strikes the right balance between flexibility and accountability.

##### Summary of the Major Provisions of the Final Rule

We are finalizing a flexible, risk-based approach to foreign supplier verification. The FSVP regulation focuses on known or reasonably foreseeable food safety hazards, identified and considered through a hazard analysis and evaluation process, rather than all adulteration covered by the adulteration provisions in section 402 of the FD&C Act. After considering the comments on the proposed rule and the subsequently revised proposal along with other stakeholder input, we continue to believe that hazard analysis, which is well accepted and understood throughout the international food safety community, provides the most effective way to implement a risk-based framework in which importers can evaluate potential products and suppliers and ensure that appropriate verification activities occur.

The FSVP regulation aligns with key components of the food safety plans that facilities that manufacture, process, pack, or hold must establish and follow under FDA’s recently issued regulations on current good manufacturing practice (CGMP) and hazard analysis and risk-based preventive controls for human food and animal food (preventive controls regulations). In particular, the FSVP final rule is consistent with the supply-chain program provisions of those regulations to the extent feasible and appropriate. The general FSVP framework, together with the modified

requirements applicable to certain importers and foods, are intended to be sufficiently general and flexible to apply to a variety of circumstances without being unduly burdensome or restrictive of trade.

Although FSVP requirements apply to most imported food under FDA's regulatory jurisdiction, certain categories of imported food are not covered under the FSVP regulation. These exemptions include certain juice, fish, and fishery products (which are already subject to verification under FDA's hazard analysis and critical control point (HACCP) regulations for those products), food for research or evaluation, food for personal consumption, alcoholic beverages, food that is transshipped, food imported for processing and future export, food exported from and returned to the United States without manufacturing/processing in a foreign country, and certain meat, poultry, and egg products regulated by the U.S. Department of Agriculture (USDA).

In the final rule, we have added new provisions to allow greater flexibility with respect to certain requirements to better reflect modern food supply and distribution chains. Under the FSVP regulation, importers are responsible for:

1. Determining the hazards reasonably likely to cause illness or injury with each food. Importers can conduct their own analysis of the potential hazards with a food or review and assess a hazard analysis conducted by another entity.

2. Evaluating the risk posed by a food, using the results of the hazard analysis, and evaluating the foreign supplier's performance. This evaluation informs the approval of foreign suppliers and the determination of appropriate supplier verification activities. An importer may rely on another entity to conduct this evaluation and to determine the appropriate supplier verification activities as long as the importer reviews and assesses the evaluation, determination, or both, as applicable. An importer must approve its own foreign suppliers.

3. Conducting supplier verification activities. In general, importers must establish and follow written procedures to ensure they only import foods from foreign suppliers they have approved. However, importers may import food from unapproved foreign suppliers, on a temporary basis when necessary and appropriate, if they subject the food from these suppliers to adequate verification activities before importing it.

Importers are responsible for determining and documenting foreign supplier verification activities (as well as the frequency with which those activities must be conducted) that are appropriate to provide assurance that hazards requiring a control in food are significantly minimized or prevented. Importers must conduct supplier verification activities for each foreign supplier before importing a food into the United States and periodically thereafter. An importer may determine, document, and conduct these activities itself or may rely on other entities to perform those tasks, as long as the importer reviews and assesses the relevant documentation, including the results of supplier verification activities.

The appropriate verification activities and their frequency will vary depending on the food, the foreign supplier, and the nature of the control. Appropriate verification activities include: onsite auditing, sampling and testing of a food, review of the foreign supplier's relevant food safety records, and other activities that are appropriate based on the evaluation of the risk posed by the food and foreign supplier performance.

When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the default appropriate verification activity under the regulation is an annual onsite audit of the foreign supplier. To provide flexibility even in these circumstances, the rule allows for the performance of a different supplier verification activity and/or less frequent onsite auditing provided an adequate written determination is made that the other approach will meet the public health purpose of supplier verification.

4. Performing appropriate activities in other circumstances. The final rule also adds flexibility and recognizes the reality of modern distribution chains by not requiring an importer to conduct supplier verification (or evaluate the risk posed by a food and the foreign supplier's performance) when the hazard requiring a control in a food will be controlled by a subsequent entity in the distribution chain in the United States. For example, if an importer's customer will control the hazard, the importer can rely on its customer to provide written assurance that the food will be processed for food safety and must disclose that the food has not been processed to control the identified hazard. If the hazard will be controlled by a subsequent entity in the distribution chain, the final rule requires disclosure that the food has not

been processed to control the identified hazard as well as a series of written assurances starting with assurances from the customer to the importer and continuing the obligation to provide written assurance of processing for food safety throughout the distribution chain. We also have provided flexibility for an importer to establish, document, and implement an alternative system that ensures adequate control, at a later distribution step, of the hazards in a food product distributed by a manufacturing/processing facility.

5. Conducting corrective actions. An importer must take appropriate corrective actions promptly if it determines that a foreign supplier of a food it imports does not produce the food in compliance with the 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) (if applicable) of the FD&C Act. This determination could be based on a review of consumer, customer, or other complaints related to food safety, verification activities, or other information. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the problem is resolved.

6. Identifying themselves as the importer of the food for each line of food product offered for importation into the United States.

7. Retaining records of FSVP activities.

#### *Modified Provisions for Certain Types of Importers*

The rule provides several exceptions to the standard FSVP requirements for certain types of importers. First, for dietary supplements and dietary supplement components, importers who establish and verify compliance with certain specifications (concerning dietary supplement components and packaging) under the dietary supplement CGMP regulations will not be required to comply with most of the standard FSVP requirements, including hazard analysis and standard supplier verification activities. The same exception 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. In contrast, importers of other dietary supplements would be required to comply with most of the standard FSVP requirements but 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 regulation, rather than verifying that hazards requiring a control are significantly minimized or prevented, as required under the standard supplier verification activity provisions.

Second, the rule establishes modified FSVP requirements for very small importers and importers of food from certain small foreign suppliers. We have aligned the definition of “very small importer” with the definitions of “very small business” under the regulations on preventive controls for human food and animal food. With respect to the importation of human food, the definition of very small importer has an annual sales ceiling of \$1,000,000, which is consistent with the \$1,000,000 annual sales ceiling for a very small business under the preventive controls for human food regulation. With respect to the importation of animal food, the definition of very small importer has an annual sales ceiling of \$2,500,000, which is consistent with the \$2,500,000 annual sales ceiling for a very small business under the preventive controls for animal food regulation.

In addition, food from three types of small foreign suppliers is not subject to standard supplier verification requirements. Those foreign suppliers are: (1) Qualified facilities under either of the preventive controls regulations, (2) farms that are not “covered farms” under the produce safety regulation in part 112 (21 CFR part 112) in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, and (3) shell egg producers not subject to part 118 (21 CFR part 118) because the shell egg producer has fewer than 3,000 laying hens. Each of these types

of producers is either exempt from their underlying FDA food safety regulations or subject to modified requirements, mostly, and in some cases entirely, because of the size of these producers.

The relatively small volume of food imported by and from these entities should reduce consumers’ exposure to, and potential risk from, this imported food. Therefore, we are proposing that in these situations the importer would not be required to conduct a hazard analysis and would be able to verify their foreign suppliers by obtaining written assurance of their supplier’s compliance with the applicable food safety regulations (or, in some cases, the supplier’s acknowledgement that it is subject to the adulteration provisions of the FD&C Act). This policy is similarly reflected in the supply-chain program provisions of the preventive controls regulations.

Third, the rule excludes from most of the standard FSVP requirements (including hazard analysis and verification that identified hazards are significantly minimized or prevented) certain types of 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 the relevant official recognition or equivalency determination;
- The importer determines that the foreign supplier of the food is in good compliance standing with the relevant food safety authority; and
- The food is not intended for further processing in the United States, *e.g.*, packaged food products and raw agricultural commodities (RACs) that will not be processed further before consumption.

These provisions are consistent with our risk-based approach to foreign supplier verification because they enable both importers and FDA to leverage the regulatory efforts of food safety authorities in countries the Agency has officially determined to have food safety systems that are comparable or equivalent to that of the United States.

#### *Costs and Benefits*

This final rule requires importers of human and animal food to establish foreign supplier verification programs. It includes requirements regarding use of qualified individuals, evaluation of hazards in food and foreign supplier performance, verification of suppliers (through activities such as onsite audits, testing, and records review), and importer identification at entry. The total annualized costs of the final rule are estimated to be approximately \$435 million per year under 3 percent and 7 percent discount rates over 10 years. In the proposed rule’s Preliminary Regulatory Impact Analysis (PRIA), we calculated costs under three different scenarios reflecting different percentages of importers who, under proposed Option 2 for supplier verification requirements, might choose to conduct onsite audits of their foreign suppliers rather than perform different permitted verification activities. We present the Scenario 1 estimate (under which 63 percent of the importers we estimated would need to conduct mandatory onsite audits of their foreign suppliers under proposed Option 1 would conduct onsite audits under the final rule) as the overall estimate to facilitate comparison with the summary tables in the PRIA and the Supplemental PRIA; however, the summary table provides totals costs under all three scenarios.

#### TOTAL ANNUAL COST SUMMARY FOR ALL ELEMENTS OF FINAL RULE

[Rounded to nearest million]

	Total
<b>Year 1</b>	
Hiring Qualified Individuals:	
Scenario 1 .....	\$34
Scenario 2 .....	33
Scenario 3 .....	32
Conducting Information Collection and Food and Supplier Evaluations .....	89
Writing and Maintaining Procedures Relating to Verification Requirements .....	51
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Receipt of Food From Approved Suppliers:	
Scenario 1 .....	245
Scenario 2 .....	241
Scenario 3 .....	237
Obtaining Written Assurances From Foreign Suppliers, Customers, and Other Entities in U.S. Distribution .....	31
Documenting Very Small Importer or Small Supplier Status .....	6
Conducting Corrective Actions .....	1

## TOTAL ANNUAL COST SUMMARY FOR ALL ELEMENTS OF FINAL RULE—Continued

[Rounded to nearest million]

	Total
Importer Identification .....	7
Grand Total Year 1:	
Scenario 1 .....	464
Scenario 2 .....	459
Scenario 3 .....	456
<b>Every Year After Year 1</b>	
Hiring Qualified Individuals:	
Scenario 1 .....	34
Scenario 2 .....	33
Scenario 3 .....	32
Conducting Information Collection and Food and Supplier Evaluations .....	74
Writing and Maintaining Procedures Relating to Verification Requirements .....	42
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Receipt of Food From Approved Suppliers:	
Scenario 1 .....	245
Scenario 2 .....	241
Scenario 3 .....	237
Obtaining Written Assurances From Foreign Suppliers, Customers, and Other Entities in U.S. Distribution .....	23
Documenting Very Small Importer or Small Supplier Status .....	6
Conducting Corrective Actions .....	1
Importer Identification .....	7
Grand Total Every Year After Year 1:	
Scenario 1 .....	431
Scenario 2 .....	426
Scenario 3 .....	422

Although the FSVP regulation does not establish safety requirements for food manufacturing and processing, it benefits the public health by helping to ensure that imported food is produced in a manner consistent with other applicable food safety regulations. The Regulatory Impact Analyses for the final rules on preventive controls for human food and standards for produce safety consider and analyze the number of illnesses and deaths that those 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 FSVP regulation will be an important mechanism for improving and helping to ensure compliance with the above-noted food safety regulations as they apply to imported food. For this reason,

and because we do not have sufficient data to determine the extent to which particular regulations might be responsible for the expected reduction in foodborne illnesses resulting from the FSMA final rules, we account for the public health benefits of the FSVP regulation in the preventive controls, produce safety, and other applicable food safety regulations instead of in this final rule.

### I. Background

#### A. FDA Food Safety Modernization Act

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety

problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to problems when they occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in Table 1 and requested comments on all aspects of these proposed rules.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 preventive controls for human food proposed rule.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 produce safety proposed rule ....	78 FR 3504, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 preventive controls for animal food proposed rule.	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.	2013 FSVP proposed rule .....	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 third-party certification proposed rule.	78 FR 45782, July 29, 2013.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA—Continued

Title	Abbreviation	Publication
Focused Mitigation Strategies to Protect Food Against Intentional Adulteration.	2013 intentional adulteration proposed rule.	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food .....	2014 sanitary transportation proposed rule.	79 FR 7006, February 5, 2014.

We also issued a supplemental notice of proposed rulemaking for the rules listed in Table 2 and requested comments on specific issues identified in each supplemental notice.

TABLE 2—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 preventive controls for human food supplemental notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 produce safety supplemental notice.	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 preventive controls for animal food supplemental notice.	79 FR 58476, September 29, 2014.
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.	2014 FSVP supplemental notice .....	79 FR 58574, September 29, 2014.

We finalized two of the foundational rulemakings listed in Table 3 in September 2015.

TABLE 3—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	Preventive controls for human food final rule.	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	Preventive controls for animal food final rule.	80 FR 56170, September 17, 2015.

As we finalize these seven foundational rulemakings, we are putting in place a modern framework for food safety that brings to bear the most current science on the regulation of food safety, is risk-based and focuses efforts on known or reasonably foreseeable hazards, and is flexible and practical given existing food safety practices. To achieve this, we have engaged in extensive outreach to the stakeholder community to find the right balance of flexibility and accountability in this regulation.

Since FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Refs. 1–3). As a result of this stakeholder dialogue, we decided to issue the four supplemental notices of proposed rulemaking to announce several changes to our proposals, share our current thinking on key issues, and

get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in food safety. We believe these seven foundational final rules will effectively implement the paradigm shift toward prevention envisioned in FSMA and be a major step forward for food safety that will help protect consumers into the future.

*B. Stages in the FSVP Rulemaking*

Section 301 of FSMA added 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. Section 805(c) of the FD&C Act directs FDA to issue regulations on the content of FSVPs.

We published a proposed rule on FSVPs in 2013 (78 FR 45730, July 29,

2013). We published new and revised provisions in a 2014 supplemental notice of proposed rulemaking (Supplemental Notice) (79 FR 58574, September 29, 2014). In the Supplemental Notice, we reopened the comment period on the proposed rule only with respect to specific proposed provisions. In addition, we emphasized that the revised provisions we included in the regulatory text were based on a preliminary review of the comments.

In this document, we use the terms “FSVP proposed regulations” or “proposed rule” to refer to the complete proposed regulatory text, including both the proposed provisions we published in the 2013 proposed rule and the new and revised provisions we published in the 2014 Supplemental Notice. We use the terms “2013 FSVP proposed rule” and “Supplemental Notice” to refer to specific text published in those documents. We use the terms “FSVP regulation,” “final rule,” and “this rule” to refer to the regulation we are establishing as a result of this

rulemaking. We also use the term “preventive controls regulations” to refer to the regulations on preventive controls for human food and preventive controls for animal food collectively.

### *C. Summary of the Major Provisions of the Proposed Rule*

The proposed FSVP regulation, set forth in proposed subpart L of part 1 (21 CFR part 1), 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 regulation was intended to work in tandem with 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 preventive and risk-based approach that assigns to the food industry the primary responsibility for food safety. For example, FSMA requires food facilities that manufacture, process, pack, or hold food to implement risk-based preventive controls (in section 103 of FSMA, codified in section 418 of the FD&C Act (21 U.S.C. 350g)), with certain exceptions. FSMA also requires FDA to establish science-based, minimum standards for farms that grow, harvest, pack, and hold certain produce, also with certain exceptions (in section 105 of FSMA, codified in section 419 of the FD&C Act (21 U.S.C. 350h)). The intent of these requirements is to ensure that all segments of the food industry meet their responsibilities under the FD&C Act to produce safe food.

While FSMA grants FDA additional enforcement tools and directs the Agency to increase its inspections of food facilities, Congress determined that more was needed to adequately control the safety risks posed by imported food. Thus, FSMA creates new obligations for food importers. The FSVP proposed regulation was intended to ensure that importers take responsibility for the safety of the food they import into the United States so no food safety gaps exist between foreign producers and U.S. consumers.

Through this and other FSMA regulations, we are establishing a modern, risk-based food safety system designed to hold those in the food safety supply chain accountable for meeting their responsibilities. In doing so, we recognize the variability within the food industry of the size of operations and the type and volume of foods produced. Therefore, we have written regulations that provide a flexible approach to food

safety, taking into account the risk posed by the food and the size of the regulated businesses. While these regulations establish strong, risk-based food safety standards, they allow firms flexibility in determining how they will meet these standards, as appropriate.

In accordance with FSMA, the FSVP regulation we proposed would require food importers to adopt programs to ensure that the food they import: (1) Is produced in a manner that provides the same level of public health protection as required under section 418 or 419 of the FD&C Act, as appropriate; (2) is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and (3) is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning allergen labeling). The proposed rule would require importers to take the following actions as part of their FSVPs:

- Use a qualified individual to perform most FSVP activities;
- Analyze known or reasonably foreseeable hazards in foods they import to determine if the hazards are significant;
- Determine and perform verification activities for foods they import, based on the hazard analysis and an evaluation of supplier risks;
- Establish and follow procedures to ensure they import foods only from foreign suppliers they have approved (except, when necessary and appropriate, from unapproved suppliers on a temporary basis);
- Review complaints, conduct investigations of adulterated or misbranded food, take corrective actions when appropriate, and modify the FSVP when it is determined to be inadequate;
- Reassess the effectiveness of the FSVP;
- Ensure that information identifying the importer is submitted upon entry of a food into the United States; and
- Maintain records of FSVP procedures and activities.

In addition to these “standard” FSVP requirements that would apply to most food importers, the proposed rule included modified requirements for the following:

- Importers of dietary supplements and dietary supplement components;
- Very small importers and importers of food from very small suppliers; and
- Importers of food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to the U.S. food safety system.

### *D. Public Comments*

We received more than 300 public submissions on the 2013 FSVP proposed rule and more than 100 public submissions on the 2014 Supplemental Notice, each containing one or more comments on various aspects of the proposal. We received submissions from diverse members of the public, including the following: Importers; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress; Federal, State, local, and tribal Government Agencies; foreign governments; and other organizations. The comments address virtually every provision of the FSVP proposed rule. In the remainder of this document, we describe these comments, respond to them, and explain any changes we made to the proposed regulation.

Some comments address issues that are outside the scope of this rulemaking. For example, we received comments asking that we increase the frequency and standardization of our inspection of foreign food facilities, improve our entry review procedures, and revise the Reportable Food Registry. We do not discuss such comments in this document.

### **II. Legal Authority**

On January 4, 2011, FSMA was signed into law. Section 301 of FSMA added section 805 to the FD&C Act 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, as appropriate; (2) the food is not adulterated under section 402 of the FD&C Act; and (3) the food is not misbranded under section 403(w) of the FD&C Act (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 must require that the FSVP of each importer is 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 section 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 must 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(d) states that records of an importer related to a foreign supplier verification program must be maintained for a period of not less than 2 years and must be made available promptly to a duly authorized representative of the Secretary of the Department of Health and Human Services (the Secretary) upon request. Section 805(g) directs FDA to publish and maintain a list of importers participating under section 805 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 must 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 to issue this regulation, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. Also, some aspects of the FSVP regulation are supported by section 421(b) of the FD&C Act (21 U.S.C. 350j(b)).

In addition to the FD&C Act, FDA's legal authority for some aspects of the regulations derives from the Public Health Service Act (PHS Act) to the extent such measures are related to

communicable disease. Authority under the PHS Act is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States \* \* \* or from one State \* \* \* into any other State" (section 361(a) of the PHS Act) (see section 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary).

### III. Comments on the Proposed Rule and Supplemental Notice of Proposed Rulemaking

#### A. Definitions (§ 1.500)

We proposed to codify definitions of several terms that we use in the FSVP regulation. As discussed in the following paragraphs, we have revised several of the proposed definitions in response to comments we received. The definitions for terms used in the FSVP regulation are set forth in § 1.500.

##### 1. Definitions Generally

(Comment 1) Some comments suggest that we use the same definition for terms used in different FSMA rulemakings.

(Response 1) We agree and have aligned the definitions used in the different regulations as much as possible. However, in some cases the definitions of terms differ because of differences in the applicable statutory provisions or in the scope or purpose of the regulations.

##### 2. Audit

We proposed to 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.

On our own initiative, we have changed the definition to refer to an "audited entity" rather than a "foreign supplier" because in some cases an importer might conduct (or rely on the results of) an onsite audit of an entity other than the foreign supplier (such as a foreign supplier's supplier) to meet FSVP requirements. In addition, consistent with auditing practice we have added discussions with employees of the audited entity to the list of activities that might be included in an audit.

(Comment 2) One comment recommends that we interpret an "independent" examination as including audits other than third-party audits, such as audits conducted by the importer or the importer's customer.

(Response 2) To the extent the comment is requesting that the definition of the term "audit" allow an importer to rely on an audit conducted by the importer itself, we agree. To the extent, however, the comment is requesting that there be no requirements for the independence of auditors, we disagree. Any qualified auditor conducting an audit relied upon by an importer would need to meet the requirements for independence set forth in § 1.506(e)(4), discussed in section III.G.7 of this document. Note, however, that under § 1.506(e)(2)(i) an importer cannot rely on a supplier's self-audit to fulfill the importer's requirement to conduct supplier verification under § 1.506 (because the supplier would have an inherent conflict of interest regarding the audit results).

(Comment 3) One comment requests that sampling and laboratory analysis not be specified as a potential component of an audit because they are separate verification activities.

(Response 3) While sampling and laboratory analysis might in some instances be conducted instead of an audit or other verification activities, we do not agree that sampling and laboratory analysis cannot also be included as a component of an audit. A qualified auditor might reasonably determine that it is appropriate to include some sampling and testing of a food or raw material or other ingredient as part of an onsite audit of a foreign supplier.

##### 3. Environmental Pathogen

We proposed to define "environmental pathogen" as a pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. The proposed definition also specified that environmental pathogens do not include the spores of pathogenic sporeformers. To provide additional clarity, the final rule specifies in the definition that examples of environmental pathogens include *Listeria monocytogenes* and *Salmonella* spp.

(Comment 4) Some comments suggest that instead of a "pathogen," the definition of environmental pathogen



should refer to “pathogenic bacteria” because the latter term is considered more relevant to protecting food safety.

(Response 4) We do not agree.

Pathogens other than bacteria might be capable of surviving in a manufacturing environment, cause food to be contaminated, and result in foodborne illness.

#### 4. Farm

We are adding a definition of “farm” to the final rule. A “farm” is a farm as defined in § 1.227 (21 CFR 1.227) in the regulation on registration of food facilities.

#### 5. Farm Mixed-Type Facility

We are adding a definition of “farm mixed-type facility” to the final rule. A “farm mixed-type facility” is an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the FD&C Act (21 U.S.C. 350d).

#### 6. Food

We proposed to define “food” as having the meaning given in section 201(f) of the FD&C Act (21 U.S.C. 321(f)), except that food would not include pesticides as defined in 7 U.S.C. 136(u).

(Comment 5) Several comments request that we exclude food contact substances from the definition of food because facilities that manufacture, process, pack, or hold food contact substances are not required to register with FDA and therefore are not subject to the proposed regulations on preventive controls. One comment suggests that we either exclude food packaging from the FSVP regulation or establish modified requirements for packaging.

(Response 5) We do not agree that it is appropriate to exclude food contact substances (including food packaging), as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)), from the definition of “food” for FSVP purposes. The definition of “food” in § 1.227, for the purposes of food facility registration, excludes food contact substances as defined in section 409(h)(6) of the FD&C Act. Consequently, a facility that manufactures/processing, packs, or holds food contact substances is not required to be registered. Because section 418 of the FD&C Act only applies to establishments that are required to register, facilities involved in the manufacturing/processing, packing, and holding of food contact substances are not subject to the preventive control regulations implementing section 418. Section 805 of the FD&C Act, however,

is not similarly limited to facilities that are required to register. Instead, section 805 applies to imports of “food.” The term “food” is defined in section 201(f)(3) of the FD&C Act to include articles used as components of food, and the case law interpreting the definition makes clear that many substances that meet the definition of food contact substances under section 409(h)(6) of the FD&C Act also meet the definition of food (see, e.g., *Natick Paperboard v. Weinberger*, 525 F.2d 1103 (1st Cir. 1975) (paperboard containing PCBs intended for food use is adulterated food); *U.S. v. Articles of Food 688 Cases of Pottery (Cathy Rose)*, 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food)). Further, we do not believe there is any evidence that Congress intended to exclude food contact substances from being considered “food” for purposes of section 805 and the FSVP regulation.

(Comment 6) Several comments request that we add raw materials and other ingredients to the definition of food for clarity and for consistency with the definition of food in the preventive controls regulations.

(Response 6) We conclude that the suggested change is unnecessary because the definition of food in section 201(f) of the FD&C Act, which we are incorporating in the FSVP regulation, defines food as including articles used for components of any such food or drink for man or animals, which includes raw materials and other ingredients.

(Comment 7) One comment states that chemicals used in processing foods (e.g., hydrochloric acid in the production of cheese) that are declared as food-grade most likely will be used in food production but sometimes will not be used for such purposes. The comment asks that we provide guidance on how to address such imported chemicals.

(Response 7) As explained in section III.B.9 of this document, substances such as chemicals that are capable of food and non-food use are subject to the FSVP regulation if they are reasonably likely to be directed to a food use. In the example provided by the comment, the application of the FSVP regulation would not be based solely on whether a substance is declared as food-grade. However, we would consider the fact that the chemical is declared as food-grade in determining whether the chemical is reasonably likely to be directed to a food use.

#### 7. Foreign Supplier

We proposed to define “foreign supplier” as, 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.

In the preamble to the proposed rule, we stated that the proposed definition of foreign supplier was generally consistent with the definition of a foreign facility under the preventive controls section (section 418) of the FD&C Act. However, we stated that the proposed definition of foreign supplier did not include firms that only pack or hold food, with no or de minimis manufacturing/processing (even if the firm is required to register with FDA under section 415 of the FD&C Act) because we tentatively concluded 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 this food, excluding a subsequent registered packer or holder who does not do any significant manufacturing/processing would be consistent with this intent. We also stated that the proposed exclusion from the definition of foreign supplier of any establishment engaging in further manufacturing/processing of a food that consists solely of the addition of labeling or any similar activity of a de minimis nature was consistent with FDA regulations on the registration of foreign food facilities in subpart H of part 1 (see 21 CFR 1.226(a)).

(Comment 8) Several comments oppose the proposed definition of foreign supplier because they believe it would require importers to go more than “one step back” in the supply chain to conduct supplier verification. The comments maintain this would be inconsistent with section 204(d)(1)(L)) of FSMA and the section 414 of the FD&C Act (21 U.S.C. 350c)). The comments assert that, when foods are obtained from entities such as brokers, distributors, and consolidators, rather than the entity that manufactured/processed, raised, or harvested the food, it would be difficult for the importer to know the identity of the producer because the consolidator might refuse to reveal this information due to concern that the importer might decide to buy directly from the producer in the future. The comments also maintain that in these circumstances, particularly with consolidated or commingled RACs, it would be impractical and burdensome to have to conduct supplier verification of the original producer of the food and could result in multiple audits of the

same farm or manufacturer. Therefore, some comments request that we define the foreign supplier as the immediate previous source of an imported food. The comments assert that under this definition, importers would conduct verification activities to assess the supplier's ability to verify that its suppliers (growers or manufacturers) were producing food consistent with U.S. requirements.

(Response 8) Although we understand the concerns related to obtaining food from an entity that did not manufacture/process, raise, or harvest the food, such as distributors, warehouses, and consolidators of RACs, we decline to revise the definition of foreign supplier as suggested. The other FSMA and FD&C Act provisions noted by the comments were enacted to serve different purposes than the FSVP provisions. Section 805(c)(2)(A) of the FD&C Act specifically directs FDA to adopt regulations requiring that each importer's FSVP is adequate to provide assurances that "the foreign supplier to the importer *produces* the imported food" (emphasis added) in compliance with the applicable U.S. standards. Therefore, we conclude that Congress did not intend supplier verification to be conducted for entities that only perform activities of a de minimis nature with respect to the imported food. Consequently, we conclude that it would not be appropriate to define "foreign supplier" so that the importer would be conducting supplier verification of an entity in the supply chain that did not perform any significant processing step, such as distributors and some consolidators of RACs.

However, we understand that the requirement to perform supplier verification on the establishment that manufactures/processes, raises, or grows the imported food could impose a greater burden on importers when the foreign supplier is not the immediate source of the imported food, such as the case with consolidated RACs. To address this concern, we have revised the provisions on hazard analysis, evaluation for foreign supplier approval and verification, and supplier verification activities to allow an importer of a food to obtain information needed to meet certain FSVP requirements from other entities, such as a distributor or consolidator of that food. As discussed in sections III.E.5, III.F.4, and III.G.4 of this document, an importer may review and assess hazard analyses, evaluations of the risk posed by a food and the foreign supplier's performance, determinations of appropriate foreign supplier verification

activities, and results of such activities conducted by other entities for an imported food to meet its FSVP requirements in these areas. We anticipate that many importers will be able to rely on activities conducted by other entities, which will reduce the need for importers to directly verify the compliance of producers from which the importers did not directly purchase the imported food. We conclude that this approach to foreign supplier verification ensures that the FSVP requirements are consistent with FSMA while limiting the burden that otherwise might be imposed on importers when the foreign supplier of a food is not the importer's direct source for the food.

(Comment 9) One comment states that firms that pack or hold food products (other than of de minimis value) could introduce hazards during these operations. The comment maintains that the proposed definition of foreign supplier conflicts with the definition of facility in the FD&C Act and appears contrary to the intent of ensuring the safety of imported food. One comment asks that we revise the definition of foreign supplier to clarify that, in addition to an entity that harvests a food, a foreign supplier might be the establishment that owns (or owns and packs) a harvested food.

(Response 9) We decline to change the definition of foreign supplier to include entities that only own, pack, or hold food. We conclude that defining foreign supplier to include a firm that only owns or packs or holds a food would not be consistent with Congressional intent, because it would have the effect of requiring that importers verify the establishment that merely owns, packs, and/or holds a food—as opposed to the establishment that "produces" a food. As stated previously, in enacting section 805(c)(2)(A) of the FD&C Act, Congress specifically directed us to adopt regulations requiring that each importer's FSVP is adequate to provide assurances that "the foreign supplier to the importer *produces* the imported food" (emphasis added) in compliance with the applicable U.S. standards.

(Comment 10) Two comments request that we revise the definition of foreign supplier to include an exception for activities conducted on RACs that do not change the RAC into processed food. The comments maintain that farms that grow and harvest produce should not be regarded as foreign suppliers if the produce is sent to a packing operation that is not part of the farm before the produce is exported. The comments assert that because the packing operation is a separate entity from the farm, the activities performed at the

packing operation (such as washing and grading) should be considered manufacturing/processing by another establishment. The comments ask that we revise the definition of foreign supplier as follows:

- Specify that activities with RACs that do not change the RAC into processed food would not constitute further manufacturing/processing that would make an establishment a foreign supplier.
- State that when an entity aggregates a RAC from multiple farms without changing the RAC into processed food, the aggregator and the farm that produced the RAC will both be considered foreign suppliers.

(Response 10) We decline to revise the definition of foreign supplier as requested. In general, though not always, an entity between the farm and the importer that performs an activity that does not change a RAC into processed food would not be the foreign supplier of the RAC because, in most but not all cases, that entity would most likely not be manufacturing/processing the RAC but would only be packing or holding the RAC. For example, a packing operation that is a separate entity from a farm that only washes and grades produce RACs incidental to packing and holding the RACs is not manufacturing/processing the RACs but only packing and holding them.

We also conclude it would not be consistent with FSMA to designate multiple foreign suppliers of the same food, which would result by specifying that both the aggregator in the example and the farm that grew the RAC would be foreign suppliers of that RAC. If an aggregator is merely packing and/or holding RACs, and not performing manufacturing/processing (and no other foreign entity is doing more than de minimis manufacturing/processing of the food before export), then the farm that grew the RAC would be the foreign supplier of the RAC.

(Comment 11) One comment asks that we clarify whether food facilities required to register, such as off-farm packing houses, are foreign suppliers. This comment also asks whether farms that are not required to register and that have on-farm packing operations are foreign suppliers. Noting that RACs often are harvested by a contract harvest company, the comment also asks us to clarify what is meant by "establishment that harvests a food" and whether, in such circumstances, the foreign supplier of the RAC would be the contract harvest company or the establishment that owns the crop and sells it to an importer.

(Response 11) The foreign supplier of a crop that is grown and harvested would either be the establishment that grew the food or, if another foreign entity later manufactured/processed the food (performing an activity of a more than de minimis nature), the foreign supplier would be the last entity in a foreign country that performed such a manufacturing/processing activity. Because, as previously stated, the definition of foreign supplier does not include firms that only pack or hold food, off-farm packing houses that solely pack or hold food would not be foreign suppliers. In such cases, assuming that no other foreign entity manufactures/processes the food (performing an activity of more than a de minimis nature) after it is grown, the farm that grows the food is the foreign supplier. Similarly, provided that no foreign entity manufactures/processes the food (performing an activity of more than a de minimis nature) after it is grown, farms that grow food and also have on-farm packing operations are foreign suppliers of the food they grow because they grew the food.

Our consideration of the comment on contract harvesting, and of comments we received on the definition of “farm” in the rulemaking on preventive controls for human food, has led us to change the definition of foreign supplier as it relates to farming operations and to make other changes to clarify the importer’s responsibilities when multiple entities in its supply chain control different hazards in the same food. The definition of “farm” in the proposed rule on preventive controls for human food referred to an entity “devoted to the growing *and* harvesting of crops, the raising of animals (including seafood), or both” (78 FR 3646 at 3795, January 16, 2013) (emphasis added). However, as discussed in the preamble to the final rule on preventive controls for human food, farming operations can take diverse forms, including those in which multiple growers share ownership of a packinghouse and those in which separate operations grow and harvest a crop (80 FR 55908 at 55926 to 55927, September 17, 2015). Therefore, the definition of farm in § 1.227 (which is included in the definitions applicable to the FSVP regulation under § 1.500 of the final rule) refers to a “primary production farm” as an operation devoted to the “growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.” This change to the definition of farm accommodates business models in

which growing, harvesting, and packing operations—each of which requires the application of controls—are conducted by different business entities.

When we referred, in the FSVP proposed rule, to an establishment that “harvests the food” as being the foreign supplier, we assumed that the grower of a food was also the harvester, and because harvesting followed growing, it was appropriate to refer to the harvesting, rather than growing, of a food in the definition of foreign supplier. However, as noted by the comment and discussed in the previous paragraph, a food is not always grown and harvested by the same establishment. Given the possibility that the growing and harvesting of a food might be conducted by separate entities, we conclude that, for purposes of the definition of “foreign supplier,” it is appropriate to regard the grower of a food, rather than the harvester, as the foreign supplier of the food. Although there are some hazards that must be controlled during harvesting (*e.g.*, worker hygiene, water quality), we believe that most people would regard the farm that grows a crop as the producer of the food rather than the establishment that harvests the crop. Given the potential complexities associated with different harvesting contractual relationships, the grower of a crop may be more easily identifiable than the harvester. In addition, making the grower the foreign supplier facilitates onsite auditing of the supplier because there is a clearly defined physical location for the farm on which the crop is grown, while the entity conducting harvesting might not own or have control over the site at which harvesting occurs (*e.g.*, mobile harvesting operations).

This change in the definition of foreign supplier from the harvester of a food to the grower of the food means that, when food is harvested on a farm by a contract harvest company, even one that takes ownership of the food, the grower of the food would be the foreign supplier (provided that no other foreign entity manufactures/processes the food by performing an activity of more than a de minimis nature).

Although the final rule defines the grower of a food, rather than the harvester, as the foreign supplier, the importer still must obtain assurances that hazards associated with the harvesting and packing of food are being significantly minimized or prevented. Without such assurances, we conclude that an importer could not meet its obligation under section 805(a)(1) of the FD&C Act of verifying that imported food is produced in compliance with

sections 418 and 419, as applicable, and that such food is not adulterated under section 402 or misbranded with respect to allergen labeling under section 403(w). We address this issue further in the discussion of the determination of appropriate supplier verification activities in section III.G.4 of this document.

(Comment 12) One comment asks that we clarify how the definition of foreign supplier compares to the definitions of “grower” and “manufacturer” in the prior notice regulation. The comment asks whether the terms grower and manufacturer, collectively, equate to the term foreign supplier. The comment notes that “grower” is defined in the prior notice regulation (21 CFR part 1, subpart I) in 21 CFR 1.276(b)(7) as a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both; “manufacturer” is defined in § 1.276(b)(9) as the last facility (as defined in § 1.227) that manufactured/processed the food. Under § 1.227, a facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a de minimis nature.

(Response 12) As previously stated, the final rule defines the foreign supplier of a crop as the grower of the food rather than the harvester. Consequently, with respect to food that is grown, the definition of “foreign supplier” for FSVP purposes differs from the definition of “grower” under § 1.276(b)(7), which includes both growing and harvesting. Regardless, definitions used in the prior notice regulation do not apply to words or phrases in the FSVP regulation, and vice versa.

(Comment 13) One comment asks that the definition of foreign supplier exclude farms that grow non-produce botanical, algal, or fungal RACs. The comment asserts that these products have a complicated supply chain that makes it difficult to identify the farms that grow them, there are no public health reasons to identify these farms, and there are no regulations governing the production of these products.

(Response 13) We decline to adopt a different approach for these particular types of RACs compared to the previously stated approach to defining the foreign supplier of a RAC. Provided these products are being imported for use as food as defined in 201(f) of the FD&C Act, importers of these products are subject to FSVP. However, the FSVP regulation does not require that the importer be the entity to gather

information about the farms. Rather, the regulation allows importers of such RACs to obtain information from other entities in the supply chain for the RAC to meet the importers' FSVP requirements for these products, provided the importer reviews and assesses the information and documents the review and assessment.

(Comment 14) Several comments request that we clarify whether certain activities are "de minimis" activities and therefore would mean the entity performing these activities for a food would not be the foreign supplier of the food. Some comments ask whether waxing, cooling, washing, and repacking are de minimis activities. Some comments maintain that sorting, packing, cooling, and holding of produce by packing houses should be regarded as de minimis activities, as should farm activities such as waxing, sorting, culling, conveying, storing, labeling, packing, packaging, and shipping of RACs.

(Response 14) The foreign supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing except for the addition of labeling or any similar activity of de minimis nature. This means that a foreign supplier is not an entity that merely performs de minimis manufacturing/processing activities, but, importantly, a foreign supplier also is not an entity that only packs or holds a food.

Whether an activity is harvesting, manufacturing/processing, packing, or holding can depend on the circumstances. For example, packing, cooling, and holding performed by an off-farm packing house (that only packs and holds produce and cools the produce incidental to packing and holding) would not make the packing house the foreign supplier, because these activities would not be considered manufacturing/processing but only packing and holding. Waxing, sorting, culling, conveying, storing, packing, and shipping of RACs when conducted on a farm would generally be considered harvesting, packing, or holding. Assuming the farm conducting these activities grows the RACs and no other entity manufactures/processes the food (except de minimis manufacturing/processing) before it enters the United States, the farm would be the foreign supplier.

With regard to the packaging of RACs, packaging is a manufacturing/processing activity but is specifically included within the farm definition. A farm that raises an animal or grows a

crop and performs packaging operations would be the foreign supplier (assuming that no other entity manufactures/processes the food except for de minimis manufacturing/processing).

Concerning the comment's reference to re-packing, re-packing is a packing activity (*i.e.*, the definition of packing includes re-packing), not a manufacturing/processing activity. We regard waxing and cooling RACs, when done by a packing operation for purposes of storage or transport, to be packing activities rather than manufacturing/processing activities.

To help explain FDA's current thinking on the classification of activities as "harvesting," "packing," "holding," or "manufacturing/processing," we will issue a draft guidance for industry on preventive controls for human food. We intend for this guidance, when finalized, to provide sufficient examples of activities within each of these definitions to inform both industry and regulators of those activities we consider to be within those definitions. The draft guidance will be available for public comment in accordance with our regulation on good guidance practices (see 21 CFR 10.115(g)(1)). We will consider comments we receive on the draft guidance in developing the final guidance.

(Comment 15) One comment, noting that coffee beans are extracted from the cherry surrounding the bean by fermentation, washing, and/or drying at a mill, asserts that because these activities are more than de minimis in nature, the mill should be regarded as the foreign supplier of the coffee beans.

(Response 15) We agree that fermentation, washing, and/or drying of raw coffee cherries (or "berries") would constitute manufacturing/processing that is not of a de minimis nature and would make the mill the foreign supplier of the coffee beans (provided no subsequent entity conducted additional manufacturing/processing that is not of a de minimis nature before export to the United States). We note, however, that under § 1.507(a)(1) of the final rule, importers of foods that cannot be consumed without the application of an appropriate control, including RACs like coffee beans, are not subject to the full requirements of the FSVP regulation (see the discussion in section III.H.1 of this document).

(Comment 16) One comment asks that we distinguish "further manufacturing/processing by another establishment" under the proposed definition of foreign supplier from the concept of substantial transformation applied by U.S. Customs and Border Protection (CBP).

(Response 16) The concept of "further manufacturing/processing by another establishment" in the definition of "foreign supplier" under the FSVP regulation and the definition of "substantial transformation" as used by CBP (*i.e.*, the emergence of an article from manufacturing processes as a new and different article, with a distinctive name, character, or use) are used for different purposes and do not necessarily refer to the same processes. Further manufacturing/processing in the context of FSVP involves direct manipulation of a food, but it need not result in a new and different article, as it can include activities such as washing and freezing.

#### 8. Good Compliance Standing With a Foreign Food Safety Authority

We proposed to define "good compliance standing with a foreign food safety authority" as meaning 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. Under § 1.513 of the final rule (discussed in section III.N of this document), modified FSVP requirements apply, subject to certain conditions and requirements, to importers of certain types of food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to the U.S. system. One of the requirements for eligibility for the modified requirements is that the foreign supplier must be in good compliance standing with the food safety authority of a country with a comparable or equivalent food safety system.

On our own initiative, we revised the definition to reference to "food producers" instead of "food manufacturers and processors" because farms might be included among food producers designated as being in good compliance standing by a foreign food safety authority.

(Comment 17) One comment questions the need for this term in the FSVP regulation given that all U.S. importers of food must ensure the safety of the food they import. The comment maintains that it is unclear whether or to what extent a foreign supplier's inclusion on a list maintained by a foreign food safety authority will

facilitate an importer's access to a foreign-supplied food. The comment also asserts that it is unclear whether any country's food safety authority can be required to develop and maintain such a list and suggests that there will be disparity among countries regarding whether such a list can and will be developed.

(Response 17) The term good compliance standing with a foreign food safety authority is used to describe one of the conditions under which an importer is eligible to import certain types of food under the modified requirements in § 1.513 of the final rule. We conclude it is appropriate to condition the use of these modified requirements on the foreign supplier of the food being in good compliance standing with 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. If the foreign supplier is not in good compliance standing, we conclude that the importer would lack adequate assurances that the foreign supplier is producing the food consistent with U.S. requirements. Although foreign authorities will not be required to designate food producers as being in good compliance standing, we believe that it is likely that some authorities will decide to do so.

(Comment 18) One comment suggests that the official registration or approval of an establishment by the relevant competent authority should be considered sufficient to meet the requirement of good compliance standing. The comment asserts that because all food establishments in the European Union (EU) are either registered with, or approved by, the national authorities, the existence of the records of these actions should be taken into account to avoid unnecessary or duplicative work.

(Response 18) We do not agree. We conclude that the fact that a foreign supplier is registered with, or approved to operate by, the food safety authority of the country in which it is located would generally not constitute a designation that the foreign supplier was in good compliance standing with that authority, absent a determination or designation by a food safety authority indicating that the supplier is in good compliance standing within the meaning in § 1.500. We believe it is possible a foreign supplier might maintain its registration or approval to operate even while it is the subject of an ongoing enforcement action due to significant non-compliance. Therefore, a foreign supplier cannot be regarded as

in good compliance standing with a food safety authority unless that authority has affirmatively designated that supplier as being in good compliance standing, either through the supplier's inclusion on a list of such suppliers, a company-specific certification, or some other manner of designation.

#### 9. Harvesting

For clarity and consistency, we are adding a definition of "harvesting" that is consistent with the definition in the preventive controls regulations. Our new definition states that harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on RACs on a farm. Harvesting does not include activities that transform a RAC into a processed food as defined in section 201(gg) of the FD&C Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of a RAC from the crop plant and removing or trimming part of the RAC (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming outer leaves of, and washing RACs grown on a farm.

#### 10. Hazard

We proposed to define "hazard" as any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

On our own initiative, we have deleted "in the absence of its control" from the definition, consistent with a corresponding change to the definition of hazard in the preventive controls regulations, because the aspect of control of a hazard is addressed under the definition of "hazard requiring a control."

(Comment 19) One comment suggests limiting the definition of hazard by referring to an agent that is reasonably likely to cause illness or injury "in the intended species" in the absence of its control.

(Response 19) We do not believe that the suggested change to the definition of hazard is necessary. We note that under § 1.504(c)(3) of the final rule, in determining whether a hazard is a "hazard requiring a control," an importer must consider, among other factors, the intended or reasonably foreseeable use of the food, including

the species for which the food was intended.

#### 11. Hazard Requiring a Control

In the Supplemental Notice, we proposed to adopt the term "significant hazard" and to define it as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

(Comment 20) Some comments request that we use a term other than "significant hazard" to refer to a known or reasonably foreseeable hazard for which a knowledgeable person would establish a control. One comment maintains that use of the term "significant hazard" could be confusing because the term is used to refer to hazards addressed in a HACCP plan through critical control points. One comment recommends using the definition of "significant hazard" instead of the term itself. Some comments recommend using the term "food safety hazard" because it has no association with HACCP principles. Some comments recommend using the term "hazard requiring control."

(Response 20) To provide more clarity, we agree that the FSVP regulation should use a term other than "significant hazard." We conclude it is appropriate to refer to such a hazard as a "hazard requiring a control." The definition states, in pertinent part, that a "hazard requiring a control" is a known or reasonably foreseeable hazard for which a knowledgeable person would establish one or more "controls or measures" to significantly minimize or prevent the hazard. The definition refers to controls or measures because the FSVP requirements apply to food that is subject to the preventive controls regulations (which require the establishment of preventive "controls"), food that is subject to the produce safety regulation (which refers to safety "measures"), and food that is subject to other FDA regulations (e.g., dietary supplement CGMPs).

(Comment 21) Some comments recommend replacing the reference to "a person knowledgeable about safe manufacturing, processing, packing, or holding food" with "a qualified individual" because a qualified individual will be responsible for conducting a hazard analysis.

(Response 21) Although a qualified individual must conduct a hazard analysis for a food, we decline to make this change to the definition of “hazard requiring a control” because we believe it is appropriate to specify that a person determining whether a known or reasonably foreseeable hazard is one for which one or more controls or measures are needed must be knowledgeable about the safe manufacturing, processing, packing, or holding of food. This is consistent with the revised definition of “hazard requiring a preventive control” in the preventive controls regulations.

(Comment 22) Some comments recommend stating in the definition of “significant hazard” (or its replacement term) that a determination of a significant hazard is based on a hazard analysis that assesses the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of a control, because severity and probability are integral to determining whether a hazard is significant.

(Response 22) We agree with the comments that this additional language is helpful. Consistent with the revised definition of “hazard requiring a preventive control” in the preventive controls regulations, this change is incorporated in the definition of “hazard requiring a control,” which under the final rule means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control or measure and its role in the facility’s food safety system.

(Comment 23) Some comments recommend that the definition of significant hazard reflect that components to manage controls should be appropriate not just to the food, the facility, and the control, but also to the intended use of the food.

(Response 23) We do not think this change to the definition of hazard requiring control is necessary because an importer already must consider the

intended or reasonably foreseeable use of a food in evaluating the hazards in the food under § 1.504(c)(3) of the final rule.

## 12. Holding

On our own initiative, we are adding a definition of “holding” that is consistent with the preventive controls regulations. Our new definition states that holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets), but does not include activities that transform a RAC into a processed food as defined in section 201(gg) of the FD&C Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

## 13. Importer

We proposed to define “importer” as the person in the United States who has purchased an article of food that is being offered for import into the United States. The proposed definition further stated that:

- 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; and
- 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.

We proposed this definition of importer based on the statutory definition of importer in section 805(a)(2) of the FD&C Act, which states that the importer is the U.S. owner or consignee of an article of food at the time of entry of the article into the United States, or if at that time there is no U.S. owner or consignee, the importer is the U.S. agent or representative of the foreign owner or consignee.

On our own initiative, we are revising the definition of “importer” to mean the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee at the time of U.S.

entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under the FSVP regulations. We conclude that this revised definition is more consistent with the statutory definition in section 805(a)(2). For the reasons explained in the following paragraphs, we also conclude that this change, along with a new definition we are adding for “U.S. owner or consignee,” better ensures that the FSVP importer is a person who has a financial interest in the food and has knowledge and control over the food’s supply chain. We are defining “U.S. owner or consignee” to mean the person in the United States who, at the time of entry of a food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

### a. General

(Comment 24) Some comments ask that we either define or clarify the term “purchased.” One comment states that CBP defines the terms owner and purchaser to include any party with a financial interest in a transaction, including, but not limited to, the actual owner of the goods, the actual purchaser of the goods, a buying or selling agent, a person or firm who imports for exhibition at a trade fair, or a person or firm who imports foods for repair or alteration. One comment maintains that in contrast to the proposed rule, the statute does not create different rules for U.S. owners and their consignees regarding their FSVP responsibilities and does not define the importer as the person who purchased an article of food. The comment asserts that because neither the statute nor the proposed rule defines “purchased,” it is unclear who is responsible for ensuring FSVP compliance.

(Response 24) We do not agree that the proposed definition would create different FSVP regulations for U.S. owners and consignees, as the proposed rule contained no requirements that differed on that basis. However, to prevent possible confusion regarding the definition of importer and to align more closely with the statutory text, we have revised the definition of importer to mean the U.S. owner or consignee of an article of food that is being offered for import into the United States. We are further defining “U.S. owner or consignee” as the person in the United States who, at the time of entry of a food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food. Thus, the final rule explicitly refers to

a U.S. “owner” of a food. Because there is a wide range of commercial arrangements between foreign owners and U.S. persons, there may be situations in which ownership of imported food has not transferred from the foreign owner at the time of entry to the United States, but a person in the United States has nevertheless purchased or agreed in writing to purchase the goods. We do not agree it is necessary to define the terms “purchased” or “purchase,” but we understand the terms to mean obtain by paying money or its equivalent.

(Comment 25) Some comments request that we clarify that the FSVP importer of a food is not necessarily the importer of record for the food as defined by CBP. However, some comments suggest that instead of creating a new definition of importer, we should adopt a definition that parallels CBP’s definition of importer of record. The comments note that under 19 U.S.C. 1484(2)(B), an “importer of record” is defined as the owner or purchaser of the merchandise or, when appropriately designated by the owner, purchaser, or consignee of the merchandise, a person holding a valid customs broker license. The comments maintain that this definition of importer of record is substantially similar to the statutory definition of importer under FSMA. (The comments also note that CBP regulations (19 CFR 101.1) define “importer” as the person primarily liable for the payment of any duties on the merchandise or an authorized agent.) The comments maintain that CBP’s definition of importer has been effective in ensuring proper enforcement of collection of customs duties and provides certainty by defining a single party responsible for entry of a product.

(Response 25) We do not agree that it is appropriate to define “importer” for FSVP purposes to match CBP’s definition of “importer” or “importer of record.” As we stated in the preamble to the proposed rule, the importer of a food for FSVP purposes might be, but would not necessarily be, the importer of record of the food under CBP provisions (*i.e.*, the individual or firm responsible for making entry and payment of import duties). We conclude that, in section 805(a)(2) of the FD&C Act, Congress adopted a definition of importer that suits the purposes of the FSVP regulation because:

- It clearly specifies the person who will be responsible for ensuring that supplier verification activities are conducted for each food imported into the United States; and

- By specifying the U.S. owner or consignee, the definition helps to ensure that the person responsible for meeting the FSVP requirements has a financial interest in the food and has knowledge and control over the food’s supply chain.

The “U.S. owner or consignee” of a food, as we have defined the term, is more likely to have knowledge of food safety practices and control over the supply chain of an imported food than a customs broker, who often is the importer of record of a food for CBP purposes. Although the CBP definition of importer may be effective in ensuring collection of customs duties and otherwise meeting CBP requirements, that is not the purpose of the FSVP regulation. Consequently, the final rule adopts a definition of importer that best serves the purposes of the FSVP requirements, consistent with the statutory provisions the FSVP regulation must implement.

(Comment 26) Some comments maintain that the importer should be the person who has a direct financial interest in the imported food or, alternatively, the last known exporter. The comments assert that the only parties who can ensure the safety of the food supply chain are entities who are directly and financially involved in the manufacture, growth, sale, receipt, or purchase of the imported food.

(Response 26) As previously stated, the definition of importer is intended in part to ensure that someone with a financial interest in the imported food, as well as knowledge and control over the food’s supply chain, is responsible for meeting the FSVP requirements. In most cases, this will be the U.S. owner or consignee of the food. However, under section 805(a)(2) of the FD&C Act and § 1.500 of the final rule, the importer for FSVP purposes could not be the exporter in the foreign country in which the food was produced. If there is no U.S. owner or consignee of a food at the time of the food’s entry into the United States, the foreign owner or consignee of the food must have validly designated a U.S. agent or representative (in accordance with § 1.509(b) of the final rule) to serve as the U.S. importer of the food for purposes of FSVP compliance. We do not agree that the last known exporter is an appropriate person to serve as the FSVP “importer” because such a person exports—as opposed to imports—the food.

(Comment 27) One comment states that retailers may contract with foreign manufacturers to produce private label products bearing the retailer’s name and purchase the products from a U.S. firm after the products have entered the

United States. The comment asks us to clarify that in this situation, the retailer would not be the importer of the food for FSVP purposes.

(Response 27) We agree that provided a U.S. entity other than the retailer owns the food, has purchased the food, or has agreed in writing to purchase the food at the time of entry (*i.e.*, is the “U.S. owner or consignee”), the retailer would not be the FSVP importer of the food. In this situation, the importer is the U.S. firm that owns the product, has purchased the product, or has agreed in writing to purchase the product when it is offered for import into the United States and the entry documentation is submitted or presented. It would not be relevant that the retailer was the entity that entered into a contract with the foreign manufacturer (as long as the retailer is not the person in the United States that owns the food, has purchased the food, or has agreed in writing to purchase the food at the time of entry). If, on the other hand, the retailer owns the food, has purchased the food, or has agreed in writing to purchase the food at the time of entry (and thus is the U.S. owner or consignee), the retailer would be the FSVP “importer.”

(Comment 28) One comment asks that we clarify that a restaurant owner is not an “importer” for FSVP purposes unless it directly imports a food for its use and chooses to accept the responsibilities of the importer. The comment asserts that failing to do this would place an added burden on restaurant owners and operators who will have to make clear to their suppliers of foreign materials that the suppliers are responsible for compliance with FSVP requirements. The comment maintains that adoption of the FSVP regulation might result in a loss of U.S. importers of foreign products due to their unwillingness to assume responsibility for FSVP compliance.

(Response 28) A restaurant located in the United States must comply with the FSVP requirements only if it meets the definition of importer under § 1.500 (*e.g.*, because it is the “U.S. owner or consignee” of the food at the time of entry or, if there is no U.S. owner or consignee at the time of entry, the foreign owner or consignee designates the restaurant as a U.S. agent or representative for purposes of serving as the FSVP “importer”). If the restaurant purchases the food from another U.S. entity, the restaurant would not meet that definition and would not be responsible for meeting the FSVP requirements. However, we have added flexibility in the final rule to allow importers, including restaurants, to



meet their FSVP obligations by relying on analyses, evaluations, and activities performed by certain other entities, provided those importers review and assess the corresponding documentation (see sections III.E.5, III.F.4, and III.G.4 of this document).

(Comment 29) One comment asks that we define the phrase “time of U.S. entry” as used in the proposed definition of importer.

(Response 29) Section 805(a)(2)(A) of the FD&C Act provides that for purposes of the FSVP regulation, the term “importer” means the United States owner or consignee of the article of food “at the time of entry of such article into the United States.” The meaning of the phrase “at the time of entry of such article into the United States” is ambiguous. It could mean that the importer is the U.S. owner or consignee at the time of submission of an entry or at the time that the article of food physically enters U.S. territory. Given it might not always be clear when an imported item physically enters U.S. territory, we conclude that Congress intended that the importer be the U.S. owner or consignee at the time of submission of entry documents. Therefore, “time of U.S. entry,” as used in § 1.500, is the time when an import entry is submitted to CBP either electronically or in paper form. Because we believe that entities engaged in the import of food into the United States will understand this term, we do not think it is necessary to include a definition for “time of entry” in these regulations.

(Comment 30) One comment expresses concern that the proposed definition of importer will create a new layer of middlemen who would assume ownership of food at the time of entry into the United States and charge fees for ensuring compliance with the FSVP requirements. The comment contends this might result in duplicative foreign supplier verifications.

(Response 30) We do not agree. We believe it is unlikely that many entities currently not food importers will enter the food importing business because of the need to adopt and implement the procedures required under the FSVP regulation. Some importers may choose to hire employees or outside consultants to assist them in meeting the FSVP requirements, but this would not need to involve third parties assuming ownership of imported food or otherwise serving in an importer role solely for the purpose of providing supplier verification services. Even if new, FSVP-oriented businesses are created to conduct supplier verification activities on behalf of some importers,

we do not see how this would result in duplicative supplier verification. Regardless, the definition of “importer” is consistent with the definition established by Congress in section 805(a)(2) of the FD&C Act.

(Comment 31) Some comments request that we define the term “consignee” because it might be confused with a similar term used by CBP. In addition, some comments suggest that the term “consignee” be restricted to persons with a direct ownership interest in the product.

(Response 31) We agree with the comments to the extent they are premised on a claim that the proposed rule did not clarify the meaning of “consignee.” Instead of defining the term “consignee,” however, we have revised the definition of “importer” so the FSVP importer is not, first, a U.S. owner, and, second, a U.S. consignee. There is no separate “consignee” category of persons who meet the definition of “importer.” Instead, under the revised definition, the “importer” is the “U.S. owner or consignee” of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under the FSVP regulation.

At the same time, we are defining “U.S. owner or consignee” to mean the person in the United States who, at the time of entry of a food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food. Under the previously proposed definition of “importer,” the “consignee” category could have caused proprietors of the U.S. premises to which imported food is to be delivered to be designated as FSVP “importers,” even when such proprietors have no connection to the imported food other than the physical receipt—even temporary receipt—of the food. Under section 805(a)(2)(B) of the FD&C Act, Congress provided that when there is no U.S. owner or consignee, the FSVP importer should be the U.S. agent or representative of a foreign owner or consignee at the time of entry into the United States. If the consignee for purposes of FSVP included the proprietor of the U.S. premises to which the merchandise is to be delivered, we believe it would be unlikely an FSVP importer would ever be the U.S. agent or representative of a foreign owner or consignee, as contemplated by section 805(a)(2)(B), because the role of FSVP importer would fall to the proprietor of

the premises before it would fall to the U.S. agent or representative. Moreover, we believe that a U.S. agent or representative of a foreign owner or consignee is more likely to have knowledge and control over the product’s supply chain, and is therefore more likely to be able to perform supplier verification activities, than the proprietor of the U.S. premises to which the merchandise is delivered (in cases where the proprietor of the U.S. premises has no connection to the food other than physical receipt).

The effect of our change to the definition of “importer,” in conjunction with the new definition of “U.S. owner or consignee,” likely will result in different entities serving as the FSVP importer in some circumstances than those who might have served as the importer under the proposed definition. For instance, in the case of a Canadian company that ships a food product to a Montana warehouse and for which delivery is made to the Montana facility in anticipation of possible orders from customers in the United States, it is possible, under the proposed rule, that the warehouse would have been the FSVP “importer” because the food might be considered to be consigned to the warehouse at the time of entry and no one in the United States at the time of entry either owned or had purchased the food. Under the final rule, however, the warehouse would not necessarily be the FSVP importer. Because there is no person in the United States at the time of entry who owns the food, purchased the food, or promised to purchase the food, there is no “U.S. owner or consignee.” Therefore, the FSVP “importer” would have to be a properly designated U.S. agent or representative.

As for those comments suggesting that a consignee needs to be a person with a direct ownership in the product, we do not agree. Section 805(a)(2)(A) of the FD&C Act provides that “importer” for purposes of section 805 means the “United States owner or consignee” (emphasis added). Because Congress used the word “or” between “owner” and “consignee,” we believe Congress intended the “United States owner or consignee” to include persons other than owners. Requiring a U.S. owner or consignee to have direct ownership over the product would be inconsistent with that intent. We also understand it is possible for U.S. persons to purchase or agree in writing to purchase food at the time of entry to the United States, even if they do not yet own the products at that time. Requiring a U.S. owner or consignee to have direct ownership in the product at the time of entry would



not account for these types of commercial arrangements.

b. U.S. Agent or Representative

(Comment 32) Several comments maintain that the U.S. agent or representative for FSVP purposes should not necessarily be the same person as the U.S. agent for a foreign food facility under the FDA food facility registration regulation (§ 1.227) and section 415(a) of the FD&C Act. The comments note that while section 805(a)(2) of the FD&C Act describes an agent acting for the foreign owner or consignee of an article of imported food at the time of entry, section 415(a) describes an agent acting for a food facility. The comments assert that Congress did not require that the U.S. agent for a foreign food facility also act as the U.S. agent for FSVP purposes, and many persons who serve as U.S. agents for facility registration purposes might not have the knowledge or ability to meet the FSVP requirements. The comments request that the FSVP regulation clarify this distinction by referring to the “U.S. FSVP agent or representative.”

(Response 32) FDA agrees in part and disagrees in part. Section 805(a)(2)(B) provides that when there is no U.S. owner or consignee with respect to an article of food, the term “importer” for FSVP means “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” (emphasis added). Section 805 does not further define the term “United States agent.” In addition, section 415(a)(1)(B) of the FD&C Act provides that foreign food facilities must submit the name of the “United States agent” for the facility as part of the facility’s registration under that section. FDA’s regulation implementing the food facility registration requirements in section 415 of the FD&C Act specifies that the registration for foreign facilities must include the name of the U.S. agent for the facility (21 CFR 1.232(d)). The facility registration regulation also defines the term U.S. agent to mean a person (as defined in section 201(e) of the FD&C Act) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of food facility registration (§ 1.227). The regulation further specifies that the U.S. agent “acts as a communications link between FDA and the foreign facility for both emergency and routine communications.”

Although Congress used the term “United States agent” in both section 805(a)(2)(B) and section 415(a)(1)(B) of

the FD&C Act, we do not interpret the use of the term “United States agent” in section 805(a)(2)(B) to mean the U.S. agent for a foreign facility under section 415(a)(1)(B). U.S. agents that foreign food facilities must designate for purposes of food facility registration perform a very different role than the “United States agent” that a foreign owner or consignee may designate under section 805(a)(2)(B) of the FD&C Act to serve as the “importer” for purposes of the FSVP regulations. For food facility registration, the “U.S. agent” acts as a communications link. For FSVP, however, an importer (whether a “United States agent” or otherwise) is responsible for the full breadth of supplier verification activities required under the FSVP regulation. These activities involve ensuring the safety of imported food, which is qualitatively different from serving as a communications link. Thus, we agree with the comments that urge us to not interpret the use of the term “United States agent” under section 805(a)(2)(B) to have the same meaning as the U.S. agent that food facilities are required to designate under section 415(a)(1)(B) and FDA’s food facility registration regulation.

We note, however, that this interpretation does not prohibit a foreign owner or consignee from designating a person who serves as a U.S. agent under the food facility regulation as the “importer” for purposes of FSVP. To the contrary, under the definition of “importer” in § 1.500, in cases in which there is no U.S. owner or consignee, it is up to the foreign owner or consignee to determine which U.S. agent or other U.S. representative will serve as the FSVP “importer.” Whomever the foreign owner or consignee designates also may be listed as a foreign facility’s U.S. agent for food facility registration purposes. We decline to adopt the term “U.S. FSVP agent or representative” because doing so is not necessary to prevent the kind of inadvertent or otherwise improper designation of FSVP importers contemplated by the comments.

(Comment 33) Some comments ask that we revise the definition of importer to specify that a person acting as a U.S. agent or representative of a foreign owner or consignee must knowingly and explicitly consent to serve as the U.S. agent or representative.

(Response 33) For cases in which a food has not been sold or consigned to a person in the United States at the time of entry, we proposed to required that, before an article of food is imported or offered for import into the United States, the foreign owner or consignee of

the article must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of “importer.” The final rule retains this requirement. Because we agree a U.S. agent or representative cannot truly function as the FSVP importer without having consented to do so, we are adding a clarification to the definition of “importer” explaining that in order for the foreign owner or consignee of the article to validly designate a U.S. agent or representative (when there is no U.S. owner or consignee) for purposes of the definition of “importer,” the U.S. agent or representative’s role must be confirmed in a signed statement of consent. The signed statement of consent must confirm that the U.S. agent or representative agrees to serve as the importer under the FSVP regulation. Because a signed statement is an explicit acknowledgment of consent, we conclude that a signed statement is an effective way of ensuring the consent of U.S. agents and representatives. In addition, we will be able to inspect the signed statements, should the need arise, allowing us to verify the accuracy of “importer” designations under the FSVP regulation. Being able to verify the accuracy of such designations will allow us to more efficiently and effectively monitor compliance with, and enforce, section 805 of the FD&C Act.

(Comment 34) Several comments express concern about the manner in which a foreign owner or consignee would designate its U.S. agent or representative. The comments state that a foreign supplier might designate a party in the United States, such as the warehouse where the imported food will be stored, without seeking an affirmative acceptance from that party, or the foreign supplier of the food might assume the agent listed on its facility registration is also the U.S. agent for FSVP purposes. Some comments note concerns regarding the process for verification of U.S. agents of foreign facilities, including the absence of a requirement to obtain formal consent from a person to serve as the agent and FDA’s failure to obtain confirmation of consent. Several comments suggest that, because the U.S. agent’s responsibilities as the importer of a food under the FSVP regulation will be substantial, the regulation should require affirmative written acceptance by the designated firm for valid designation of a foreign owner or consignee’s U.S. agent or representative.

(Response 34) We agree that a person should not be required to serve as the U.S. agent or representative of a foreign owner or consignee unless the person has agreed to serve in this capacity. As

explained in Response 33, we therefore are adding a clarification to the definition of “importer” stating that when the foreign owner or consignee of the article must designate a U.S. agent or representative (when there is no U.S. owner or consignee) for the purposes of the definition of “importer,” the U.S. agent or representative’s role should be confirmed in a signed statement of consent. The signed statement of consent must confirm that the U.S. agent or representative agrees to serve as the importer under the FSVP regulation. In accordance with these changes, we also have revised the provisions regarding refusal of admission in proposed § 1.514(a) to specify that if there is no U.S. owner or consignee at the time an article of 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 appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.

(Comment 35) One comment states that the requirement for foreign producers to obtain a U.S. agent in order for their product to be imported into the United States could be considered a technical barrier to trade according to the World Trade Organization (WTO).

(Response 35) We do not agree that the regulation requires that foreign producers obtain U.S. agents or otherwise imposes a barrier to trade. To the extent that the comment’s reference to U.S. agents relates to who may be an FSVP “importer,” the definition of importer in § 1.500 is flexible and does not require that the importer be a U.S. agent. Instead, the FSVP importer is the U.S. owner or consignee of the imported food. A U.S. agent or representative functions as the FSVP importer of a food only if there is no U.S. owner or consignee of the food at the time of entry. Notably, the importer can be a foreign national residing in the United States and need not be a U.S. citizen. The definition of importer thus serves to identify persons with financial interests in the imported food who are likely to be able to ensure the safety of the food, while also providing flexibility that does not unduly burden trade.

(Comment 36) One comment states that FDA’s explanation of the proposed definition of “importer” indicates the rule implies a regulatory pressure for foreign producers to sell or distribute products through U.S. persons in a manner inconsistent with U.S. obligations under the U.S.-Korea Free Trade Agreement (KORUS).

(Response 36) We do not agree that the definition of “importer” in § 1.500 is

inconsistent with U.S. obligations under the KORUS. Under National Treatment and Market Access for Goods, Article 2.8.6 to 2.8.8, neither party may, as a condition for engaging in importation or for the importation of a good, require a person of the other party to establish or maintain a contractual or other relationship with a “distributor” in its territory. The term “distributor” under the KORUS is defined as a “person of a party” who is responsible for the commercial distribution, agency, concession, or representation in the territory of that party of goods of the other party. The term “person of a party” is defined as a national or an enterprise of a party to the agreement. The term “enterprise” means any entity constituted or organized under applicable law, whether or not for profit, and whether privately or governmentally owned or controlled, including any corporation, trust, partnership, sole proprietorship, joint venture, association, or similar organization.

The U.S. owner or consignee need not be a United States “distributor” within the meaning of the KORUS because it need not be a U.S. national or U.S. enterprise constituted or organized under U.S. law responsible for commercial distribution, agency, concession, or representation in the United States. For example, the U.S. owner or consignee could be a Korean national or enterprise residing or maintaining a place of business in the United States. Alternatively, if there is no U.S. owner or consignee of a food at the time of entry, the foreign owner or consignee could designate a U.S. agent or representative who is a Korean national (or a national of another country) but who resides or maintains a place of business in the United States. Under those circumstances, such a Korean national or enterprise would be the FSVP “importer.” Consequently, we are not requiring any person whose imports fall within the scope of the KORUS to establish or maintain a contractual or other relationship with a “distributor” or other entity in its territory. Therefore, the definition of “importer” is not inconsistent with U.S. obligations under the KORUS, and we do not believe the rule exerts any pressure on foreign producers to rely on U.S. persons to distribute food in a manner that is inconsistent with the KORUS.

#### 14. Known or Reasonably Foreseeable Hazard

In the Supplemental Notice, we deleted the proposed term “hazard reasonably likely to occur” and replaced

it with the term “known or reasonably foreseeable hazard.” We proposed to define “known or reasonably foreseeable hazard” as a potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

(Comment 37) One comment suggests that we use the term “reasonably anticipated contaminants” as a phrase that clearly defines all hazards, whether deliberate or accidental, that can cause adulteration in the food supply.

(Response 37) We decline to make this change because “hazard” is a widely understood term in food safety and the word “contaminant” might suggest a substance that comes into contact with or is added to a food, but not all hazards arise from such contaminants. As discussed in section III.E.3.b of this document, importers are required to consider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced for economic gain.

(Comment 38) One comment asks that we delete the reference to “potential” hazards as redundant because the proposed definition of “hazard” refers to agents “reasonably likely” to cause illness or injury.

(Response 38) We are deleting the word “potential” before the phrase “biological, chemical (including radiological), or physical hazard” because we agree the use of that word is redundant. The remaining portion of the definition of “known or reasonably foreseeable hazard” includes both a hazard that is known to be associated with a food or the facility in which it is manufactured/processed, as well as a hazard that “has the potential to be” associated with a food or facility.

(Comment 39) One comment requests that the definition of “known or reasonably foreseeable hazard” also refer to hazards that might be associated with the location or type of farm on which a food is grown or raised. The comment cites as an example the potential effect on a food of the agricultural methods used on the farm that produced the food.

(Response 39) We conclude this change is unnecessary because the potential effect of the location or type of farm on which a food is grown or raised on whether a hazard requires a control will be addressed as part of the hazard evaluation conducted under § 1.504(c) of the final rule, which considers factors such as those related to the harvesting and raising of the food.

## 15. Lot

We proposed to define “lot” as the food produced during a period of time indicated by a specific code.

(Comment 40) Several comments request that “lot” be defined by criteria other than time. Some comments assert that the proposed definition appears to ignore other factors such as common characteristics (e.g., origin, variety, type of packing) and maintain that multiple lots can be produced during the same time but with different lot designations. These comments suggest that lot be defined as a body of food designated with common characteristics that is separable by such characteristics from other bodies of food. One comment asserts that growers and processors define lot differently based on their company practices and the specific characteristics of the process and product. As examples of such definitions, the comment lists the following:

- A specific planting block of specified size prepared and planted on a given day, raised with common agricultural inputs, and scheduled for harvest on a selected date.
- A quantity of finished product that passes over a processing line during a given period of time.

This comment requests that importers be permitted to independently define lot and make the definition available to FDA during an inspection.

One comment suggests that lot be defined as a batch, or a specified identified portion of a batch or, in the case of food produced by a continuous process, a specific identified amount of food produced during a specified period of time, or in a specified quantity, on a specified equipment line. This comment would define “batch” as a specific quantity of a food produced during a specified time period during a single cycle of manufacture, and it would define “code” as a unique and distinctive group of letters, numbers and/or symbols from which the manufacturing and packaging history of the associated lot or batch of food can be determined.

(Response 40) We agree that a change to the definition of lot is appropriate, as we believe the reference to a period of time indicated by a specific code might be misinterpreted to mean that the “specific code” must be based on time (such as a date), which was not our intent. Although the term “lot” is associated with a period of time, the establishment that produces a food has the flexibility to develop its own coding system for lots, with or without any indication of time in the code. For

example, a lot code could be based on a date, time of day, production characteristic (such as those mentioned in the comments), combination of date/time/production characteristic, or any other characteristics the establishment finds appropriate. To clarify that the definition of lot would not require that the time of production be “indicated” by the lot code and acknowledge the establishment’s flexibility to determine the code, we have revised “period of time indicated by a specific code” to “period of time and identified by an establishment’s specific code.”

## 16. Manufacturing/Processing

We proposed to define “manufacturing/processing” as 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 the definition provided include cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. The proposed definition stated that for farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding.

We are finalizing the definition of “manufacturing/processing” largely as proposed. However, we are adding “boiling”, “canning”, and “evaporating”, and “treating to manipulate ripening” to the list of activities that we classify as manufacturing/processing, as well as drying/dehydrating RACs to create a distinct commodity. We are also adding “extruding” and “pelletizing” but limiting the applicability of these activities to the manufacture/processing of animal food. We are making these changes so that the definition of manufacturing/processing in this regulation aligns with the definitions in the regulations on preventive controls for human food and animal food. For a discussion of the classification of these and other activities, see section IV of the preamble to the final rule on preventive controls for human food (80 FR 55908 at 55924 through 55936).

(Comment 41) Several comments express concern regarding the proposed definition of “manufacturing/processing” and what may constitute activities that are a part of harvesting, packing, or holding. One comment asks that we classify the following activities, whether they occur on or off the farm,

as part of harvesting/post-harvest handling operations because there is no substantial transformation of the produce item into a different product in commerce: cutting, trimming, washing, waxing, cooling, mixing, labeling, and packaging of fresh produce RACs. One comment requests that coring, artificial ripening, waxing, cutting, labeling, stickering, packaging, and fumigation be included in the definition of “harvesting” and not “manufacturing/processing.”

(Response 41) We conclude that the definition of “manufacturing/processing” in § 1.500 is appropriate because it is consistent with the definition of the term in the regulations on preventive controls for human food and for animal food. With respect to the comments regarding whether particular activities involving produce should be classified as manufacturing/processing, as previously stated, the final rule on preventive controls for human food addresses the scope of manufacturing/processing (80 FR 55908 at 55924 through 55936).

(Comment 42) One comment suggests that the definition of “manufacturing/processing” refer to making food from one or more “raw materials and/or ingredients” rather than “ingredients.”

(Response 42) We do not believe the change is necessary because raw materials in the context of the definition of “manufacturing/processing” are food ingredients.

## 17. Pathogen

We proposed to define “pathogen” as a microorganism of public health significance.

(Comment 43) Some comments assert that, because the significance of a pathogen for public health depends on an organism’s severity and exposure, “pathogen” should be defined as a microorganism of such severity and exposure that it would be deemed of public health significance. Some comments suggest that the definition refer to “human or animal” public health significance.

(Response 43) We decline to make these changes because the definition already addresses the public health significance of a pathogen and it is unnecessary to indicate that a pathogen might affect humans or animals. The definition’s reference to microorganisms “of public health significance” takes into account factors such as the severity of illness and the route of exposure. In addition, the term “microorganism of public health significance” is broad enough to address both humans and animals.

## 18. Qualified Auditor

In the Supplemental Notice, we proposed to add a definition for “qualified auditor,” which we proposed to define as a person who is a qualified individual and has technical expertise obtained by a combination of training and experience appropriate to perform onsite audits. We further stated that a foreign government employee could be a qualified auditor.

(Comment 44) Some comments ask that we revise the definition of qualified auditor to include persons who have technical expertise obtained by a combination of training, experience, or education appropriate to perform audits. Some comments ask us to recognize that training and/or experience can make a person a qualified auditor; the comments state that people with experience performing audits likely have applicable training but might not have completed a specific regimen of courses. Some comments maintain that a person might be sufficiently qualified to conduct an audit through experience only and allowing an individual to be deemed qualified through training and/or experience is critical for food additive and generally recognized as safe (GRAS) substance facilities. Some comments maintain that we should recognize the role of the education of a potential qualified auditor as well as training and experience to meet the criteria.

(Response 44) We agree a qualified auditor might obtain the necessary auditing expertise through education, training, or experience, or some combination of those sources of expertise, and we have revised the definition of qualified auditor accordingly. (As discussed in section III.D of this document, the requirement that a qualified auditor have such education, training, and/or experience is separately set forth in § 1.503(b) of the final rule.) However, we believe it is likely that a person would need at least some actual experience in auditing (including by assisting or observing others in the performance of an audit) to meet the definition of a qualified auditor, *i.e.*, it would be difficult to obtain the necessary technical expertise solely through education and/or training that does not involve assisting or observing others in the performance of an audit.

(Comment 45) Some comments object to the proposed requirement that a qualified auditor must be a qualified individual with certain technical auditing expertise. One comment asserts that a qualified auditor should not be required to have the broader skills of a

qualified individual. One comment maintains that a qualified auditor should not be required to have knowledge, skills, and abilities beyond those of a qualified individual; instead, the definition should give a qualified individual the discretion to conduct an audit himself/herself or identify someone to perform this function.

(Response 45) We do not agree with the comments. For purposes of FSVP, the final rule defines a qualified individual as a person with the education, training, or experience (or a combination thereof) necessary to perform the activities needed to perform an activity required under the FSVP regulations. (We did not intend that every qualified individual who performs an FSVP activity would need to have the education, training, or experience needed to perform *all* FSVP activities—only the activity or activities the person is performing; therefore, we have revised the definition of “qualified individual” to refer to the performance of “an activity required under this subpart”.) Thus, whatever FSVP activity is being conducted, including onsite auditing, the individual conducting the activity must have adequate education, training, or experience (or some combination thereof) to properly conduct the activity. However, in the case of onsite auditing, the qualified individual conducting the auditing must have additional expertise—specifically, technical expertise that is needed to adequately perform the auditing function.

Further, we conclude that the person conducting an audit must not only have expertise in conducting audits but also a broader understanding of food safety processes and procedures. The scope of an audit can be a review of an entire range of food safety processes or procedures or a component of an overall system of such processes and procedures. It is therefore critical that the auditor has education, training or experience required of qualified individuals, as well as education, training, or experience specific to conducting audits. The definition of qualified auditor does not require or prohibit a qualified individual working on the importer's behalf from selecting the person who will conduct an onsite audit. However, the person selected to conduct an onsite audit must meet the definition of a qualified auditor.

(Comment 46) One comment asks that we define qualified auditor under the FSVP regulation the same way we define qualified auditor under the regulation on preventive controls for animal food.

(Response 46) The definitions of qualified auditor in the FSVP and preventive controls for animal food regulations are essentially the same. Therefore, no changes are needed.

(Comment 47) Some comments ask that we define or provide guidance on the criteria for the technical expertise required under the definition of qualified auditor. One comment asks that we consider training courses that would certify individuals similar to the courses being developed to become a qualified individual.

(Response 47) A qualified auditor might acquire the appropriate technical expertise through education, training (including training that results in accreditation under a recognized facility auditing or certification scheme), or experience, or some combination of those criteria. We intend to provide more information in the FSVP draft guidance on how persons might obtain the necessary expertise to be qualified auditors for FSVP purposes.

(Comment 48) One comment asks how an importer can determine whether a foreign government employee has sufficient knowledge of U.S. regulations to serve as a qualified auditor, given that such officials often inspect and certify firms according to national requirements. One comment requests guidance on how an importer may rely on audits performed by unaccredited foreign government employees and how foreign governments can create audit programs to assist firms that export food to the United States. One comment suggests that we recognize foreign government employees as qualified auditors after they receive training and pass an assessment organized by the foreign government according to U.S. regulations.

(Response 48) The standard for being a qualified auditor does not differ when the audit is performed by a foreign government employee. Auditors often audit against multiple schemes, and we see no reason why a foreign government employee with appropriate technical expertise obtained by a combination of education, training, and/or experience could not audit against FDA's standards. There also is no requirement that audits be performed by accredited auditors for the purpose of the FSVP regulation. We currently do not envision establishing a program to recognize individuals as meeting the definition of qualified auditor for the purposes of FSVP. However, we do intend to conduct outreach, develop training modules, and provide technical assistance to facilitate compliance with this rule.

(Comment 49) Some comments ask that we include in the definition of

qualified auditor properly trained Federal auditors and what the comments described as State and private auditors operating under contract with the Federal government.

(Response 49) We agree that government employees of different levels of government may be qualified auditors (provided they otherwise meet the definition of qualified auditor). We therefore have revised the definition of qualified auditor to state in part that a government employee, including, but not limited to, a foreign government employee, may be a qualified auditor. As for the comment suggesting that private auditors operating under contract with the Federal government may be qualified auditors, we note that nothing in the definition of qualified auditor prevents private auditors from serving as qualified auditors (provided they otherwise meet the definition of qualified auditor).

(Comment 50) One comment suggests that the definition of qualified auditor should include third-party auditors accredited under FDA's third-party auditing regulations.

(Response 50) We agree and have revised the definition of qualified auditor to state that a qualified auditor could be an audit agent of a certification body accredited in accordance with subpart M of part 1 (the regulations implementing section 808 of the FD&C Act (21 U.S.C. 384d)). (The final rule on the accreditation of third-party certification bodies, published elsewhere in this issue of the **Federal Register**, refers to third-party auditors also as "certification bodies.") As a result of making this change, it is no longer necessary to specify in the definition of "qualified individual" that a qualified individual includes, but is not limited to, a third-party auditor (certification body) that has been accredited in accordance with section 808 of the FD&C Act, as we previously proposed (because a qualified auditor must also be a qualified individual).

(Comment 51) One comment maintains that in addition to auditors accredited under FDA's third-party certification regulations, a qualified auditor could be a qualified individual who is not a third-party auditor accredited under those regulations. However, one comment asserts that not requiring the use of accredited auditors or an accredited system is not a good idea from a food safety perspective, particularly for RACs originating in a part of the world that has a history of shipping microbiologically contaminated products to the United States.

(Response 51) We believe that a person need not be an auditor formally accredited under the third-party certification regulations or any other accreditation system to have the technical expertise needed to appropriately perform an onsite audit. Under the definition of qualified auditor, a person may obtain the necessary technical expertise through a combination of education, training (including training that is rigorous but does not lead to formal "accreditation"), and/or experience. For example, a government employee might be less likely than a private sector auditor to be accredited, but the government employee might still be a qualified auditor and be appropriately suited to conduct onsite audits of foreign suppliers. However, importers have the responsibility to choose qualified auditors even though we are not requiring that auditors be formally accredited.

(Comment 52) One comment, stating that it uses its internal auditors to conduct onsite audits of its foreign suppliers, suggests that the definition of qualified auditor be revised to allow the use of internal auditors when they have no direct financial interest in the foreign supplier.

(Response 52) Although we agree with the comment, we do not believe that it is necessary to change the definition as suggested. An importer's employee could be a qualified auditor if he or she has the expertise required under the definition. In addition, the final rule does not prohibit an importer or one of its employees from conducting verification of the supplier.

#### 19. Qualified Individual

We proposed to define "qualified individual" as a person who has the necessary education, training, and experience to perform the activities needed to meet the FSVP requirements. The proposed definition states that a qualified individual may be, but is not required to be, an employee of the importer. The proposed definition 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. The proposed definition also states that:

- A 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; and
- A foreign government employee could be a qualified individual.

(Comment 53) One comment asks that we clarify in the definition that a qualified individual could have the necessary education, training and experience to perform FSVP activities "or a combination thereof."

(Response 53) We agree and have changed the definition to state that a qualified individual must have education, training, or experience (or a combination thereof) necessary to perform an FSVP activity. (We have separately set forth the requirement that a qualified individual have such education, training, and/or experience in § 1.503(a) of the final rule.)

(Comment 54) One comment asserts that the term "necessary education" in the proposed definition is misleading and suggests that the definition require a qualified individual to have "skills consistent with the requirements."

(Response 54) We have changed the definition of qualified individual so the term "necessary education" is not included. However, we do not agree that the use of the term "necessary" in the revised definition is misleading. The definition of qualified individual makes clear that the required education, training, or experience is that which is needed to conduct the FSVP activity or activities the person is performing.

(Comment 55) One comment, noting "qualified individual" is defined differently in the proposed regulations on preventive controls, asserts that using the same term with different meanings in different regulations could lead to confusion. The comment suggests that the FSVP regulation use the term "FSVP qualified individual."

(Response 55) We decline to make this change. The definition of "qualified individual" in the FSVP regulation makes clear that the necessary qualifications are specific to FSVP activities performed by the individual, and the definition of "qualified individual" in the preventive controls regulations likewise makes clear that the necessary qualifications are specific to the activities required under those regulations. To the extent the comment objects to the differences in the definitions for "qualified individual" across the different regulations, we disagree. Fundamentally, the definition of "qualified individual" in the FSVP regulation is aligned with the definition of qualified individual in the preventive

controls regulations. In each case, a qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform activities required under the regulations. However, the definitions vary as a result of the different activities a qualified individual must perform under each rule.

(Comment 56) Some comments suggest that we establish specific standards or minimum qualifications for qualified individuals. One comment maintains that the definition should require an understanding of FDA regulations. Some comments ask that we provide examples of, or guidance regarding, necessary education, training, and experience so that importers can determine whether their employees meet the standard. One comment asks that qualifications not be restricted to a certain type of course or program as this would unnecessarily raise the cost of compliance and disqualify well-suited individuals from compliance roles.

(Response 56) We intend to address in guidance what appropriate education, training, and experience qualified individuals should have to conduct FSVP activities. To maximize flexibility, persons will not be required to complete a particular course or program to become a qualified individual under the FSVP regulations; rather, persons will be able to obtain the necessary education, training, and/or experience through a variety of methods and experiences. The principal concern is that the education, training, and experience equip them to conduct the FSVP activity or activities they are performing.

(Comment 57) One comment requests that we include a requirement for certification with specific criteria for competence for performing FSVP activities because merely requiring that an individual be knowledgeable in the food process would not adequately ensure the individual is qualified to perform FSVP activities.

(Response 57) We decline to require that a person obtain a particular certification to act as a qualified individual on behalf of an importer. As stated previously, we want to provide flexibility as to how a person can obtain the necessary education, training, and/or experience.

(Comment 58) One comment stresses that the determination as to whether an individual is qualified to develop and oversee an importer's FSVP should be a performance-based evaluation, not a paperwork exercise.

(Response 58) We agree with the comment to the extent that the comment suggests that an importer should only

use a person to conduct FSVP activities who the importer has determined has the education, training, or experience (or a combination thereof) necessary to perform those activities. Whether a person is qualified to perform those activities should be determined by the importer on a case-by-case basis.

(Comment 59) One comment suggests that we add to the definition a requirement that the qualified individual understands the language of the country in which the foreign supplier is located.

(Response 59) We agree a qualified individual must be able to read and understand the language of any records that the individual must review in performing FSVP activities. This would ensure the individual responsible for performing FSVP activities is able to provide meaningful supplier verification, and is especially important in the imports context in which individuals in the United States must verify suppliers in countries where records may be kept in languages other than English. We therefore have revised the definition of "qualified individual" to specify that a qualified individual must have the ability to read and understand the language of any records the person must review in performing FSVP activities (this requirement is separately set forth in § 1.503(a) of the final rule). As discussed more fully in section III.K.3.a of this document, we have deleted the proposed requirement in § 1.510(b) of the proposed rule that all FSVP records be maintained in English, and we have added a requirement that, upon Agency request, the importer must provide an English translation of a record in another language in a reasonable period of time.

(Comment 60) One comment requests that we clarify the statement in the proposed definition of qualified individual regarding the "standard curriculum" for training in the development and application of risk-based preventive controls recognized by FDA as adequate. The comment also asks that we explain how a qualified individual could be qualified through job experience to develop and implement a food safety system and state whether and how the Agency will recognize industry providers of training programs. One comment requests that we provide a process by which foreign training in risk-based preventive controls can be recognized as equivalent or adequate. The comment asserts that it would be unreasonable to expect FDA-recognized training to be available in all languages and in all countries exporting food to the United States, and it also would be unreasonable to require

foreign suppliers to travel to the United States to obtain the required training.

(Response 60) As discussed in the preamble to the final rule on preventive controls for human food, we are working to develop general guidance on hazard analysis and preventive controls. We also intend to work with the Food Safety Preventive Controls Alliance (FSPCA) to develop selected sections of model food safety plans for several food types that will provide instructional examples. In addition to the preventive controls curriculum, we intend to develop a curriculum regarding FSVP that will be available as an option for importers and other stakeholders. It will be the responsibility of a person providing training in preventive controls to ensure the training is at least equivalent to that provided under a standardized curriculum recognized as adequate by FDA. Training providers will not need to obtain express approval from the Agency to use any particular curriculum. In addition, the qualified individuals used by importers to perform FSVP activities related to preventive controls will not be required to obtain training in the United States.

However, we have concluded it is not necessary to include in the regulation a requirement that qualified individuals performing FSVP activities related to a foreign supplier's preventive controls complete a specified training in preventive controls. Instead, the draft guidance on FSVPs will provide recommendations on the type of training that qualified individuals should have, including, for persons who assess foreign suppliers' preventive controls, training in the development and application of preventive controls available in (or comparable to) the curriculum that FDA is developing with the FSPCA. The draft guidance also will provide recommendations for training for individuals who will be conducting verification activities regarding suppliers of food that is subject to the produce safety regulations or other FDA food safety regulations.

(Comment 61) One comment suggests that we revise the definition of qualified individual to refer to a person being qualified to "develop and apply" a food safety program rather than "develop and implement" such a program to be consistent with the proposed regulations on preventive controls for human food.

(Response 61) Although we agree that this change would be appropriate, we have deleted the reference to specialized training in preventive controls from the definition of qualified individual. However we will take this suggestion into consideration in developing our

guidance on appropriate training for qualified individuals.

(Comment 62) One comment suggests that we consider including requirements for ongoing training to ensure qualified individuals stay current in the latest developments relevant to their credentials.

(Response 62) Because the definition for “qualified individual” already requires that such individuals be qualified to perform FSVP activities, we do not believe it is necessary to establish specific requirements for ongoing training. If developments over time cause a person’s education, training, and experience to be inadequate to perform FSVP activities, that person would no longer be a qualified individual and the individual might need to obtain additional education, training, or experience.

(Comment 63) One comment requests that we specify that to be considered a qualified individual, a foreign government employee should meet the same stringent requirements as those who are privately employed.

(Response 63) All persons acting as qualified individuals for an importer—whether located in the United States or another country, whether a government official or privately employed—will be required to have the education, training, or experience (or a combination thereof) necessary to perform their FSVP activities. Thus, the standard for being a qualified individual does not vary depending on whether an individual is a foreign government employee.

## 20. Ready-To-Eat Food

On our own initiative, we are adding a definition of “ready-to-eat food” that is consistent with the preventive controls regulations. The definition states that ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

## 21. Receiving Facility

Also on our own initiative, we are adding a definition of “receiving facility” that is consistent with the preventive controls regulations. The definition states that a receiving facility means a facility that is subject to subparts C and G of part 117 (21 CFR part 117) (the regulations on hazard analysis and risk-based preventive controls and supply-chain programs for human food) or subparts C and E of part 507 (21 CFR part 507) (the corresponding regulations for animal

food) and that manufactures/processes a raw material or other ingredient it receives from a supplier. In accordance with the language used in the final regulations on preventive controls, we refer to the supplier provisions in those regulations as provisions on “supply-chain programs” instead of “supplier programs.”

## 22. Very Small Foreign Supplier

In the Supplemental Notice, we proposed to define “very small foreign supplier” 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 \$1 million, adjusted for inflation.

(Comment 64) We received many comments on the proposed definition of very small foreign supplier. Some comments support the definition while others question the breadth of the definition and the percentage of imported food it would exclude from full FSVP requirements. Some comments suggest different eligibility criteria, such as number of employees. Some comments assert that basing the definition on the U.S. dollar value of sales would provide an unfair advantage to foreign firms compared to American firms of comparable size because many foreign suppliers are located in countries with currencies valued much lower than the U.S. dollar. Some comments assert that using a monetary criterion for very small status is impractical because of fluctuations in foreign exchange rates and because those rates are not related to any risk in food; the comments maintain that using this criterion would jeopardize a foreign supplier’s predictability of business and have negative effects on international trade.

Some comments assert that “very small” status should be based on the foreign supplier’s sales of food exports to the United States rather than its total food sales. One comment suggests that it might be difficult for foreign suppliers to determine their average annual monetary value of food sales because many crops can be used for both food and non-food purposes (such as soil improvement, planting seed, and biofuels). Some comments suggest that the reference to food “sales” include returns received by members of cooperatives for the crops the members provide.

One comment states that if a very small foreign supplier is defined on the basis of dollar revenues, we should

clarify whether the adjustment for inflation is to be based on the U.S. inflation rate or the rate in the supplier’s country. The comment also suggests that a neutral outside source such as the World Bank be used to determine the inflation rate rather than using rates estimated by individual governments.

(Response 64) As discussed more fully in section III.M.1 of this document, in response to these comments and other comments related to the modified requirements we proposed for very small foreign suppliers, we have deleted the proposed provisions applicable to food imported from “very small foreign suppliers.” Instead, in alignment with the supply-chain program provisions of the preventive controls regulations, § 1.512 of the final rule includes modified requirements for importers of food from certain small foreign manufacturers/processors and farms. The modified requirements include, among other things, the following:

- Annually obtaining written assurance from the importer’s foreign supplier that the supplier meets the specified criteria as a certain type of small facility or farm under FDA regulations on preventive controls, produce safety, or shell egg production, storage, and transportation;
- Obtaining written assurance at least every 2 years that the small supplier is in compliance with applicable regulations or (for some small suppliers) that it acknowledges it is subject to the adulteration provisions of the FD&C Act;
- Evaluating the foreign supplier’s compliance history and approving suppliers; and
- Establishing procedures to ensure the use of approved suppliers.

As discussed in section III.M.1 of this document, we conclude that these modified requirements for food from certain small foreign suppliers are appropriate to align the FSVP and preventive controls provisions to help provide parity in supplier verification requirements for domestic and foreign food producers. We further conclude that basing eligibility for the modified requirements on different criteria, such as the supplier’s sales of food to the United States, would not be consistent with this approach. We believe it is appropriate for these modified verification requirements to be based on the underlying food safety regulations (*i.e.*, the regulations on preventive controls, produce safety, and shell egg production) because those regulations themselves provide for modified requirements or exemptions for these food producers. Because the modified verification provisions for certain small



foreign suppliers are based on the underlying food safety regulations, a foreign supplier's qualification for these modified requirements or exemptions depends on the eligibility criteria specified in those regulations. Concerns regarding the appropriateness of these eligibility criteria are beyond the scope of this rulemaking.

### 23. Very Small Importer

In the Supplemental Notice, we proposed to 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 \$1 million, adjusted for inflation. We stated that the proposed annual sales ceiling of \$1 million was consistent with the definition of "very small business" in the proposed rule on preventive controls for human food. However, we noted that the definition of "very small business" in the proposed rule on preventive controls for animal food included an annual sales ceiling of \$2,500,000 and different sales ceilings applied to smaller entities subject to (or not covered under) the proposed produce safety regulations (*i.e.*, \$500,000 in annual produce sales for "small businesses," \$250,000 in annual produce sales for "very small businesses," and \$25,000 in annual produce sales for certain farms not covered under the produce safety regulations), and we sought comment on whether and, if so, how we should take these definitions into account in defining very small importers and very small foreign suppliers.

(Comment 65) Some comments support defining "very small importer" consistently with the definition of "very small business" in the regulation on preventive controls for human food. Other comments support a definition of very small importer for animal food that is consistent with the proposed definition of very small business in the preventive controls for animal food regulation. Some comments asserting that our proposed definition is inconsistent with some other FSMA definitions of small entities nevertheless also express concern about practical challenges of having different annual sales ceilings for different types of imported food. Some comments support using an annual food sales ceiling of \$500,000 as originally proposed.

(Response 65) We agree with the comments that the definition of very small importer should be consistent

with the definitions of very small business in the preventive controls regulations. This is particularly important for importers that are also subject to those regulations. We believe that defining the terms consistently will contribute to a level playing field between domestic and imported food and will help avoid a situation in which a facility would be a very small business under the preventive controls regulations but not a very small importer under FSVP, or vice versa.

Given that our very small importer definition was already designed to track the definition of very small business in the preventive controls for human food regulation, we are only adding new language to address the inconsistency between the very small importer definition and the very small business definition in the regulation on preventive controls for animal food. Therefore, the final rule states that, with respect to animal food, a very small importer means an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale—as discussed in the following paragraphs). For importers that import both human and animal food, the \$1 million ceiling applies to the human food imported and the \$2.5 million ceiling applies to the animal food imported. For example, if an importer imports \$1.5 million of human food and \$1 million of animal food, the importer would be a very small importer for the purposes of its animal food (*i.e.*, the importer would be subject to modified requirements for this food) but would not be a very small importer for the purposes of its human food (*i.e.*, the importer would be subject to the standard supplier verification requirements for this food). This is consistent with the way facilities that produce both human and animal food domestically are treated under the preventive controls regulations.

Another change we are making to the very small importer definition to make it more consistent with the very small business definitions in the preventive controls regulations is to address the circumstances in which an importer charges fees for importing food. Because the definition in the Supplemental Notice concerned "sales of food," it was unclear how entities that charge fees but do not "sell" food would be treated. As discussed more fully in section III.M of this document, a principal reason that we are comfortable with modified

requirements for food imported by very small importers is that these firms are likely to be importing a relatively low volume of food into the United States. As we stated in the preamble to the proposed rule, sales of food is a proxy for volume. We need a different proxy for importers of food that do not have food sales, such as certain warehouses and repacking facilities. Therefore, we are clarifying that importers that do not have sales of food, per se, should calculate the U.S. market value of the food they import to determine whether they do not exceed the monetary ceiling for being a very small importer. If an importer has some sales of food and conducts some of its food importation business in exchange for fees, the importer must add the sales of food and the U.S. market value of the food imported without sale to determine whether it is a very small importer.

(Comment 66) One comment finds the phrase "on a rolling basis" in the definition of very small importer to be confusing.

(Response 66) In response to this comment and to be consistent with the very small business definitions in the preventive controls regulations, we are removing the phrase "on a rolling basis" from the definition. Instead, we are specifying that the average annual sales must be calculated, adjusted for inflation, during the 3-year period preceding the applicable calendar year.

(Comment 67) Some comments request that we base annual sales on different criteria. Several comments request that the annual sales ceiling be based on sales to the United States rather than worldwide. Some comments similarly request that the ceiling apply only to the value of food imported into the United States rather than an importer's total annual food sales. Some comments assert that it would be difficult for FDA to determine which products are intended for export and which are for domestic consumption. One comment supports an annual sales ceiling of \$2 million if we decide to base the number on worldwide sales.

(Response 67) We disagree that the annual sales ceiling should be based on sales to the United States rather than worldwide or only to the value of food imported as opposed to an importer's total annual food sales. By establishing modified requirements for very small importers, we are providing practical allowances for entities we believe pose a relatively low risk of causing harm to consumers. An importer that sells more than the ceiling dollar amount poses more risk. We also affirm our tentative conclusion from the proposed rule that, given the risk to overall public health,



the modified requirements we put in place are 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 in compliance with sections 402 and 403(w) of the FD&C Act (as applicable). This approach is consistent with the approach we are taking with respect to very small businesses under the preventive controls regulations.

#### *B. Applicability and Exemptions (§ 1.501)*

We proposed to specify (in § 1.501(a)) that the FSVP regulations would apply to all food imported or offered for import into the United States and to the importers of such food, except to the extent that we set forth proposed exemptions in § 1.501. In response to comments, we have made some changes to the exemptions and added certain exemptions.

##### **1. Exemption for Certain Juice and Seafood Products**

In accordance with section 805(e) of the FD&C Act, we proposed to exempt from the FSVP regulation juice, fish, and fishery products imported from a foreign supplier that is required to comply with, and is in compliance with, the regulation on juice in part 120 (21 CFR part 120) or the regulation on fish and fishery products in part 123 (21 CFR part 123) (proposed § 1.501(b)). We further proposed to specify that importers of juice or fish and fishery products that are subject to the requirements applicable to importers of those products under § 120.14 or § 123.12, respectively (the “HACCP importer regulations”), must comply with those requirements.

(Comment 68) One comment expresses concern about the proposed exemption for seafood products. The comment maintains that because the seafood HACCP regulation does not require onsite auditing to verify the foreign supplier’s compliance with that regulation, there is no assurance of compliance. The comment contends that the exemption for seafood products is not consistent with congressional direction and the stated intent of the FSVP regulation.

(Response 68) We do not agree. The exemption for fish and fishery products in § 1.501(b)(1) of the final rule provides that the FSVP regulation does not apply to products imported from a foreign supplier that is required to comply with, and is in compliance with, the

regulation on fish and fishery products in part 123. Among other things, part 123 requires importers to comply with requirements for imported fish and fishery products, which may include implementing written procedures for ensuring that imported products were processed in accordance with the HACCP regulation, including the use of “affirmative steps” such as obtaining continuing lot-specific certificates from an appropriate foreign government inspection authority or competent third party, or regularly inspecting foreign processor facilities (see § 123.12). Thus, § 1.501(b)(1) makes clear that importers of fish and fishery products are responsible for verification, but must do so under the regulation specific to fish and fishery products in part 123. As for the comment that the seafood HACCP exemption is inconsistent with congressional intent, we do not agree. Section 805(e) of the FD&C Act states that the FSVP 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 regulation for seafood (as well as juice). Thus, Congress specifically exempted facilities that are required to comply with, and are in compliance with, the seafood HACCP regulation from the scope of the FSVP regulation. We therefore conclude that it is consistent with congressional intent to exempt from the FSVP regulation the importation of seafood that is required to comply with, and is in compliance with, the seafood HACCP regulation in part 123.

(Comment 69) One comment asserts that the proposed exemption for juice is narrower than the statutory exemption because it applies to imported juice products but not ingredients. The comment requests that the exemption be applied to all ingredients and raw materials used in a facility that is subject to and in compliance with the juice HACCP regulation provided those ingredients will be used in the production of juice products subject to the HACCP regulation.

(Response 69) We agree with the comment that we should broaden this exemption. As we stated in the preamble to the FSVP proposed rule, the meaning of the reference to a juice or seafood “facility” in section 805(e)(1) and (e)(2) of the FD&C Act is subject to multiple interpretations (78 FR 45730 at 45745). We discussed the possibility that the reference to “facility” might be intended to apply to a foreign supplier of juice or seafood or to an importer of such food. We tentatively concluded that Congress intended that section

805(e)(1) and (e)(2) apply to food being imported from foreign suppliers in compliance with FDA requirements for juice or seafood HACCP.

However, as the comment notes, applying section 805(e)(1) and (e)(2) only to food being imported from HACCP-compliant foreign facilities would mean that importers that are also juice or seafood facilities would need to conduct supplier verification for the raw materials and other ingredients they import for use in juice and seafood products that are processed in accordance with the HACCP regulations. However, in enacting section 805(e)(1) and (e)(2), we believe that Congress intended to exclude food covered by and in compliance with the HACCP requirements from section 805 of the FD&C Act. This exclusion likely reflects a determination that the HACCP regulations in parts 120 and 123 make application of section 805 unnecessary because those regulations require processors to adequately address applicable hazards.

We therefore conclude that a more reasonable interpretation is that Congress intended to exempt from the FSVP requirements the activities of a facility that are subject to the juice or seafood HACCP regulations in part 120 or 123. Under this interpretation, the exemption applies not only to the importation of food produced by a foreign supplier subject to and in compliance with those regulations, but also to the importation of raw materials or other ingredients by U.S. facilities for use in processing juice and seafood products in accordance with the regulations. We conclude that this interpretation would fulfill the apparent goal of section 805(e)(1) and (e)(2) because importers that manufacture/process juice or seafood under the HACCP regulations will be addressing all the hazards in the raw materials or other ingredients they import in accordance with those regulations. Accordingly, § 1.501(b)(2) of the final rule states the FSVP regulation does not apply with respect to raw materials or other ingredients an importer uses in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided the importer complies with the relevant regulation when manufacturing or processing the juice or seafood product.

(Comment 70) Some comments express concern regarding the statement in the preamble to the proposed rule that we are considering whether in the future we should initiate a rulemaking to revise the HACCP importer regulations in light of the FSVP regulation and FSMA’s increased

emphasis on importers' role in ensuring the safety of imported food. The comments assert that although the HACCP importer regulations do not require onsite audits of foreign suppliers, other requirements under the HACCP regulations ensure food safety. One comment questions whether revising the juice HACCP regulation would result in additional safety because juice producers must process juice to achieve a 5-log reduction in the pertinent microorganisms for juice, a requirement that is not mandated in the FSMA proposed rules.

(Response 70) We agree that the juice and seafood HACCP regulations have requirements applicable to importers in §§ 120.14 and 123.12, respectively. At the same time, we recognize that section 805 of the FD&C Act and the implementing regulation in this final rule set forth a more comprehensive approach to verification than the existing juice and seafood HACCP regulations. Consistent with the statement in the preamble to the proposed rule, we therefore think it is appropriate to consider whether the Agency should in the future initiate a rulemaking to revise the regulations applicable to importers of juice and seafood. We believe that the comment on the juice HACCP processing requirements is misplaced because the FSVP regulation concerns verification that the food safety requirements applicable to the manufacturing/processing, growing, or raising of food are met, not the establishment of the food safety requirements themselves.

## 2. Exemption for Food Imported for Research or Evaluation

In proposed § 1.501(c), we proposed to exempt from the FSVP regulation food that is imported for research or evaluation use, provided that:

- The food is not intended for retail sale and is not sold or distributed to the public;
- The food is labeled with the statement "Food for research or evaluation use"; and
- When filing entry with CBP, 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.

We further proposed to specify that 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. We proposed this exemption from the FSVP

requirements consistent with section 805(f) of the FD&C Act.

(Comment 71) One comment asks that we require that the statement "Food for research or evaluation use" be placed on a permanently affixed label.

(Response 71) We do not believe that it is necessary to specify that the label be permanently affixed to the food covered by this exemption. However, in proposing to require that the food eligible for this exemption be labeled with the statement "Food for research or evaluation use," we stated that this requirement was 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 therefore expect that such labels will be securely attached to the food so they remain on the food until the food is used for research or evaluation to ensure that it is not sold or distributed to the public.

(Comment 72) One comment maintains that the regulation should not require the importer to declare electronically that a food will be used for research and evaluation purposes, asserting that the requirement to label the food should be sufficient.

(Response 72) We do not agree. We stated in the preamble to the proposed rule that the intent of requiring this declaration at entry was to help ensure that the food is, in fact, not intended for retail sale and is not sold or distributed to the public. The electronic declaration requirement also provides an efficient and effective means of determining whether a food is exempt under § 1.501(c). For example, the electronic declaration will mean that the designation for research and evaluation use is readily available to FDA during entry review of the food. We believe that the electronic declaration requirement will allow us to efficiently enforce this exemption and thus efficiently enforce section 805(f) of the FD&C Act.

(Comment 73) Some comments request that we interpret "small quantity" flexibly to allow for variance based on the type of food product, the purpose of the research or evaluation, and other factors. Some comments suggest that we interpret research and evaluation use on a case-by-case basis. One comment asserts that the amount of food needed for research or evaluation varies and is not always a small quantity; therefore, the comment suggests that we remove the term "small quantity" or replace it with a phrase such as "amounts not to exceed the amount reasonably sufficient to conduct" the research or evaluation. Some comments maintain that the quantity should not matter as long as

the imported food will be used exclusively for research or evaluation and will not enter commerce.

(Response 73) We do not agree that we should remove or replace the term "small quantity" in § 1.501(c). In drafting section 805(f) of the FD&C Act, Congress specified that the exemption for research and evaluation purposes is for "small quantities" of food. Thus, it would not be consistent with the intent of the exemption if we removed the specification that the exemption applies to small quantities of food. As for replacing the term "small quantity" with a term such as "amounts not to exceed the amount reasonably sufficient to conduct" the research or evaluation, we decline this request for the same reason; the limitation regarding "small quantities" is consistent with congressional intent. To the extent the comments take the position that some flexibility is needed in administering the "small quantities" limitation, we agree. Because we understand that the amount of food used in research can vary based on the type of food, the nature of the research, and other factors, we intend to address in the FSVP draft guidance the quantity of food that is consistent with the "small quantities" limitation under different circumstances.

(Comment 74) One comment suggests that we modify the exemption for food imported for research or evaluation to require unused amounts to be properly managed to ensure they do not enter commerce.

(Response 74) We agree and have revised the exemption to specify that any unused amounts must be properly disposed of. This requirement will help ensure that all food imported under this exemption is in fact used for the intended purpose of the exemption: research or evaluation. As such, this requirement will assist us in meeting our statutory obligation under section 805(f) of the FD&C Act to provide an FSVP exemption for small quantities of food imported for research and evaluation purposes.

(Comment 75) Some comments request an exemption from the FSVP requirements for food samples imported for trade shows. The comments maintain that trade show food samples provide an important marketing opportunity for small and medium companies at the early stage of expanding their business in the United States, and they contend it would be difficult for such companies to comply with the FSVP regulation.

(Response 75) We do not agree that it is appropriate to exempt from the scope of the FSVP requirements food samples

imported for consumption at trade shows. Section 805(f) of the FD&C Act directs FDA to establish an exemption for food imported in small quantities for research and evaluation purposes, “provided that such foods are not intended for retail sale and are not sold or distributed to the public.” Because food imported for consumption at trade shows would be sold or distributed to the public generally (*i.e.*, anyone could attend the trade show), we conclude that exempting such food from the FSVP regulation would be inconsistent with the limitation in section 805(f). We also believe such an exemption would be inconsistent with the broader intent of section 805, which is to help ensure the safety of imported food.

(Comment 76) One comment requests that pet food imported for use in in-home studies conducted under contracts with pet owners be exempt from the FSVP requirements.

(Response 76) Provided that food imported for use in such in-home studies is imported in small quantities and meets the additional requirements of § 1.501(c), we agree that such food would be exempt from the FSVP requirements. Because the food would be used as part of a defined study with a discrete set of test subjects for research and evaluation purposes, it does not appear that such food would be sold or distributed to the general public.

(Comment 77) One comment asks that we clarify that if materials produced in a research and development facility will be used in products that are consumed by the public, such as in market research activities like home-use tests, consumer panels, and sales samples, the facility will be subject to the FSVP regulation.

(Response 77) Imported food that is sold or distributed to the public is not eligible for the exemption for food for research and evaluation purposes in § 1.501(c). Therefore, if the comment is referring to a foreign supplier that is a research and development facility but is producing food to be distributed or made available to the public generally (rather than provided under defined research conditions with a discrete set of test subjects), that food imported from that foreign supplier would not be exempt from FSVP. If the comment is referring to an importer that is a research and development facility using imported food to produce food products to be distributed to the public, the importer will be subject to FSVP for that food. If the importer is also a “facility” under section 415 of the FD&C Act and therefore subject to the preventive controls regulations, and if the facility has established and implemented

supply-chain program requirements for an imported raw material or other ingredient in compliance with subpart G of part 117 or subpart E of part 507 with respect to the food, the facility would be deemed to be in compliance with the FSVP requirements, except for the requirements in § 1.509 (see § 1.502(c) of the final rule).

(Comment 78) One comment suggests that if a facility conducts research and development activities on the same site at which food is manufactured or processed, the exemption should apply only to the food intended for research or evaluation purposes instead of all food from the facility.

(Response 78) We agree. The exemption for food imported for research or evaluation applies only to food that meets the requirements for the exemption set forth in § 1.501(c) of the final rule. Importation of other food from a foreign supplier that also provides food for research or evaluation would not be exempt from the FSVP requirements.

(Comment 79) Some comments request that first shipments of a food imported into the United States be exempt from the FSVP requirements. According to the comments, the FSVP regulation might prohibit emerging products from entering the United States and hinder innovation by foreign suppliers.

(Response 79) We do not agree. In enacting section 805(f) of the FD&C Act, Congress specified that the exemption for research and evaluation apply only for “food . . . for research and evaluation purposes.” Congress further specified that the exemption applies “provided that such foods are not intended for retail sale and are not sold or distributed to the public.” Extending the exemption to all “first shipments” of a particular food would not be consistent with that limited exemption.

### 3. Exemption for Food Imported for Personal Consumption

Consistent with section 805(f) of the FD&C Act, we proposed to exempt from the FSVP regulation food that is imported for personal consumption, provided such food is not intended for retail sale and is not sold or distributed to the public (proposed § 1.501(d)). We proposed to specify that 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.

(Comment 80) One comment asserts that the term “small quantity” is subjective and asks whether we will

clarify the term. However, one comment asks that we not define “small quantity” because doing so might conflict with other FDA food regulations (*e.g.*, 21 CFR 1.277(b)(1) and 1.327(m)) that refer to food for “personal consumption” or “personal use” without further elaboration. This comment suggests that if we do define “small quantity” for personal consumption, we should allow importation of a supply of a given food that would permit at least a number of years’ worth of personal consumption (assuming the food item is shelf stable).

(Response 80) We conclude it is not appropriate to define “small quantity” for purposes of the exemption for food imported for personal consumption. The determination of what quantity of food is “consistent with a non-commercial purpose” must be made on a case-by-case basis and might vary depending on the type of food and other factors. In some cases, a supply that exceeds what one person might consume in a relatively short period of time might suggest a commercial purpose (and thus fall outside of the personal consumption exemption for FSVP). In other cases, a small supply that one person might consume over a period of years might be consistent with a personal consumption purpose and therefore might fall within the scope of the personal consumption exemption in § 1.501(d). However, in all cases the quantity of imported food would have to be consistent with a non-commercial purpose and the food could not be sold or distributed to the public in order to be subject to the exemption.

(Comment 81) One comment expresses concern that the exemption for personal consumption might be abused. The comment asserts that foods are often shipped or smuggled into the United States purportedly for personal use but are instead sold at ethnic food stores. The comment recommends that FDA and State and local agencies share information about such food to better control such violations.

(Response 81) We agree it is important that agencies involved in ensuring the safety of food imported into the United States share relevant information when possible and permitted by law. We routinely work with our State and local regulatory partners to address activities affecting the safety of imported food, and we intend to include implementation of the FSVP regulation among these activities. To the extent we become aware of any abuses of the personal consumption exemption in § 1.501(d), we intend to take appropriate action in response.

#### 4. Exemption for Alcoholic Beverages

Under proposed § 1.501(e), we proposed to exempt from the FSVP regulation 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 (FAAA) (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.

We also proposed that the FSVP regulation would not apply to food other than alcoholic beverages that is imported from a foreign supplier described in § 1.501(e)(1) provided that such food:

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

We tentatively concluded that these provisions were consistent with the provisions on alcohol-related facilities in section 116 of FSMA (21 U.S.C. 2206(a)) and the proposed regulation on preventive controls for human food.

(Comment 82) Some comments request that we exempt from the FSVP requirements importation of raw materials and ingredients (*e.g.*, grapes, grains, hops, flavors) used to produce alcoholic beverages. The comments maintain that such an exemption would be consistent with the regulations on preventive controls for human food and accreditation of third-party auditors. The comments further assert that such an exemption would ensure consistency between domestic and foreign facilities and be consistent with Congressional intent regarding section 116 of FSMA.

(Response 82) For the reasons stated in the following paragraphs, we agree that some importers that import raw materials and other ingredients used to produce alcoholic beverages should be exempt from the FSVP regulation, but only with respect to alcoholic beverages an importer manufactures/processes, packs, or holds at a facility that meets the requirements to be exempt from the

preventive controls regulation under § 117.5(i) and as further described in the following paragraphs.

We believe that the context and purpose of FSMA supports this approach. Section 116(a) of FSMA provides that, except as provided by certain listed sections in FSMA, nothing in that act, or the amendments made by it, shall be construed to apply to a facility that (1) under the FAAA (or chapter 51 of subtitle E of the Internal Revenue Code of 1986) 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).

The regulation on preventive controls for human food includes provisions implementing section 116 of FSMA. As reflected in the final rule on preventive controls for human food, FDA has determined that the alcoholic beverage exemption contemplated by section 116 exempts from the preventive controls regulation alcoholic beverages at facilities meeting the two specified conditions in section 116. (The exemption from the preventive controls regulation also applies with respect to food other than alcoholic beverages at facilities described in the exemption, provided such food is in prepackaged form that prevents direct human contact with the food and constitutes not more than 5 percent of the overall sales of the facility.) Notably, we interpret the exemption to apply not only to domestic facilities that are required to secure a permit, registration, or approval from the Secretary of the 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.

In the FSVP proposed rule, we discussed two possible approaches to interpreting section 116 of FSMA for purposes of the FSVP regulation. In doing so, we noted that section 116 is premised in part on status as a facility required to register under section 415 of the FD&C Act (section 116(a)(2) of FSMA). We also noted that under the definition of “importer” in the proposed rule, an “importer” under the FSVP regulation might be a registered facility but would not necessarily be one. Given section 116’s emphasis on status as a facility that is required to register under section 415 of the FD&C Act, we noted

that one approach to implementing section 116 would be to base an exemption from the FSVP regulation on whether the importer of an alcoholic beverage was a registered facility. The second approach we identified was to focus on the foreign supplier and to exempt from the FSVP regulation alcoholic beverages from foreign suppliers that would be exempt from the preventive controls regulation. As explained in the proposed rule, we proposed to adopt the second approach.

In reaching this tentative conclusion we noted that, under the first approach, firms might import the same product (*e.g.*, a bottled alcoholic beverage) and one firm would be eligible for the alcoholic beverage exemption from the FSVP regulation 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.

The second approach of focusing on the foreign supplier, however, tentatively seemed to be more consistent with FDA’s approach to alcoholic beverages in the proposed regulations on preventive controls for human food. Under this approach, if an alcoholic beverage is being imported, the foreign supplier would, by definition, be a facility that is required to register with FDA. Our proposed definition of “foreign supplier” meant 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 § 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 on 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. We tentatively concluded that this interpretation was consistent with the preventive controls proposed regulation because, 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.

In proposing this second approach, however, we created an unanticipated inconsistency with the preventive controls regulation. Under the proposed FSVP regulation, a facility that meets the requirements for the alcoholic beverage exemption under § 117.5(i) of the regulation on preventive controls for human food could nevertheless be subject to the FSVP regulation if it imports, for example, raw materials to be used in the manufacture/processing of alcoholic beverages. Because the importer/facility would be exempt from the preventive controls regulation under § 117.5(j), it would not be required to establish and implement a risk-based supplier program under that regulation. That would mean that the importer would not be exempt from most FSVP requirements under the proposal to deem importers in compliance if they are required to establish and implement a risk-based supplier program under the preventive controls regulation, and are in compliance with those requirements. This is because only importers required under the preventive controls regulation to establish and implement such a supplier program could be deemed in compliance under that proposal. Under the proposed FSVP regulation, such an importer would not be exempt from FSVP because the food it imports would not be alcoholic beverages from a foreign supplier that meets the proposed requirements for the FSVP alcoholic beverage exemption. For facilities that meet the requirements for the alcoholic beverage exemption under § 117.5(i) and that also import raw materials for use in the manufacture/processing of alcoholic beverages, the result of this proposed approach would be to simultaneously exempt such facilities from the supplier verification requirements of the preventive controls regulation by operation of § 117.5(i), while requiring such facilities to conduct supplier verification activities under the FSVP regulation because they import food that would not be subject to the FSVP proposed exemption for alcoholic beverages.

We conclude that such a result would not be consistent with the risk-based public health principles underlying section 805 of the FD&C Act and FSMA generally. In enacting section 116 of FSMA, Congress must have considered it a lower public health priority to apply FSMA's core requirements to the manufacture/processing, packing, and holding of alcoholic beverages. Congress

may have made such a conclusion in light of the potential antimicrobial function of the alcohol content in such beverages and the concurrent regulation of alcoholic beverage-related facilities by both FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB). In this context, we concluded that section 116 of FSMA should be interpreted to indicate that the manufacturing, processing, packing, or holding of alcoholic beverages at most alcohol-related facilities should not be subject to the preventive controls requirements of FSMA. For that reason, we established § 117.5(i). As discussed in the previous paragraphs, we included supplier verification requirements in the preventive control regulation. As a result, requiring alcohol-related facilities that are exempt from the supplier verification requirements in the preventive controls regulation under § 117.5(i) to nevertheless conduct supplier verification for imported ingredients used in the manufacture/processing of alcoholic beverages would effectively undo part of the exemption established by § 117.5(i).

For these reasons, we conclude that it is appropriate to adjust the scope of the alcoholic beverage exemption in the FSVP regulation. The final rule continues to exempt the alcoholic beverages that the proposed rule proposed to exempt, but also adds an exemption for food used in the production of alcoholic beverages that is based on the first approach to interpreting section 116 of FSMA that we discussed in the proposed rule, with additional limitations. Specifically, the final rule adds an exemption that only applies to importers required to be registered under section 415 of the FD&C Act, when such facilities are exempt from the preventive controls regulation under § 117.5(i). This exemption applies to food, such as grapes, hops, grains, and other ingredients, that is used by the importer in the manufacturing/processing, packing, or holding of alcoholic beverages.

Also in this final rule, we are clarifying the exemption for food that is not an alcoholic beverage imported from foreign suppliers described in § 1.501(e)(1) that is in prepackaged form preventing any direct human contact with the food, when such food constitutes not more than 5 percent of the overall sales of the facility. Instead of using the term "food other than alcoholic beverages" to describe the applicability of the exemption, as we proposed, we are now using the term "food that is not an alcoholic beverage."

#### 5. Inapplicability to Food That Is Transshipped or Imported for Further Processing and Export

We proposed that the FSVP regulations would not apply to food that is transshipped through the United States to another country or to food that is imported for future export and that is neither consumed nor distributed in the United States.

(Comment 83) One comment expresses concern that the exemptions for transshipped food and food imported for further processing inappropriately shift the burden for ensuring the safety of imported food to the domestic manufacturer.

(Response 83) As stated in the preamble to the proposed rule, section 805 of the FD&C Act is designed to require importers to take affirmative steps to verify the compliance of the food with U.S. safety requirements. Given that context, we tentatively concluded that section 805 is not intended to apply to food that is neither consumed nor distributed in the United States and that is imported for further processing and export. We have not received any comments in response to the proposed rule that have caused us to change this tentative conclusion. The final rule therefore retains the exemption for transshipped food and for food that is imported for further processing and export. However, we are making several clarifications to these exemptions. First, we are clarifying that the exemption for transshipment only applies to food that is neither consumed nor distributed to the public in the United States. Second, the exemption for food that is imported for export applies when the food is being imported for processing, followed by export. Third, this exemption applies when the food is not consumed or distributed to the public in the United States. (The proposed rule proposed to specify that the exemption would apply when the food is not "consumed or distributed" in the United States, but did not explain that distributed means "distributed to the public.")

To the extent that the comment suggests that the exemptions place an unfair burden of ensuring the safety of imported food on U.S. manufacturers, we do not agree. By definition, U.S. manufacturers are not involved in the manufacturing/processing of transshipped food and thus are not affected by such food. We also believe the exemptions are consistent with the intent of section 805 of the FD&C Act.

(Comment 84) One comment asks whether the exemption for transshipped food applies to all imported food or only

food that is bonded by CBP, which permits merchandise to be moved from one port to another without the merchandise being appraised or duties imposed.

(Response 84) The exemption for transshipped food applies to all food that is transshipped through the United States to another country, provided that the food is not consumed or distributed to the public in the United States. The exemption does not hinge on whether the food is bonded by CBP.

#### 6. U.S. Goods Returned

(Comment 85) Several comments asked that the transshipment exemption apply to food that is produced in and exported from the United States and is returned to the exporter after being rejected by the foreign purchaser or a foreign government (referred to as “U.S. goods returned” or “American goods returned”), sometimes for reasons other than the safety of the food. (Several other comments also asked for such an exemption, independent of the transshipment exemption.) One comment maintains that conducting verification for food that is returned to its U.S. producer in its original packaging would not constitute risk-based verification because there would be no hazards in such food. One comment asserts that because entries of U.S. goods returned are easily identified by their Harmonized Tariff Schedule (HTS) code, FDA should be able to manage any risks with such food through other mechanisms, including the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) electronic import screening system. The comments maintain that the FSVP requirements should not apply to U.S. goods returned because there is no foreign supplier of the food and the “importer” of the food would be conducting verification of its own operations.

(Response 85) We agree in part and disagree in part. Considering the context of section 805 of the FD&C Act, under which the importer must take affirmative steps to verify the compliance of imported food with U.S. safety requirements, we reaffirm our tentative conclusion (stated in the preamble to the proposed rule) that section 805 is not intended to apply to food that is neither consumed nor distributed in the United States. Therefore, we are finalizing § 1.501(f) with a few minor changes.

We think that similar considerations make it reasonable to conclude that the FSVP requirements do not apply to food that is manufactured/processed, raised, or grown in the United States, exported,

and then returned to the United States. Although section 805 of the FD&C Act applies to “each importer” and “the food imported by the importer or agent of an importer,” we think that section 805 of the FD&C Act is not intended to apply to circumstances in which there would not be a true foreign supplier of the food. Applying FSVP requirements in such circumstances would not be consistent with the underlying purpose of the FSVP provisions. Section 805(c)(2)(A) states that FDA’s implementing regulations must 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 must 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. Food that is originally manufactured/processed, grown, harvested, or raised in the United States is generally already subject to sections 402, 403(w), 418, and 419 of the FD&C Act, as applicable, and is therefore already subject to requirements that the food be as safe as other food produced and sold in the United States. Therefore, there is no reason to subject such food to the FSVP requirements and doing so would not be consistent with the context and purpose of section 805. Consequently, the final rule includes a provision, § 1.501(g), specifying that the FSVP regulation does not apply to such U.S. foods returned to the United States.

#### 7. Raw Agricultural Commodities

(Comment 86) Some comments request that we exempt commingled or consolidated RACs (other than fruits and vegetables) from the FSVP regulations. Some comments request specific exemption for such RACs as dairy products, coffee and cocoa beans, and milled rice, canola meal, and cottonseed used for animal food. The comments maintain that these RACs generally are low-risk foods and are further processed at facilities in the United States that are required to register under section 415 of the FD&C Act, and that the U.S. facilities will address any hazards in the foods. The comments assert that, because of the complexity of RAC supply chains, it

would be prohibitively expensive for importers to conduct supplier verification for all of the farms associated with consolidated shipments of RACs. The comments maintain that RACs may change hands many times between the farm and the foreign port facility and also between the importer and the U.S. facility that manufactures/ processes the RAC. The comments also contend that, because distributors may refuse to reveal their suppliers for competitive reasons or may not know the identity of the farms where the RACs are grown, it might not be possible for the importer to identify the growers. Some comments assert that exemption from FSVP is appropriate because FDA has not established standards for growers and traders of RACs that are not subject to the produce safety regulation and has limited standards for others in RAC supply chains.

(Response 86) We decline to exempt importers of RACs that are not subject to the produce safety regulation from the FSVP regulation. Although we have not established specific safety requirements for these RACs under the produce safety regulation, the requirements for FSVP are separate from the requirements for produce safety. We do not believe that an exemption for all RACs other than fruits and vegetables—whether commingled, consolidated, or otherwise—is appropriate. As discussed in response to other comments, section 805 of the FD&C Act applies to “each importer” and “the food imported by the importer or agent of an importer.” Given Congress’ decision to include exemptions for some types of food (*e.g.*, seafood and juice products subject to, and in compliance with, FDA’s HACCP regulations), but not RACs, we believe that Congress intended for FDA to establish FSVP regulations to ensure that imported RACs of the type discussed in the comments are as safe as similar RACs produced in the United States. As such, the RACs discussed in the comments are subject to the FSVP regulation, and importers of such RACs generally must conduct supplier verification activities in accordance with the FSVP requirements. However, if an importer determines under § 1.504(f) of the final rule that there are no hazards requiring a control in a particular RAC, the importer would not be required to determine what foreign supplier verification and related activities would need to be conducted, and the importer would not have to conduct such activities (see section III.E.7 of this document).

In addition, as discussed in more detail in section III.H.2 of this

document, under § 1.507 of the final rule, an importer will not be required to conduct the standard supplier verification activities when the hazards in a food (including a RAC) will be significantly minimized or prevented by the importer's customer. Instead, the importer will be required to (1) disclose in documents accompanying the food that the food is not processed to control identified hazards, and (2) obtain written assurance that its customer or an entity after its customer is processing the food for food safety. Similar procedures also are available when an entity in the distribution chain after the importer's immediate customer is processing the food for food safety. The final rule also would not require compliance with the standard supplier verification requirements for foods that could not be consumed without the application of an appropriate control (as may be the case with some RACs discussed in the comments) or when the importer implements a system that ensures control of the hazards in a food at a later distribution step.

#### 8. Produce Rarely Consumed Raw and Food Intended for Commercial Processing

(Comment 87) One comment asks that we exempt from the FSVP requirements produce that is rarely consumed raw and produce that is intended for commercial processing (presumably, processing that would adequately reduce the presence of pathogens), asserting that such an exemption would be consistent with the exemption for such foods from the produce safety regulation. Another comment opposes the exemption of produce rarely consumed raw from the produce safety regulation and asks that these products not be exempt from the FSVP regulation.

(Response 87) The final rule does not exempt from the FSVP regulation produce rarely consumed raw or produce intended for commercial processing, whether or not the processing would adequately reduce the presence of microorganisms of public health significance. Regarding produce rarely consumed raw, we are allowing importers to rely on the provisions in §§ 1.505, 1.506, and 1.507 instead of providing an exemption. For some produce in this category, an importer might determine it is appropriate to conduct supplier verification activities to ensure that hazards in the food have been significantly minimized or prevented before importation. For other produce in this category, we are establishing requirements in § 1.507 that we believe are generally more suitable

to ensuring the safety of many of these foods than the standard FSVP requirements and that would not require the importer to conduct standard supplier verification activities. As described in section III.H.2 of this document, the final rule provides flexibility for situations in which an entity in the United States that is not the importer will control the hazards in a food.

Regarding imported produce intended for commercial processing, under § 1.502(c) of the final rule, when the importer itself is a receiving facility as defined in the preventive controls regulations and either (1) implements preventive controls for the hazards in the food, (2) is not required to implement a preventive control under § 117.135 or § 507.34, or (3) has implemented a supply-chain program for the food in compliance with the preventive controls regulations, the importer would be deemed in compliance with most of the FSVP requirements (except for the requirements in § 1.509). When such processing is performed by the importer's customer or a subsequent entity, the flexibility provided in § 1.507 would allow the importer to forego supplier verification activities provided it meets certain other requirements to help ensure that the processing is adequately performed before the food is consumed.

#### 9. Products Not for Use as Food

(Comment 88) One comment suggests that for a food that may be used for either a food or non-food use, FDA should regard each shipment of the product offered for import to be food that is subject to the FSVP regulation unless the statement "Not for food use" is included in the commercial documentation accompanying the shipment.

(Response 88) Under FDA's regulation implementing the prior notice requirements of the Bioterrorism Act, prior notice must be submitted for each article of food that is imported or offered for import into the United States (21 CFR 1.281(a)). In our interim final rule on prior notice, we explained that we will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (e.g., submitter, transmitter, manufacturer, grower, shipper, importer, owner, ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use (68 FR 58974 at 58987, October 10, 2003). In the prior notice final rule, we clarified that we consider a dual use

substance to be "food" for the purpose of prior notice if it is reasonably likely to be directed to a food use (73 FR 66294 at 66301, November 7, 2008). Thus, an article of food is subject to the prior notice requirements if it is capable of multiple uses, provided that it is reasonably likely to be directed to a food use. We believe that a similar approach is appropriate with respect to FSVP. Therefore, we conclude that a substance that is capable of multiple uses is subject to the FSVP regulation if it is reasonably likely to be directed to a food use. We believe this standard is appropriate because it will subject substances that are reasonably likely to be directed to a food use to the FSVP regulation, more so than basing the application of the FSVP regulation on the existence of a "Not for food use" statement that might not necessarily reflect industry practice or the likely use of the substance.

#### 10. Food From Foreign Suppliers That Are Part of Same Corporate Structure

In the preamble to the proposed rule, we stated that some importers might obtain food from foreign suppliers who are part of the same corporate structure as the importer and who might, 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 sought comment on whether such importers should be required to conduct foreign supplier verification or should be subject to different FSVP requirements.

(Comment 89) Several comments request that we exempt from the FSVP regulations food that is imported from a foreign supplier who is part of the same corporate structure as the importer. The comments assert that when the importer and the foreign supplier follow the same food safety standards and practices, supplier verification is unnecessary. Some comments request that we exempt from the FSVP regulation food that is imported from a foreign supplier that is an affiliate of the importer; some comments request that the exemption apply when the foreign supplier of a food is under the same corporate structure as the importer and/or is subject to the same integrated, company-wide approach to food safety as the importer. However, some comments express concern that such an exemption might lead to fraudulent schemes to make it appear as if the importer and the foreign supplier are integrated companies.

(Response 89) We decline to exempt from the FSVP regulation food an



importer obtains from a foreign supplier that is part of the same corporate structure as the importer. We also decline to establish an exemption from the FSVP requirements when the foreign supplier and importer may otherwise be affiliated, and when the foreign supplier and importer are part of the same company-wide “approach” to food safety. We conclude that the fact that an importer and its foreign supplier are affiliated and may be operating within a unified corporate structure or food safety system does not necessarily ensure that the foreign supplier is operating in compliance with sections 402 and 403(w) of the FD&C Act (where applicable). Nor does such a relationship necessarily ensure the foreign supplier is operating in compliance with processes and procedures that provide the same level of public health protection as the requirements under the preventive controls or produce safety regulations, where applicable. Consequently, importers should be required to conduct supplier verification in these circumstances. However, we agree that an importer’s corporate affiliation with its foreign supplier might provide the importer with greater assurance regarding the supplier’s compliance with applicable requirements under the FD&C Act. Therefore, an importer of a food from a foreign supplier that is part of the same corporate structure as the importer and/or is subject to the same integrated, corporate approach to food safety may take this into account in evaluating the foreign supplier’s performance under § 1.505 of the final rule and determining appropriate supplier verification activities for the supplier under § 1.506.

(Comment 90) One comment asserts that requiring supplier verification for imports from suppliers with the same corporate parent may increase trade burdens in violation of WTO agreements. The comment provided the example of Company A in San Diego that imports finished packaged cereal from Company A in Tijuana, Mexico. The comment states that under the proposed rule, the company would be required to conduct supplier verification of itself, but the company would not be required to conduct supplier verification if it had manufactured the cereal in California. The comment maintains that without exempting the Tijuana-produced food from FSVP, U.S.-produced goods would receive favorable treatment because FSVP would impose a paperwork burden for intra-company imports.

(Response 90) We do not agree. FSVP would not impose a trade or paperwork

burden for the intra-company imports described in the comment. If the company in the example manufactured the cereal product in California, the company would be subject to the supply-chain program requirements in the preventive controls for human food regulation, and therefore would be required to verify its ingredient suppliers. It also would be required to review its supply-chain program records to determine whether the program is effective. Therefore, it is not correct that if the company manufactured the cereal product in California, it would not need to conduct verification activities with respect to the product. In addition, FSVP-related verification activities for the cereal product manufactured in Tijuana need only be commensurate with the risk posed by the cereal, and the importer of the cereal can take the intra-company relationship into account in evaluating the foreign supplier and determining appropriate verification activities. Therefore, we do not believe the FSVP regulation increases trade burdens on importers of suppliers with the same corporate parent.

We also note that the California facility would be part of a domestic U.S. Integrated Food Safety System (IFSS) that includes multiple Federal, State, territorial, tribal, and local regulatory and public health agencies (see the discussion of the IFSS in Response 105). Inspections of domestic food facilities (including farms, manufacturing facilities, and retail facilities) are overseen by a mix of Federal, State, local, tribal, and territorial agencies. When compared to this comprehensive system of domestic oversight for food production and distribution from farm to retail (discussed in more detail in section III.C.1.g of this document), we believe that the supplier verification requirements for imported foods under the FSVP regulation are no more burdensome than the oversight and control measures applied to domestic foods. Consequently, the California facility would be subject to oversight that is no less burdensome than the verification that the Tijuana facility would face under FSVP.

#### 11. Other Requests for Exemption

(Comment 91) One comment requests an exemption from FSVP based on an agreement with the foreign government of the country in which the foreign supplier is located. One comment suggests a product-specific exemption for a foreign supplier who was in compliance with the foreign government’s applicable regulations.

(Response 91) As discussed more fully in section III.N of this document

and in the preamble to the proposed rule, we are excluding from many of the standard FSVP requirements food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the importer documents that certain conditions are met. These modified FSVP requirements are set forth in § 1.513 of the final rule. Depending on the scope of the official recognition or equivalence determination regarding a foreign food safety authority, these modified FSVP requirements might apply to all foods from suppliers in the relevant country or only certain products or commodities.

(Comment 92) One comment suggests that exemptions from the FSVP regulation be based on factors such as the size of the company, the type of food, and the risk posed by the food.

(Response 92) As discussed previously, the final rule contains exemptions or partial exemptions for several types of foods consistent with exemptions provided under section 805(e) of the FD&C Act. These include exemptions for juice and seafood products and thermally processed low-acid foods packaged in hermetically sealed containers (“low-acid canned foods” or LACF) (discussed in section III.C.2 of this document), subject to certain conditions. Although the final rule does not exempt very small importers from the FSVP requirements, it contains modified provisions for these importers that will significantly reduce the number of FSVP requirements they must meet (see § 1.512 of the final rule and section III.M of this document). In addition, the FSVP regulation takes into account the risk posed by foods in several ways (e.g., no verification activities required when there are no hazards in a food, certain supplier verification activity provisions for foods with hazards that can result in serious adverse health consequences or death to humans or animals (SAHCOHDA)). These provisions of the rule adequately address the different risks posed by different foods and businesses of different sizes.

(Comment 93) One comment states that cattle, poultry meat, and egg products should be exempt from the FSVP regulations because they are subject to regulation by the USDA’s Food Safety and Inspection Service (FSIS). One comment asks whether the FSVP regulation applies to live animals intended for consumption, specifically cattle. The comment asserts that for live cattle imported from Canada, the Canadian government and USDA’s



Animal and Plant Health Inspection Service (APHIS) and FSIS share responsibility for verifying safety (with respect to bovine spongiform encephalopathy (BSE)), and it would be duplicative to require the importer to comply with the FSVP regulation with respect to such cattle.

(Response 93) We agree that an exemption is appropriate with respect to cattle, poultry, and egg products, but not live animals. The final rule adds § 1.501(h), which states that the FSVP regulation does not apply to meat, poultry, and egg products that at the time of importation are subject to the requirements of the USDA under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). We conclude that this provision is consistent with the context and purpose of FSMA generally, and with section 805 of the FD&C Act in particular. In enacting section 805, Congress intended to ensure that food imported into the United States is produced in a manner consistent with U.S. standards. At the same time Congress enacted section 805, it also enacted section 403 of FSMA (21 U.S.C. 2251), entitled “Rule of Construction,” which states that nothing in FSMA must be construed to alter or limit the jurisdiction of the Secretary of the Department of Agriculture. For many decades, USDA has exercised authority and responsibility over the import of such meat, poultry, and egg products, and has adopted detailed regulations and procedures implementing this authority. In light of USDA’s role with respect to the importation of these products, and also in light of section 403 of FSMA, we conclude that Congress did not intend the FSVP regulation to apply to meat, poultry, and egg products that at the time of importation are subject to USDA requirements under the FMIA, PPIA, and EPIA, respectively. We therefore conclude that § 1.501(h) is consistent with Congress’ intent in promulgating section 403 of FSMA and section 805 of the FD&C Act.

However, we do not agree that the FSVP regulation should not apply to live animals, including cattle, intended for consumption. Live animals raised for food, even though not in their final, edible form, are considered to be food under the FD&C Act (see *United States v. Tomahara Enterprises Ltd.*, Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food); *United States v. Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio 1995) (live hogs are food)). Further, live

animals, such as poultry and cattle, are not subject to the USDA requirements under the FMIA or PPIA at the time of importation. Indeed, FDA has exercised authority and responsibility over the importation of live food animals. For example, FDA’s final rule on prior notice requirements specifically includes live animals that are imported for food use (see 73 FR 66294 at 66306). Only food that is subject to the requirements of the USDA under the FMIA, the PPIA, or the EPIA at the time of importation are excluded from the scope of the FSVP regulation under § 1.501(h).

However, with respect to live animals that are eventually processed at FSIS-inspected slaughter and production plants or inspected by States under cooperative agreements with FSIS, we expect that importers likely will determine, in accordance with § 1.507 of the final rule, that the live animals could not be consumed without application of an appropriate control in the supply or distribution chain, so that the importers will not be required to conduct an evaluation under § 1.505 or supplier verification activities under § 1.506. The principal hazards for such live animals are chemical hazards such as unlawful drug residues and BSE. FSIS and APHIS have comprehensive regulatory requirements that control these hazards, including HACCP requirements. FSIS-regulated meat and poultry establishments are required to conduct a hazard analysis and consider the food safety hazards that might be expected to arise from, for example, drug residues, and are also required to develop systems to guard against these hazards. In addition, FSIS oversees the requirements related to the identification and control of hazards, and collects samples of meat, poultry, and egg products and analyzes the samples at FSIS laboratories for chemical residues of veterinary drugs, among other contaminants. Thus, when USDA-regulated establishments are in compliance with the USDA-administered HACCP and other requirements, the hazards associated with the live animals processed at such establishments ordinarily would be controlled and the live animals could not be consumed without such controls.

However, importers of live animals of species such as bison and elk that are not processed at USDA-regulated slaughter and production plants under HACCP requirements might determine that there are drug residues or other hazards requiring control. Importers of such live animals might therefore be required to conduct supplier

verification for the foreign supplier that raised the animals.

### C. Purpose and Scope of FSVPs (§ 1.502)

In § 1.502 of the proposed rule, we proposed that importers be required to have an FSVP for each food they import that would provide adequate assurances that the standard of food safety set forth in section 805 of the FD&C Act would be met. We included a modification of that proposed requirement with respect to microbiological hazards in thermally processed low-acid foods packaged in hermetically sealed containers (low-acid canned foods or LACF). In the Supplemental Notice, we revised proposed § 1.502 to include provisions under which importers who were in compliance with the supplier program provisions of the preventive controls regulations (or whose customers were in compliance with those provisions) would be deemed in compliance with most of the FSVP requirements. As discussed in the following paragraphs, the final rule includes several changes to proposed § 1.502 in response to comments and on our own initiative.

#### 1. Requirement To Develop and Follow an FSVP

We proposed to require importers to develop, maintain, and follow an FSVP for each food imported that provides adequate assurances that the foreign supplier is producing the food in compliance with processes and procedures that provide 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 was applicable, and was 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 FD&C Act.

On our own initiative, to clarify the relevant requirements, we have revised § 1.502(a) to refer not only to sections 418 and 419 of the FD&C Act but also to “the implementing regulations” for those sections, *i.e.*, the preventive controls and produce safety regulations, respectively. In addition, because we are interpreting section 403(w) of the FD&C Act regarding misbranding with respect to allergen labeling to be inapplicable to animal food, we have revised § 1.502(a) to specify that an importer’s FSVP must provide assurance that a foreign supplier is producing a food in compliance with section 403(w) “if applicable.” We have made corresponding changes to other

provisions in the FSVP regulation citing this FSMA standard for FSVPs.

a. Meaning of “For Each Food”

(Comment 94) Several comments ask that we clarify the meaning of proposed § 1.502(a) with respect to having an FSVP “for each food.” For example, the comments ask whether importers would be required to have a different FSVP for each of similar foods (e.g., red and green grapes) or even different package sizes (e.g., 9-count and 12-count) of the same food product. The comments maintain that having to develop an FSVP for each individual food product would be burdensome without contributing to food safety. Some comments ask that importers be allowed to have an FSVP for foods that are of the same “type.” Some comments suggest that importers be permitted to include foods in similar commodity groups (e.g., different types of squash and zucchini) in the same FSVP. Some comments suggest that importers be allowed to have one FSVP for produce grown, harvested, and packed under the same conditions.

(Response 94) We decline to make the suggested changes. Section 805(c)(2)(A) of the FD&C Act requires that the FSVP of each importer be adequate to provide assurances that each foreign supplier to the importer produces “the imported food” in compliance with the standard set forth in that provision; it does not state that an importer’s FSVP would be for a “type of food” from a foreign supplier. However, we agree with the comments that an importer should not be required to establish separate FSVPs for different versions of the same food when the differences in the products will not impact the safety of the food. For example, it might be appropriate for an importer to develop a single FSVP covering several different packaging sizes or formats for a particular food, provided that these packaging differences do not pose different hazards that need to be controlled by the foreign supplier and addressed in supplier verification activities. We intend to provide additional examples of what constitutes the same food for purposes of establishing an FSVP for the importation of the food in the FSVP draft guidance.

Although an importer must have an FSVP for each food it imports from each foreign supplier, we conclude (as discussed more fully in section III.E.2 of this document) that it might be appropriate to conduct a hazard analysis for a “type” of food, such as different varieties of the same fruit or vegetable, provided all aspects of the hazard analysis are applicable to all foods that the importer regards as being of the

same type. However, it would not be appropriate to use the same hazard analysis for foods that, though very similar, have different hazards requiring control. For example, even if two foods were grown, harvested, and packed under the same conditions, it would not be appropriate to use the same hazard analysis for both foods if one food was susceptible to certain microbiological hazards but the other food was not.

It is also important to note that importers must establish an FSVP for each foreign supplier of a food. Thus, if an importer obtains a particular food from multiple foreign suppliers, the importer must have a separate FSVP for each supplier. This is appropriate because the FSVP regulation requires importers to consider not just hazards inherent in the foods they import, but also the performance history and characteristics of the foreign suppliers of the food, and to conduct supplier verification activities that are tailored to the particular food and foreign supplier. However, as discussed elsewhere in this document, importers may be able to rely on foreign supplier evaluations and verification activities conducted by other entities in meeting these requirements.

(Comment 95) Some comments request that we provide guidance on appropriate processes for safely producing products that fall into similar categories.

(Response 95) The FSVP regulation does not establish requirements for the safe production of food; those requirements are set forth in other FDA regulations, including those on produce safety and preventive controls for human and animal food. However, as stated previously, the FSVP draft guidance will provide additional examples regarding what importers may regard as the same food that can be addressed in a particular FSVP.

b. Role of Importer’s Corporate Headquarters

(Comment 96) Several comments state that § 1.502(a) should acknowledge that an importer’s corporate headquarters might establish or develop the importer’s FSVP for a food and might do the same for a contract manufacturer. The comments add that FDA should conduct its inspections of importers accordingly.

(Response 96) The requirements to develop FSVPs and keep records apply to importers as defined in § 1.500 of the final rule, and § 1.502(a) accordingly does not refer to a particular “facility” but to the importer. For purposes of FDA inspection of importers, the importer’s location is where the

importer conducts business. This might be, but is not required to be, the place where the importer retains its FSVP records. For some importers that import food into the United States through multiple ports, the importers’ FSVPs for the foods they import might be developed and maintained at a single location, such as a corporate headquarters. However, while entities other than the importer may conduct activities to satisfy various FSVP requirements (provided that the importer reviews and assesses results of those activities, among other things), an importer of a food is responsible for maintaining and administering its FSVP. Therefore, if a contract manufacturer for a U.S. food facility is the importer of a food under § 1.500, the contract manufacturer would be required to maintain and administer the FSVP for the food.

c. Entity Controlling the Hazards

(Comment 97) One comment states that the requirement to have an FSVP for an imported food should be limited to a food that a hazard analysis indicates may contain a significant hazard that is addressed by a foreign supplier, because sometimes the importer, not the foreign supplier, will control the hazards in the food.

(Response 97) We agree that it will not be necessary for an importer that is also a food facility under section 415 of the FD&C Act and is controlling hazards under the preventive controls regulations to comply with the majority of the provisions of this rule. As discussed in section III.C.3 of this document, under § 1.502(c) of the final rule, if an importer is a receiving facility that implements preventive controls for the hazards in a food in accordance with § 117.135 or § 507.34 for a food it imports, the receiving facility is deemed to be in compliance with the requirements of the FSVP regulation, except for the requirements in § 1.509. For these reasons, it is not necessary to change § 1.502(a) as suggested.

d. Adequate Assurances of Foreign Supplier’s Adherence to Food Safety Standards

(Comment 98) Some comments suggest that we explain what constitutes “adequate assurances” that foreign suppliers are producing food in accordance with the standard specified in § 1.502(a). One comment suggests that when considering whether adequate assurances exist, the importer should consider issues such as whether the foreign supplier has an adequate food safety plan that accounts for all hazards in a food. One comment asks

that we specify what kind of assurance of compliance importers need from their suppliers (*e.g.*, certification with the International Standards Organization (ISO), HACCP compliance, reports of FDA inspections), adding that the requirements should be the same for both domestic and foreign establishments. One comment states that the need to provide adequate assurance of compliance with the relevant standards elevates the importance of clear definitions of those standards.

(Response 98) Importers must obtain adequate assurances of foreign supplier compliance with the applicable standards stated in § 1.502(a) primarily through foreign supplier verification activities conducted under § 1.506 of the final rule, which must reflect the evaluation of the food and foreign supplier conducted under § 1.505. Section 1.506(c) states that foreign supplier verification activities must provide the adequate assurance that the hazards requiring a control in imported foods have been significantly minimized or prevented (because such control of hazards provides assurance that the standard specified in § 1.502(a) is met). Section 1.506 specifies the foreign supplier verification activities that are appropriate under different circumstances for providing adequate assurances of compliance.

For foreign suppliers subject to the preventive controls or produce safety regulations, the adequate assurances that importers must obtain through their FSVPs primarily will be that the supplier is producing the food in a manner that provides the same level of public health protection as the applicable regulations. For foreign suppliers subject to the preventive controls regulations, adequate assurance of compliance would include, as the comments suggest, a consideration of the adequacy of the supplier's food safety plan as well as other elements of the preventive controls regulations and whether the supplier's processes and procedures provide the same level of public health protection as the processes and procedures required under those regulations. As such, the processes and procedures used by foreign farms and facilities covered by the produce safety and preventive controls regulations are expected to provide no more—and no less—public health protection than those used by domestic farms and facilities. Section III.G.4 of this document addresses the specific information that importers must review under § 1.506 of the final rule when conducting supplier verification activities to assess whether the supplier

is producing food in accordance with U.S. standards.

#### e. Same Level of Public Health Protection

(Comment 99) Several comments request that we provide clarity regarding the nature of processes and procedures that will provide the same level of public health protection as those required under the preventive controls or produce safety regulations. Some comments express concern that permitting use of the “same level of public health protection” standard raises questions about whether there will be a level playing field for domestic and foreign producers. Some comments state that we must apply the same food safety standards (in particular the produce safety regulation) to domestic and foreign producers. Some comments assert that we should also require verification of foreign supplier compliance with USDA requirements concerning fertilizers, herbicides, pesticides, and fumigants.

One comment states that the “same level of public health protection” language appears to allow foreign suppliers to establish alternative standards to preventive controls and produce safety requirements within the FSVP regulations, even though there is no process for adopting alternative procedures under the preventive controls regulations and the ability to adopt alternative procedures under the produce safety regulation is limited. Some comments ask that we specify how importers should determine whether use of an alternative procedure results in the same level of public health protection and which entity is permitted to make a determination regarding the same level of public health protection. One comment recommends that we allow a flexible approach for meeting the same level of public health protection standard because of issues raised by the application of preventive controls requirements to foreign facilities. One comment requests that the regulation specify the standards that verification activities must meet to demonstrate an equivalent level of public health protection, but adds that if these standards are instead to be set forth in guidance, it should be a level 1 guidance and the Agency should hold public meetings and advisory committee meetings. One comment suggests that we include a requirement for importers to identify when a foreign supplier is using an alternative procedure if use of alternative procedures is not an option for domestic firms under the applicable food safety regulations.

(Response 99) As the comments note, FSMA itself (section 805(c)(2)(A) of the FD&C Act) directs FDA to establish regulations that require importers to obtain assurances that their foreign suppliers are using processes and procedures that provide the same level of public health protection as those required under the preventive controls or produce safety regulations, as appropriate. Importers must determine whether particular processes and procedures used by foreign suppliers that differ from those required under the preventive controls or produce safety regulations nevertheless provide the same level of public health protection, although FDA will be able to review such determinations as part of records reviews of importers for compliance with the FSVP requirements.

The produce safety regulation includes provisions (§ 112.12) permitting the use of alternatives to certain requirements in the regulation provided the producer of the food (the farm) has adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable provision and would not increase the likelihood that the produce was adulterated. The produce safety regulation also includes provisions (subpart P of part 112) under which States, tribes, and foreign countries may request a variance from the produce safety requirements when the State, tribe, or foreign country determines that the variance is necessary in light of local growing conditions and the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated and to provide the same level of public health protection. Although the preventive controls regulations do not include similar alternative or variance procedures, those regulations are designed to allow facilities the flexibility to tailor their processes and procedures in a manner that is appropriate to the food and the facility, with management components that are appropriate to the food, the facility, and the nature of the preventive controls and their role in the facility's food safety system.

To the extent that the comment is suggesting that § 1.502 include a requirement that importers document each procedure used by a foreign supplier that differs from the preventive controls or produce safety regulations, we conclude it is not necessary to do so. However, where such use of such alternative procedures is relevant to an importer's evaluation of a foreign supplier's performance under § 1.505 or

the results of foreign supplier verification activities under § 1.506, information about the alternative procedures must be included in the documentation for these FSVP requirements. With respect to the variance provisions under the produce safety regulations for States, tribes, and foreign countries, there may be circumstances in which approved variances are relevant to determining whether a particular foreign supplier's processes and procedures provide the same level of public health protection as the requirements under section 419 of the FD&C Act. Audits of suppliers following procedures, processes, or practices specified in an approved variance from the produce safety regulation conducted for the purpose of FSVP compliance may consider that FDA, in granting the variance, determined that those procedures, processes, or practices are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and to provide the same level of public health protection as the requirements under section 419.

We conclude it is not necessary to state in the regulation specific actions that importers must take in evaluating whether alternative procedures used by foreign suppliers provide the same level of public health protection as procedures required in the regulations implementing sections 418 and 419 of the FD&C Act.

(Comment 100) One comment maintains that food safety regulations in the EU, and particularly in France, provide the same level of public health protection as the FSMA standards and urges that we recognize these standards.

(Response 100) We do not have sufficient information at this time to determine whether the food safety regulations in particular countries or regions provide the same level of public health protection as U.S. standards. However, importers may find that compliance with the laws of France and other EU countries is relevant to determining whether foods are being produced using processes and procedures that provide the same level of public health protection as those required under FDA's regulations. In addition, as discussed in section III.N of this document, FDA has established a systems recognition initiative, under which we are conducting comprehensive assessments of foreign food safety systems to determine whether they provide similar protections to those offered under the U.S. system and a similar level of oversight and monitoring. As discussed in more detail in section III.N, the

systems recognition program is based on the principle that foreign food producers can meet U.S. food safety requirements by providing assurances that these foods are produced according to the food safety standards of a country whose food safety system we have found to be comparable. Under § 1.513 of the final rule, once we have made a determination that a foreign food safety system is comparable to ours, certain foods within the scope of such a determination may be imported under modified FSVP requirements (provided that certain conditions are met). These provisions will allow the importation of such food without being subject to most of the standard FSVP requirements.

(Comment 101) Some comments state that, to ensure that the concept of "same level of public health protection" is applied consistently, FDA must conduct risk assessments of foods to formulate an appropriate risk matrix that can be applied domestically and internationally. The comments request that, before we issue the final rules on produce safety and FSVPs, we issue for public comment the risk model that we intend to use for evaluating requests for variances under the produce safety proposed regulation.

(Response 101) We do not agree. This rule establishes a flexible, risk-based approach to foreign supplier verification based in significant part on a requirement that importers understand the hazards in the foods they import so they can take appropriate steps to verify that their suppliers have adequately controlled these hazards. We believe that a system of hazard analysis, control, and verification is well accepted and understood throughout the international food safety community and provides the most effective way to implement a risk-based framework for foreign supplier verification. We have confidence that importers will be able to implement FSVPs based on their own hazard analyses or their review of analyses conducted by others, without our having to conduct risk assessments for all foods to generate a risk matrix that all food producers would use. As stated previously, we intend to issue guidance to assist importers and foreign and domestic producers in complying with the new regulations that we are adopting under FSMA, including guidance on the analysis of hazards in food. With respect to variances under the produce safety regulation, we note that the final rule adopting that regulation published elsewhere in this issue of the **Federal Register** addresses how FDA will evaluate requests for variances submitted in accordance with subpart P of part 112.

#### f. Relevant Statutory Requirements

(Comment 102) One comment states that FSVPs should be limited to verifying foreign supplier compliance with the preventive controls or produce safety regulations. One comment states that the FSVP regulation should not impose any additional obligations on foreign suppliers beyond those required under other FDA regulations, and should be based on relevant international standards and conform to U.S. international obligations.

(Response 102) The purpose and scope of importers' FSVPs, as set forth in § 1.502(a) of the final rule, implements the standard mandated in FSMA for FSVPs. Consequently, it requires importers to take steps to ensure that their foreign suppliers are producing food in a manner consistent with the preventive controls or produce safety regulations, to the extent that those regulations apply to the foreign supplier's production of a food, and to ensure that the food from the supplier is not adulterated and is not misbranded with respect to allergen labeling, if applicable. The FSVP regulation does not impose on foreign suppliers any requirements that they are not already subject to under the FD&C Act and implementing regulations, including the regulations on preventive controls and produce safety. In addition, the FSVP regulation is drafted to be consistent with U.S. obligations under international agreements.

(Comment 103) One comment suggests that the phrase "if either is applicable" when referring to the preventive controls and produce safety provisions be interpreted to mean that if a type of produce is covered by section 419 (and the produce safety regulation), it must be in compliance with section 419, rather than meaning that any imported "produce" would be subject to section 419.

(Response 103) We agree. If an imported item of produce is not subject to the produce safety regulation, the importer would not be required to verify that the produce was grown in accordance with that regulation.

(Comment 104) One comment suggests that the requirement to have an FSVP be limited to problems that "cause a risk to the public health," which the comment maintains would be consistent with the statement in the preamble to the proposed rule that the regulation should focus on foreseeable food safety risks identified through hazard assessment rather than all risks covered by the adulteration provisions. The comment contends that not all adulterants cause a food safety risk and

many forms of adulteration are not amenable to discovery by the importer.

(Response 104) We do not believe that the proposed change is necessary. The importance of the existence of a risk to public health is incorporated in the definition of “hazard,” meaning any biological, chemical, or physical agent that is reasonably likely to cause illness or injury. Except as specified otherwise, each importer would need to have an FSVP for each food that it imports from each foreign supplier and to conduct a hazard analysis for each type of food in accordance with § 1.504 of the final rule. However, under § 1.504(f), if an importer determines there are no hazards requiring a control in a food, the importer would not be required to conduct an evaluation of the risk posed by the food and the foreign supplier’s performance and would not be required to conduct supplier verification activities.

#### g. U.S. International Obligations

(Comment 105) One comment notes that domestic farms supplying foods directly to retailers are not subject to supplier verification requirements because the supplying entity (*i.e.*, the farm) and receiving entity (*i.e.*, the retailer) are not subject to the regulations on preventive controls, which contain supplier program provisions. The comment asks that we revise the FSVP provisions regarding produce to ensure that there are no differences in treatment between domestic and foreign suppliers with respect to the obligations of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (Ref. 4).

(Response 105) The FSVP regulation aligns with the supply-chain program provisions of the preventive controls regulations by requiring importers to verify that their suppliers have systems in place to significantly minimize or prevent the hazards associated with the foods they are supplying and that their suppliers meet or provide the same level of public health protection as required under applicable FDA safety standards. In addition, an importer conducting supplier verification under the preventive controls regulations for imported raw materials or other ingredients would be deemed in compliance with most of the FSVP requirements.

Nevertheless, the supply-chain program provisions of the preventive controls regulations do not apply to certain domestic entities, including restaurants or retail food establishments. However, this does not mean that farms that supply produce to such entities are

subject to different or lesser safety standards than foreign farms that supply produce to U.S. importers subject to the FSVP regulation. To the contrary, the requirements in the produce safety regulation apply with equal force to domestic and foreign farms.

Under the food safety system envisioned by FSMA, supplier verification of imported produce to be sold by U.S. retailers is needed to ensure a consistent level of oversight and protection for domestic and imported food. Consistent with other provisions of FSMA, FDA is taking several steps to establish a more comprehensive, effective, risk-based approach to domestic food safety oversight and enforcement. We are working through the Partnership for Food Protection (PFP), a group of dedicated professionals from Federal, State, local, tribal, and territorial governments with roles in protecting the food supply and public health, to develop and implement a national Integrated Food Safety System (IFSS) for domestic compliance oversight (Ref. 5). We are also adopting a new domestic inspection paradigm, stemming from our authority to inspect under section 704 of the FD&C Act (21 U.S.C. 374), focused on whether firms are implementing systems that effectively prevent or significantly minimize food contamination in compliance with the new FSMA regulations, including those on preventive controls and produce safety. This new paradigm involves a major reorientation and retraining of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities, as well as thousands of State, local, and tribal inspectors.

In addition, section 201 of FSMA (section 421 of the FD&C Act (21 U.S.C. 350j)) mandates that we inspect domestic high-risk facilities not less than once every 3 years. We are currently meeting this mandate and we intend to significantly exceed it as part of our strategy to implement the new food safety standards. We intend there to be an FDA or State inspection of every domestic high-risk human food facility annually to verify compliance with the new regulations.

Our implementation of the final rule on produce safety (published elsewhere in this issue of the **Federal Register**) will entail a broad, collaborative effort to foster awareness and compliance domestically. Our strategy includes guidance, education, technical assistance, and verification. Verification will be achieved through the actions of multiple public and private entities, including inspections by FDA and

partner agencies, USDA audits, marketing agreements, and private audits required by commercial purchasers. In keeping with this broad vision, we intend to focus our domestic efforts on several important activities, including the following:

- Supporting and collaborating with public and private parties involved in audits and other accountability and verification activities;
- Conducting targeted domestic on-farm surveys and risk-based inspections to understand current practices and identify gaps in compliance; and
- Taking administrative compliance and enforcement action when needed to correct problems that put consumers at risk.

We have the authority to inspect farms subject to the produce safety regulation under section 704 of the FD&C Act. We will target our inspections on the basis of risk. We intend to rely heavily on the States to conduct a large proportion of the routine inspections of farms, and we are committed to working closely with the States to verify compliance with the new FSMA requirements. In addition to FDA and State inspections, we will leverage third-party audits conducted by USDA and others with a goal of annual verification of all domestic farms subject to the produce safety rule.

In contrast, we expect to have a far less robust system of direct public oversight of foreign food facilities and farms that are subject to the new FSMA regulations. We have less ability to physically inspect and take enforcement actions against those who produce food abroad for export to the United States due to legal and practical limitations. For example, diplomatic and practical logistics associated with conducting foreign inspections in most countries complicate, and in some cases make impossible, the kind of routine unannounced inspections of establishments that we conduct in the United States. As a result, neither we nor our IFSS partners can rely on unannounced inspections abroad in the same way as we can domestically.

We also face challenges in conducting “for cause” inspections of foreign facilities when we have evidence of a compliance problem. Domestically, we can respond to a refusal to permit inspection or a refusal to permit access to or copying of records by obtaining inspection warrants in the federal courts. For foreign inspections, however, we do not have the same access to the courts, and it can be challenging to compel inspections and access to records when needed. We also face diplomatic and logistical challenges

in conducting foreign civil and criminal investigations and prosecutions when violations occur that do not hinder our domestic enforcement efforts. In addition to legal issues related to extraterritoriality, practical and operational challenges to our foreign enforcement activities include obtaining visas and official travel documents, finding qualified translators, procuring foreign travel authorizations, difficulties in coordinating with foreign authorities, and extradition.

Because of these challenges, we largely rely on the cooperation of foreign governments when conducting inspections in foreign countries and bringing enforcement actions against foreign businesses and individuals. Today, our main approach to oversight of imported food is reactive, involving sampling and testing food at ports of entry. However, with the increased volume of imported foods coming across U.S. borders and limited resources, we are able to physically examine less than 2 percent of food offered for import each year.

Given the difficulties in conducting direct FDA regulatory oversight of foreign producers, FSMA requires importers to share responsibility for verifying the safety of imported food. The FSVP regulation requires that U.S. importers, who are domestic entities under direct legal jurisdiction, take action to ensure the safety of the food they import by performing risk-based supplier verification activities. Combined with FDA's foreign inspections and enforcement efforts, the FSVP requirements will help ensure that imported food is subject to the same level of risk-based oversight and accountability that applies to domestic food under our comprehensive, integrated domestic food safety system.

In establishing these requirements for supplier verification by importers, we are integrating practices that industry has adopted in the last two decades to ensure that imported food is produced under modern food safety standards. Global industry best practices include not only risk-based, prevention-oriented standards for producing safe food but also verification measures to ensure that those standards are being met, including supplier verification and other supply-chain management activities. These oversight and verification approaches also are recognized by the Codex Alimentarius Commission (Codex) and are consistent with the approach of export oversight agencies in governments of countries with which the United States trades (see the discussion of Codex and relevant Codex standards and guidelines in Response

106). Therefore, in relying on the FSVP regulation to help ensure that oversight of imported food matches the level of domestic oversight made possible under FSMA, we are relying on mechanisms that are consistent with internationally recognized standards.

Our goal is for our domestic implementation strategy, including outreach, inspection frequencies, and other mechanisms to achieve compliance, to be operational on a schedule that corresponds with the dates by which domestic food producers are required to comply with the new FSMA standards. We have designed the compliance dates for importers under this final rule in a parallel fashion. As described in section IV.B of this guidance, an FSVP importer whose foreign supplier is subject to new FSMA requirements will not have to comply with the FSVP regulation until after its supplier is required to comply with its new requirements.

(Comment 106) Some comments assert that assigning responsibility for ensuring food safety to importers could result in events that might breach WTO agreements, such as importer-specific supplier verification lists, different importers imposing different verification criteria on the same foreign supplier, and additional and more frequent onsite auditing. Some comments maintain that oversight of foreign suppliers is best left to the private sector, and imposing requirements on importers might be inconsistent with WTO obligations.

(Response 106) We do not agree. Supplier verification of imported food is needed to ensure a consistent level of oversight and protection for domestic and imported food. Requiring importers to share responsibility for ensuring that imported food is safe is consistent with industry practice, principles of Codex, and the approaches of export oversight agencies of many U.S. trading partners.

As a member of the WTO trade agreements, the United States has assumed international obligations including those set out in the SPS Agreement. The SPS Agreement requires that measures adopted by WTO members to protect human or animal health be risk-based and that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

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 under the SPS Agreement 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) (Food Import Guidelines) issued by the Codex Committee on Food Import and Export Inspection and Certification Systems (Ref. 6) note the importance of clearly defined legislation on import control systems and recognize the value of importer verification systems. The Food Import Guidelines recognize the need for importing countries to perform inspections and audits where appropriate in exporting countries, and also acknowledge the utility of additional activities in ensuring that imported foods are safe. The Guidelines recommend that standards should be based on risk and, as far as possible, applied equally to imported and domestic food.

The FSVP regulation contains requirements to ensure that imported foods are produced in compliance with processes and procedures that provide the same level of public health protection as those required under the preventive controls and produce safety regulations, and 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 FD&C Act. These underlying preventive controls regulations are based on and conform to scientific evidence and international food safety standards, including the HACCP Annex to the Codex General Principles of Food Hygiene (Annex to CAC/RCP 1–1969 (Rev. 4–2003)) (HACCP Annex) (Ref. 7). In developing these regulations, we also considered the recommendations of the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53–2003) (the Codex Code) (Ref. 8). Similarly, components of the FSVP regulation, including the hazard analysis requirements, are consistent with principles in the HACCP Annex that require private sector food producers to play a role in implementing HACCP by conducting hazard identification, evaluation, and subsequent control operations. In addition, certain FSVP requirements correlate with Codex codes and principles on food safety relating to the basic definition of food safety standards and to the Codex standards for labeling of allergens in prepackaged foods (Refs. 7, 9).

Many countries have adopted similar food safety regulations mandating that certain principles and conditions be applied to food manufacturing and food

importation. These include mandatory HACCP programs for seafood and other foods.

In addition to aligning with Codex standards and guidance, the FSVP regulation incorporates a risk-based approach to food safety that allows importers the flexibility to tailor the supplier verification activities they conduct so that they provide adequate assurance that hazards in the food they import have been significantly minimized or prevented. The regulations are also designed to require verification that imported food meets the same standards that apply to domestic food (including the preventive controls and produce safety regulations) and align with the supplier verification provisions that apply to food from domestic suppliers under the preventive controls regulations.

Regarding the comments' assertion that the FSVP regulation will result in more onsite auditing of foreign suppliers, we note that the FSVP regulation does not require importers to conduct onsite audits of foreign suppliers. Instead, applying risk-based principles, importers are required to determine appropriate supplier verification activities based on the risks associated with the food being imported and the capabilities of the foreign supplier of the food. Because the FSVP requirements are flexible and not prescriptive, we do not agree that the FSVP regulations will significantly increase costs or impede trade.

With respect to the possibility that different importers might subject the same foreign supplier to different verification activities, we believe it is unlikely that different importers would identify significantly different hazards requiring control for the same food from the same foreign supplier. We do not expect that to happen because all importers likely will be considering similar information on hazards associated with particular foods that is available from food producers, consultants, trade associations, industry-related publications, and regulatory agencies. Therefore, we anticipate that different importers are likely to conduct (or obtain documentation of) similar supplier verification activities for particular types of food. In addition, the final rule allows importers to rely on verification activities conducted by other importers for the same food imported from the same foreign supplier. This flexibility reduces the potential extent to which foreign suppliers might be subject to different verification activities by different importers. We also note that, to the extent private food safety audit

scheme owners and benchmarking organizations continue to develop tools to verify that foreign suppliers produce food consistent with FDA food safety standards, importers could rely on such audit schemes to help meet FSVP requirements. If this were to occur, multiple importers of the same food from the same foreign supplier might choose to rely on the same supplier audit conducted in accordance with such a scheme.

(Comment 107) One comment maintains that, to satisfy WTO obligations, we need to ensure that domestic and foreign supplier verification requirements are aligned, and therefore need to require that domestic food facilities conduct supplier verification with respect to RACs (if RACs are subject to the FSVP regulation as proposed).

(Response 107) The regulations on preventive controls for human and animal foods include supply-chain program requirements that are closely aligned with the FSVP supplier verification requirements, which we believe, for the reasons previously stated, are consistent with our WTO obligations. Raw materials and other ingredients such as RACs that are manufactured/processed at domestic U.S. receiving facilities (as well as at foreign receiving facilities) are within the scope of the supply-chain program requirements in the FSVP and preventive controls regulations.

## 2. Low-Acid Canned Foods

In accordance with section 805(e)(3) of the FD&C Act, we proposed that, with respect to those microbiological hazards that are controlled by the LACF regulation set forth in part 113 (21 CFR part 113), the importer of an LACF would be required to verify and document that the food was produced in accordance with part 113. For all matters not controlled by part 113 (e.g., hazards other than microbiological hazards addressed under part 113), the importer would be required to have an FSVP as specified in proposed § 1.502(a). In the preamble to the proposed rule, we noted that an LACF importer would not know if it was importing the food from a foreign supplier whose facility was in compliance with part 113 unless it conducted some appropriate form of verification, such as auditing. We therefore suggested that, in addition to providing assurance that non-microbiological hazards in LACF were adequately controlled, following the FSVP provisions would also be an appropriate verification approach for all

hazards, including microbiological hazards.

On our own initiative, we are adopting corresponding FSVP requirements for the importation of raw materials and other ingredients of LACF by LACF manufacturers, for reasons similar to those we stated (in section III.B.1 of this document) for exempting from the FSVP regulation importers of juice or seafood raw materials or other ingredients that are manufacturers or processors of juice or seafood products. As we stated with respect to section 805(e)(1) and (e)(2) of the FD&C Act regarding juice and seafood, we conclude that in enacting section 805(e)(3), Congress intended to exclude from the FSVP provisions food covered by and in compliance with the LACF regulation in part 113 (with respect to microbiological hazards addressed under those regulations), likely reflecting a conclusion that the LACF regulation makes supplier verification under FSVP unnecessary for microbiological hazards because importers who are in compliance with the LACF regulation will be addressing the microbiological hazards in such food. We therefore conclude that a more reasonable interpretation of section 805(e)(3) than what we originally proposed to adopt is that Congress intended to exempt from the FSVP requirements the activities of a facility that are subject to the LACF regulation in part 113 with respect to microbiological hazards.

Based on this interpretation, we are applying section 805(e)(3) not only to the importation of LACF produced by foreign suppliers subject to and in compliance with the LACF regulation, but also to the importation of raw materials and other ingredients by U.S. facilities for use in manufacturing or processing LACF. Therefore, § 1.502(b)(2) of the final rule states that with respect to microbiological hazards that are controlled by part 113, an importer is not required to comply with the FSVP requirements for raw materials or other ingredients that it imports for use in the manufacturing or processing of LACF provided that the importer is in compliance with part 113 with respect to the LACF that it manufactures or processes from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by part 113, the importer must have an FSVP for the raw materials and other ingredients that it uses in the manufacture or processing of LACF.

(Comment 108) One comment requests that we advise importers of



LACF to conduct finished product testing for typical pathogens and spoilage organisms because finished canned goods can be contaminated and might be used in producing other products.

(Response 108) We do not agree that periodic sampling and testing of an imported LACF would be an appropriate means of verifying control of all hazards in such food. The primary hazard of concern for LACF is *C. botulinum* toxin, and strict controls as required under part 113 are needed to address this hazard. Sampling and testing cannot provide statistically valid assurance that potential pathogens in LACF products are adequately controlled.

Section 805(e) of the FD&C Act states that the section 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. In accordance with section 805(e), § 1.502(b) of the final rule provides that with respect to those microbiological hazards that are controlled under part 113, an importer of an LACF must verify and document that the food was produced in accordance with part 113. An importer of an LACF 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. Although the proposed rule suggested that an audit would be an appropriate form of verification, we conclude that an audit might not be necessary. Although the importer may still choose to do an audit, an appropriate verification activity might also be reviewing the scheduled processes and processing and production records required under part 113 that relate to the specific LACF being offered for import, as well as verifying that cans are not swollen or leaking. With respect to hazards other than microbiological hazards controlled under part 113 that an importer might identify, an importer of an LACF must have an FSVP as specified in § 1.502(a). For such an FSVP, sampling and testing might be appropriate verification activities in addition to an audit (or an audit might be used to verify control of non-microbial as well as microbial hazards).

(Comment 109) One comment, noting that proposed § 1.502(b) does not address acidified foods, states that if we intentionally omitted acidified foods from § 1.502(b), we should provide a

rationale for treating acidified food differently than LACF.

(Response 109) The provisions regarding LACF in § 1.502(b) reflect the statutory exemption (in section 805(e) of the FD&C Act) from the FSVP requirements for microbiological hazards in LACF. There is no analogous statutory exemption for acidified foods.

An importer of acidified foods can consider the processor's current scheduled processes, established in accordance with the regulation on acidified foods in part 114 (21 CFR part 114), when conducting the hazard analysis required in § 1.504 and the evaluation required in § 1.505. An importer of acidified foods could, through its hazard analysis, determine that the microbiological hazards associated with the imported food are addressed by controls in the supplier's scheduled processes established under part 114. In turn, an importer of acidified foods can consider the processor's current procedures when determining what supplier verification activities are appropriate. For example, an importer might determine that reviewing its foreign supplier's validated scheduled process and records and reports is an appropriate supplier verification activity. As another example, it may be appropriate for an importer to review its foreign supplier's procedures for complying with the requirements of part 114, including frequent testing and recording of results, to verify that the finished equilibrium pH values for an acidified food are not higher than 4.6 (see § 114.80(a)(2)) and to confirm the response to any deviations from scheduled processes (see § 114.89).

### 3. Importers in Compliance With Supply-Chain Program Provisions in the Preventive Controls Regulations

In the Supplemental Notice, we proposed to specify (in § 1.502(c)) that if an importer was required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer was in compliance with the supplier program requirements in those regulations, the importer would be deemed in compliance with the FSVP regulation (except for the requirement to identify the importer at entry of the food into the United States). We proposed this change in response to several comments and consistent with our intent (as stated in the preambles of the proposed rules on FSVP and preventive controls for human food) to avoid imposing redundant supplier verification requirements on importers that also are

food facilities that would be required to comply with any supplier verification provisions in the preventive controls regulations.

(Comment 110) Although the comments agree that there should not be redundant supplier verification requirements under the FSVP and preventive controls regulations, the comments differ in their views on how the regulations should achieve this. Some comments state that, rather than deem importers in compliance with the preventive controls supplier program provisions to be in compliance with the FSVP requirements, the regulations should deem receiving facilities that are in compliance with the FSVP requirements to be in compliance with the preventive controls supplier program provisions. One comment suggests that the preventive controls supplier program requirements be applied only to verification of domestic suppliers unless the imported food was exempt from the FSVP requirements. However, some comments assert that entities subject to the preventive controls regulations are in a better position to determine the safety of imported ingredients in the context of the finished food product. Some comments request that the FSVP and preventive controls final rules allow for recognition of supplier verification performed under either rule, even if the verification was performed by a third party. Some comments request that the preventive controls regulations include a provision exempting from the supplier program requirements any food that had already been subject to verification under the FSVP regulation, even if the verification was conducted by a third party. Some comments suggest that a facility receiving such food for processing should be required to ensure that the importer met its FSVP obligations; one comment suggests that such a facility be required to annually obtain written assurance of FSVP compliance from the importer.

(Response 110) We conclude that it is appropriate, under § 1.502(c)(3) of the final rule, to deem to be in compliance with most of the FSVP requirements those importers that are receiving facilities that have established and implemented a risk-based supply-chain program in compliance with the regulations on preventive controls for human food or animal food (subpart G of part 117 and subpart E of part 507, respectively). Given that we have aligned the supply-chain program provisions of the preventive controls regulations and the FSVP requirements to the extent appropriate and feasible, the preventive controls regulations

allow importers that are receiving facilities to take advantage of that fact so they do not have to conduct duplicative verification activities. Under the preventive controls regulations, receiving facilities that are importers in compliance with the FSVP requirements and have documentation of activities conducted under § 1.506(e) need not conduct verification activities for that raw material or other ingredient (see §§ 117.405(a)(2) and 507.105(a)(2)). The issue of what, if any, additional effect the preventive controls regulations should give to an importer's FSVP is beyond the scope of this rulemaking. However, we note that importers that are receiving facilities might obtain raw materials and other ingredients from both domestic and foreign suppliers. Given that receiving facilities should already be complying with other provisions in the preventive controls regulations, we believe that the preventive controls regulations avoid unnecessary duplication while ensuring that raw materials and other ingredients from both domestic and foreign suppliers are subject to appropriate verification activities.

In addition, we have broadened § 1.502(c) to include not just those importers that have implemented a supply-chain program in accordance with the preventive controls regulations, but also two other circumstances in which the importer is also a food facility. These circumstances are:

- When the importer/facility is not required to have a supply-chain program under the preventive controls regulations because it implements preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34; and
- When the importer/facility is not required to implement a preventive control under § 117.136 or § 507.36 (e.g., because the food is a type of food that cannot be consumed without application of an appropriate control, or because the facility's customer or a subsequent entity in the distribution chain is controlling the hazards and certain other conditions are met).

In the Supplemental Notice, we proposed to specify, in § 1.504(g) of the proposed regulations, that if the preventive controls an importer and/or its customer implemented in accordance with the preventive controls regulations were adequate to significantly minimize or prevent all significant hazards in an imported food, the importer would not be required to determine appropriate foreign supplier verification and related activities or to conduct any such activities. We included § 1.504(g) in the revised proposed rule because proposed

§ 1.502(c) did not encompass certain circumstances in which a receiving facility is not required to have a supply-chain program for a raw material or other ingredient.

Rather than separately specify, in § 1.504(g), the requirements for importers that control all hazards requiring a control, we have broadened the scope of § 1.502(c) to incorporate these circumstances. Thus, § 1.502(c)(1) specifies that if an importer is a receiving facility that implements preventive controls for the hazards in a food in accordance with § 117.135 or § 507.34, then the importer is deemed to be in compliance with the FSVP regulation, except for the requirement to identify the importer at entry in § 1.509.

In addition, § 1.502(c)(2) of the final rule deems in compliance with the FSVP regulation (except the requirements of § 1.509) importers that are food facilities who are not required to implement a preventive control for a hazard in a food they import in accordance with § 117.136 or § 507.35 (in the regulations on preventive controls for human food and animal food, respectively). Under those provisions, a food manufacturer/processor is not required to implement a preventive control when it identifies a hazard requiring a preventive control and one of the following applies:

- The manufacturer/processor determines and documents that the type of food (e.g., a RAC such coffee beans) could not be consumed without application of an appropriate control (see §§ 117.136(a)(1) and 507.36(a)(1));
- The manufacturer/processor relies on its customer who is subject to the preventive controls requirements to ensure that the identified hazard will be significantly minimized or prevented, and the manufacturer/processor meets certain disclosure (i.e., that the food has not been processed to control identified hazards) and written assurance requirements (see §§ 117.136(a)(2) and 507.36(a)(2));
- The manufacturer/processor relies on its customer who is not subject to the preventive controls requirements to provide assurance it is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements, and the manufacturer/processor meets certain disclosure and written assurance requirements (see §§ 117.136(a)(3) and 507.36(a)(3));

- The manufacturer/processor relies on its customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and the

manufacturer/processor meets certain disclosure and written assurance requirements (see §§ 117.136(a)(4) and 507.36(a)(4)); or

- The manufacturer/processor has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food it distributes (see §§ 117.136(a)(5) and 507.36(a)(5)).

We conclude that it is appropriate to exempt from the FSVP requirements importers that are facilities importing a food and acting in accordance with § 117.136 or § 507.36 with respect to that food, because compliance with those requirements will provide adequate assurance of the safety of this food. The FSVP regulation contains similar provisions regarding foods that cannot be consumed without application of a control and foods whose hazards will be controlled by the importer's customer or a subsequent entity in the distribution chain. These provisions, which appear in § 1.507 of the final rule, are discussed in section III.H of this document. Because these FSVP provisions so closely align with the preventive controls regulations, we see no need for importers that are receiving facilities to have to comply with both §§ 1.507 and 117.136 or § 507.36, as applicable. Although the preventive controls regulations do not include a provision comparable to § 1.502(c)(2) that deems receiving facilities that are importers to be in compliance with § 117.136 or § 507.36 if they are in compliance with § 1.507 in the FSVP regulation, we do not believe that such receiving facilities need to comply with these provisions in both the FSVP and preventive controls regulations. Therefore, we intend to consider receiving facilities that are importers to be in compliance with § 117.136 or § 507.36, as applicable, if they are in compliance with § 1.507.

(Comment 111) One comment asks that we state how we will certify that an importer/facility is in compliance with the preventive controls supplier program requirements.

(Response 111) Although we will inspect food facilities for compliance with the preventive controls regulations, including the supply-chain program provisions, we will not "certify" or otherwise designate a facility as being in compliance with the supply-chain program requirements. Rather, an importer that expects to be deemed in compliance with most of the FSVP requirements under § 1.502(c)(3) will be responsible for ensuring that it is in compliance with the supply-chain program provisions of the preventive

controls regulations and will need to be able to demonstrate its compliance during an inspection.

(Comment 112) Some comments suggest that § 1.502(c) should specify § 507.37 rather than § 507.43 to refer to the supplier program provisions in the regulations on preventive controls for animal food.

(Response 112) Because the supply-chain program provisions in the regulations on preventive controls for animal food are in subpart E of part 507, § 1.502(c)(3) of the FSVP final rule cites that subpart.

#### 4. Importer Whose Customer Is in Compliance With the Preventive Controls Supply-Chain Program Requirements

We proposed, in § 1.502(d), that if an importer's customer was required to establish and implement a risk-based supply-chain program under the preventive controls regulations (for either human or animal food), and the importer annually obtained written assurance that its customer was in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulation (except for the requirement to identify the importer at entry of the food into the United States and the requirement to maintain records of the written assurances).

We conclude that it is appropriate to address verification requirements that apply when an importer's customer controls the hazards in an imported food in the same provisions as those that apply to control of hazards by entities after the importer's customer in the U.S. distribution chain. As previously stated, these provisions are set forth in § 1.507 of the final rule. In section III.H.2 of this document we discuss § 1.507 and respond to the comments we received regarding proposed § 1.502(d) concerning importers whose customers are in compliance with the supply-chain program provisions of the preventive controls regulations.

#### *D. Personnel Developing and Performing FSVP Activities (§ 1.503)*

We proposed to require, in § 1.503, that importers use a qualified individual to conduct most FSVP activities, and provided several exceptions to this proposed requirement. We then updated this proposal in the Supplemental Notice with a revised reference to one of the exceptions and deleted one of the exceptions because it was no longer applicable under the changes to the proposed rule provided by the Supplemental Notice. As the proposal

was updated in the Supplemental Notice, the exceptions to the requirement to use a qualified individual were the activities required under proposed §§ 1.506(a) (procedures to ensure the importation of food from approved suppliers), 1.509 (identification of the importer at entry), 1.510 (recordkeeping), 1.511(c)(2) (procedures to ensure the importation of dietary supplements from approved suppliers), and 1.512(b)(5) (recordkeeping by very small importers).

In addition, as stated in sections III.A.18 and III.A.19 of this document, we have concluded that it is appropriate to specify the general qualifications that qualified individuals and qualified auditors must have in provisions outside of the definitions of those terms—specifically, in § 1.503 of the final rule. Under § 1.503(a), a qualified individual must have education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity. Under § 1.503(b), a qualified auditor must conduct any audit conducted in accordance with § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A) and must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

In the final rule, for several reasons we are eliminating the proposed exemption of the performance of certain FSVP activities from the requirement to use a qualified individual, as well as the proposed exemption for certain importers from having to use a qualified individual to meet FSVP requirements. First, requiring use of a qualified individual to meet all FSVP requirements is consistent with the goal of aligning the FSVP regulation with the preventive controls regulations. Those preventive controls regulations (§§ 117.4(a)(2) and 507.4(a)(2)) require that every person engaged in the manufacturing, processing, packing, or holding of food subject to the preventive controls regulations, including the supply-chain program provisions, must be a qualified individual. This requirement applies to all tasks related to these activities, including such tasks as ensuring the receipt of food from approved suppliers and recordkeeping.

Second, we note that the FSVP final rule makes the definition and requirements for qualified individuals more flexible and less burdensome than as originally proposed, thus making the requirement applicable to a wider variety of tasks. Instead of a qualified

individual having to possess necessary education, training, *and* experience (as we initially proposed), the final rule states that a qualified individual must have education, training, or experience—or a combination of these elements—necessary to perform an assigned FSVP activity. This allows importers more flexibility in meeting the requirement to have qualified individuals perform required tasks. This also means that the final rule does not require any particular education, training, or experience beyond what is needed to successfully perform the FSVP task to which the qualified individual is assigned, whether the task is a core component of the FSVP requirements (*e.g.*, hazard analysis, supplier verification activities) or something requiring expertise not necessarily directly related to food safety, such as recordkeeping or ensuring that the importer is identified as the FSVP importer for the food at entry. In light of the revised definition of a qualified individual, we conclude that a person who meets the definition should always perform any activity required under the FSVP regulation. Any other individual might not necessarily have the ability to effectively perform the activity.

With respect to the proposed exemption from the use of a qualified individual requirement for the development of procedures to ensure the use of approved foreign suppliers, we note that in the Supplemental Notice we had substituted the requirement to establish and follow such procedures for a proposed requirement (set forth in the proposed rule) to maintain a written list of foreign suppliers. That change effectively transformed this requirement from an administrative one to a substantive one. Requiring use of a qualified individual for developing and implementing procedures to ensure the use of approved suppliers is consistent with the principle stated in the preamble to the proposed rule that education and training are important to ensure the development of FSVPs. Similarly, although recordkeeping and ensuring that the importer is properly identified as the importer of the food at entry may require comparably less food safety training and experience, we conclude that persons responsible for meeting these FSVP requirements should have the education, training, and/or experience needed to effectively perform these tasks.

In the proposed rule, we also proposed to exempt from the requirement to use a qualified individual the following types of importers:

- Importers of certain dietary supplements and dietary supplement components who are in compliance with proposed § 1.511(a) or (b); and
- Importers of food from foreign suppliers in countries whose food safety systems FDA has recognized as comparable or determined to be equivalent to that of the United States in accordance with proposed § 1.513.

Although the modified FSVP requirements applicable to these importers under §§ 1.511(a) and (b) and 1.513 of the final rule are limited (in the case of § 1.511(a) and (b), to recordkeeping and/or identification of the importer at entry), we believe that it is nevertheless appropriate that persons with necessary education, training, and/or experience perform the tasks required under these provisions.

(Comment 113) One comment on proposed § 1.503 states that importers should not be required to have a qualified individual conduct the review of a foreign supplier's food safety records.

(Response 113) We do not agree. We conclude that to adequately review and understand a foreign supplier's food safety records, a person must have adequate education, training, and/or experience regarding the food safety operations addressed in the records, including, where applicable, training in the principles of hazard analysis and risk-based preventive controls and measures to ensure produce safety. Review of food safety records requires an understanding of the applicable food safety principles.

(Comment 114) One comment states that a foreign government employee who is designated as a qualified individual by the foreign government should have the authority to conduct any kind of verification activities under the FSVP regulations without having to be accredited as a third-party auditor.

(Response 114) The importer of a food, not a foreign government or any other entity, is responsible for determining whether a person who is to conduct FSVP activities has the education, training, and/or experience necessary to conduct those activities in accordance § 1.503(a) of the final rule. The FSVP regulations do not require that a qualified auditor or qualified individual be accredited under any accreditation scheme or system, including FDA's regulations on the accreditation of third-party certification bodies implementing section 808 of the FD&C Act, as long as the person otherwise satisfies the requirements to be a qualified auditor or individual under § 1.503.

#### *E. Hazard Analysis (§ 1.504)*

In the Supplemental Notice, we made several changes to the proposed requirements concerning importers' analysis of the hazards in the foods they import in response to several comments and to align the FSVP requirements with the proposed supply-chain program provisions in the preventive controls regulations. These revisions primarily involved changing the requirement to analyze hazards that are reasonably likely to occur to a requirement to analyze known or reasonably foreseeable hazards (to determine if these hazards are significant), as well as the addition of a proposed requirement that importers consider hazards intentionally introduced for purposes of economic gain.

As discussed in the following paragraphs, we are making several additional changes to the hazard analysis provisions in response to comments. We also are adding flexibility by broadening the proposed provision allowing an importer to rely on a hazard analysis conducted by its foreign supplier (rather than conducting an entirely separate evaluation of hazards using information that the importer itself has obtained). As described further in the following paragraphs, the final rule permits reliance on a hazard analysis conducted by additional entities in importers' supply chains.

##### **1. General**

(Comment 115) Some comments suggest that the hazard analysis provisions in the FSVP regulations should cross-reference the hazard analysis provisions in the regulations on preventive controls for human food.

(Response 115) We conclude that this is not necessary or appropriate. Although the hazard analysis provisions in the two regulations are very similar, there are some differences in the requirements that primarily reflect the difference in scope between the FSVP regulation and the preventive control for human food regulation. The former generally apply to importers who must analyze the hazards in the foods produced by their foreign suppliers, while the latter primarily apply to food facilities that must determine the hazards for the food that they themselves manufacture, process, pack, or hold.

(Comment 116) Some comments request that we not apply the FSVP regulation to any food until we have conducted a risk assessment and made a risk management determination for

each food according to internationally agreed standards and after public comment. The comments assert that requiring importers to identify hazards and conduct verification will cause small businesses to withdraw from the market or choose too carefully which products to import and from which geographic regions, stifling international trade. The comments maintain that this will happen not because there are hazards in particular foods but because the importer or foreign supplier cannot scientifically identify it or because the verification requirements will be unnecessarily stringent or costly for most foods. However, the comments assert that most foods do not present a food safety risk and that there is no scientific proof that specific foods covered by FSMA are unsafe or need to be made safer.

The comments also assert that we must conduct the risk assessments to meet U.S. obligations under the SPS Agreement. The comments object to what they regard as FDA's shifting of its obligation to conduct risk assessments to the private sector by requiring importers to conduct hazard analyses.

The comments also request that the FSVP regulations be applied only to designated high-risk foods for at least 5 years after we have designated such foods.

(Response 116) We do not agree with the suggested approach to the determination of risks in imported foods. There are known hazards in many types of food, and many types of domestic and foreign foods have been identified as the source of foodborne illness outbreaks in the United States. As stated previously, we conclude that it is appropriate to require importers to analyze the hazards in the foods they import and conduct foreign supplier verification activities that take into account the risks posed by these hazards and provide assurances that suppliers are following procedures to ensure food safety consistent with U.S. standards, including the preventive controls and produce safety regulations. Therefore, we do not believe that the comments provide a justification for requiring that we conduct individual risk assessments of specific foods before we require importers to conduct hazard analyses and supplier verification activities. However, we note that to the extent that the comments express particular concern about the ability of smaller entities to comply with the FSVP regulations, § 1.512 of the final rule (discussed in section III.M of this document) specifies modified requirements for very small importers

and importers of food from certain small foreign suppliers.

We also deny the request that the FSVP regulation be applied only to foods that we have designated as high risk for at least 5 years after we make such designations. Under the regulation, importers will be responsible for determining the hazards in the food they import, evaluating the risk posed by that food and the characteristics of the foreign supplier, and determining appropriate foreign supplier verification activities based on that evaluation. Thus, the regulation allows importers the flexibility to tailor the supplier verification they conduct to the nature of the risks posed by the foods they import. In addition, as discussed in section IV.B of this document, we are providing considerable time for importers to adjust their procedures and practices (if necessary) to come into compliance with the regulation. Consequently, we conclude that it is unnecessary and not in the interest of public health to delay implementation of the FSVP regulation until we conduct risk assessments and designate high-risk foods, or to limit the scope of the regulation to high-risk foods for 5 years.

## 2. Requirement To Conduct a Hazard Analysis

We proposed to require that an importer identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each food it imports to determine whether there are any significant hazards (proposed § 1.504(a)). We further proposed to define a “significant hazard” as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records), as appropriate to the food, the facility, and the control.

We also proposed that the hazard analysis be written (proposed § 1.504(a)).

As discussed in section III.A.11 of this document, the final rule uses the term “hazard requiring a control” instead of “significant hazard.” Following is a discussion of comments on other aspects of the proposed hazard analysis requirements in § 1.504(a).

(Comment 117) One comment requests that we replace “illness data” with “FDA foodborne illness data” to

ensure that a review of illness data is based on a well-known and relatively easy-to-access source of information.

(Response 117) We decline to make the change because illness data from any reliable source, not just FDA, would be relevant in evaluating known or reasonably foreseeable hazards. For example, importers might consider data on foodborne illnesses published by the Centers for Disease Control in determining whether hazards that cause such illnesses are hazards that require a control.

(Comment 118) Some comments ask that we change proposed § 1.504(a) to refer to “experience, illness data, scientific reports, or other information” instead of “and other information” because they believe that there might not be any such data or reports regarding animal food.

(Response 118) We decline this request. We agree that in some cases some of the specified types of information might not be available. For example, there would be no illness data for a food that has never been associated with a foodborne illness. However, changing the provision as requested would allow importers to choose which information to evaluate, irrespective of whether the information is available. We conclude that importers must consider each of these types of information—to the extent that each type exists for a food—in conducting a hazard analysis.

(Comment 119) One comment suggests that importers should be required to evaluate known or reasonably foreseeable hazards for each “type of food” rather than each “food.” The comment maintains that it would be unnecessarily burdensome to require a separate hazard analysis for each individual food imported; instead, the comment requests that importers be permitted to group foods appropriately by type for purposes of hazard analysis.

(Response 119) We agree and have changed § 1.504(a) accordingly. We conclude that it might be appropriate to analyze the hazards for a particular type of food, rather than an individual food product, if the resulting determination of hazards requiring a control will apply for all foods of this type. For example, it might be appropriate to conduct a hazard analysis for multiple product sizes of a particular food, or to conduct one hazard analysis applicable to two or more related foods that are manufactured, processed, grown, or harvested under very similar conditions if all such food involves the same hazards. However, if foods that might be said to be of the same “type” have different hazards that require a control,

it generally would not be appropriate to use the same hazard analysis for each of those foods.

## 3. Hazard Identification

### a. General Types of Hazards

We proposed to require, in § 1.504(b)(1), that an importer’s analysis of the known or reasonably foreseeable hazards in each food include the following types of hazards:

- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
- Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
- Physical hazards.

(Comment 120) Some comments ask that we delete “decomposition” from the listing of chemical hazards. The comments assert that many products used in the animal food industry have begun decomposition but are processed in a controlled system to halt decomposition before harmful toxins are formed. The comments maintain that the inclusion of “natural toxins” among chemical hazards addresses the Agency’s concerns about hazards associated with uncontrolled decomposition or spoiled foods resulting from chemical changes induced by the microbial breakdown that releases potentially hazardous toxins, and that including “decomposition” would be redundant and unnecessary because some levels of decomposition do not pose an animal food safety risk.

(Response 120) We decline to make this change. Decomposition of animal food consists of microbial breakdown of normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by abnormal odors, tastes, textures, colors, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, potentially resulting in illness or death. Thus, decomposition can be a hazard requiring a control in animal food.

(Comment 121) Some comments ask that we add the term “nutrient deficiencies or toxicities” to the list of chemical hazards because animal safety is related to established nutrient deficiencies and toxicities.

(Response 121) We agree that nutrient deficiencies or toxicities may be hazards in animal food (for reasons discussed in the preventive controls for animal food rulemaking) and have revised the list of chemical hazards accordingly.

**b. Reasons for Presence of a Hazard**

We proposed to require, in § 1.504(b)(2), that an importer's analysis of hazards include hazards that may be present in a food for any of the following reasons:

- The hazard occurs naturally;
- The hazard may be unintentionally introduced; or
- The hazard may be intentionally introduced for purposes of economic gain.

(Comment 122) Several comments object to the proposed requirement to consider hazards that might be intentionally introduced for purposes of economic gain. Some comments assert that because economically motivated adulteration (EMA) is nearly always an issue of product quality and integrity rather than food safety, requiring importers to consider EMA hazards would provide little benefit to food safety. Some comments suggest that it would not be appropriate to require consideration of EMA hazards because such hazards often are addressed by a corporate parent company rather than at the facility level. Some comments maintain that addressing EMA requires a completely different approach than that used for unintentional adulteration and that it would be better to address EMA in an importer's food defense plan. Some comments therefore request that we consider proposing regulations on EMA in a future rulemaking rather than in the FSVP regulation.

(Response 122) We decline to delete this requirement. EMA can and has resulted in safety concerns, including, as in the case of melamine in infant formula and pet food, the deaths of humans and animals. The fact that a plan for addressing EMA might be developed at the corporate level is irrelevant to whether an importer can determine whether EMA in a particular food is known or reasonably foreseeable. Further, we disagree that economically motivated adulteration requires a completely different approach than unintentional adulteration. Although we acknowledge that many firms currently might not include EMA in their analyses of safety hazards in food, as we stated in the Supplemental Notice, some of the measures that industry uses in supplier verification programs, such as audits and sample testing, are used to guard against EMA. Moreover, we believe that the burden posed by having to analyze potential EMA hazards is limited because, as with hazards that occur naturally or that may be unintentionally introduced, we define hazards to include only those agents that have the potential to cause illness or injury. In

the EMA context, we anticipate that importers will identify such hazards in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration of a food. Therefore, we conclude it is appropriate that importers consider EMA hazards under the FSVP regulation.

(Comment 123) Some comments assert that it would be more appropriate to address EMA hazards separately from the hazard analysis because they are not considered as part of the hazard analysis when designing a food safety plan; rather, the comments maintain that EMA should be considered as part of supplier verification.

(Response 123) We do not agree. Importers are required to conduct a hazard analysis under § 1.504 of the final rule precisely to understand what manner of supplier verification under § 1.506 is needed and appropriate. Therefore, importers need to evaluate EMA as part of the hazard analysis for a food so that, if EMA is determined to be a hazard requiring a control for that food, importers can conduct appropriate supplier verification activities to obtain assurance that the food has not been intentionally adulterated for economic gain.

(Comment 124) One comment asserts that looking retrospectively at instances of economic adulteration might not be effective because it would be less likely that others would engage in such activity in the future.

(Response 124) We are not aware of evidence supporting the comment's assertion. However, given that it would not be feasible or appropriate to require importers to speculate about, and guard against, any conceivable form of EMA of a food, we conclude that it is reasonable to require importers to consider, among other things, whether a food has been previously linked to EMA that might cause harm to consumers.

(Comment 125) Some comments assert that the analysis of hazards intentionally introduced for economic gain should be limited to whether there is a history of any particular EMA. Some comments request that we limit the requirement to consider hazards that might be intentionally introduced for economic gain to such hazards that are "already known" or for which there is a "historical precedent."

(Response 125) As with other hazards, importers need only consider EMA hazards that are known or reasonably foreseeable. This means that importers are not required to consider purely speculative hazards. We expect that EMA hazards will be identified in rare circumstances, usually in cases where

there has been a pattern of EMA in the past. The revisions suggested by the comments are unnecessary and could be interpreted to narrow the requirement that importers consider hazards that are known or reasonably foreseeable. We continue to believe that this requirement is appropriate, even for EMA, and we reiterate that we would not expect importers to consider merely hypothetical EMA scenarios for their food products. This is consistent with our position on EMA in the preventive controls regulations.

(Comment 126) One comment requests that if the requirement to consider EMA is included in the final rule, it should be limited to "food safety" hazards that might be intentionally introduced for economic gain.

(Response 126) We conclude that this change is unnecessary. Because "hazards" are defined as certain agents that are reasonably likely to cause illness or injury, the requirement to consider hazards that might be introduced for purposes of economic gain is already limited to EMA that relates to food safety. EMA that relates to the quality of food (for example) but not food safety is beyond the scope of this rulemaking.

(Comment 127) Some comments request that importers be given flexibility to determine appropriate verification activities for EMA hazards. Some comments assert that testing should not be the only suitable control or verification measure for EMA because for many facilities it would be impractical to test every imported lot of ingredients.

(Response 127) Section 1.506 of the final rule provides importers flexibility in determining appropriate supplier verification activities for all hazards—including EMA—consistent with the evaluation of the risk posed by a food and the foreign supplier's performance, among other factors, conducted in accordance with § 1.505.

(Comment 128) Some comments suggest that we publish a list of previous instances of EMA that importers should use in considering possible EMA hazards.

(Response 128) Although we agree that it would be useful to have a centralized list involving all previous instances of EMA, creating such a list would likely be unduly resource-intensive for FDA and therefore would not be consistent with the efficient enforcement of section 805 of the FD&C Act. We therefore decline this request. We note, however, that information about incidents of EMA is widely

available from public sources (Refs. 10–12).

(Comment 129) One comment asks that we require importers to identify harmless economically motivated adulterants during the review process.

(Response 129) Although we encourage importers to identify—and verify control of—all EMA, we think it is appropriate to treat EMA consistently with our general approach to hazard analysis and only require identification of those agents that have the potential to cause illness or injury. We therefore decline this request.

#### 4. Hazard Evaluation

##### a. Probability and Severity of Hazards

We proposed in § 1.504(c)(1) to require that the importer's hazard analysis include an assessment of the probability that hazards will occur in the absence of controls and the severity of the illness or injury if the hazards were to occur.

(Comment 130) Some comments suggest that the provision should require importers to consider any relevant geographic, temporal, agricultural, or other factors that might affect the severity or probability of a hazard.

(Response 130) We do not believe it is appropriate to address these factors within the basic requirement to assess the probability that hazards will occur in the absence of controls and the severity of illness or injury if the hazards were to occur. Rather, we think that this requirement, stated in § 1.504(c)(1), establishes the general scope of the hazard analysis. However, we agree that such factors might be relevant in a hazard evaluation for a food, such as year-to-year fluctuation of aflatoxin levels in some RACs due to weather conditions. We therefore believe it is appropriate to include these factors in the list of factors that must be considered in the hazard evaluation required under § 1.504(c)(3) of the final rule. Thus, we have revised the list of factors that a hazard evaluation must address under § 1.504(c)(3) to include, among “other relevant factors,” the temporal (e.g., weather-related) nature of some hazards, such as levels of natural toxins.

##### b. Environmental Pathogens in Certain Ready-To-Eat Foods

We proposed that a hazard evaluation would have to include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment that would significantly

minimize the pathogen (proposed § 1.504(c)(2)).

In the final rule, we have revised this requirement to specify that instead of receiving a treatment to significantly minimize the pathogen, the ready-to-eat food might include a control measure (such as a formulation that is lethal to the pathogen) that would significantly minimize the pathogen, because controls such as formulation can function as a “kill step,” and the provision should make clear that such controls can be used in lieu of “treatment.” This change is consistent with corresponding provisions in the preventive controls regulations.

(Comment 131) Some comments ask that we expand the requirement to evaluate environmental pathogens to include all foods, not just certain ready-to-eat foods.

(Response 131) We conclude that this change is not needed because importers will be required, under § 1.504(b)(1)(i), to consider whether there are any known or reasonably foreseeable environmental pathogens in a food. The requirement in § 1.504(c)(2) is designed to address the specific safety concern known to be associated with ready-to-eat foods that are exposed to the environment before packaging and would not undergo treatment (or otherwise include a control measure) to significantly minimize environmental pathogens.

(Comment 132) One comment requests that we limit the requirement concerning ready-to-eat foods that are exposed to the environment to such foods that are “capable of supporting pathogen growth to, or survival at, infectious levels.”

(Response 132) We decline to make this change because this suggestion prejudices the outcome of the hazard analysis for a wide variety of food products. An importer may consider factors such as whether the formulation of a food would not support the growth of a pathogen to increased numbers, or would cause pathogens to die off over time, in determining whether an environmental pathogen is a hazard requiring a control. If an importer determines that any environmental pathogens in a ready-to-eat food would not pose a hazard that requires a control, the importer would need to document the basis for that determination in its written hazard analysis.

(Comment 133) Some comments request that we delete this proposed requirement or define what is meant by a ready-to-eat food that is “exposed to the environment.”

(Response 133) We decline this request. The Appendix to the 2013 proposed rule on preventive controls for human food provides examples of food products that are, or are not, exposed to the environment (78 FR 3646 at 3819).

(Comment 134) One comment asks that the requirement specify that a qualified individual must determine that exposure of the ready-to-eat food to the environment before packaging would constitute a risk of introduction of a significant hazard. The comment asserts that a qualified individual is best suited to make a determination of whether the exposure poses an actual risk.

(Response 134) We decline to make this change. As with all activities required under the FSVP regulation, a qualified individual must conduct the hazard analysis for each food that the importer imports. Therefore, it is unnecessary to specify in § 1.504(c)(2) that a qualified individual must make the determination of whether exposure to the environment of a ready-to-eat food might result in the development of an environmental pathogen that requires a control.

##### c. Hazard Evaluation Factors

We proposed, under § 1.504(c)(3), that an importer's hazard evaluation of a food would have to consider the effect of the following factors on the safety of the finished food for the intended consumer:

1. The formulation of the food;
2. The condition, function, and design of the foreign supplier's establishment and equipment;
3. Raw materials and ingredients;
4. Transportation practices;
5. Harvesting, raising, manufacturing, processing, and packing procedures;
6. Packaging and labeling activities;
7. Storage and distribution;
8. Intended or reasonably foreseeable use;
9. Sanitation, including employee hygiene; and
10. Any other relevant factors.

(Comment 135) Some comments request that importers be required to consider the hazard evaluation factors only “as appropriate” because not all factors will be relevant in every case. The comments maintain that because an importer is not always procuring a finished food, a hazard analysis of a foreign supplier conducted for FSVP purposes has a narrower scope than a hazard analysis conducted as part of a food safety plan. The comments also assert that importers might not always know all foreseeable uses of an ingredient when initially sourcing it from a foreign supplier. Therefore, the



comments maintain that importers should have the flexibility to apply the listed factors as they deem appropriate.

(Response 135) We decline to require that importers only consider the hazard evaluation factors “as appropriate.” We understand that importers might import raw materials or other ingredients and that this might affect how some of the factors are evaluated, such as the intended use of a raw material that is used in many foods. But importers must at least consider the potential effect of each of the factors on the safety of the finished food. If a factor is not relevant with respect to a particular food, the consideration might be brief. With regard to the importation of raw materials or other ingredients, we note that the final rule includes provisions applicable to when an imported raw material or other ingredient will be processed further in the United States.

(Comment 136) Some comments express concern that the proposed requirement to consider the condition, function, and design of the foreign supplier’s establishment and equipment would necessitate an onsite audit of the foreign supplier. Some comments request that if onsite audits are required, we should provide guidance regarding such audits.

(Response 136) Importers will not be required to conduct onsite audits of potential foreign suppliers as part of the hazard analysis of a food under § 1.504(c)(3)(ii) of the final rule. We have revised this hazard evaluation factor from the “condition, function, and design of the foreign supplier’s establishment and equipment” to the “condition, function, and design of the establishment and equipment of a typical entity that manufactures/ processes, grows, harvests, or raises this type of food.” This change is designed to make clear that importers must consider how a typical establishment and equipment used to manufacture/ process, grow, harvest, or raise a food affect the hazards in the food, rather than the potential effect of a particular foreign supplier’s operations. (The requirement to consider a particular foreign supplier’s performance is located in § 1.505 of the final rule, which sets forth the requirements for evaluation for foreign supplier approval and verification.) Importers can obtain information about the nature of establishments that produce a particular food and the equipment they use by consulting a number of sources of information other than audits. These may include, for example, trade journals and other publications, academic literature, and materials obtained

directly from potential foreign suppliers.

(Comment 137) Some comments suggest that we substitute “expected use” for “intended or reasonably foreseeable use” because they believe that the former is too vague to provide clear direction to importers and the Agency regarding compliance obligations.

(Response 137) We decline this request. Although we agree that the term “expected use” has the potential to communicate both intended and reasonably foreseeable use, we are concerned that the term might not be universally interpreted that way. For example, an importer might interpret “expected use” to mean “probable use” and consequently not consider reasonably foreseeable uses as part of the hazard evaluation. Therefore, we are retaining the term “intended or reasonably foreseeable use” to make it clear that an importer must consider use that is reasonably foreseeable in addition to intended use.

#### 5. Review of Another Entity’s Hazard Analysis

We proposed to provide that if the importer’s foreign supplier had analyzed the known or reasonably foreseeable hazards for the food to determine whether there were any significant hazards, the importer could meet its requirement to determine whether there were any significant hazards by reviewing and assessing the hazard analysis conducted by the foreign supplier (proposed § 1.504(d)).

As described in sections III.E.5, III.F.4, and III.G.4 of this document, we conclude that it is appropriate to allow importers to obtain certain information needed to meet their FSVP responsibilities from other entities, in some cases in their supply chains, for the foods they import. Therefore, we have revised § 1.504(d) to provide that if another entity (including the foreign supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for a food to determine whether there are any hazards requiring a control, the importer may meet its requirement to determine whether there are any hazards requiring a control for the food by reviewing and assessing the hazard analysis conducted by that entity. The importer is also required to document its review and assessment of the other entity’s hazard analysis, including documenting that the hazard analysis was conducted by a qualified individual.

(Comment 138) Some comments assert that importers’ opportunities to rely on a hazard analysis conducted by

the foreign supplier might be limited because many suppliers would not want to share their hazard analyses.

(Response 138) We recognize that, due to commercial confidentiality concerns or other reasons, there might be circumstances in which some foreign suppliers might be reluctant to share their hazard analyses of foods that importers seek to obtain from them. However, we also believe that some foreign suppliers will desire to share their hazard analyses as a means of attracting customers for their products. In those cases, we want to provide importers with the flexibility to eliminate redundancy that would have occurred by not requiring the importer to conduct an independent hazard analysis when the foreign supplier has already conducted one.

(Comment 139) One comment suggests that we substitute “food safety hazard” for “hazard” so importers do not conclude that they must address all types of hazards.

(Response 139) We conclude that this change is unnecessary because this provision refers to another entity’s analysis of known or reasonably foreseeable hazards for a food, and a hazard is specifically defined in the FSVP regulation as an agent that is reasonably likely to cause illness or injury if not controlled, *i.e.*, it affects the safety of the food.

#### 6. Biological Hazards in RACs That Are Fruits or Vegetables

We proposed to provide that an importer of a RAC that is a fruit or vegetable would not be required to determine whether there were any significant microbiological hazards in such food (proposed § 1.504(e) in the Supplemental Notice). We stated in the preamble to the proposed rule that the hazard analysis requirements were not needed for RACs that are fruits or vegetables and that are subject to the regulation on produce safety in part 112 because FDA has already identified the biological hazards associated with fruits and vegetables and has proposed requirements for measures intended to prevent the introduction of these hazards into produce.

(Comment 140) Several comments ask that we clarify proposed § 1.504(e). Some comments ask that we specify that imported food is subject to the produce safety regulation when applicable, which would directly address the microbial hazards in the food. The comments assert that biological hazards are very significant in some fruits and vegetables and importers should consider them. The comments ask whether the provision is intended to

apply to RACs that are fruits or vegetables that are not covered under the produce safety regulation. Some comments ask that we clarify how the FSVP and produce safety regulations work together. Some comments assert that all fresh produce must be subject to supplier verification, including evaluation of hazards, whether covered under the FSVP regulation or the produce safety regulation.

(Response 140) We proposed to “exempt” importers of RACs that are fruits or vegetables that are “covered produce” (as that term is defined in the produce safety regulation) from having to analyze the microbiological hazards in such food. Although proposed § 1.504(e) did not specifically state that the “exemption” from hazard analysis only applies when the imported RACs are “covered produce” as defined in proposed § 112.3, the preamble to the proposed rule essentially stated that the exemption only applies in these circumstances and explained the reason for the exemption. Specifically, the preamble explained that the exemption is appropriate because FDA has designed the produce safety regulation so that compliance with the regulation would ensure that microbiological hazards are adequately addressed. (Although proposed § 1.504(e) refers to “microbiological” hazards, it should have referred to “biological” hazards because “hazard” is defined in both the proposed and final rules on produce safety as any “biological agent” that is reasonably likely to cause illness or injury in the absence of its control.) Indeed, the produce safety regulation is intended to minimize the risk of serious adverse health consequences or death from the introduction of known or reasonably foreseeable biological hazards in produce, and to provide assurance that fruits and vegetables are not adulterated because of such hazards. To make this clear, we have revised § 1.504(e) to state that an importer of a RAC that is a fruit or vegetable is not required to determine whether there are any biological hazards requiring a control in such food only if the RACs are “covered produce” as defined in § 112.3 (*i.e.*, produce that is subject to the produce safety regulation in accordance with §§ 112.1 and 112.2).

In addition, we are clarifying that this partial exemption from the hazard analysis requirements is appropriate because the biological hazards in such fruits or vegetables require a control and compliance with the regulation in part 112 significantly minimizes or prevents the biological hazards. Although importers of such RACs need not conduct a hazard analysis with respect

to the biological hazards in this food, they must conduct supplier verification for the food in accordance with § 1.506 of the final rule to ensure that all hazards in the RACs, including biological hazards, are significantly minimized or prevented.

(Comment 141) Some comments request that importers of RACs that are fruits or vegetables not be required to analyze non-biological hazards in the food. The comments assert that there have been no outbreaks linked to chemical or physical hazards in imported produce, no examples of EMA in fresh produce, and no chemical contamination of fresh produce at levels reasonably likely to cause illness. The comments maintain that analyzing non-biological hazards would be very burdensome because it would likely require a visit to the location in which the food is grown, and would be complicated by the seasonal nature of fruit and vegetable production and harvesting.

(Response 141) We decline to make this change. In the preamble to the proposed rule on produce safety (78 FR 3504 at 3524), we acknowledged that there can be non-biological hazards in produce, and a reference memorandum to that proposed rule provided an overview of the chemical, physical, and radiological agents that are reasonably likely to occur in produce at the farm and are capable of causing adverse health effects (Ref. 13). Our analysis of those hazards led us to conclude that they rarely pose a risk of serious adverse health consequences or death for consumers of produce, making it unnecessary to establish a new regulatory regime for their control under section 105 of FSMA. We stated that existing programs, such as the registration of pesticides with the Environmental Protection Agency (EPA) and State and industry efforts to control the presence of pesticides and mycotoxins in produce, are sufficient to keep these hazards under control. We also noted that FDA monitors natural toxins, pesticides, industrial chemicals, other chemical contaminants, and radionuclides in food. For these reasons, we tentatively concluded that it was appropriate to limit the scope of the produce safety regulations to biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards (78 FR 3504 at 3524). We have reaffirmed this conclusion in the final rule on produce safety published elsewhere in this issue of the **Federal Register**.

Thus, although the produce safety regulation does not address non-biological hazards in fruits or vegetables, such hazards are sometimes associated with this food. We conclude that it is appropriate to require importers to determine whether there are any such hazards requiring a control in a fruit or vegetable they are importing because section 805 of the FD&C Act requires importers to verify that produce is produced not only in compliance with the produce safety regulation issued in accordance with section 419 of the FD&C Act but also in accordance with section 402, *i.e.*, that it is not adulterated. As we stated in the preamble to the FSVP proposed rule, we do not believe that the analysis of non-biological hazards will create a significant burden for importers of fruits and vegetables; importers will need to be aware of how a crop is produced and whether there have been non-biological hazards, such as pesticide residues, associated with it. We believe that in many cases importers can obtain the information they need to assess non-biological hazards from public sources, such as any regulations applicable to the control of such hazards, scientific literature, and information on FDA’s Web site (including guidance documents, import alerts, recall notices, warning letters, and untitled letters), as well as information from the foreign suppliers themselves. The consideration of chemical and physical hazards for RACs that are fruits and vegetables is consistent with the requirements for these products under the regulation on preventive controls for human food.

(Comment 142) One comment notes that importers of produce must include chemical and physical contamination hazards when they analyze hazards in imported produce while domestic purchasers of produce need only confirm that the produce was produced in compliance with the produce safety regulation, which requires the control of biological hazards but not chemical or physical hazards. The comment asserts that this constitutes inconsistent treatment of domestic and imported products and may invite a challenge before the WTO.

(Response 142) We do not agree. The FSVP regulation does not result in different treatment of foreign and domestic produce producers with respect to chemical and physical hazards in produce. Although the produce safety regulation does not address such hazards, the presence of such hazards may cause produce—whether produced domestically or overseas—to be adulterated under section 402 of the FD&C Act. Therefore,

both domestic and foreign producers of produce are prohibited from distributing produce contaminated with certain chemical and physical hazards, and domestic and foreign-produced produce is held to the same standard.

(Comment 143) One comment suggests that instead of “fruits or vegetables,” the provision should refer to RACs that are “fresh, intact fruits, nuts, culinary herbs, or vegetables.” The comment maintains that this change is needed because many importers will not be aware of FDA’s scheme to distinguish RACs from processed foods and may not understand that the Agency considers fruits and vegetables to include nuts and culinary herbs. The comment suggests a corresponding change to proposed § 1.504(f).

(Response 143) We decline to make this change because the produce safety regulation refers to fruits, nuts, culinary herbs, and vegetables collectively as “fruits and vegetables.” We believe it would be confusing, and could imply a different meaning, if we were to adopt a different term to capture the same set of food in the FSVP regulation.

(Comment 144) Some comments suggest that this provision state whether importers of RACs that are fruits or vegetables must analyze hazards other than biological hazards.

(Response 144) We agree and have revised § 1.504(e) to specify that importers of RACs that are fruits or vegetables must analyze hazards other than biological hazards in such food.

#### 7. No Hazards Requiring a Control

We proposed to provide, in § 1.504(f), that if an importer evaluates the known and reasonably foreseeable hazards in a food and determines that there are no significant hazards, the importer would not be required to determine what foreign supplier verification and related activities to conduct under § 1.505 and would not be required to conduct such activities under § 1.506. We proposed that this provision would not apply if the food is a RAC that is a fruit or vegetable and that is subject to the produce safety regulation.

Consistent with the change to § 1.504(e) discussed in Response 140, we have revised § 1.504(f) to state that it does not apply if the food is a RAC that is a fruit or vegetable that is “covered produce” as defined in § 112.3 in the produce safety regulation.

(Comment 145) Some comments assert that we should declare certain foods, such as chocolates, confectionery, jams, preserves, baked goods, and non-alcoholic beverages, to be safe, as the Agency has done with several products

under the proposed rule on produce safety.

(Response 145) We are finalizing proposed § 1.504(f) because we agree that there are many foods that have no hazards requiring a control. In the preamble to the proposed rule, we suggested salt and certain food-grade chemicals as examples of food for which, depending on the circumstances, there might not be any hazards that would be reasonably likely to occur. Other examples of food for which there might be no hazards requiring a control include, but are not limited to, many crackers, most bread, dried pasta, many types of cookies, many types of candy (e.g., hard candy, fudge, maple candy, taffy, toffee), honey, molasses, sugar, syrup, soft drinks, and jams, jellies, and preserves from acid fruits.

However, because many of these foods can be made using a variety of ingredients under different processes by different manufacturers, we decline to completely exempt these foods from the FSVP regulation by declaring them to be “safe.” Rather, we conclude that it is appropriate to require importers to determine whether there are any hazards requiring a control in a particular food. However, as previously stated, importers will be able to rely on hazard analyses conducted by other entities, including analyses that find no hazards requiring a control in foods.

(Comment 146) Some comments request that importers be required to reevaluate food and foreign supplier risks annually even when an importer determines that there are no significant hazards in a food.

(Response 146) We do not agree. Under § 1.505(c) of the final rule, importers will be required to reevaluate the risk posed by a food as well as a foreign supplier’s performance when the importer becomes aware of new information about these matters (including new information about potential hazards), or at least every 3 years (see section III.F.3 of this document). We conclude that it is unnecessary to require more frequent reevaluation of the risks in a food and a foreign supplier’s performance for those foods for which an importer determines that there are no hazards requiring a control.

(Comment 147) Some comments maintain that proposed § 1.504(f) conflicts with proposed § 1.504(e), which exempts importers of RACs that are fruits or vegetables from having to analyze the biological hazards in such produce. Some comments suggest that § 1.504(f) creates an assumption that there are always significant hazards in

fruits and vegetables subject to the produce safety regulations.

(Response 147) We do not believe that § 1.504(f) conflicts with § 1.504(e). As we stated in the preamble to the proposed rule, this exception is appropriate because for such food the importer is not conducting a hazard analysis to identify the biological hazards that need to be significantly minimized or prevented. If we did not specify that § 1.504(f) did not apply to RACs that are fruits or vegetables that are covered produce, an importer of such food might mistakenly conclude that because it had determined that there were no non-biological hazards requiring a control in the food, the importer need not conduct supplier verification. However, because there are presumed to be biological hazards associated with all fruits and vegetables that are covered produce under the produce safety regulation, even if there are no non-biological hazards in a fruit or vegetable, the importer must conduct supplier verification to obtain assurances that the food was grown and harvested consistent with the produce safety regulation and is not adulterated.

#### 8. Hazards Controlled by the Importer or Its Customer

In the Supplemental Notice, we proposed to provide (in § 1.504(g)) that if the preventive controls that the importer and/or its customer implement in accordance with the proposed preventive controls requirements in subpart C of part 117 are adequate to significantly minimize or prevent all significant hazards in a food, the importer would not be required to determine or conduct appropriate foreign supplier verification. Proposed § 1.504(g) further stated that if the importer’s customer controlled one or more such hazards, the importer would be required to annually obtain from the customer written assurance that it had established and was following procedures (identified in the written assurance) that would significantly minimize or prevent the hazard.

As set forth in § 1.507 of the final rule and discussed in section III.H of this document, we have broadened the circumstances under which certain importers are not required to conduct an evaluation under § 1.505 or supplier verification activities under § 1.506 when the hazard requiring a control in a food will be adequately controlled by another entity and certain other requirements are met. We discuss those provisions and respond to the comments on proposed § 1.504(g) in section III.H.

#### *F. Evaluation for Foreign Supplier Approval and Verification (§ 1.505)*

In the Supplemental Notice, we replaced a proposed requirement that importers conduct a compliance status review of the food and foreign supplier with a requirement to evaluate the risks associated with a food to be imported (as determined in the hazard analysis for the food) and the potential foreign supplier of that food. Although the comments generally support this more comprehensive, “holistic” approach to selecting suppliers, several comments suggest changes regarding the proposed risk factors or the proposal to require reevaluation of risk. As discussed in the following paragraphs, we have made some relatively minor changes with respect to the proposed food and foreign supplier factors, and the final rule permits importers to rely on evaluations of these factors conducted by other entities (except for the foreign supplier), provided that the importer reviews and assesses the evaluation and documents the review and assessment. In addition, we have revised the provisions concerning reevaluation of these factors so that they take the place of the proposed requirements on FSVP reassessment.

##### **1. Evaluation for Approving Suppliers and Determining Verification Activities**

We proposed (in § 1.505(a)(1)(i) through (vi)) to require importers, in determining the appropriate supplier verification and related activities to conduct, to consider the following:

- The hazard analysis for the food conducted under proposed § 1.504, including the nature of the hazard.
- The entity that will be applying controls for the hazards, such as the foreign supplier or the foreign supplier’s raw material or ingredient supplier.
- The foreign supplier’s procedures, processes, and practices related to the safety of the food.
- Applicable FDA food safety regulations and information regarding the foreign supplier’s compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert.
- The foreign supplier’s food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food, and the supplier’s record of correcting problems.
- Any other factors as appropriate and necessary, such as storage and transportation practices.

We also proposed to require importers to document their risk evaluations.

##### **a. General**

(Comment 148) Some comments request that we define “risk” because some people might not understand the difference between “risk” and “hazard” as the terms are frequently interchanged in common usage. One comment suggests that the regulations define “risk” as “the chance or probability that harm will occur, taking into account both the likelihood that a hazard will occur in the absence of controls to prevent it and the severity of the illness or injury that the hazard might cause.”

(Response 148) Although we conclude that it is not necessary to include a definition of risk in the codified provisions, we agree that, in the context of food safety science, a risk is different from a hazard. Although the regulations on preventive controls for human food and for animal food do not include a definition of “risk,” in those regulations we regard risk in the way that it is described in the Codex Alimentarius, which defines “risk” as “a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in a food.” Therefore, a risk posed by a food is the potential effect on health related to the hazards in the food.

Because Codex defines risk in relation to inherent food hazards only, rather than also considering the effect of actions by a producer or supplier of a food, we conclude that, to apply the term “risk” consistently throughout the FSMA regulations, § 1.505 of the FSVP regulation should not refer to the “risks” posed by a foreign supplier. Therefore, we have revised § 1.505(a) so that it refers, in § 1.505(a)(1)(iii)(A) through (C) of the final rule, to factors related to the foreign supplier’s “performance” rather than the “risks” associated with the foreign supplier. These factors, which we have not substantially changed in the final rule, are the supplier’s food safety-related processes and procedures, its compliance with FDA food safety regulations, and its food safety history with the importer and others.

(Comment 149) Several comments ask that we revise § 1.505(a)(1) to state that importers must consider the food and foreign supplier factors in deciding whether to approve a supplier, rather than in selecting appropriate supplier verification activities.

(Response 149) We do not agree that the use of the factors should be limited in this way. Many comments assert that factors such as a foreign supplier’s compliance status and contractual performance history can play an important role in determining

appropriate verification activities, such as in concluding that onsite auditing on an annual basis of a highly-compliant foreign supplier is not necessary even when the supplier is providing foods with SAHCODHA hazards. Therefore, we conclude that it is appropriate that importers evaluate certain safety factors related to a food and the foreign supplier in deciding what supplier verification activities (and the frequency of such activities) are needed to provide adequate assurance of the safety of the food.

Although proposed § 1.506(a) stated that importers must have procedures to ensure that they import food only from foreign suppliers approved based on the evaluation conducted under proposed § 1.505, we have revised § 1.505(a)(1) to make clear that an importer must conduct an evaluation of the foreign supplier’s performance and the risks posed by a food to both approve foreign suppliers and determine appropriate foreign supplier verification activities.

(Comment 150) Some comments ask that we revise § 1.505(a) to give importers the flexibility to consider only those factors that they conclude are appropriate for a particular food and foreign supplier. As an example, one comment states that an importer typically would not review a supplier’s FDA compliance history to determine a verification activity but might consider it later as part of the actual verification and qualification of the supplier.

(Response 150) We decline to make this change. We conclude that generally each of the factors set forth in § 1.505(a) will be relevant to approving a foreign supplier for a particular food and to determining appropriate verification activities for the supplier. If a particular factor is of little or no relevance with respect to a particular food and foreign supplier, the importer might only need to briefly consider that factor. For example, an importer that has never obtained food from a potential foreign supplier would not have any direct “history” with that supplier; for a foreign supplier that has just begun exporting food and, therefore, would not have been inspected by FDA, there might not be any associated warning letters or other compliance-related documents. However, with respect to a foreign supplier’s compliance with FDA food safety regulations, we believe that there would be very few circumstances in which this factor would not be relevant to deciding whether to approve a foreign supplier as a source of a food and selecting appropriate supplier verification activities.

**b. Hazard Analysis**

On our own initiative, we have revised § 1.505(a)(1)(i) to include the hazard analysis “of the food conducted under § 1.504” because, as discussed in section III.E.5 of this document, under § 1.504(d) of the final rule an importer may review and assess a hazard analysis conducted by another entity.

(Comment 151) One comment states that, when considering the hazard analysis, the requirement to include the nature of the hazard should refer to the nature of the “hazard requiring control” because importers should evaluate supplier risks primarily as they relate to those hazards.

(Response 151) We agree that referring to the nature of the hazard requiring a control is appropriate and have revised § 1.505(a)(1)(i) accordingly.

**c. Entity Applying Controls**

(Comment 152) Several comments express concern regarding the proposed requirement to consider the entity that will be applying hazard controls because it refers not only to the foreign supplier but to the foreign supplier’s raw material or ingredient supplier (proposed § 1.505(a)(1)(ii)). Several comments state that the importer’s responsibility to conduct supplier verification should be limited to its direct supplier’s compliance with applicable regulations, maintaining that this would be consistent with the Bioterrorism Act requirements, which provide for the identification of the immediate non-transporter previous source and subsequent recipient. Some comments state that requiring importers to document the actions of their suppliers’ suppliers would require a major change to the produce supply chain because the identity of a broker’s or aggregator’s suppliers often is proprietary information.

(Response 152) We do not agree that it is inappropriate to require importers to consider which entities control hazards, regardless of whether the entity is the foreign supplier, the foreign supplier’s supplier, or some other entity in the supply chain. The records requirements of the Bioterrorism Act serve a different function and are not directly applicable to the scope of evaluations conducted in accordance with the FSVP provisions of FSMA. Moreover, knowing the entity or entities that will be significantly minimizing or preventing the hazards in a food is directly relevant to the type of foreign supplier or other verification activity that the importer will need to conduct under § 1.506 or § 1.507 of the final rule. For example, when a foreign supplier’s

raw material supplier is controlling a hazard in a food that the importer obtains from the foreign supplier, the importer might conclude that reviewing the foreign supplier’s records of verification that its supplier produced the raw material in accordance with the preventive controls or produce safety regulations is more appropriate than auditing the foreign supplier with respect to this hazard.

In the final rule, we are revising § 1.505(a)(1)(ii) to require consideration of the entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier’s raw material or other ingredient supplier, or another entity in the importer’s supply chain. (The provision refers to significant minimization or prevention of hazards in accordance with the change we are making to proposed § 1.506(c), discussed in section III.G.3 of this document.) We conclude that this clarification is needed to address circumstances such as when a foreign supplier grows produce but another entity performs certain activities, such as harvesting the produce. Entities that fit the definition of “farm,” such as harvesters, might be required to significantly minimize or prevent hazards under the produce safety regulation. To ensure that the importer will meet its obligation under section 805(a)(1) of the FD&C to perform supplier verification activities to verify that the imported food is produced in compliance with sections 418 and 419, as applicable, and not adulterated under section 402 or misbranded under section 403(w), the importer must evaluate which entities in the supply chain have either significantly minimized or prevented the hazards or verified that the hazards were significantly minimized or prevented. The results of this evaluation might be a factor in determining (1) whether to approve the foreign supplier (the grower of the produce) or (2) the type and frequency of verification activities. Consequently, we conclude that importers must consider the entities that will be significantly minimizing or preventing the hazards or verifying significant minimization or prevention of the hazards in the foods they import as part of the evaluation conducted for supplier approval and determination of supplier verification activities.

**d. Foreign Supplier’s Safety Procedures, Processes, and Practices**

(Comment 153) Some comments express concern about how the confidentiality of a foreign supplier’s food safety procedures, processes, and practices will be ensured, considering that some information regarding these matters might include data of a commercially sensitive nature. The comments suggest that we revise these provisions to respect the right of foreign companies not to disclose confidential information to third parties (the comments raise this same concern with respect to information regarding a foreign supplier’s food safety performance history under proposed § 1.505(a)(1)(v)).

(Response 153) We decline to make this change. As discussed in section III.K.6 of this document, under § 1.510(f) of the final rule, records obtained by FDA in accordance with the FSVP regulation will be subject to the public disclosure provisions in part 20 (21 CFR part 20), including the protections against disclosure of trade secrets and commercial or financial information that is privileged or confidential. How foreign suppliers and importers choose to handle the issues surrounding the sharing of any confidential information with each other is between those parties. While we recognize that there might be some suppliers who are reluctant to provide information relevant to the kind of verification activities required by this rule, we believe that many suppliers will agree to such activities in order to facilitate the exportation of their products to the United States and access new customers.

**e. Supplier’s Compliance With Applicable FDA Food Safety Regulations**

On our own initiative, we have modified the proposed requirement to consider applicable FDA food safety regulations and the foreign supplier’s compliance with those regulations to address circumstances in which a potential foreign supplier is in a country whose food safety system we have officially recognized as comparable or determined to be equivalent to the U.S. system. Section 1.505(a)(1)(iii)(B) of the final rule requires importers, when applicable, to consider the relevant laws and regulations of a country whose food safety system we have officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier’s compliance with those laws and regulations. This means that if an

importer's potential foreign supplier is located in a country whose food safety system we have officially recognized as comparable or determined to be equivalent (as discussed in section III.N of this document), the importer would consider, as part of its evaluation of the supplier, the supplier's compliance with the laws and regulations of that country rather than its compliance with U.S. food safety law. As discussed in section III.N, this reflects the nature of FDA recognition of the comparability of a foreign food safety authority in a systems recognition arrangement.

(Comment 154) Some comments express concern about the availability to importers of information about foreign suppliers' compliance with FDA food safety regulations. Some comments state that information about warning letters and import alerts often is not available on the FDA Web site in a timely manner and it can be difficult to navigate the Web site. Some comments assert that any requirement to consider foreign supplier compliance information should be limited to information that is available on our Web site or to information that is publicly available. One comment states that we should not require a prescriptive review of regulatory information unless we develop a system that allows importers to efficiently monitor new regulatory enforcement actions. One comment asks that we consider developing online databases that importers could use to obtain information on foreign suppliers.

(Response 154) We agree with the comments that the requirement to consider information on a foreign supplier's compliance with applicable FDA food safety regulations—as well as information on the other factors in § 1.505(a)(1)—should be limited to information that is publicly available or that the importer has otherwise been able to obtain (e.g., from a foreign supplier). We currently have searchable online databases for warning letters and import alerts; both of these databases are available to the public from our Web homepage at <http://www.fda.gov>. Other relevant compliance-related information available on FDA's Web site includes recall notices and notices of suspensions of facility registrations. We are considering ways to make this information more accessible to importers who will now be required to check the compliance history of their suppliers. To make clear that an importer must consider such publicly available information, § 1.505(a)(1)(iii)(B) of the final rule specifies that the applicable information includes whether the foreign supplier is the subject of any “other FDA

compliance action related to food safety.” We also note that, although the requirement to consider information on supplier compliance with applicable FDA food safety regulations is limited to publicly available information or information that the importer has otherwise obtained, if we became aware that an importer did not consider information that it had obtained relating to a supplier's FDA compliance, that would be a violation of the requirement.

(Comment 155) Some comments assert that this provision should be deleted because an importer's evaluation of the food and the foreign supplier should focus on information pertaining to risks identified in the imported food rather than the supplier. The comments note that if a foreign supplier were subject to an FDA warning letter or import alert for a food other than the food the importer was importing, that information would not be relevant to the importer's risk evaluation.

(Response 155) We do not agree. We conclude that evidence that a foreign supplier had received a warning letter or been placed on import alert with respect to a particular food, even a food different than the food an importer is considering obtaining from the foreign supplier, could be relevant to deciding whether to source a food from the supplier. In particular, a pattern of non-compliance, even if it did not involve the particular food that the importer sought to obtain, should affect an importer's decision on whether to approve a foreign supplier and, if so, what supplier verification activities would be appropriate with respect to this supplier.

(Comment 156) Some comments suggest that the scope of data sources reviewed be expanded to include Food Facility Registration Module (FFRM) status, Reportable Food Registry (RFR) entries, and outcomes from recent FDA CGMP inspections.

(Response 156) In accordance with section 415(a)(5) of the FD&C Act regarding disclosure of certain food facility registration information, information regarding whether a particular food facility is registered is generally not publicly available; however, as stated previously, FDA may publicize actions to suspend a facility's registration, which would be relevant information under § 1.505(a)(1)(iii)(B). In addition, importers may obtain information about a foreign facility's registration status from the foreign facility. Information from the RFR that we make available in our RFR annual reports is generally not provided on a company-specific basis. Under section

417(h) of the FD&C Act (21 U.S.C. 350f(h)), a record in the RFR is subject to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552), except that FDA registration numbers and information derived from such registrations are protected from disclosure to the extent that they would disclose the identity or location of a specific registered person in accordance with section 415(a)(5) of the FD&C Act. In addition, confidential commercial information in such records is also protected from disclosure, and in many cases the name of the original producer of the food may constitute confidential commercial information. We also generally do not proactively make available information related to FDA inspections of foreign suppliers, including Form FDA 483s and Establishment Inspection Reports (EIRs), although it is possible that an importer could obtain such information from a foreign supplier or from FDA through a FOIA request. Any confidential commercial information, trade secret information, or other protected information in Form FDA 483s and EIRs that we provide through a FOIA request would be redacted (i.e., deleted) in accordance with the disclosure exemptions set forth in the FOIA and FDA's public information provisions in part 20.

#### f. Foreign Supplier's Food Safety History

(Comment 157) One comment suggests that, to be consistent with the preventive controls regulations and to avoid an implied requirement to perform testing and auditing, we should revise proposed § 1.505(a)(1)(v) to state that a foreign supplier's food safety performance history “includ[es] available information” about results from testing foods for hazards, audit results relating to the safety of the food, and the supplier's record of correcting problems. One comment states that § 1.505(a)(1)(v) should not obligate an importer (or a foreign supplier through its importer) to provide FDA with details of an audit because this would have a chilling effect on the number of audits to which a supplier submits. The comment asks that we revise § 1.505(a)(1)(v) to refer to supplier performance history that is “relevant to the intended use” of raw materials or ingredients and to make the provision consistent with the corresponding provision in the proposed regulation on preventive controls for animal food.

(Response 157) We have revised this provision (§ 1.505(a)(1)(iii)(C) in the final rule) to make it consistent with the corresponding provisions in the

preventive controls regulations by specifying that the foreign supplier's food safety history includes available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems. We agree that § 1.505(a)(1)(iii)(C) does not require importers to conduct additional testing or auditing, but rather requires them to consider the results of any such activities that the importer has conducted in assessing the performance of its supplier in evaluating or reevaluating the concerns associated with use of a particular supplier, including when considering obtaining an additional food from an approved supplier. We have not limited the requirement to consider only the supplier's history with the importer that is "relevant to the intended use" of a food because some actions of a supplier, such as how quickly it has acted to address safety problems that have emerged in food it has provided to an importer, do not necessarily relate to the intended use of a food but are nevertheless important in assessing a supplier.

#### g. Other Factors as Appropriate and Necessary

(Comment 158) One comment encourages us to make it clear to FDA investigators that additional considerations, including transportation and storage practices, are not required in all cases and might not be reflected in importers' records. As an example, the comment notes that some food additive and GRAS substances do not require refrigeration and are stored and transported in sealed containers; the comment asserts that changes in those storage and transportation conditions would not create a significant hazard.

(Response 158) We agree that it is possible that an importer might consider the nature of a food as well as a potential foreign supplier and appropriately conclude that there are no "other" factors that will have a significant effect on (1) whether the importer should approve the use of the supplier or (2) what supplier verification activities might be appropriate with respect to assessing the safety of the food obtained from that supplier. Regarding the example provided in the comment, we agree that storage and transportation may not be relevant factors for foods that do not require refrigeration and that are stored and transported in sealed containers. To the extent the comment is requesting a change to the codified to that effect, we do not believe that is necessary.

#### h. Guidance on Evaluating Food Risk and Foreign Supplier Performance

(Comment 159) Several comments request that we develop guidance on the specific information that importers should consider under each factor in § 1.505(a)(1).

(Response 159) We anticipate that the FSVP guidance, once finalized, will provide recommendations on the information that importers should consider for each factor in § 1.505(a)(1).

#### 2. Approval of Foreign Suppliers

Under proposed § 1.506(a), importers would be required to establish and follow written procedures to ensure that they import foods only from foreign suppliers approved based on the risk evaluation they conducted under proposed § 1.505 (or when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods they subject to adequate verification activities before using or distributing). Thus, there was an implicit requirement that importers "approve" their foreign suppliers on the basis of the risk evaluation they conducted. Section 1.505(b) of the final rule makes this requirement clear by specifying that an importer must approve its foreign suppliers (and document the approval) on the basis of the evaluation the importer conducts under § 1.505(a) or the importer's review and assessment of an evaluation conducted by another entity under § 1.505(d) (discussed in section III.F.4 of this document).

#### 3. Reevaluation of Food Risks and Foreign Supplier Performance

We proposed (in § 1.505(b)) to require importers to promptly reevaluate the risk posed by a food and other factors associated with a food or foreign supplier when the importer becomes aware of new information about these factors. We further proposed that if an importer determined that it was appropriate to continue to import the food from the foreign supplier, the importer would have to document the reevaluation and its determination.

(Comment 160) Some comments suggest that we delete the proposed requirement to reevaluate risks in § 1.505(b) because importers would be required to reevaluate the factors affecting food and supplier risks when they become aware of new information about these risks under the FSVP reassessment requirements in § 1.508 of the proposed rule.

(Response 160) We agree that we should eliminate potentially redundant requirements to reevaluate food risks

and foreign supplier performance. However, we conclude that we should do so by deleting the FSVP reassessment requirements in proposed § 1.508 and essentially placing those requirements in § 1.505 of the final rule. We are taking this approach because changes in the risk posed by a food or the performance of the foreign supplier are the principal reasons why it might be necessary to reassess the appropriateness of an importer's FSVP for a food and supplier. Consistent with this approach, the final rule specifies, in § 1.505(c)(1), that if an importer becomes aware of new information about the food and supplier-related factors in § 1.505(a)(1), the importer must promptly reevaluate the concerns associated with those factors and document this reevaluation. Section 1.505(c)(1) further requires that if the importer determines that any of the matters addressed in the evaluation have changed (such as the emergence of a new hazard or a significant supplier compliance problem), the importer must promptly determine (and document) whether to continue to import the food from the foreign supplier and whether the verification activities it conducts need to be changed. Under § 1.505(c)(2), if in any 3-year period an importer has not reevaluated the food and supplier concerns on the basis of new information, the importer must conduct a reevaluation and take other appropriate actions, if necessary, in accordance with § 1.505(c)(1). The importer is required to document such a reevaluation and any subsequent actions it takes under § 1.505(c)(1).

(Comment 161) One comment suggests that, in addition, to being required to document a determination (following a reevaluation of risks) that it is appropriate to continue to import a food from a foreign supplier, importers should be required to document a determination to discontinue importing a food from a foreign supplier.

(Response 161) We agree. Because § 1.505(c)(1) of the final rule requires importers to document their determination as to whether to continue to import food from a foreign supplier, this would include a decision to discontinue use of a supplier.

(Comment 162) Some comments suggest that importers should be required to conduct a reevaluation of food and supplier risks annually regardless of whether the importer becomes aware of new information about risks. The comments maintain that an annual reevaluation would not be overly burdensome, adding that if no changes were required, the importer could simply note that determination. Regarding the proposed FSVP



reevaluation provisions, several comments maintain that, when an importer finds that there are no hazards in a food, the importer should be required to reassess the FSVP annually because importers sometimes incorrectly determine that no hazards are present. On the other hand, several comments assert that importers should not be required to reassess their FSVP at least every 3 years because this is not required by FSMA (unlike the requirement to reanalyze a food safety plan under FSMA's preventive controls provisions) and would not be risk-based because importers do not need to respond to changed conditions within a manufacturing facility, as is the case with facilities' management of food safety plans.

(Response 162) We conclude that it is not necessary to require importers to conduct a reevaluation of the factors in § 1.505(a)(1) annually even when importers do not acquire new information about these factors. We see no reason to establish a different requirement for when an importer has determined that there are no hazards in a food. Instead, § 1.505(c)(2) of the final rule requires importers to reevaluate the factors at least every 3 years. Because importers also are required to conduct a reevaluation when they become aware of new information about the factors, we believe that the 3-year minimum requirement to reevaluate the factors strikes an appropriate balance by providing adequate assurance that importers' FSVPs will remain effectively risk-based without imposing an unnecessary burden on importers. We believe that a requirement to reevaluate within a defined period is necessary because some importers might fail to actively seek information about potential food risks or supplier performance or fail to actually reevaluate these concerns when they become aware of relevant new information. Because changes to food risks and supplier performance are not uncommon, we believe that the 3-year minimum reevaluation requirement likely will have little effect on those importers who are in compliance with the requirement to reevaluate the food and supplier when they become aware of new information.

(Comment 163) Regarding the proposed FSVP reassessment provisions, one comment expresses concern about the suggestion in the preamble to the proposed rule that new information about potential hazards might include changes to the source of raw materials (78 FR 45730 at 45761). The comment states that produce packing operations routinely source

RACs from numerous farms and it would be impractical for importers to reassess their FSVPs every time a new farm is used as a source of a RAC. The comment asserts that the importer should only be expected to ensure that the foreign supplier has controls to qualify suppliers providing ingredients to the foreign supplier.

(Response 163) We do not agree. Obtaining a RAC from a new farm would necessitate conducting an evaluation under § 1.505(a) to determine whether it would be appropriate to source the RAC from the farm and, if so, what the appropriate foreign supplier verification activities for the farm should be. However, as discussed in the following subsection of this document, the importer could rely on another entity (such as a distributor or consolidator in the supply chain for the RAC) to conduct the evaluation of the risk of the food, the entity controlling the hazard, and the foreign supplier's performance.

#### 4. Review of Evaluation or Reevaluation by Another Entity

Consistent with the discussion in sections III.A.7 and III.E.5 of this document, we conclude that it is appropriate to give importers the flexibility to either conduct their own evaluation of the risk posed by a food, the entity that significantly minimizes or prevents hazards in a food or verifies that the hazards have been significantly minimized or prevented, and the foreign supplier's performance under § 1.505(a), or to rely instead on an evaluation conducted by another entity (other than the foreign supplier). For example, an importer of oranges might rely on such an evaluation conducted by a firm that obtains oranges from many farms and exports them to the United States. In this case, the aggregator of the oranges would evaluate the risk posed by the food and the performance of the individual farms in deciding whether to accept oranges from particular farms and in determining what supplier verification activities should be conducted for each farm. Therefore, § 1.505(d) of the final rule provides that if an entity other than the importer (and other than the foreign supplier) has, using a qualified individual, performed the evaluation described in § 1.505(a) or the reevaluation described in § 1.505(c), the importer may meet its requirement under the applicable provision by reviewing and assessing the evaluation or reevaluation conducted by the other entity. If the importer relies on another entity's evaluation or reevaluation, the importer must document its review and assessment of that evaluation or

reevaluation, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

#### G. Foreign Supplier Verification Activities (§ 1.506)

We proposed to require importers to conduct certain activities to verify that their foreign suppliers are producing food in a manner consistent with FDA requirements. In response to comments we received, in the Supplemental Notice we issued changes to the proposed requirements, including requiring importers to establish procedures to ensure the use of approved suppliers (rather than requiring importers to maintain a list of their suppliers) and changes regarding the manner and documentation of verification activities that importers must conduct. As discussed in the following paragraphs, the final rule incorporates additional changes to the proposed verification activity provisions in response to comments.

In the final rule, we have added significant flexibility in performing supplier verification to reflect modern supply chains. As with other FSVP requirements, we are allowing entities other than the importer to conduct supplier verification activities. In general, entities other than the importer (and other than the foreign supplier) may conduct verification activities as long as the importer reviews and assesses the results of those activities. This additional flexibility is consistent with the flexibility we are allowing with respect to hazard analysis and determination of verification activities and is consistent with the flexibility afforded to receiving facilities implementing supply-chain programs under the preventive controls regulations. To incorporate this flexibility and specify the importer's ultimate responsibility, we have made small revisions, like changing some of the verbs to passive voice (*e.g.*, changing "evaluation you conduct" to "evaluation conducted" in § 1.506(a)) and adding short, clarifying phrases (*e.g.*, changing "you must establish and follow written procedures for conducting appropriate foreign supplier verification activities" to "you must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted" in § 1.506(b)). We also have made small changes to make clear that the verification activities to which the importer subjects unapproved suppliers must take place before "importing the food" rather than before "using or distributing the food."

We also have made more significant changes, such as adding provisions that explicitly allow an importer to rely on the following:

- A determination of appropriate foreign supplier verification activities made by an entity other than the importer (and other than the foreign supplier) if the importer reviews and assesses whether the determination is appropriate (§ 1.506(d)(3)); and
- The performance of activities by an entity other than the importer (and other than the foreign supplier) provided that the importer reviews and assesses the results of these activities (§ 1.506(e)(2)).

The supply-chain program requirements of the preventive controls regulations include corresponding versions of these provisions.

In addition, we have made changes to the terminology used in this section to reflect the change in § 1.505 from “risk evaluation” to “evaluation for foreign supplier approval and verification” and from “evaluation of food and supplier risks” to “evaluation of the foreign supplier’s performance and the risk posed by a food.” Finally, as in other sections of the final rule, we have made additional changes to the codified for consistency with the supply-chain program provisions of the preventive controls regulations.

These and other changes are described more fully in the paragraphs that follow.

#### 1. Procedures To Ensure Use of Approved Suppliers

In the original proposed rule, we proposed to require importers to maintain a written list of foreign suppliers from which the importers obtain food. In response to comments that maintaining such a list would pose logistical or administrative burdens, in the Supplemental Notice we deleted this proposed requirement. Instead, in accordance with several comments, we proposed (in revised § 1.506(a)) that importers be required to establish and follow written procedures to ensure they import foods only from foreign suppliers they have approved based on the risk evaluation they conduct. In addition, we proposed to allow importers, when necessary and appropriate, to obtain food from unapproved suppliers on a temporary basis if the importer subjects the food to adequate verification activities before using or distributing it. We also proposed that importers be required to document their use of these procedures.

In the final rule, we have revised § 1.506(a) to reflect that an entity other than the importer might conduct the evaluation described in § 1.505. In

addition, we have deleted the word “risk” in the phrase “risk evaluation” when describing the evaluation conducted under § 1.505 to reflect the terminology change in that section. Finally, we have added § 1.506(a)(2) to explicitly allow an importer to rely on another entity (other than the foreign supplier) to establish the procedures and perform and document the activities required in proposed § 1.506(a) (finalized as § 1.506(a)(1)) to ensure that importers import foods only from foreign suppliers they have approved (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods the importer subjects to adequate verification activities before importing the food), provided that the importer reviews and assesses that entity’s documentation of the procedures and activities. Section 1.506(a)(1) also requires importers to document their review and assessment.

#### a. Use of Approved Suppliers

(Comment 164) Several comments express support for replacing the proposed requirement to maintain a list of foreign suppliers with a requirement to use procedures to ensure the use of approved suppliers. One comment questions how an importer would know whether a food is from an approved supplier if it did not have a list of such suppliers, and states that there is a need to ensure that an importer is using a complete, accurate, and updated approval process.

(Response 164) We agree that, whether through use of a single list, multiple lists, or some other mechanism, importers will need to adopt and follow procedures to enable them to confirm that the food they import is from suppliers they have approved in accordance with the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods importers subject to adequate verification activities before using or distributing). The procedures importers use will need to ensure that the importer can accurately identify approved suppliers and to reflect changes in such suppliers (e.g., addition of new approved suppliers, deletion of suppliers no longer deemed approved).

#### b. Temporary Use of Unapproved Suppliers

(Comment 165) Two comments suggest that, instead of referring to “unapproved” suppliers, the regulation should refer to foreign suppliers that are

used on a “contingency” or “provisional” basis.

(Response 165) We decline to make this change. The key feature of these suppliers is that they are not approved, thereby necessitating that the importer conduct or review and assess documentation of adequate verification of the food obtained from the supplier before importing the food.

(Comment 166) Some comments request that importers be given considerable flexibility to import from unapproved suppliers on a temporary basis. One comment states that use of an unapproved supplier should be deemed “necessary and appropriate” as long as the importer can provide a necessary and adequate reason to use the unapproved supplier.

Some comments recommend that use of unapproved suppliers be restricted to a designated time period during which the importer must approve the supplier. One comment requests that we provide guidance on what constitutes “temporary” use of an unapproved supplier and on the circumstances under which use of an unapproved supplier might be appropriate.

(Response 166) We agree that importers should have some flexibility to import food from unapproved suppliers, particularly when unexpected circumstances arise that make it impossible for an importer to obtain a food from an approved supplier. We continue to believe that these circumstances will be limited. Examples of circumstances in which the use of an unapproved supplier on a temporary basis would be “necessary and appropriate” include a problem with a long-standing supplier due to an equipment breakdown or an environmental or weather-related crisis (e.g., severe drought or flooding). Because the importer would be unable to immediately fully evaluate the potential supplier, the importer would need to take other steps to verify that the food obtained from the unapproved supplier is safe. We also agree that the use of unapproved suppliers is only appropriate on a temporary basis, though we decline to specify a particular time limitation on such use, given that the appropriate time period might vary depending on the circumstances. We intend to provide additional guidance on these issues.

(Comment 167) Some comments state that the importer should be required to follow guidelines on their “conditional” approval procedures and conduct a reassessment of their hazard analysis for the food.

(Response 167) It is unclear what the comments mean by “guidelines,” but

we do intend to provide guidance on the temporary use of unapproved suppliers. An importer does not necessarily need to reanalyze hazards when using an unapproved supplier unless the nature of the food or the hazards associated with the food have changed. The hazard analysis relates to the type of food being imported and is not necessarily related to the particular supplier providing the food.

(Comment 168) One comment states that it should not be necessary to require verification of food from an unapproved foreign supplier if other importers have imported the same food from that supplier.

(Response 168) An importer must subject food from an unapproved foreign supplier to adequate verification activities before importing the food, but the importer does not need to perform the verification activities itself. As previously described, while the importer is ultimately responsible for compliance with the requirements in § 1.506, other entities may perform certain key activities as long as the importer reviews and assesses documentation of those activities. Consistent with this approach, if one importer has already conducted appropriate verification activities (*e.g.*, sampling and testing) for a food from a foreign supplier, another importer could, depending on the specific circumstances, review and assess that documentation in lieu of conducting the activities itself. In accordance with § 1.503, the individual performing the verification activities must be a qualified individual.

(Comment 169) Some comments suggest activities that importers should be permitted to conduct to verify food from unapproved foreign suppliers before using or distributing the food. These activities include the following: Obtaining certification that a food is produced in accordance with good agricultural practices or good manufacturing practices; testing the imported food; obtaining a certificate of analysis; and obtaining an official verification “result” from the exporting country, the foreign supplier, or FDA. One comment maintains that it is likely that verification procedures for an unapproved supplier would be similar to the procedures used to verify an approved supplier and should be based on the importer’s hazard analysis.

(Response 169) We agree that food verification activities under § 1.506(a)(1) should be based, at least in part, on the hazard analysis conducted under § 1.504. The adequacy of the verification activities will vary depending on the food, the hazard, and the nature of the

control, as well as information that the importer may have about the supplier. Depending on the circumstances, it may be appropriate for an importer to review and assess a certificate, test the imported food, obtain a certificate of analysis, obtain information from the exporting country or other relevant government authority, or conduct some other verification activity.

(Comment 170) One comment asks that we issue guidelines to direct importers to first consider domestic suppliers before seeking to obtain a food from an unapproved foreign supplier.

(Response 170) We do not agree. Such a directive would be beyond the scope of section 805 of the FD&C Act, which requires importers to take appropriate steps to ensure that the food they import is safe.

#### c. Documentation of Use of Procedures To Ensure Use of Approved Suppliers

(Comment 171) One comment suggests that, instead of having to document use of procedures to ensure importation of food from approved suppliers, an importer should be required to provide evidence to FDA upon request that the importer is using these procedures.

(Response 171) We do not agree with this suggested change. If an importer did not document its use of these receipt-from-approved-supplier procedures, it is unclear how it would be able to demonstrate to FDA investigators that it had actually followed such procedures.

#### 2. Written Procedures for Foreign Supplier Verification

We proposed to require importers to establish and follow adequate written procedures for conducting foreign supplier verification activities with respect to the foods imported. The comments generally support this requirement, which we are finalizing in § 1.506(b) of the final rule.

(Comment 172) One comment asks that we consider providing model verification activity procedures that importers could use.

(Response 172) We intend to provide general guidance on complying with this requirement. However, it is unlikely that we will be able to provide model verification activity procedures for all foods, hazards, and suppliers. In addition to guidance, we will conduct outreach to assist importers in complying with the final rule.

#### 3. Purpose of Supplier Verification

We initially proposed to require that importers’ foreign supplier verification activities provide adequate assurance that identified hazards are adequately

controlled (proposed § 1.506(c)). In response to comments that the proposal was inconsistent with the statute and was improperly limited to hazard control, in the Supplemental Notice we revised the proposed requirement to specify, consistent with section 805(a)(1) of the FD&C Act, that foreign supplier verification activities must provide adequate assurances that the foreign supplier produces 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, and produces the food in compliance with sections 402 and 403(w) of the FD&C Act.

As discussed in response to the following comment, in the final rule we are returning to an approach to supplier verification activities similar to what we had originally proposed, in part to align the FSVP regulation with the supply-chain provisions of the preventive controls regulations. We also are changing the first word in § 1.506(c) to refer to “The” foreign supplier verification activities rather than “Your” activities to reflect the flexibility we are providing with respect to the entity who must conduct supplier verification activities.

(Comment 173) Several comments express support for the revised proposed purpose of supplier verification activities. However, one comment states that the purpose of verification activities should be as originally proposed, while one comment states that FSVPs should be designed to ensure that the foreign supplier is producing food in compliance with sections 402 and 403(w), which the comment contends would more closely align the FSVP requirements with domestic requirements.

(Response 173) Upon consideration of the comments on this revised provision as well as the need to align the FSVP regulation with the supply-chain provisions of the preventive controls regulations, the final rule requires that foreign supplier verification activities provide assurance that the hazards requiring a control in imported food have been significantly minimized or prevented. This requirement is consistent with the corresponding requirement in the preventive controls regulations, *i.e.*, that the “supply-chain program must provide adequate assurance that a hazard requiring a supply-chain applied control has been significantly minimized or prevented” (see §§ 117.410(c) and 507.110(c)). As stated in the FSVP proposed rule and the Supplemental Notice, alignment

with the preventive controls regulations is appropriate to avoid imposing redundant requirements (because entities may be both registered food facilities subject to the preventive controls regulations and food importers subject to the FSVP regulation). In addition, we conclude that this modification is consistent with the hazard identification framework of the final rule. Under the final rule, importers are required to comprehensively analyze and evaluate hazards requiring a control (see §§ 1.504 and 1.505). Requiring such analysis and evaluation makes the most sense if the supplier verification activities performed in accordance with § 1.506 are designed to specifically address the hazards that importers have identified and evaluated.

However, we emphasize that this change regarding the requirement of supplier verification activities in § 1.506(c) does not alter the fundamental purpose of importers' FSVPs. Consistent with section 805(c)(2)(A) of the FD&C Act, § 1.502(a) of the final rule directs importers to develop, maintain, and follow FSVPs that provide adequate assurances that their foreign suppliers produce the imported food in compliance with processes and procedures that provide the same level of public health protection as those required under sections 418 and 419 of the FD&C Act (if applicable) and the implementing regulations, as well as assurances that their suppliers are producing food that is not adulterated or misbranded with respect to allergen labeling. The requirement of supplier verification in § 1.506(c) does not change the requirement in § 1.502(a) but instead specifies what we conclude is an appropriate and functional measure for gauging whether foreign supplier verification activities can provide the statutory assurances of food safety. In short, we conclude that conducting activities to verify that hazards requiring a control have been significantly minimized or prevented will serve as an effective mechanism for providing assurance that a foreign supplier is producing food in compliance with the preventive controls or produce safety regulations (when applicable) and that the imported food is not adulterated or misbranded with respect to allergen labeling.

The requirement of supplier verification in § 1.506(c) encompasses situations in which hazards are significantly minimized or prevented directly by a foreign supplier as well as when hazards are addressed by entities in an importer's supply chain other than

the foreign supplier. When an entity other than the foreign supplier is significantly minimizing or preventing the hazards in a food, an importer would need to conduct supplier verification activities to ensure that its foreign supplier is verifying that the hazard is being significantly minimized or prevented or otherwise verify that the other entity is significantly minimizing or preventing the hazard.

As previously discussed, one situation in which an entity other than the foreign supplier significantly minimizes or prevents the hazards in a food is when produce growing and harvesting operations are performed by different business entities. When the foreign supplier of produce is the grower and another entity that is subject to the produce safety regulation performs certain activities such as harvesting, an importer might review applicable records maintained by the harvester, such as records of training for harvest workers and records related to agricultural water quality used in harvest operations. The importer would review such records for hazards not being significantly minimized or prevented by the grower of the produce. As discussed elsewhere, we are allowing various entities to determine, conduct, and document verification activities that apply to foreign suppliers, provided that the importer reviews and assesses applicable documentation provided by that entity and documents the review and assessment. To satisfy the requirements of § 1.506(c), an importer could obtain documentation of review by another entity of applicable records maintained by the harvester or packer and also review and assess the entity's documentation (and document that review and assessment).

(Comment 174) One comment asks whether verification activities also should provide assurance of supplier compliance with sections 416 (concerning sanitary transportation) and 420 (concerning intentional adulteration) of the FD&C Act (21 U.S.C. 350e and 350i, respectively).

(Response 174) We address specifics about the responsibilities of shipping facilities and receiving facilities under section 416 of the FD&C Act in the 2014 proposed rule on sanitary transportation (79 FR 7006, February 5, 2014). We will address comments regarding the responsibilities of shippers and receivers in the final rule on sanitary transportation. However, because the sanitary transport procedures that we proposed in accordance with section 416 are focused on shipment by rail and motor vehicle within or into the United States, that regulation, if finalized as

proposed, would generally not be applicable to transport in foreign countries. For the purpose of supplier verification under the FSVP regulation, whether evaluating transportation practices is necessary will depend on the particular supplier and the particular food being imported. If certain transportation practices could lead to hazards, an importer would need to verify that such hazards are significantly minimized or prevented.

With respect to intentional adulteration, hazards that may be intentionally introduced by acts of terrorism are the subject of the 2013 proposed rule on intentional adulteration (78 FR 78014, December 24, 2013) that we issued to implement section 420 of the FD&C Act. Under the FSVP regulation, importers need only consider hazards that are known or reasonably foreseeable. This means that importers are not required to consider purely speculative hazards. However, there may be circumstances in which intentional adulteration may present a known or reasonably foreseeable hazard, so part of providing assurance that the hazards in a food have been significantly minimized or prevented might, depending on the circumstances, include ensuring that the food is not intentionally adulterated. In those circumstances, importers may include intentional adulteration in their hazard evaluation and conduct appropriate verification activities for that hazard. One way an importer could do that would be to review a foreign supplier's vulnerability assessment and, if applicable, their plan under the intentional adulteration regulation (once finalized), documenting the measures the supplier would take to mitigate vulnerability to intentional adulteration.

(Comment 175) Two comments contend that asking importers to conduct verification activities to provide assurances that the foreign supplier is producing food in compliance with processes and procedures that provide the same level of public health protection as those required under the preventive controls or produce safety regulations is unrealistic because there are no established standards for determining "same level of public health protection." One comment requests more clarity on the meaning of "same level of public health protection."

(Response 175) As stated in Response 173, § 1.506(c) of the final rule does not specify that importers must conduct supplier verification activities to provide assurances that the foreign supplier is producing food in compliance with processes and

procedures that provide the same level of public health protection as those required under the preventive controls or produce safety regulations. In addition, we responded to comments requesting clarity regarding the nature of processes and procedures that will provide the same level of public health protection in Response 99. As previously noted, our draft guidance on FSVPs will include recommendations on how importers should assess foreign suppliers' processes and procedures to determine whether they provide the same level of public health protection as those required under the preventive controls or produce safety regulations.

(Comment 176) One comment suggests that the requirement to conduct activities to provide certain assurances be revised to refer only to food that will not be subject to further processing (including a pathogen mitigation or kill step) because when a food will be subject to further processing, the FSVP regulation should not apply.

(Response 176) We do not believe that this change is necessary. When a food will be subject to further processing by the importer under the preventive controls regulations, the importer will be deemed to be in compliance with most, but not all, of the FSVP requirements if the importer is required to establish and implement a risk-based supply-chain program under the preventive controls regulations for the imported food and is in compliance with those requirements. In other circumstances involving further processing of a food in the United States, the importer might import the food in accordance with § 1.507, as discussed in section III.H of this document.

(Comment 177) Several comments maintain that the revised proposed rule continues to suggest that the primary purpose of supplier verification is control of hazards. The comments maintain that FDA should recognize that importers' records might not show a listing of each hazard and corresponding verification activity.

(Response 177) We agree that importers will not be required to separately document the verification of each individual hazard in an imported food. The FSVP requirements generally do not require documentation of individual hazards and their controls, but rather require documentation with respect to the food and the foreign supplier of the food (*e.g.*, a hazard analysis for a type of food, a food and supplier evaluation, verification activities appropriate for a food and the supplier). On the other hand, some circumstances might necessitate

documentation related to a single particular hazard, such as when the importer determines that there is only one hazard in a food and the importer documents this determination and its determination regarding appropriate supplier verification activities for the food. In addition, when a SAHCODHA hazard in a food will be controlled by the foreign supplier, the importer must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer makes an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities conducted under § 1.506(e)(1) and/or less frequent onsite auditing are appropriate to provide adequate assurances that the foreign supplier is producing the food in accordance with § 1.506(c).

#### 4. Foreign Supplier Verification Activities

In the Supplemental Notice, we revised our proposed approach to requirements for foreign supplier verification activities in several ways. We discuss the comments on these changes and other aspects of the proposed supplier verification activity requirements in the following paragraphs.

For clarity, § 1.506(d)(1)(i) of the final rule states that an importer must determine and document which verification activities, as well as the frequency with which the activity or activities must be conducted, to provide adequate assurances that the food the importer obtains from the foreign supplier is produced in accordance with § 1.506(c). To reflect changes we are making to § 1.506(c), we have revised § 1.506(d)(1)(i) to specify that verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that hazards have been significantly minimized or prevented (*e.g.*, when an entity other than the grower of produce subject to part 112 harvests or packs the produce, or when the foreign supplier's raw material supplier prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under § 1.505. Section 1.506(d)(1)(ii) specifies appropriate supplier verification activities: Onsite audits, sampling and testing, review of the foreign supplier's relevant food safety records, and other supplier verification activities determined to be appropriate. The

addition of this list of appropriate supplier verification activities is to aid understanding of the requirements and is not a substantive change from the proposed rule.

We also have added § 1.506(d)(3) to explicitly allow an importer to rely on a determination of appropriate foreign supplier verification activities (including the frequency with which such activities must be conducted) by another entity in an importer's supply chain. To take advantage of this provision, an importer must review and assess whether the entity's determination is appropriate based on the evaluation conducted in accordance with § 1.505. In addition, the importer must document the review and assessment, including documenting that it was made by a qualified individual.

Section 1.506(e) of the final rule, regarding the performance of foreign supplier verification activities, is generally the same as proposed § 1.506(d)(1), with certain changes to provide more flexibility to importers. Section 1.506(e)(1) requires the importer to conduct and document (or obtain documentation of) supplier verification activities in accordance with the determination made under § 1.506(d) and sets forth documentation requirements for these activities. Section 1.506(e)(2) explicitly allows an importer to rely on the performance of verification activities by other entities as long as the importer reviews and assesses the results of the verification activities in accordance with § 1.506(e)(3), and documents the review and assessment.

Section 1.506(e)(3) makes clear that importers must promptly review and assess the results of supplier verification activities and document the review and assessment. This provision also requires that if the results of the verification activity do not provide adequate assurances that the hazards in the food from the foreign supplier have not been significantly minimized or prevented, the importer must take appropriate action in accordance with § 1.508(a) of the final rule (concerning corrective actions). Finally, because we do not believe that it is necessary for public health for the importer itself to retain documentation of supplier verification activities conducted by other entities, § 1.506(e)(3) does not require the importer to retain this documentation, provided that it can obtain the underlying documentation and make it available to FDA upon request, in accordance with the recordkeeping provisions in § 1.510(b).

We have reflected importers' greater flexibility in meeting supplier

verification requirements by adding various phrases throughout § 1.506. For example, we are changing “you must conduct and document one or more . . . supplier verification activities” in § 1.506(e)(1) to “you must conduct (and document) or obtain documentation of one or more . . . supplier verification activities.” Similarly, in § 1.506(e)(1)(ii), documentation of sampling and testing must include documentation that the testing was conducted by a qualified individual. We added this to ensure that even if the importer itself is not conducting sampling and testing, the sampling and testing must be performed by a qualified individual.

In addition, as a general matter, the final rule does not allow foreign suppliers to perform verification activities of themselves because of the potential for a conflict of interest (codified in § 1.506(e)(2)(ii)). However, we recognize that many suppliers have onsite sampling and testing regimes that are reliable, and we see no need to require an importer to duplicate those efforts. Therefore, § 1.506(e)(2)(ii) allows an importer to rely on sampling and testing of food conducted by a foreign supplier as long as the other criteria for the verification activity are met. We emphasize that it is still the importer's responsibility to ensure that the verification activities conducted for a particular food and foreign supplier are appropriate.

We also have added flexibility to the verification activity of reviewing a foreign supplier's relevant food safety records. Section 1.506(e)(1)(iii) provides that when reviewing a foreign supplier's relevant food safety records is the appropriate verification activity, documentation must include the conclusions of the review. This change helps to ensure that an importer has all the information it needs to review and assess the documentation if the importer is relying on another entity to conduct the records review, and is consistent with the documentation requirements for other verification activities.

We have made additional changes to the verification activity provisions as described in the following paragraphs.

#### a. Verification Activity Requirements

In the proposed rule, we requested comment on two alternatives for supplier verification activity requirements. “Option 1” would have established 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 verified had been controlled by its raw material or

ingredient supplier. “Option 2” would have required the importer to determine the supplier verification activity it would use for all hazards that the foreign supplier controlled or for which it verified control.

Under Option 1, for a SAHCODHA hazard that was to be controlled at the foreign supplier's establishment, the importer would have been required to conduct and document initial and subsequent periodic (at least annual) onsite audits of the foreign supplier. For non-SAHCODHA hazards to be controlled by the foreign supplier and all hazards for which the supplier verified control by its raw material or ingredient supplier, Option 1 would have required that the importer conduct one or more of the following activities: Onsite auditing of the foreign supplier, periodic or lot-by-lot sampling and testing of the food, review of the foreign supplier's food safety records, or some other procedure established as being appropriate based on the risk associated with the hazard.

On the other hand, Option 2 of the original proposal would have allowed the importer to determine, for all hazards either controlled by the foreign supplier or for which the foreign supplier verified control by its supplier, which of the previously listed verification activities would be appropriate to verify that the hazard was adequately controlled.

We received many comments that supported Option 1 for supplier verification activities and many that supported Option 2. In the Supplemental Notice, we proposed an approach to supplier verification activity requirements that is a hybrid of the original proposal's Option 1 and Option 2. We proposed to establish a general rule under which an importer would be required to conduct and document one or more of the previously listed supplier verification activities for each foreign supplier before using or distributing the food and periodically thereafter. Importers would be required to use the risk evaluation they conduct to determine which verification activity or activities are appropriate and the frequency with which those activities must be conducted. However, with respect to foods with a SAHCODHA hazard that would be controlled by the foreign supplier, the importer would be required to conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer documented a determination, based on the risk evaluation, that instead of initial and annual onsite supplier

auditing, some other supplier verification activities and/or less frequent onsite auditing would be appropriate to provide adequate assurances of safety. We are finalizing the requirement as proposed in the Supplemental Notice.

(Comment 178) Several comments support the revised approach to supplier verification activity requirements because they believe that it will provide flexibility to importers to determine appropriate supplier verification steps based on the importer's assessment of the risks posed by the food and supplier. However, several comments oppose the lack of a mandatory onsite auditing requirement for SAHCODHA hazards. One comment states that granting flexibility to importers might lead to confusion and place additional responsibility on FDA staff for validating an importer's verification methods.

(Response 178) We believe that giving importers the flexibility to tailor their supplier verification activities to unique food risks and supplier characteristics more closely aligns with the statutory requirement that importers perform risk-based verification activities. We continue to believe that annual audits would be appropriate for many foods and suppliers, particularly when there is a SAHCODHA hazard in a food. However, we think that even when there is a SAHCODHA hazard in a food, it is possible that an importer might reasonably conclude that because of its supplier's excellent compliance and performance history, annual audits are not needed to ensure the safety of the food. An importer who chose to conduct an alternative activity in these circumstances would need to maintain documentation that the activity provides adequate assurances of safety, and this documentation would be available for FDA review during any inspection of the importer or review of the importer's records.

(Comment 179) One comment suggests that the FSVP supplier verification provisions cross-reference the supplier program provisions in the preventive controls regulations as a way of aligning the rules.

(Response 179) We have strived to make the FSVP supplier verification requirements as consistent with the preventive controls regulations' supply-chain program provisions as is feasible and appropriate. For ease of reading and to facilitate a comprehensive understanding of the FSVP requirements, we set forth those requirements in one place—subpart L of part 1—rather than require the reader to switch back and forth between subpart

L of part 1 and part 117 or part 507 (the preventive controls regulations) through the use of cross-references.

However, as previously stated, § 1.502(c) of the final rule applies to importers that are receiving facilities who are in compliance with certain provisions in part 117 or part 507. Thus, this provision does refer to the supply-chain program provisions in the preventive controls regulations.

(Comment 180) Some comments ask that we provide guidance on how to determine whether a hazard is a SAHCODHA hazard and differentiate such hazards from significant hazards. Some comments request that we provide guidance on circumstances under which verification activities other than annual onsite auditing would provide adequate assurance of safety when there is a SAHCODHA hazard in a food.

(Response 180) As discussed in section III.A.11 of this document, we have replaced the term “significant hazard” with the term “hazard requiring a control.” A hazard requiring a control is a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish one or more controls or measures to significantly minimize or prevent the hazard and components to manage those controls or measures (see the definition of “hazard requiring a control” in § 1.500). All SAHCODHA hazards require a control, but not every hazard requiring a control has the potential to result in serious adverse health consequences or death. For additional information on how we interpret the SAHCODHA standard, see our guidance on the RFR (Ref. 14), which addresses statutory requirements for “reportable foods.” As explained in that guidance, a “reportable food” is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause SAHCODHA. The guidance includes examples of circumstances under which food might be reportable.

(Comment 181) One comment asks that we provide guidance on how importers should verify that their foreign suppliers are verifying the safety practices of their raw material or other ingredient suppliers.

(Response 181) As stated in the preamble to the proposed rule, an importer might rely on a review of its foreign supplier's food safety records to verify that the foreign supplier is verifying that its raw material or other ingredient supplier is controlling a

hazard in the raw material or other ingredient. For example, because a foreign supplier that is subject to the supply-chain program requirements under the preventive controls regulations would be required to have documentation (e.g., audit results) of its program for verification of its raw material supplier as part of its compliance with those regulations, an importer obtaining food from that supplier might review this documentation in conducting verification of the supplier. However, the FSVP regulation gives importers flexibility to choose the most appropriate verification activity for the circumstance.

(Comment 182) One comment maintains that importers should have discretion as to whether to include the results of supplier verification activities as part of official activities.

(Response 182) To the extent that the comment suggests that importers may disregard the results of supplier verification activities, we do not agree. Importers have the flexibility to determine appropriate verification activities based on the food and supplier evaluations they conduct, but they may not disregard the results of those activities. Instead, importers must review such results and document the review and assessment. If the results do not provide adequate assurances that the imported food is produced in accordance with the standards in this rule, the importer must take appropriate corrective action in accordance with § 1.508.

(Comment 183) Some comments suggest that, if there is no mandatory requirement for annual onsite auditing, importers should be required to affirmatively inform FDA if they determine that verification activities other than annual auditing are appropriate, and the Agency should specify the documentation required to justify the use of such activities.

(Response 183) We do not believe that an affirmative reporting requirement is warranted. When we inspect importers and review their records to determine compliance with the FSVP regulations, we will review the importer's documentation of the determination of appropriate verification activities. We believe that our ability to conduct inspections and review records provides appropriate tools to ensure compliance. The appropriateness of the justification for a given verification activity will depend on the particular food and supplier. We intend to provide general guidance on the requirements in this rule, but given the rule's flexibility, we will be unable to specify particular

documentation required for every circumstance.

(Comment 184) Some comments ask that we make clear that an importer is allowed to rely on activities performed by others instead of activities that it has itself conducted.

(Response 184) We agree and have changed the codified to specify that an importer may either conduct (and document) foreign supplier verification activities or obtain documentation of verification activities conducted by others (e.g., the results of a third-party audit of a foreign supplier) (§ 1.506(e)(1)). In addition, as discussed previously, § 1.506(e)(2) permits an importer to rely on the results of verification activities performed by other entities (other than the foreign supplier). The importer remains ultimately responsible for the performance of appropriate supplier verification activities.

#### b. Need for Multiple Supplier Verification Activities

We proposed to specify, in § 1.506(d)(3), that based on an importer's risk evaluation of a food and foreign supplier, it might be necessary for the importer to conduct more than one supplier verification activity to address an individual hazard or risk factor or multiple hazards or risk factors.

(Comment 185) One comment recommends that we delete this provision because it is confusing and contrary to other provisions.

(Response 185) We have deleted this provision as redundant because § 1.506(d) and (e) of the final rule require the performance of multiple foreign supplier verification activities when it is determined, based on an evaluation of the hazards in a food and foreign supplier performance in accordance with § 1.505, that conducting more than one activity is necessary to provide adequate assurances of safety.

#### c. Requirements for Food From Certain Farms, Facilities, and Egg Producers

In the Supplemental Notice, we proposed to require that if a foreign supplier of a food is a farm that is not subject to the produce safety regulation in accordance with § 112.4 regarding a food being imported, the importer would not need to comply with the standard supplier verification activity requirements if the importer did the following:

- Documented, at the end of each calendar year, that the food provided by the foreign supplier was not subject to the produce safety regulation; and



- Obtained written assurance, at least every 2 years, that the foreign supplier was producing the food in compliance with the FD&C Act.

We stated that this modified supplier verification activity was appropriate because FDA had determined that this food did not pose a sufficient risk to public health that it needed to be subject to the standard produce safety requirements.

We are finalizing modified requirements applicable to the importation of food from a farm that grows produce and is not a covered farm under the produce safety regulation in accordance with certain provisions. In addition, we are adding provisions that provide for modified requirements applicable to the importation of food from a qualified facility, as defined under the preventive controls regulations, or a shell egg producer with fewer than 3,000 laying hens. These requirements, which are included in the modified FSVP requirements in § 1.512 of the final rule, are discussed in section III.M of this document.

#### d. Substitution of Results of Certain Inspections for Onsite Auditing

We proposed to permit importers to rely on, instead of an onsite audit of a foreign supplier, 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 by which the onsite audit would have been required to be conducted (proposed § 1.506(d)(5)). For inspections that were conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, we proposed that the food that was the subject of the onsite audit would have to be within the scope of the official recognition or equivalence determination, and the foreign supplier would have to be in, and under the regulatory oversight of, that country.

(Comment 186) Some comments oppose the proposed provisions allowing for the substitution of the results of certain inspections for onsite audits of foreign suppliers. The comments assert that an FDA inspection might not assess the relevant lines or processes, there might not be timely access to inspection results, and the proposed rule does not establish parameters for the results of such inspections. The comments are concerned that foreign suppliers might not allow their importers to audit their

facilities for FSVP purposes if the supplier had been subject to an FDA inspection in the last year.

(Response 186) We decline to delete this provision. We believe that inspection results likely will be available to importers on a timely basis, and a lack of timely access in some cases would not warrant entirely eliminating the opportunity to rely on inspection results. In addition, we believe it is unlikely that there would be many foreign suppliers willing to risk losing customers by refusing to be audited because they had recently been inspected by FDA. However, we have made certain changes that we believe address some of the concerns of the comments. To clarify the scope of this provision (which we have moved to § 1.506(e)(1)(i)(E) so that it is part of the requirements for onsite audits), we have added language specifying the food safety standards that an inspection must address, when the inspection is not conducted by a food safety authority in a country whose food safety system FDA has officially recognized as comparable or equivalent. In those cases, an importer may rely only on the written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations. If another authority's inspection does not assess compliance with FDA food safety regulations, the other authority's inspection would not, as a general matter, substitute for an onsite audit.

We have also revised who can perform such inspections to include representatives of other Federal agencies (such as the USDA) and representatives of State, local, tribal, or territorial agencies. These entities are all part of FDA's Integrated Food Safety System, and their inclusion in § 1.506(e)(1)(i)(E)(1) adds flexibility to the rule. Although representatives of foreign governments are not included in this provision, they are still able to conduct onsite audits for FSVP purposes as long as they are qualified auditors and they consider applicable FDA food safety regulations. Importers may rely on such audits to satisfy the requirements of this rule if the audits provide a basis for the importer to determine that the foreign supplier used processes and procedures that provide the same level of public health protection provided by the preventive controls or produce safety regulations, as applicable, and produces the food in compliance with requirements concerning adulteration and misbranding with respect to allergen labeling.

However, 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 safety authority need not inspect for compliance with relevant FDA standards. Under § 1.506(e)(1)(i)(E)(2) of the final rule, provided that the food that is the subject of the onsite inspection or audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, the country with the comparable or equivalent food safety system, the inspection or audit may inspect for compliance with the standards that FDA has recognized as comparable or equivalent.

(Comment 187) One comment asks that we provide information on how we will make available to importers the results of inspections of foreign suppliers by FDA and comparable foreign authorities.

(Response 187) As a routine matter, we do not intend to proactively make available the results of all foreign inspections, either to importers or other members of the public. However, under the FOIA and FDA's implementing regulations in part 20, members of the public (including importers) may submit requests for records in FDA's files, including records of foreign food establishment inspections. In accordance with FOIA, FDA generally makes those records available, except to the extent those records are covered by one or more of the nine exemptions enumerated in the statute (5 U.S.C. 552(b)).

Importantly, exemption 4 of FOIA protects from mandatory disclosure trade secrets and confidential commercial information (5 U.S.C. 552(b)(4)). In addition, section 301(j) of the FD&C Act requires withholding of trade secret information from the public, and the Trade Secrets Act also prohibits disclosure of trade secrets and confidential commercial information unless specifically authorized by law (see 18 U.S.C. 1905). Accordingly, when we receive FOIA requests for foreign inspection reports that are intended for public disclosure (as opposed to requests submitted by the foreign establishment itself), ordinarily we will redact trade secret and confidential commercial information before we release the materials to the public. Given the restrictions on our ability to provide unredacted inspection reports for public disclosure, we recommend that an importer directly ask the foreign supplier for a copy of the results of any government inspection of that foreign supplier.

(Comment 188) Some comments recommend that importers be permitted to rely on the results of an inspection of a supplier by FDA or a comparable/ equivalent food safety authority for longer than 1 year after the date that the onsite audit would have been required to be conducted. One comment states that under National Organic Program (NOP) regulations, an organics certificate is valid until withdrawn, usually up to 18 months after the issue date; therefore, the comment recommends that the FSVP regulations allow for reliance on an inspection for at least 15 months post-issue date. The comment adds that if we cannot permit this, we should require auditing firms to change the way they conduct business, such as by issuing a document on the date of the audit acknowledging its completion and (if applicable) the absence of critical findings. Other comments ask that we change the period in which the inspection needs to have been conducted to within 2 or 3 years of the date by which the importer determined that an onsite audit was appropriate.

(Response 188) We disagree with these comments. We are allowing the specified inspection results to be substituted for an onsite audit because we believe that such inspections may provide an importer with information on the foreign supplier's food safety practices that is sufficiently similar to information that can be obtained from an onsite audit. In addition, use of such inspection results may lessen the burden of conducting supplier verification activities by eliminating the need for an onsite audit. At the same time, we believe that requiring the inspection to have been conducted within 1 year of the date that the onsite audit would have been required to be conducted is appropriate to ensure that any inspection provides relevant and meaningful information that is similar to the information that could be obtained from an audit. Allowing the inspection to be conducted more than 1 year from the date an audit would have been required would make it more likely that the inspection would address different processes and procedures from what an audit would have addressed.

As one comment notes, NOP organic certificates are valid until withdrawn (either suspended or revoked for cause by the certifying agent or voluntarily surrendered by the certified operation), although it is incorrect to suggest that certificates are valid up to 18 months after issuance. Regardless, NOP inspections serve a different function from onsite FSVP audits. Unlike onsite FSVP audits, NOP inspections do not

address whether the processes and procedures of foreign food producers provide the same level of public health protection as sections 418 and 419 of the FD&C Act, and that foreign food is produced in accordance with sections 402 and 403(w) of the FD&C Act, as applicable. Regarding the comment suggesting that if we do not allow for more than a 1-year period, we should instead require auditing firms to change the way they conduct business, such as by issuing a document on the date of the audit acknowledging its completion and (if applicable) the absence of critical findings, such a request is beyond the scope of this rulemaking. The FSVP regulation does not impose any requirements on audit firms, and we do not believe it is necessary to do so in order to efficiently enforce Congress' directive in section 805 of the FD&C Act to ensure that imported food is as safe as domestically-produced food. However, nothing in this rulemaking would preclude audit firms from changing the way they conduct business as the comment suggests, though it is unclear how such a change would be helpful to the importer in meeting the requirements of this rule.

(Comment 189) One comment asks that we explain what is regarded as a food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent.

(Response 189) In section III.N of this document we discuss our systems recognition initiative, under which are assessing food safety systems in other countries to determine whether they provide a similar system of protections as that provided under the U.S. food safety system and therefore can be officially recognized as comparable to the U.S. system. We also discuss food safety equivalence determinations. In response to the specific comment, a systems recognition agreement would specify the relevant food safety authority for the country under a particular agreement.

(Comment 190) One comment requests that we accept a State inspection of a foreign supplier as an audit, suggesting that the Manufactured Food Regulatory Program Standards and other programs could be used to evaluate State programs as equivalent food safety authorities.

(Response 190) As stated previously, we have changed § 1.506(e)(1)(i)(E)(1) to allow an importer to rely on the results of an inspection of a foreign supplier conducted by officials from State, local, tribal, or territorial food safety authorities. As discussed in section III.N

of this document, systems recognition only applies to foreign countries.

## 5. Review of Results of Verification Activities

We proposed to require importers to promptly review the results of their foreign supplier verification activities and, if the results of the review showed that the risks for the food or foreign supplier were not adequately controlled, to take appropriate corrective action (proposed § 1.506(d)(6)). This requirement is codified in § 1.506(e)(3) of the final rule, with the following changes to ensure consistency with other supplier verification activity provisions:

- Importers must promptly review and assess the results of verification activities that they conduct (or obtain documentation of) or that other entities conduct.
- Importers must document their review and assessment.
- Importers must take appropriate action under § 1.508(a) if the results of verification activities do not provide adequate assurances that hazards requiring a control have been significantly minimized or prevented.
- Importers are not required to retain documentation of verification activities conducted by other entities provided that they can obtain such documentation and make it available to FDA in accordance with § 1.510(b).

(Comment 191) One comment requests that we delete the requirement to review results promptly. The comment maintains that this requirement is too prescriptive and that importers should have the flexibility and discretion to review results in a timely manner.

(Response 191) We do not agree. We believe that it is reasonable and appropriate to require importers to promptly review the results of their verification activities so that they can determine whether the results suggest that there is a problem with a supplier and, if so, take steps to address the problem on a timely basis. In the absence of any such review, the verification activities would not serve their intended purpose of ensuring the safety of imported food, as contemplated by section 805 of the FD&C Act.

## 6. Documentation and Other Requirements for Supplier Verification Activities

In response to concerns primarily regarding the documentation of foreign supplier audits that importers would be required to retain and make available to FDA investigators, in the Supplemental

Notice we added provisions specifying the content of documentation of importers' supplier verification activities. We also proposed other requirements regarding how these activities should be conducted.

(Comment 192) One comment recommended that we not establish specific requirements regarding the format of required documentation.

(Response 192) We agree. The regulations we have adopted do not specify a particular format in which documentation of supplier verification activities must be recorded.

(Comment 193) Some comments express concern that importers might have limited access to qualified auditors and appropriately certified laboratories; the comments recommend that we provide training and certification opportunities. One comment states that we should require auditors to be trained and certified to U.S. standards.

(Response 193) We do not have plans to provide training and certification opportunities for qualified auditors. (We note that, under § 1.500 of the final rule, examples of potential qualified auditors include (but are not limited to) an audit agent of a certification body (also known as a third-party auditor) that has been accredited under subpart M of part 1 (FDA's regulations implementing the third-party certification provisions of FSMA).) We believe there are many opportunities for auditing training available in the private sector, particularly for third-party auditors. We do not agree that auditors must be trained and certified "to U.S. standards" if this refers to being trained by FDA. What is important is that audits conducted for FSVP purposes be conducted by qualified auditors, who are qualified individuals who have the technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform onsite auditing to meet FSVP requirements, and that the audits be conducted in accordance with the requirements for such audits in § 1.506(e)(1)(i) of the final rule, discussed in section III.G.4 of this document.

(Comment 194) Several comments state that FDA should specify which verification activities and corrective actions must be recorded and the circumstances under which the records must be made available or submitted to the Agency.

(Response 194) As specified in § 1.506(e)(1), except for when an importer relies on performance of activities by other entities in accordance with § 1.506(e)(2), importers must document the supplier verification

activities they conduct. If an importer relies on verification activities conducted by another entity, the importer is not required to retain documentation of those activities, provided that it can obtain the documentation and make it available to FDA in accordance with § 1.510(b). In addition, any corrective action taken in accordance with § 1.508 must be documented. Under § 1.510(b)(1), importers must make FSVP records available promptly to an authorized FDA representative, upon request, for inspection and copying. In addition, under § 1.510(b)(3), upon our written request, importers must send records to us electronically or through other prompt means. For more information about the circumstances under which records must be made available or submitted to FDA, see the discussion of § 1.510 in section III.K.3 of this document.

#### a. Onsite Auditing

In the Supplemental Notice we acknowledged the concerns that having to make full reports of onsite audits of foreign suppliers available to FDA would make suppliers reluctant to be audited or result in less robust audits, and we agreed that importers should not be required to retain full audit reports. Instead, we proposed (in § 1.506(d)(1)(i)) that importers be required to retain documentation of audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor. We also proposed to retain the provision in the proposed rule requiring, for food subject to one or more FDA food safety regulations, that an onsite audit consider those regulations and include a review of the supplier's written food safety plan, if any, and its implementation. In addition, we proposed to require that an onsite audit of a supplier be performed by a qualified auditor.

Section 1.506(e)(1)(i)(B) of the final rule includes the requirement that an onsite audit of a foreign supplier of a food subject to one or more FDA food safety regulations consider those regulations and include a review of any food safety plan and its implementation. However, as previously discussed, we recognize that there might be circumstances in which a company imports a food from a 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, but the modified

requirements for certain food from certain suppliers in such countries in § 1.513 of the final rule do not apply. To account for these circumstances, § 1.506(e)(1)(i)(B) of the final rule specifies that, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent.

(Comment 195) Some comments request that audits that are conducted to meet FSVP requirements by auditors accredited under the third-party auditing regulations that FDA is developing under section 808 of the FD&C Act should not be required to meet the proposed requirements for audits conducted under that regulation, including the requirements to submit the audit reports to FDA and to report serious findings to the Agency. The comments assert that applying such requirements to audits conducted for FSVP by third-party auditors accredited under the FDA system would create a disincentive to use such auditors to meet FSVP requirements.

(Response 195) As we have stated in public meetings regarding the FSVP proposed rule, we will not require that audits conducted to meet FSVP requirements by third-party auditors accredited under FDA's third-party certification regulation (in subpart M of part 1) meet the requirements for audits conducted under that regulation, which is set forth in a final rule published elsewhere in this issue of the **Federal Register**. The only audits that must meet the requirements of the third-party certification regulation are regulatory audits performed for the purposes of the issuance of (1) certifications required for participation in the Voluntary Qualified Importer Program (VQIP) under section 806 of the FD&C Act (21 U.S.C. 384b) and (2) mandatory import certifications under section 801(q) of the FD&C Act, as well as consultative audits conducted in preparation for a regulatory audit. To make clear that those auditing requirements do not apply to audits conducted solely for FSVP purposes, § 1.506(e)(1)(i)(C) of the FSVP final rule states that if an onsite audit is conducted solely to meet FSVP requirements by an audit agent of a certification body that has been accredited under the third-party certification regulation, the audit is not subject to that regulation.

(Comment 196) Noting that facility certifications issued by accredited third-party auditors are required for participation in VQIP, one comment questions whether there is a difference in the scope of audits conducted to meet

FSVP requirements and audits conducted in accordance with FDA's third-party certification regulation. The comment asserts that while proposed § 1.506(d) would require that audits conducted to meet FSVP requirements consider all FDA food safety regulations, audits conducted in accordance with the proposed third-party certification regulation must determine a facility's compliance with the FD&C Act. The comment asks what accredited third-party audits will entail given that the FD&C Act addresses more than just food safety requirements.

(Response 196) The scope of accredited third-party audits conducted in accordance with the third-party certification regulation is addressed in the final rule on third-party certification published elsewhere in this issue of the **Federal Register** (see Response 7 in the preamble to the final rule).

(Comment 197) Several comments address the standards that we will require onsite audits of foreign suppliers to meet. Some comments recommend that when third-party audits are used, FDA should require that audits be conducted in accordance with nationally or globally accepted standards, such as schemes that are benchmarked in accordance with the Global Food Safety Initiative (GFSI). One comment recommends that we take into consideration audits conducted by recognized auditing firms and certification bodies. One comment suggests that for fruits and vegetables, good agricultural practice (GAP) and good manufacturing practice (GMP) certificates issued by independent third-party certification bodies accredited by competent authorities should be accepted. One comment states that audits conducted to meet FSVP requirements should be held to the same standards as audits performed domestically. One comment maintains that some private food safety auditing standards provide the same level of public health protection as the FSMA standards.

(Response 197) We agree that audits conducted to meet FSVP requirements should be held to the same standards as audits performed domestically for the purpose of supplier verification. To the extent that the results of GFSI, GAP, or any other audit schemes appropriately verify that the foreign supplier produces the food consistent with FDA food safety standards, importers may use audits conducted under those schemes to meet the requirements of the FSVP regulation. We understand that, as of the publication of this document, many of the widely used food safety auditing schemes are considering whether and

how to revise their practices in light of the requirements of FDA regulations, including our new FSMA regulations. We further understand that the updating of schemes is a lengthy process that often involves engagement with experts and other stakeholders. Therefore, we believe it is premature to reach any definitive conclusions as to whether importers can rely on the results of audits conducted under any existing auditing schemes to verify compliance with the safety requirements of this rule. Over time, we expect that scheme owners and benchmarking organizations will develop tools to assess their schemes against FDA requirements to demonstrate the levels of health protection their schemes provide. We believe there is value in such efforts and foresee possible implications for the Agency's work. Until such time, if an importer chooses to use a GFSI, GAP, or other similar audit, the importer might need to supplement that audit to meet the requirements of § 1.506 or otherwise determine that the audit meets the requirements of this section. Even after scheme owners and benchmarking organizations update their tools to reflect the new FDA food safety requirements, it will remain the importer's responsibility to determine whether the results of any particular audit are adequate to conclude that a foreign supplier produces a food in accordance with the standards required by this rule.

(Comment 198) One comment states that the WTO Agreement on Technical Barriers to Trade (TBT Agreement) encourages WTO members to reduce multiple certification and testing requirements by entering into mutual recognition agreements to facilitate trade. The comment also suggests that we adopt a regulatory scheme similar to that in the juice and seafood HACCP regulations in parts 120 and 123, including allowing foreign government officials to conduct verification audits of suppliers.

(Response 198) Because the FSVP regulation is a food safety measure and therefore are not subject to the TBT Agreement, the provisions in the TBT Agreement regarding mutual recognition agreements do not apply. We agree that reducing multiple testing and certification requirements for food safety is an important guiding principle, and the FSVP regulation does not impose multiple testing and certification requirements on suppliers. The FSVP regulation provides importers with flexibility to determine appropriate supplier verification activities and allows multiple importers to rely on the same results of auditing, testing, and

other verification measures. We believe that as importers and foreign suppliers become more familiar with the FSVP requirements, more suppliers are likely to arrange to be audited and share the audit results with multiple U.S. importers.

We agree that it is appropriate to allow foreign government officials to conduct audits. Under the final rule, onsite audits must be performed by qualified auditors. As we discussed in section III.A.18 of this document, foreign government employees may be qualified auditors, and the standard for being a qualified auditor does not differ when the audit is performed by a foreign government employee. We see no reason why an importer could not rely on an audit of a foreign supplier conducted by a foreign government employee with appropriate technical expertise obtained through education, training, and/or experience, as long as the foreign official considers applicable FDA food safety standards. The importer could rely on such an audit to meet the requirements of this rule if the audit allows the importer to determine whether the foreign supplier uses processes and procedures that provide the same level of health protection provided by the produce safety or preventive controls regulations, as applicable, and produces the food in compliance with sections 402 and 403(w) of the FD&C Act, as applicable. At this time, we do not envision establishing a program to recognize individuals as meeting the definition of qualified auditor for the purposes of FSVP. However, we intend to conduct outreach, develop training modules, and provide technical assistance to facilitate compliance with the FSVP regulation, including regarding importers' reliance on the results of onsite audits of foreign suppliers.

As for other potential ways to design the FSVP regulation to be similar to the importer requirements in FDA's juice and seafood HACCP regulations, we do not agree that doing so would be appropriate. As stated in the preamble to the proposed rule, section 805 of the FD&C Act contemplates a more comprehensive approach to supplier verification than the juice and seafood HACCP regulations. The juice and seafood importer provisions were adopted more than a decade ago, and the U.S. Government Accountability Office has expressed concerns with the effectiveness of the seafood importer provisions (see 78 FR 45730 at 45745). In light of FSMA's increased emphasis on the safety of imported food and importers' role in ensuring food safety, as well as the adoption of the FSVP

regulation, we will consider whether it would be appropriate in the future to initiate a rulemaking to revise the regulations applicable to importers of juice and seafood.

(Comment 199) One comment suggests that we consult the Good Manufacturing Practice and Quality Assurance Guides for Food Additives and GRAS Substances developed by the International Food Additives Council when evaluating audits of foreign suppliers of food additives and GRAS substances.

(Response 199) When evaluating audits of foreign suppliers, we will consider whether the audits verify compliance with applicable food safety requirements contained in the FD&C Act and any FDA regulations to which the food is subject.

(Comment 200) One comment maintains that the added value of an audit conducted by an importer is limited especially when the supplier is already certified or audited. The comment states that importers should be able to provide “data on paper—in the form of an up-to-date dossier” in place of conducting duplicative supplier verification activities. Another comment recommends that importers rely on third-party audits to avoid unnecessary multiple audits of foreign suppliers and suggests that importers who rely on the report of a third-party audit of a supplier be deemed in compliance with the supplier verification requirements.

(Response 200) As a general matter, we agree that if an importer can obtain documentation of an foreign supplier audit conducted in accordance with the requirements of the FSVP regulation (e.g., performed by a qualified auditor and evaluating compliance with applicable FDA food safety standards), the importer can rely on it provided that the importer reviews and assesses the results of the audit. We have explicitly added this flexibility in § 1.506(e)(2) of the final rule. We anticipate that many importers will, in accordance with the FSVP regulation, rely on audits conducted by third-party auditors or by other entities rather than conducting their own separate audit of the supplier.

(Comment 201) One comment states that the frequency of auditing conducted to meet FSVP requirements should take into consideration risks in the food and the quality control capability of suppliers.

(Response 201) We agree. Section 1.506(d)(1) of the final rule states that an importer must determine and document which verification activity or activities (including, potentially, onsite audits) are needed, as well as the frequency with which those activities must be

conducted, to provide adequate assurances that the hazards in the food obtained from the foreign supplier are significantly minimized or prevented. This determination must be based on the evaluation of the food and the foreign supplier conducted under § 1.505.

(Comment 202) One comment requests that the regulation specify that importers must accept verification results of other importers on the same food from the same foreign supplier to avoid multiple verifications.

(Response 202) We decline to require importers to accept verification results of other importers. However, § 1.506(e)(2) of the final rule does allow an importer to rely on verification activities performed by other entities (other than the foreign supplier), and such other entities may include other importers of the same food from the same foreign supplier. In such cases, the importer must review and assess the results of those activities and document the review and assessment. The importer remains ultimately responsible for the safety of the food it imports and its own compliance with this regulation. In accordance with § 1.503, the individual performing the verification activities must be a qualified individual.

(Comment 203) Some comments object to limiting the Agency's access to complete audit reports. On the other hand, some comments request that the regulation clearly specify that we will not require review of a full audit report. One comment asks us to clarify that summary data and recognized auditor or foreign government certification are adequate. The comment maintains that it is unrealistic to expect foreign suppliers to provide highly confidential data to importers.

(Response 203) As stated in the Supplemental Notice, we conclude that we do not need to see full audit reports to effectively monitor importer compliance with the supplier verification requirements. Section 1.506(e)(1)(i)(D) only requires that an importer retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor. We conclude that it is unnecessary to state in the regulatory text that importers need not retain full audit reports. We believe that the information required under § 1.506(e)(1)(i)(D) is the information our investigators will need to assess the adequacy of the audit and, thus, the

importer's compliance with the FSVP requirements. In turn, if an importer is relying on another entity (such as a third-party auditor hired by a foreign supplier) to conduct the audit, the importer would need to obtain the relevant information regarding the audit to fulfill its obligation to review the results of the audit. As for the comment that it is unrealistic to expect foreign suppliers to provide highly confidential data to importers, we recognize that, due to commercial confidentiality concerns or other reasons, there might be circumstances in which some foreign suppliers might be reluctant to share food safety information with importers. However, we also believe that some foreign suppliers will desire to share such information as a means of attracting customers for their products.

(Comment 204) One comment contends that making audit conclusions or corrective actions available to FDA could result in suppliers refusing to allow unannounced audits. Therefore, the comment suggests that FDA only review an importer's procedures for verifying suppliers, including procedures for audits, rather than the results of the procedures. Alternatively, the comment contends that importers should only be required to provide documentation of corrective actions taken to address significant deficiencies that create a risk to public health.

(Response 204) We do not agree that we should only review an importer's procedures for verifying suppliers. We also need to be able to confirm that those procedures are followed by reviewing the importer's records, including documentation of review and assessment of audit results and any necessary corrective actions taken. As to whether this will result in suppliers refusing to allow unannounced audits, we note that nothing in the final rule requires that audits be unannounced. Nevertheless, there may be some advantages to unannounced audits, as discussed in the preamble to the proposed rule on third-party certification (see 78 FR 45782 at 45812, July 29, 2013).

With respect to whether importers should only be required to provide documentation of corrective actions taken to address significant deficiencies that create a risk to public health, we do not agree. Section 805(a)(1) of the FD&C Act requires each importer to perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, among other requirements. If imported food is

adulterated or misbranded with respect to allergen labeling, corrective action is required to satisfy the requirements of section 805(a)(1). Because we can only efficiently enforce section 805(a)(1) if we are able to verify such corrective action, and because we can only verify corrective actions if importers provide appropriate documentation, the final rule requires documentation of all corrective actions. However, the particular corrective action warranted could differ depending on the circumstances, including the level of risk to public health posed by the particular non-compliance. The importer's documentation would reflect whatever corrective action might be warranted.

(Comment 205) One comment states that the regulations should recognize that documentation of audits might be maintained by an importer's corporate parent rather than at an individual facility.

(Response 205) We do not object to documentation of audits being maintained by an importer's corporate parent. In accordance with § 1.510(b)(2) of the final rule, offsite storage of records is permissible, as long as such records can be retrieved and provided onsite within 24 hours of request for official review.

#### b. Sampling and Testing

We proposed (in § 1.506(d)(1)(ii)) that sampling and testing of a food could be conducted by either the importer or the foreign supplier. We proposed that importers be required to retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing. We are finalizing these requirements in § 1.506(e)(1)(ii). In addition, we are adding the requirement that importers retain documentation of the date of the report of the testing because we believe that the date of the report can be important. As previously stated, we are also adding language stating that importers must retain documentation that the testing was performed by a qualified individual (to clarify that testing must be conducted by a qualified individual).

(Comment 206) One comment requests that we clarify that testing could be conducted on behalf of an importer or foreign supplier.

(Response 206) We agree. An importer or a foreign supplier may hire another entity to conduct the testing on its behalf; the importer or supplier need not conduct the actual testing itself. In addition, under § 1.506(e)(2)(i) of the final rule, sampling and testing may be conducted by other entities provided the importer reviews and assesses the results of the testing.

(Comment 207) One comment maintains that because testing documentation is routinely maintained by the testing entity, importers should be required to either retain "or have access to" such documentation.

(Response 207) Importers must obtain the required testing information so that, in accordance with § 1.506(e)(3), they can review the testing results and, if appropriate, take corrective action to address supplier non-compliance. However, as previously noted, § 1.510(b)(2) does allow offsite storage of records if they can be retrieved and provided onsite within 24 hours of request for official review.

(Comment 208) One comment suggests that proposed § 1.506(d)(1)(ii) be revised to reflect that, when outside laboratories are used, the importer might not have access to information about the dates on which tests were conducted, but only information on the dates on which the tests were reported.

(Response 208) We do not agree. Information on the dates on which testing was conducted is standard information in laboratory testing reports and may be important information. However, we agree that the date on which the test results were reported is also important information, so we are revising § 1.506(d)(1)(ii) by adding a reference to "the date of the report of the testing." This change is consistent with the approach taken in the preventive controls regulations for documentation of sampling and testing.

(Comment 209) Some comments suggest that because testing often is more efficient when it is conducted by the supplier, FDA should develop guidance on when "test and hold" procedures could be used.

(Response 209) We recognize that it could be appropriate for testing to be performed by suppliers in certain circumstances. Section 1.506(e)(2)(ii) of the final rule allows for suppliers to perform testing as a verification activity as long as the importer reviews and assesses the relevant documentation.

(Comment 210) One comment suggests that testing should be the preferred activity when detecting or identifying the presence or absence of pathogenic bacteria, allergens, and spoilage organisms.

(Response 210) To the extent that the comment suggests that testing is the preferred supplier verification activity for pathogenic bacteria or allergens, we do not agree. Although testing plays an important role in ensuring the safety of food, contamination with microbial pathogens and some allergens is likely to be non-homogeneous and the numbers of pathogens are likely to be low. A negative result therefore does not guarantee the absence of contamination. An importer should take this into account when deciding which verification activity (or activities) is appropriate. Because of the limitations of sampling and testing, the processes and procedures a supplier has in place to minimize contamination, and the management of those processes and procedures, are key in determining when sampling and testing is appropriate as a verification activity. We discussed the role of testing in ensuring the safety of food in the proposed rule on preventive controls for human food (see the Appendix to the proposed rule (78 FR 3646 at 3818 through 3820), with reference numbers corrected in the **Federal Register** of March 20, 2013 (78 FR 17142 at 17149 through 17151)). For more information about other food safety issues, many of which helped inform both this rulemaking and the preventive controls rulemakings, see generally the proposed, supplemental, and final rule on preventive controls for human food (78 FR 3646; 79 FR 58524, September 29, 2014; 80 FR 55908).

In many cases, an onsite audit to verify control of hazards may be more appropriate than sampling and testing, or may be appropriate to use in conjunction with sampling and testing. Onsite audits provide the opportunity to review a supplier's food safety plan (if the supplier has one) and written procedures and to observe the implementation of those procedures, as well as to review records. In addition, an auditor can interview a supplier's employees to assess their understanding of the food safety measures for which they are responsible. Therefore, an audit can provide for a more comprehensive assessment of food safety implementation than testing. For these reasons, when a SAHCODHA hazard in a food will be controlled by the foreign supplier, importers must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter (unless they make an adequate written determination (based on the evaluation conducted under § 1.505) that, instead of such auditing, other supplier verification activities

and/or less frequent onsite auditing are appropriate to provide adequate assurances that the hazards in the food from the foreign supplier are significantly minimized or prevented).

With respect to spoilage organisms, if there is reason to believe spoilage may have occurred (*e.g.*, the product may have been temperature abused during shipment), testing to enumerate certain types of organisms might be appropriate. However, if the testing for spoilage organisms is to verify production processes and procedures, a supplier audit of such procedures and their implementation might be more informative.

(Comment 211) Several comments request that we establish minimum laboratory standards to ensure that laboratories used to test imported foods follow performance standards that are equivalent to U.S. standards. Several comments ask us to issue a proposed rule regarding the accreditation of laboratories and model standards to be used by accredited laboratories in accordance with section 202 of FSMA (section 422 of the FD&C Act (21 U.S.C. 350k)). One comment asks us to require that the laboratory reports on which importers rely align with international standards.

(Response 211) We stated in the preamble to the proposed rule our tentative conclusion that, although we would expect sampling and testing conducted to meet FSVP requirements to be performed in accordance with any applicable regulations or widely accepted industry standards, it was not appropriate to specify testing standards in the FSVP regulation. Although the final rule does not include specific requirements for laboratory testing, importers may not rely on the results of testing that was not conducted in accordance with methodologies and procedures designed to ensure valid and accurate results. We are currently developing a proposed rule to implement section 202 of FSMA. The proposed rule might include proposed circumstances under which use of accredited laboratories and model testing standards would be required.

(Comment 212) One comment suggests that laboratories should make certificates of current accreditation from recognized laboratory accreditation bodies available to importers to provide assurance that the laboratory is in compliance with recognized standards.

(Response 212) We agree that importers could benefit from using accredited laboratories and that it could be beneficial for laboratories to make certificates of accreditation available.

However, such requirements are beyond the scope of this rulemaking.

#### c. Review of Foreign Supplier Food Safety Records

We proposed (in § 1.506(d)(1)(iii)) that importers be required to retain documentation of each review of relevant supplier food safety records, including the date(s) of review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual. We are finalizing this requirement in § 1.506(e)(1)(iii). We are adding a requirement that an importer must retain documentation of the conclusions of the review because they are essential to determining whether and what corrective actions are necessary.

(Comment 213) One comment suggests that this provision refer to “food safety compliance records” rather than “relevant food safety records.”

(Response 213) We do not agree. The suggested revision might be interpreted as limiting the provision to only those records that relate to a compliance action with a relevant authority. However, it might be appropriate for an importer to review a broader set of food safety records, including records documenting that the food safety procedures that the supplier has established to control hazards 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.

(Comment 214) One comment maintains that importers should not be required to have a qualified individual conduct a review of supplier food safety records; the comment states that a qualified individual is not required for review of food safety records of a supplier of a raw material or other ingredient under the proposed regulations on preventive controls for animal food.

(Response 214) We do not agree. We believe that an importer must have a qualified individual conduct all foreign supplier verification activities to ensure that these activities are performed adequately. The final rule on preventive controls for animal food requires use of a preventive controls qualified individual to review supplier food safety records (see §§ 507.49(a)(4) and 507.175(b)).

#### d. Other Appropriate Verification Activities

We proposed to allow importers to conduct supplier verification activities other than those previously discussed if such activities were appropriate to address the risks associated with the food and the foreign supplier (proposed § 1.506(d)(1)(iv)). Although we did not specify how importers would be required to document the performance of such verification activities, we requested comment on whether the final rule should include such requirements and, if so, what they should be.

We are finalizing this provision in § 1.506(e)(1)(iv)(A). To allow flexibility as to who must conduct the verification activities, consistent with other provisions of the final regulatory text, we have revised the phrase “You may conduct and document other supplier verification activities . . .” to “You may conduct (and document) or obtain documentation of other supplier verification activities . . .” We are also adding § 1.506(e)(1)(iv)(B) in response to comments, as discussed below.

(Comment 215) One comment suggests that importers could use third-party remote video auditing systems as an alternative verification measure under proposed § 1.506(d)(1)(iv).

(Response 215) Depending on the circumstances, including the hazard analysis, the evaluation for foreign supplier approval and verification, and the specific characteristics and capabilities of the third-party remote video auditing system, an importer could determine that it is appropriate to use such a system as an appropriate alternative verification activity under § 1.506(e)(1)(iv) of the final rule.

(Comment 216) Some comments suggest that the regulation should not specify requirements for the documentation of such alternative verification activities. One comment states that although FDA might specify minimum parameters for documentation, it would be better to allow specific industry sectors to develop their own forms. Some comments suggest that for these alternative activities, importers should be required to document the date of the activity, the findings, any corrective actions taken, and justification that the activity provides at least the same level of assurance as the other verification activities in the regulations, particularly when there is a SAHCODHA hazard in a food.

(Response 216) As with the previously discussed verification activities, we conclude that it is



appropriate to include certain requirements for documentation of alternative verification conducted under § 1.506(e)(1)(iv). Requiring such documentation will allow us to review the appropriateness of any particular verification activity to determine an importer's compliance with the FSVP regulation, thereby allowing us to efficiently enforce the requirements in section 805 of the FD&C Act. Therefore, § 1.506(e)(1)(iv)(B) of the final rule requires importers to document their use of such alternative activities by retaining a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by qualified individual. We do not believe it is necessary to specifically require an importer to document a justification that the activity provides at least the same level of assurance as the other verification activities, because § 1.506(d)(1) already requires importers to document their determination of the nature and frequency of appropriate supplier verification activities for a particular food and foreign supplier.

#### 7. Independence of Qualified Individuals

We proposed to specify that a qualified individual who conducted any foreign supplier verification activities could not have a financial interest in the supplier and payment could not be related to the results of the activity (proposed § 1.506(d)(7)). However, this provision would not prohibit an importer or one of its employees from conducting verification activities. In the final rule, we have moved this provision to § 1.506(e)(4) and modified it so that it no longer prohibits the existence of a financial interest, but rather prohibits the existence of financial conflicts of interest that influence the results of verification activities in § 1.506(e)(1). The rule continues to specify that payment must not be related to the results of the activity.

(Comment 217) One comment recommends that the conflict of interest provisions in the FSVP regulation be consistent with those in the preventive controls regulations. One comment suggests that the provisions be revised to specify that a qualified individual must not have a "direct personal" financial interest in the foreign supplier.

(Response 217) The conflict of interest provisions in the final rule are the same as those in the preventive controls regulations. We do not believe it is appropriate to limit the type of financial

interest of concern here to a "direct personal" financial interest, particularly since it is unclear what would count as a "direct personal" financial interest as opposed to any other financial interest. If the qualified individual has a financial conflict of interest that influences the results of verification activities, the qualified individual would be precluded from being able to independently conduct verification activities under the FSVP regulation. We believe that this limitation appropriately ensures that qualified individuals act objectively and are free from any undue commercial pressures that could compromise the performance of verification activities.

(Comment 218) One comment requests that we clarify that an importer or its employee may conduct a verification activity "even if the foreign supplier is an affiliate, subsidiary, or parent company of yours."

(Response 218) We decline to add this language. We recognize the variety of business relationships that can exist between importers and foreign suppliers, including a parent-subsidiary relationship or an affiliate relationship. Regardless of how the two entities relate to each other, the conflict of interest provisions in § 1.506(e)(4) are designed to maintain the integrity of the verification activities performed as part of an importer's FSVP. Section 1.506(e)(4) does not prohibit an importer or its employee from conducting a verification activity even if the foreign supplier is an affiliate, subsidiary, or parent company of the importer, and the language requested by the comment is unnecessary. Nevertheless, any financial conflict of interest that may exist cannot influence the results of the verification activity. We expect that if an importer or its employee conducts a verification activity for a foreign supplier that is an affiliate, subsidiary, or parent company of the importer, there will be protections in place to ensure the integrity of the verification activity, including, for example, ensuring that the individual conducting the verification activity is not penalized for identifying food safety concerns. In addition, any payment for the verification activity cannot influence the results of the activity.

(Comment 219) One comment states that the independence provisions should only extend to employees related to a foreign supplier's business, marketing, and distribution because it would be too burdensome to expect an importer to know about any stockholding relationship, deals, or other potentially unethical practices.

(Response 219) We do not believe that the independence requirement is too burdensome. An importer could, for example, ask the qualified individual to attest to whether it has any financial interest in the foreign supplier and, if the qualified individual has one, take steps to ensure that any such interest does not influence the results of the verification activity. The final rule does not per se prohibit the qualified individual from holding any stock or having ever had any dealings with the entity that is the subject of the verification activities.

(Comment 220) One comment states that it is unreasonable to suggest any qualified auditor would not have an interest in the outcome or success of the activities of the supplier. Another comment states that because the activities of employees are influenced by their employers, there can be no assurance that the results of employee activities will be impartial.

(Response 220) We disagree. The relevant requirement in § 1.506(e)(4) is that payment of the qualified individual conducting a verification activity must not be related to the results of the activity. We believe this requirement is necessary to ensure the integrity of the performance of verification activities under this rule.

(Comment 221) Several comments ask that we make clear that the independence requirements would not exclude the use of first-party (internal) audits. One comment states that the regulations should not preclude a manufacturer from using its own qualified auditors from conducting onsite audits or using its qualified employees to conduct other supplier verification activities.

(Response 221) Under § 1.506(e)(4), the independence of qualified individual requirement does not prohibit an importer or its employees from conducting supplier verification activities. It does, however, prohibit a qualified individual who conducts any verification activities from having a financial conflict of interest that may influence the results of an audit or other verification activity. In addition, due to the potential for a conflict of interest, the final rule (in § 1.506(e)(2)(ii)) provides that importers may not rely on the foreign supplier itself or employees of the foreign supplier to perform supplier verification activities (except with respect to sampling and testing of food). A foreign supplier's audit of itself would therefore not be an appropriate verification activity under the regulation.

(Comment 222) One comment suggests that we not impose limitations

on use of second-party audits (*i.e.*, audits by an employee of a company conducting the verification activities).

(Response 222) To the extent that the comment is asking whether importers may use their own employees to conduct audits of foreign suppliers, this is permissible under the final rule.

(Comment 223) One comment suggests that we consider the conflict of interest provisions in the NOP regulations (7 CFR 205.501(a)).

(Response 223) The conflict of interest provisions in the NOP regulations are tailored to the concerns addressed in those regulations. We regard some provisions, such as 7 CFR

205.501(a)(11)(i), which mandates that a certifying agent not certify an entity if the certifying agent has held a commercial interest in the provision of consulting services, as similar to the requirement we are finalizing here. Many other provisions would not translate at all, *e.g.*, the requirement that a certifying agent must prevent conflicts of interest by not giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification (7 CFR 205.501(a)(11)(iv)). Having reviewed the conflict of interest provisions in the NOP regulations as the comment suggests, we continue to believe that our conflict of interest provisions are well suited for the FSVP regulation.

#### 8. Food Stored for an Extended Time Before Export

In the preamble to the proposed rule, we requested comment on what foreign supplier verification activities might be appropriate for foods that are exported to the United States long after they are produced in a foreign country.

(Comment 224) Some comments state that no additional foreign supplier verification activities are necessary for specific products such as gelatin, which has a shelf life of about 5 years and as a result can be exported long after production. These comments recommend that FDA rely on safety procedures of foreign countries. Other comments see challenges with conducting certain verification activities, such as onsite audits, in situations when there is an extended delay between the production and export of a food. Some comments recommend that we understand different scenarios in which this may occur, stating that it will be easier to develop a procedure or recommend appropriate supplier verification activities once there is a better understanding of the specific circumstances.

(Response 224) As the compliance date for the FSVP regulation approaches, we expect that there will be discussion of scenarios in which different supplier verification activities will be appropriate. The final rule includes considerable flexibility for an importer to determine and conduct the supplier verification activities that are most appropriate given various factors related to the food and the supplier, in accordance with §§ 1.504, 1.505, and 1.506. Consequently, we conclude that it is not necessary to establish provisions specifically applicable to the importation of food stored for an extended period before export.

#### *H. Foods That Cannot Be Consumed Without Control of Hazards and Foods Whose Hazards Are Controlled After Importation (§ 1.507)*

In response to comments, we have included, in § 1.507 of the final rule, new provisions to address certain circumstances in which a hazard requiring a control is identified in a food but foreign supplier verification is unnecessary. These provisions in § 1.507 are consistent with similar provisions in the preventive controls regulations.

In response to the proposed rule, we received comments addressing a variety of circumstances under which the hazards in imported food typically are not controlled until after the food arrives in the United States. As discussed in section III.B.7 of this document, several comments request that we exempt from the FSVP regulation importers of certain RACs, in particular coffee beans and cocoa beans, which purportedly cannot be consumed without undergoing processing involving the application of controls that will address all hazards in the food.

Other comments relate to circumstances under which an importer's customer or a subsequent entity controls the hazards in an imported food. As stated in sections III.C.4 and III.E.8 of this document, we proposed to allow for certain alternatives to supplier verification when an importer's customer controlled a hazard in a food. Under proposed § 1.502(d), if an importer's customer was required to establish and implement a supply-chain program under the preventive controls regulations for a food that the importer imported, the importer would be deemed to be in compliance with most of the FSVP requirements if it annually obtained from the customer written assurance that the customer was in compliance with the supply-chain program provisions.

The proposed rule also included proposed provisions in § 1.504(g) regarding when an importer or its customer was controlling the hazards in a food in accordance with the preventive controls regulations but was not required to have a supply-chain program under those regulations (because the importer's preventive controls were adequate to significantly minimize or prevent each hazard, or because the importer relied on its customer to control a hazard and annually obtained written assurance of such control). Under proposed § 1.504(g), the importer in such circumstances would not be subject to the FSVP requirements for evaluating the food and foreign supplier (proposed § 1.505) or conducting supplier verification activities (§ 1.506). However, if the importer's customer controlled one or more hazards, the importer would be required to annually obtain from the customer written assurance that it was following procedures to significantly minimize or prevent the hazard.

We received several comments regarding the proposals to permit importers to obtain written assurance from a customer controlling a hazard in an imported food. Although there is general support for not requiring the importer to conduct supplier verification under these circumstances, many comments object to the proposed requirement to obtain written assurance from customers. Other comments raise concerns about what FSVP requirements should apply when an entity in the distribution chain beyond the importer's customer controls the hazards in the imported food.

In the following paragraphs, we respond to these comments and discuss the requirements under § 1.507 of the final rule applicable to importers of food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation.

#### 1. Food That Cannot Be Consumed Without Application of Controls

(Comment 225) Some comments note that, in the case of the cocoa bean and coffee bean supply chains, the importer does not have a direct relationship with the thousands of farms (the foreign suppliers) involved in the production of the beans. Some comments ask for an exemption from supplier verification activities for foods such as cocoa and coffee beans because current distribution systems do not rely on the farms to control the hazards; instead, the hazards are controlled at the U.S.

processing facility for the beans, which may or may not be the importer.

(Response 225) We agree that an importer of a food should not need to conduct supplier verification when the importer knows that a subsequent entity in its distribution chain is controlling the hazard in the food. Moreover, the foods specifically mentioned by these comments, cocoa beans and coffee beans, are types of food that could not be eaten without processing that would control the typical hazards requiring a control. We believe there are few other foods in this category. Examples of such foods might include grains (for human consumption) and some RACs that are rarely consumed raw (again, as long as they are imported for human consumption). The FSVP regulatory text does not refer to RACs rarely consumed raw because “rarely consumed raw” is not the same as “could not be consumed without application of an appropriate control.” However, depending on the facility, the RAC, and the food produced by the manufacturer/processor, there may be some circumstances where a manufacturer/processor could determine that a particular RAC that passes through its facility could not be consumed without the RAC being processed to control any hazards. Because some or all of the important food safety risks will be controlled before these foods reach consumers, we do not believe it is necessary for importers to conduct the evaluation under § 1.505 or supplier verification under § 1.506 for hazards in these foods. Therefore, § 1.507(a)(1) of the final rule provides that an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if the importer determines and documents that the type of food (*e.g.*, RACs such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control for the hazard by an entity in the supply or distribution chain other than the importer.

## 2. Control of Hazards by an Importer's Customer or Subsequent Entities in the Distribution Chain

(Comment 226) We received many comments objecting to our proposal to require importers to obtain annual written assurance from a customer controlling a hazard under either proposed § 1.502(d) or § 1.504(g). Some comments state that an importer may have so many customers that it would not be practical or reasonable to obtain written assurance annually from all customers. Other comments express concern that a customer may be unwilling to disclose confidential trade

secrets in order to identify in writing the procedures the customer has established and is following to control the hazard. Some comments state that an importer may not know the identity of all its individual customers, particularly if the importer sells its products to a distributor who then sells to other entities. Some comments oppose the written assurance requirement because they maintain that it does not contribute to safety given that it does not guarantee that the customer is actually doing anything to effectively minimize or prevent the hazard. Some comments ask that we delete the written assurance requirement because it raises the question of whether the importer must evaluate the adequacy of the customer's procedures, and the importer might not have the capability to do this.

Other comments suggest that, if the final rule includes a written assurance requirement, one of the following time intervals that should be required to obtain the assurance:

- Every 2 years;
  - Every 3 years or when new information warrants; or
  - Only at the beginning of the importer-customer relationship.
- Some comments maintain that there should be a mechanism for when an importer's customer's customer (or a subsequent entity in the distribution chain) controls all the hazards in a food. Some comments suggest that this be addressed by requiring the importer to specify in contracts for sale that the ultimate purchaser must control all hazards before distributing the food to consumers. Some comments suggest that importers could be required to notify their customers of actual or potential hazards in the food that have not been controlled.

(Response 226) In consideration of these comments, we are establishing, in § 1.507, a series of provisions that relieve an importer from the requirements to conduct an evaluation of the food and foreign supplier under § 1.505 and supplier verification activities under § 1.506 when a subsequent entity in the importer's distribution chain is controlling the hazard in a food. We conclude that compliance with certain requirements will provide adequate assurance that hazards in such food are being controlled by an entity in the importer's distribution chain and will adequately inform entities in that distribution chain that the food requires a control. These requirements concern the following:

- Disclosure in documentation provided by the customer of an importer, to accompany the food, that the food is “not processed to control

[identified hazard]”, identifying a specific hazard or hazards (*e.g.*, *Salmonella*, *Listeria monocytogenes*) the importer has identified as requiring a control;

- Written assurances from the importer's customer regarding appropriate processing of the food for safety; and
- Provisions holding the customer and subsequent entities in the distribution chain accountable for the written assurances.

These requirements vary based on whether the importer's customer controls the hazard in a food (and, if so, whether the customer is or is not subject to the preventive controls regulations) or whether an entity subsequent to the customer in the distribution chain controls the hazard (and, if so, whether the subsequent entity is subject to the preventive controls regulations).

The first of these provisions, § 1.507(a)(2), addresses the situation in which an importer's customer who is subject to the preventive controls regulations (for human or animal food) is controlling the hazard requiring control in a food. Under § 1.507(a)(2), an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if it relies on its customer who is subject to the preventive controls regulations to ensure that the identified hazard will be significantly minimized or prevented and the importer:

- Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and
- Annually obtains from the customer written assurance, subject to the requirements of § 1.507(c), that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard. Under § 1.507(c), an importer's customer or a subsequent entity in a food's distribution chain that provides a written assurance under § 1.507(a)(2), (3), or (4) must act consistently with the assurance and document the actions it takes to satisfy the assurance.

The required disclosure regarding the lack of processing to control hazards is consistent with the suggestions of some comments. The disclosure documents accompanying the food could be the bills of lading or other papers, or disclosure might be made on the label of the food's container.

Section 1.507(a)(3) of the final rule addresses the situation in which an importer's customer is *not* subject to the preventive controls regulations (*e.g.*,

because it is a qualified facility or a retail food establishment). Under § 1.507(a)(3), an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if it relies on its customer who is not subject to the preventive controls regulations to provide assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and the importer:

- Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

- Annually obtains from the customer written assurance, subject to the requirements of § 1.507(c), that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements. Because the importer’s customer is not subject to the preventive controls regulations, rather than providing assurance that it is significantly minimizing or preventing a hazard (as required under § 1.507(a)(2)), it is appropriate for the importer’s customer to provide assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements. These food safety requirements might include FDA’s food CGMP regulations in subpart B of part 117 or subpart B of part 507 (for qualified facilities), or applicable State or local food safety regulations (for retail establishments).

Section 1.507(a)(4) of the final rule addresses the situation in which an entity in the importer’s distribution chain beyond the importer’s customer is controlling the hazard in a food. Under § 1.507(a)(4), an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if it relies on its customer to provide assurance that the identified hazard will be adequately controlled by an entity in the distribution chain subsequent to the customer and the importer:

- Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

- Annually obtains from its customer written assurance, subject to the requirements of § 1.507(c), that the customer will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is not processed to control an identified hazard. The importer must also obtain written assurance that its customer will only sell the food to another entity that agrees, in writing, that it will either: (1) Follow procedures

(identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the preventive controls requirements) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the preventive controls requirements); or (2) obtain written assurance from its customer similar to that which the importer’s customer must provide.

The final provision in § 1.507 applicable to control of hazards by entities in an importer’s distribution chain, § 1.507(a)(5), allows for the possibility that another approach could ensure the control of an identified hazard in a food. Under § 1.507(a)(5), an importer is not required to conduct an evaluation under § 1.505 or supplier verification under § 1.506 if it has established, documented, and implemented a system that ensures adequate control, at a subsequent distribution step, of the hazards in a food it distributes, and the importer documents its implementation of that system. We do not have any examples of such a system, but we do not want to preclude the development or use of such systems. If an importer avails itself of this provision, we would evaluate its system during our inspection of the importer.

The provisions allowing for hazards to be controlled by an importer’s customer or an entity in the distribution chain subsequent to the customer accommodate the realities of modern food production. A food might pass through multiple entities in the distribution chain before a control is applied. However, the control must eventually be applied. Under § 1.507(c), the customer or a subsequent entity in the distribution chain for a food that provides a written assurance under § 1.507(a)(2), (3), or (4) must act consistently with the assurance and document the actions it takes to satisfy the written assurance. This requirement is supported by sections 701(a) and 805(c)(2)(B) of the FD&C Act, the latter of which provides that the FSVP regulations must include other requirements the Secretary 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.

In the preventive controls regulations for human and animal food, facilities may also rely on subsequent entities in their distribution chains to apply controls. Those provisions also provide for the combination of (1) disclosure of documentation to a direct customer that the food is “not processed to control

[identified hazard]”; (2) written assurances from the customer regarding appropriate procedures to ensure that the food will receive further processing for food safety; and (3) provisions holding the direct customer accountable for its written assurances. Under those regulations, a facility that provides the written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance. Because the preventive controls regulations hold the customer accountable for its written assurance, the FSVP regulation would not be ensuring that imported food is as safe as domestically-produced food if the FSVP provisions did not do the same.

When a hazard will not be significantly minimized or prevented by an importer’s customer but by some subsequent entity in the distribution chain, the importer’s customer must still pass forward documentation to that subsequent entity disclosing the need to control the hazard. The written disclosure must state that the food has not been processed to address the hazard identified as requiring a control. This requirement is supported by sections 701(a), 805(a)(1), and 805(c)(2)(B) of the FD&C Act. Ordinarily it is not apparent from visual examination of a food whether a hazard has been addressed. Consequently, without labeling, a subsequent entity in the distribution chain might not know that an entity upstream in the supply chain has not significantly minimized or prevented a hazard and is relying on a downstream entity to do so. Therefore, we conclude that information that food has not been processed to address an identified hazard is necessary for an importer to fulfill its obligations under section 805(a)(1) to perform risk-based verification activities to ensure that the imported food meets applicable food safety requirements. We also conclude that the disclosure requirement is consistent with section 805(c)(2)(B) because the preventive controls regulations include a comparable provision, and including this requirement in the FSVP regulation helps ensure that food imported into the United States is as safe as food produced and sold within the United States. In addition, the labeling is necessary for the efficient enforcement of the FD&C Act because labeling is critical for FDA to hold entities responsible for their obligations under this regulatory scheme. Further, when a hazard can cause a communicable disease, we conclude that the labeling requirement, in addition to the requirement that the importer’s

customer or subsequent entity act in accordance with the assurance, is necessary to prevent the spread of communicable disease from one State into another State and is therefore authorized under sections 311, 361, and 368 of the PHS Act (42 U.S.C. 243, 264, and 271).

The overarching goal of the § 1.507 provisions is to reflect that in modern supply and distribution chains, steps to ensure food safety can occur before an importer receives a food or after it distributes a food that it has imported. When those steps are all performed by a subsequent entity in the distribution chain, the requirements for an evaluation of the risk posed by the food and the foreign supplier's performance (under § 1.505), and for the conduct of supplier verification and related activities (under § 1.506), are unnecessary to ensure the safety of the food with respect to those hazards for the ultimate consumer.

These provisions reflect a balance of flexibility and accountability for ensuring the safety of such food. We continue to believe that annual written assurance from an importer's customer is an appropriate mechanism to ensure that its customer is aware of the hazard requiring a control and is taking responsibility for ensuring that the hazard is controlled. We believe that less frequent receipt of assurances would not provide an adequate level of monitoring or accountability. We do not believe that importers' customers or subsequent entities in the distribution chain will need to provide all details of their processes to state in writing the procedures used to control the hazard. For example, a customer could merely state that its processing includes a lethality step for microbial pathogens of concern. The specific assurances that are required when an importer's customer or a subsequent entity in the distribution chain is controlling a hazard are designed to be practical while helping ensure that an entity is held accountable for processing the food to make it safe for consumers. Of course, for any assurance to be meaningful, the importer must understand the substance of the assurance, which must address control of the hazards identified by the importer in accordance with § 1.504.

In response to the comment regarding what importers might need to do with written assurances (such as evaluate a customer's safety procedures), § 1.507 does not require importers to assess whether their customers are controlling hazards in accordance with the assurance they provide. Instead, we may, if necessary, rely on the requirement in § 1.507(c) that the

customer act consistently with the written assurance it provides (and document its actions) to determine whether an importer's customer or a subsequent entity in the distribution chain is in compliance with the requirements in this rule.

Section 1.507(b) of the final rule establishes certain requirements for the written assurances that are required under this section. A written assurance must include the following:

- The effective date of the assurance;
- The printed names and signatures of authorized officials of the entity providing the assurance; and
- The assurance required under the applicable provision of § 1.507(a).

(Comment 227) One comment expresses concern that proposed § 1.504(g) might create confusion regarding what entity is controlling a hazard in a food in circumstances in which imported food is repurposed (redirected to another use) as a result of quality rejection by the customer or for other reasons. To illustrate this, the comment states that an importer might purchase spinach from a foreign supplier to be used in its customer's canning process that includes a validated kill step to control microbiological hazards, but the spinach does not meet the customer's quality specifications. The comment suggests that the customer might repurpose the spinach for use in individually quick frozen (IQF) spinach or spinach dip, each of which is made without a validated kill step. The comment maintains that it is unclear how the importer can bear the responsibility to ensure that appropriate verification activities have been performed because it is likely to be unaware of the customer's repurposed use of the spinach. Alternatively, the comment states that if the customer was subject to supplier verification requirements under the preventive controls for human food regulation, it would need to go back to the importer to ensure that appropriate supplier verification activities had been conducted, resulting in multiple verification activities and processing delays leading to spoiled spinach. The comment therefore asks that we consider mechanisms that could support a requirement for consistent standards on entry of imported foods into the United States, such as creating a repository of audit reports, accessible by multiple importers, to allow sharing of audit costs and reports so that only one annual onsite audit of a foreign supplier is conducted.

(Response 227) We appreciate the safety and economic concerns associated with imported food that is

redirected for a purpose different from its original intended use. As discussed in section III.G.4 of this document, § 1.506(e) of the final rule allows multiple importers to rely on the results of an onsite audit of a foreign supplier, which has the potential to reduce supplier verification costs for both importers and suppliers. We also believe that the ability to import food in accordance with § 1.507(a)(2) when an importer's customer will significantly minimize or preventing the hazards in food could result in reduced burdens on importers because food and supplier evaluation and supplier verification activities are not required in such circumstances.

With respect to the comment's example of "repurposed" spinach, we note that if the importer's customer provided written assurance that it would significantly minimize or prevent biological hazards in the spinach in a canning process in accordance with § 1.507(a)(2), but instead used the spinach to make IQF spinach or spinach dip without significantly minimizing or preventing the hazard, the importer's customer would be in violation of § 1.507(c). However, the assurance requirement in § 1.507(a)(2) does not require that the customer provide assurance as to the specific food it will manufacture or process from the imported food. Instead, it requires that the customer provide assurance that it will significantly minimize or prevent the identified hazard in the food. It is likely that there is more than one way that the customer could act consistently with that assurance. If the customer determines not to manufacture/process spinach in the originally-contemplated canning process, there are likely other foods that the customer could manufacture/process using procedures that would significantly minimize or prevent the identified hazard. Assuming that occurs, there would be no violation of § 1.507(c).

(Comment 228) One comment asserts that the absence of a definition of "customer" could result in requiring an importer that sells food directly to consumers who are expected to cook the food to obtain multiple letters from consumers to comply the requirement in proposed § 1.504(g) to obtain written assurances that customers are controlling hazards. The comment suggests that we define "customer" as a business that purchases the imported food for further processing or distribution, as stated in the preamble to the proposed rule.

(Response 228) We do not believe that it is necessary to include a definition of "customer" in the FSVP regulation.

However, we agree that a “customer” under § 1.507 of the final rule is not an individual consumer of the food. Instead, a “customer” under § 1.507 is an entity that is subject to the preventive controls regulations or is otherwise subject to applicable food safety requirements (e.g., a retail food establishment or restaurant subject to State or local food safety requirements).

#### *I. Corrective Actions and Investigations Into FSVP Adequacy (§ 1.508)*

In § 1.507 of the proposed rule, we proposed that importers be required to review complaints of any customer, consumer, or other complaint to determine the adequacy of their FSVPs, conduct investigations into potential adulteration of the food they import, take corrective actions to address foreign supplier non-compliance, and investigate the potential inadequacy of their FSVPs and make modifications when appropriate. As discussed in the following paragraphs, we are making several changes to these proposed requirements. We also are renumbering this section to § 1.508 to accommodate other revisions to the codified provisions.

##### 1. General Comments

(Comment 229) One comment agrees with the requirements in proposed § 1.507 but does not believe that the proposed rule would establish adequate regulatory oversight of importers.

(Response 229) Under § 1.508 of the final rule, importers will be required, under certain circumstances, to take corrective actions and investigate the adequacy of their FSVPs, which we believe will promote more robust and effective FSVPs. However, it is FDA’s responsibility to ensure that importers are in compliance with the FSVP regulation, and we intend to meet this responsibility by conducting regulatory inspections of importers and by providing guidance, outreach, and training to assist importers in meeting the FSVP requirements.

(Comment 230) One comment suggests that we use complaint and investigation data obtained from State and local regulatory agencies. The comment maintains that these agencies play an important role given the local intelligence they maintain and their work with consumer complaints and food product investigations.

(Response 230) We appreciate the significant role that State and local regulatory agencies play in ensuring food safety in the United States. We will continue to work and share data, including investigative and compliance data, with these agencies to help protect

the public health. The purpose of § 1.508, however, is to require importers to perform their own investigations and take their own corrective actions, rather than establish new procedures for FDA compliance and enforcement activities.

(Comment 231) Several comments contend that the recordkeeping associated with proposed § 1.507 would be substantially burdensome.

(Response 231) We do not agree that the recordkeeping requirements in § 1.508 will impose unreasonable burdens on importers. We believe that taking corrective actions is an important responsibility for importers and retaining records of these actions is essential to our ability to oversee importers. Nevertheless, because we are removing certain proposed requirements, as discussed in the following paragraphs, we have reduced the recordkeeping burden associated with § 1.508 of the final rule.

##### 2. Review of Complaints

We proposed to require importers to promptly review any customer, consumer, or other complaint that the importer receives to determine whether the complaint relates to the adequacy of the importer’s FSVP (proposed § 1.507(a)).

(Comment 232) Although some comments support the proposed requirement to review complaints to determine whether they relate to the importer’s FSVP, several comments oppose the requirement or ask that it be modified. Some comments oppose a requirement to review complaints because complaint review is already part of reasonable business practice. Several comments maintain that the proposed requirement would be overly burdensome and that the time and effort to correlate complaints to the adequacy of FSVP would not be justified. Some comments maintain that a majority of complaints concern the quality, rather than safety, of food. Some comments claim that complaints are not always a strong indicator of problems and cannot be used to draw conclusions about the adequacy of an FSVP. Some comments suggest focusing on the importer’s program of review and corrective actions, rather than on individual complaints. One comment contends that the PRIA for the proposed rule does not reflect the complexity of a complaint review.

Some comments state that complaint review is required under the proposed FSVP regulation but not the preventive controls regulations. Some comments assert that the requirement to review complaints may be duplicative given the

reporting requirements related to the RFR.

Several comments suggest limiting the requirement to review complaints to those related to food safety. One comment asserts that complaints unrelated to food safety are not under FDA authority. One comment asks that importers be required to consider whether complaints relate to the adequacy of the FSVP only if specific facts suggest a potential relationship to supplied ingredients. One comment suggests limiting the sharing of complaints with FDA to emergency situations because this exchange could be counterproductive to importers’ proactive efforts to collect and react to complaint information.

(Response 232) We have removed the proposed requirement in proposed § 1.507(a) to review complaints. In the preambles to the proposed rules on preventive controls for human food and animal food, we requested comment on whether and how a facility’s review of complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards (78 FR 3646 at 3768; 78 FR 64736 at 64809, October 29, 2013). In the preventive controls final rules, we did not establish a requirement for a review of complaints as a verification activity. We determined that, although we agree that reviews of complaints occasionally do uncover food safety issues such as undeclared allergens, complaint reviews are more likely to be useful in providing information and feedback for continuous improvement of the food safety system rather than as a verification of preventive controls. We think that the same reasoning applies to the FSVP regulation.

In addition, removing the complaint review requirement is consistent with our intent, as stated in the FSVP proposed rule and Supplemental Notice, to coordinate the FSVP regulation with any supplier verification provisions that might be included in the regulations on preventive controls for human and animal food (78 FR 45730 at 45740; 79 FR 58574 at 58576 through 58577). As we said in the preambles to the final rules on preventive controls, we nevertheless encourage firms to review complaints as part of standard business practice.

##### 3. Investigation

In proposed § 1.507(b), we proposed to require that, if an importer became aware that an article of food it imported was 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 would have to promptly investigate the cause or causes of such adulteration or misbranding and document the investigation.

(Comment 233) Some comments support requiring importers to investigate adulteration of food from foreign suppliers. However, some comments express concern that importers might not have the capacity to conduct an investigation. Some comments suggest limiting the requirement to conduct investigations to those that are related to food safety or, more specifically, to those related to adulteration or misbranding that might pose a risk to public health; the comments assert that not all adulterants pose a food safety risk.

(Response 233) We are deleting the requirement to conduct investigations when importers become aware that food they import is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. We believe that the obligation to respond to negative information about food safety is partly addressed in § 1.505(c)(1) of the final rule, which requires importers to reevaluate the risk posed by a food or a foreign supplier's performance when they become aware of new information about these factors. We believe that a requirement to conduct investigations as specified in proposed § 1.507(b) would be unnecessarily duplicative and would not substantially contribute to the public health. In addition, removing the investigations requirement in proposed § 1.507(b) is consistent with the goal of aligning the FSVP regulation with the supply-chain program provisions in the preventive controls regulations, which do not require investigations in the circumstances identified in proposed § 1.507(b). We note, however, that investigating potential adulteration to determine whether it poses a risk to food safety is prudent, and we encourage importers to undertake such investigations when appropriate.

#### 4. Corrective Actions

We proposed, in proposed § 1.507(c), that importers be required to promptly take appropriate corrective actions if they determined that a foreign supplier of food they import 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 a food that was adulterated under section 402 or misbranded under

section 403(w) of the FD&C Act (the standard for FSVPs set forth in FSMA and proposed § 1.502(a) of the FSVP regulation). We proposed that this determination could be based on an investigation into adulteration conducted under proposed § 1.507(b), the supplier verification activities the importer conducted under proposed § 1.506 or § 1.511(c), the FSVP reassessment conducted under proposed § 1.508, or otherwise. Proposed § 1.507(c) further stated that the appropriate corrective actions would depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding had been adequately addressed. We further proposed to require that importers document any corrective actions taken in accordance with § 1.507(c).

To reflect changes we are making to other provisions in this final rule, we have revised the requirement to take corrective actions (§ 1.508(a) of the final rule). With respect to the basis for a determination that a corrective action is needed, we are replacing the reference to § 1.508 with a reference to § 1.505(c) to reflect the replacement of FSVP reassessment with reanalysis of the food and foreign supplier. We also are removing the reference to investigations conducted under proposed § 1.507(b) because we are deleting that provision. In addition, § 1.508(a) states that a determination that corrective action is needed could be based on a review of consumer, customer, or other complaints related to food safety. Under the proposed rule, such a determination could also have been based on a complaint, but given our decision to remove the requirement to review complaints, we conclude that it is appropriate to direct importers to the fact that complaints may serve as the basis of the determination. With all of these revisions, § 1.508(a) of the final rule states that a determination that a corrective action is needed could be based on a review of consumer, customer, or other complaints related to food safety, verification activities conducted under § 1.506 or § 1.511(c), a reevaluation of the risk posed by the food and the foreign supplier's performance conducted under § 1.505(c), or any other relevant information the importer obtains.

(Comment 234) One comment asserts that, because not all adulterants cause an actual food safety risk, the requirement to take corrective actions should be limited to situations in which the foreign supplier's failure causes a risk to public health. Similarly, one

comment requests that the proposed requirement (in § 1.507(d)) to investigate to determine the adequacy of the importer's FSVP be limited to situations in which the foreign supplier's failure causes a risk to public health.

(Response 234) We decline to make changes in response to these comments. To the extent that the comments suggest that importers need not take corrective actions if they believe that the food they import does not cause a risk to public health, we note that section 805(a)(1) of the FD&C Act states that each importer must perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. If a food that an importer imports is adulterated or misbranded with respect to allergen labeling, not taking corrective action would be inconsistent with section 805(a)(1). However, the particular corrective action warranted could differ depending on the circumstances, including the level of risk to public health posed by the particular non-compliance. For example, if non-compliance could cause a serious risk to public health, we would expect an importer to stop importing food from that supplier until the non-compliance was corrected. However, we might not expect this type of corrective action when the non-compliance could be corrected through other measures. All corrective actions are relevant to decisions that an importer may need to make with regard to a supplier. If, for example, a supplier's facility has filthy conditions or the food it supplies is contaminated with filth, an importer may find it inappropriate to approve that supplier even though filth often does not pose a risk to public health.

(Comment 235) One comment maintains that RACs will already have been consumed before responsibility for non-compliance or adulteration can be assigned and corrective actions taken.

(Response 235) We do not agree that RACs in all cases will necessarily have been consumed before an importer has the opportunity to take corrective action. Regardless, under § 1.508(a) of the final rule, importers must promptly take whatever corrective actions are appropriate depending on the circumstances. In some circumstances, the appropriate corrective actions may prevent problems from recurring. For instance, in some cases the appropriate corrective actions might include discontinuing use of the foreign supplier until the cause or causes of non-compliance, adulteration, or



misbranding have been adequately addressed.

(Comment 236) Some comments object to the proposed requirement's reference to discontinuing use of a foreign supplier under certain circumstances, asserting that discontinuing use of a supplier is an extreme response that should be reserved for only the most serious situations. Some comments suggest that if the foreign supplier implements appropriate corrective actions following a nonconformance, the importer should be permitted to continue to source from that supplier.

(Response 236) We decline to delete the reference to possible discontinuation of use of a foreign supplier. Section 1.508(a) of the final rule does not specify conditions under which importers must cease using a foreign supplier; rather, it states that such action, even if only on a temporary basis, might be an appropriate corrective action under certain circumstances. We believe that some supplier actions, such as a failure to promptly or effectively respond to serious safety concerns identified in the food they have supplied, might warrant temporary or even permanent discontinuation of use of that supplier. However, we agree with the comments that responsive actions by a foreign supplier to address its nonconformance could make it unnecessary for the importer to discontinue importing food from the supplier.

(Comment 237) Several comments suggest that an importer's corrective actions need not necessarily require a physical visit to a foreign supplier.

(Response 237) We agree, and the final rule does not require that an importer visit the foreign supplier's establishment as part of any corrective action conducted under § 1.508(a).

(Comment 238) One comment recommends that actions taken to be removed from import alert be considered corrective.

(Response 238) We agree that actions taken to remove a foreign supplier from an import alert might be appropriate corrective actions under § 1.508(a), provided that those actions correct the underlying problem that precipitated the need for corrective actions under that provision.

(Comment 239) Some comments suggest we keep any information and dialogue concerning potential corrective actions confidential.

(Response 239) As discussed in section III.K.6 of this document, § 1.510(f) of the final rule states that records obtained by FDA in accordance with the FSVP regulation (which would

include documentation of corrective actions taken under § 1.508(a)) are subject to the public information regulations in part 20. The provisions in part 20 provide protections from public disclosure for trade secrets and confidential commercial information.

#### 5. Investigations To Assess Adequacy of FSVP

We proposed to require, in § 1.507(d), that if an importer determines, by means other than the verification activities conducted under proposed § 1.506 or § 1.511(c) or the FSVP reassessment conducted under proposed § 1.508, that a foreign supplier of food does not 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, 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 importer must promptly investigate to determine whether its FSVP is adequate and, when appropriate, modify the FSVP. We also proposed to require that the importer document any investigations, corrective actions, and changes to the FSVP that it undertakes in accordance with this requirement.

To reflect changes we are making to other provisions in this final rule, we have revised the requirement to investigate to determine the adequacy of FSVPs (§ 1.508(b) of the final rule). With respect to the means by which an importer might determine that a foreign supplier does not produce food in accordance with applicable requirements, we are replacing the reference to § 1.508 with a reference to § 1.505(c) (reevaluation of foreign supplier performance and the risk posed by a food).

#### 6. No Limitation of Obligations

In the proposed rule, we proposed to specify (in § 1.507(e)) that § 1.507 does not limit an importer's obligations with respect to other laws enforced by FDA, such as those relating to product recalls. This provision is codified in § 1.508(c) of the final rule.

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

We proposed to require that FSVP importers be identified as the importer of the food that they bring into the United States when the food is imported or offered for import. Specifically, we proposed to require that, for each line entry of food product offered for importation into the United States, the importer's name and Dun & Bradstreet

Data Universal Numbering System (DUNS) number identifying the importer be provided electronically when filing entry with CBP. This proposed requirement was intended to ensure that food importers are accurately identified so that we can effectively implement and monitor compliance with the FSVP regulation in a risk-based manner.

In response to comments, we have replaced the proposed requirement that importers obtain a DUNS number and ensure that it is provided when filing entry with a requirement to provide the importer's unique facility identifier recognized as acceptable by FDA. However, as discussed in the following paragraphs, we anticipate that we will issue a guidance document that recognizes DUNS numbers as being acceptable to FDA. The final rule also adds a requirement to provide an electronic mail address for the importer as part of the identification at entry.

#### 1. Provision of Importer's DUNS Number

We proposed to require importers to obtain a DUNS number from Dun & Bradstreet and to ensure, for each line of entry of food product, that the importer's name & DUNS number are provided electronically when filing entry with CBP. We proposed to require the use of a DUNS number because, as a numerical identifier assigned to a specific business location, use of the DUNS number would provide more accurate identification of importers than use of the firm's name and address. We requested comment on the proposed use of DUNS numbers to identify importers under the FSVP regulation as well as comments on the use of alternative identifiers.

(Comment 240) Some comments oppose this proposed requirement generally because they believe it is unnecessary or would not assist FDA in monitoring importers. One comment questions the need for the proposed requirement given Agency statements that it cannot inspect its way to food safety. Some comments oppose the proposed requirement because they assert that we already receive adequate information to establish the identity of the importer in accordance with the prior notice regulation.

(Response 240) We do not agree with the comments. Although the prior notice regulation requires the submission of the name and full address of the importer of a food (21 CFR 1.281(a)(12)), the entity named as the importer for prior notice might not necessarily be the importer of the food for purposes of FSVP, as the term

“importer” is defined in § 1.500. We agree that we cannot ensure the safety of food through our inspections alone, which is why Congress directed us to promulgate these regulations to require importers to conduct foreign supplier verification to ensure that the food they import is as safe as food produced in the United States. Although we cannot inspect each and every food product that is imported into the United States, we can use our authority under section 805 of the FD&C Act to help ensure that importers conduct appropriate foreign supplier verification activities.

We conclude that requiring importers (under § 1.509) to ensure that they are accurately identified at entry will help us efficiently and effectively ensure that importers are complying with the FSVP requirements. For example, we might use this information to create a comprehensive and up-to-date database that will allow us to efficiently and effectively identify and locate importers for inspection. At the same time, knowing the identity of importers will also 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 provision, we need to know, at the time of importation, who the importer is. While we currently receive information identifying the importer through prior notice submissions in accordance with section 801(m) of the FD&C Act, the entities identified in prior notice submissions are not necessarily the importers for the purposes of FSVP, as discussed previously. Without information identifying the FSVP importer, we would be less equipped to account for the rigor and effectiveness of importers’ FSVPs in allocating our resources for examining food in accordance with section 421(b).

Finally, obtaining the identity of the importer at entry will likely 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 of, location of, and other information deemed necessary by [FDA] about, importers participating under [section 805].” For all these reasons, the requirements regarding the identification of importers are consistent with sections 421(b), 805, and 701(a) of the FD&C Act, the last of which authorizes us to promulgate regulations for the efficient enforcement of the FD&C Act.

(Comment 241) Several comments oppose requiring importers to obtain a DUNS number to provide when filing entry of products. Some comments maintain that requiring use of the DUNS number would cause confusion and impose unnecessary costs and burdens on importers because other adequate or even superior means of importer identification exist, such as information required for CBP entry and prior notice. One comment states that the existing facility registration system is sufficient to meet FSMA’s directives, less burdensome, and more secure. One comment maintains that requiring use of DUNS numbers would cause importers to incur costs to create or modify their internal systems and relationships with brokers to establish a new numbering system and index the new identifier to the appropriate documents. Some comments express concern about FDA relying on a privately owned and operated system when government-issued numbers could serve the same purpose. Some comments question whether FSMA gives FDA legal authority to require importers to obtain a DUNS number. Some comments are concerned that requiring use of a DUNS number might raise security and fraud risks because a DUNS number would not have the same protections under the FOIA as an FDA registration number. Some comments express concern that the requirement would give the Agency access to importers’ business information in the DUNS database or otherwise lead to disclosure of confidential information (e.g., through erroneous designation of a company as the importer of a food).

Instead of, or as an alternative to, use of a DUNS number, some comments suggest that importers be allowed to use other identifiers, such as the following:

- The taxpayer identification number (TIN) used with CBP;
- The FDA facility registration number (if the importer is a registered facility);
- The form used to meet the prior notice requirements (modified to allow identification, where appropriate, of a U.S. agent or representative as the importer for FSVP purposes); or
- The CBP importer of record number.

Some comments suggest that instead of requiring identification at entry, we should require importers to register with FDA.

(Response 241) We conclude that it is necessary to establish, in § 1.509(a) of the final rule, an importer identification requirement specifically for the FSVP regulation to ensure that the identified importer at the time of entry is, in fact,

the “importer” of the food as defined in § 1.500 of the final rule. In addition, we conclude that use of a unique facility identifier, such as a DUNS number, is an appropriate mechanism for accurately identifying importers responsible for complying with the FSVP regulation because such identifiers provide unique identification numbers, which will allow us to efficiently and accurately identify importers. The DUNS number system, for instance, is an internationally recognized system that is updated on a regular basis and makes numbers available at no cost. DUNS numbers also provide for site-specific identification of business entities.

We conclude that use of FDA registration numbers would not be appropriate for FSVP importer identification purposes because not all “importers” under § 1.500 will necessarily be facilities required to register under section 415 of the FD&C Act. Likewise, not all importers under § 1.500 will necessarily be “importers of record” for purposes of CBP entry submissions and therefore will not necessarily have CBP importer of record numbers. Any other CBP-required identifying information also would not necessarily identify the FSVP importer because CBP requirements do not incorporate the definition of “importer” under § 1.500. We do not believe that revising the information required for prior notice would be appropriate because the prior notice regulation serves a different purpose than the FSVP regulation. For these reasons, we do not agree that using the alternative identifiers suggested by the comments would allow FDA to accurately identify FSVP importers. Consequently, they would not allow FDA to efficiently enforce section 805 of the FD&C Act in the ways described in response to the previous comments.

With respect to concerns about use of unique facility identifiers leading to the disclosure of confidential information or posing security risks, any confidential information that we obtain regarding importers would be subject to the applicable protections from public disclosure under part 20 of our regulations (see section III.K.6 of this document). Those protections include, among other things, exemptions from public disclosure for trade secret information and confidential commercial information (§ 20.61). As for concerns regarding security risks, we intend to take appropriate measures to secure all electronic data provided to the Agency, including data about the identification of importers.

For these reasons, we believe that requiring unique facility identifiers is the most appropriate way to accurately identify food importers for purposes of monitoring FSVP compliance. To provide additional flexibility beyond what we had proposed, the final rule does not require the submission of DUNS numbers for importers of foods offered for importation into the United States. Instead, it requires the submission of a unique facility identifier recognized as acceptable by FDA. We anticipate that we will issue guidance specifying which unique facility identifier or identifiers FDA recognizes as acceptable, and we expect to state that we recognize DUNS numbers as acceptable identifiers. Although we will allow importers to request the use of different identification numbers, it is possible that our information technology systems will not be able to accommodate any numbers other than those that we may specifically recognize as acceptable in guidance. If that is the case, we would have to manually review entry submissions that include alternate unique facility identifiers.

In addition to the importer's name and DUNS number, the final rule also requires that the importer's electronic mail address be provided as part of the identification at entry. This requirement follows from our request for comment on whether we should require the submission of any additional identifiers for importers. We believe that an electronic mail address is an appropriate additional identifier to require for importers, especially because electronic mail addresses allow for quick and efficient communications between FDA and importers. We anticipate that we might use the electronic mail addresses to notify at least some of the persons listed at those addresses that they have been identified as FSVP importers, including persons who have been designated as the U.S. agent or representative of a foreign owner or consignee for purposes of the definition of "importer." We also might use electronic mail addresses to communicate with importers more generally, including to help us resolve any questions regarding a food offered for importation to potentially facilitate review of that food. Requiring electronic mail addresses is thus grounded in the statutory objective of efficiently enforcing the food safety and FSVP requirements of the FD&C Act. By requiring electronic mail addresses for importers, we would be able to communicate efficiently and effectively with importers regarding their role

under the FSVP regulation and with respect to the food they offer for import.

(Comment 242) Some comments maintain that if an importer has multiple U.S. locations, it will only have a single DUNS number that will not provide information about the food's destination (*i.e.*, a specific importer facility). On the other hand, one comment maintains that having a different DUNS number for each corporate location would be confusing. Some comments suggest that, if we were to require importers to use DUNS numbers, importers should be allowed to use a single DUNS number (*e.g.*, for their corporate headquarters) even if they have multiple U.S. sites.

(Response 242) As discussed in the previous paragraphs, the final rule does not require that an importer's DUNS number be provided for each line of entry of food. Instead, it requires that a unique facility identifier recognized as acceptable by FDA be provided. However, we anticipate that we will issue guidance that will recognize DUNS numbers as acceptable. We understand that DUNS numbers are specific to physical locations; therefore, an importer with more than one physical location likely would have more than one DUNS number. In that circumstance, the importer should generally provide the DUNS number that applies to the location at which the importer retains its records of FSVP activities for the food for which it provides its DUNS number at entry under § 1.509(a), as that typically is the location that FDA investigators would need to visit to inspect the importer for compliance with the FSVP regulation. If an importer elects to retain its FSVP records for the food at its corporate headquarters, we would expect the importer to provide the DUNS number for its headquarters when it provides the information required under § 1.509(a).

(Comment 243) One comment, stating that FDA databases include multiple assigned numbers (*e.g.*, Central File Number (CFN), Firm Establishment Identifier (FEI)) for a firm due to slight changes in names and addresses and fraudulent or misguided submissions, recommends that we take steps to prevent the issuance of multiple DUNS numbers for the same importer.

(Response 243) We are unable to restrict importers' ability to seek DUNS numbers for multiple office or facility locations. However, as stated previously, we will expect importers to provide the unique facility identifier for the location at which the importer retains its FSVP records for the food for which it submits the unique facility identifier.

(Comment 244) Some comments express concern that the process of applying for and receiving a DUNS number can be lengthy and might delay imports.

(Response 244) We do not agree that the process of applying for whatever unique facility identifier that we recognize as acceptable will delay imports. With respect to DUNS numbers, although we understand that it might take up to 45 business days to receive a DUNS number (when obtained at no charge), importers will have more than a year (in some cases much longer) to come into compliance with the FSVP regulation, which will provide importers who do not currently have a DUNS number with ample time in which to obtain one.

(Comment 245) One comment states that there should be an affirmative requirement for the importer of record for a food to provide the name and DUNS number of the FSVP importer on its entry declaration, because the importer of record is responsible for the entry.

(Response 245) The final rule requires that the FSVP importer be identified at the time of entry, so the unique facility identifier for importers will be a mandatory data element in the entry filing process with CBP. However, because a food's importer of record might not necessarily be the food's FSVP importer, we do not think that the requirement to provide the unique facility identifier should fall to the importer of record. Instead, we believe that it is appropriate for the requirement to apply to a person who is subject to the requirements of the FSVP regulation. Depending on who files entry with CBP, an importer of record for a food may or may not be the FSVP importer. Of course, the FSVP importer of a food might arrange to have the importer of record for the food provide the FSVP importer's identification information at entry. In any case, it is the importer's responsibility to ensure that the information identifying the importer is provided at entry by some entity.

(Comment 246) Some comments assert that we should only require information on a line-entry basis when there is more than one importer for a shipment or when the CBP importer differs from the FSVP importer.

(Response 246) We do not agree. We conclude that FSVP importer identification is needed on a line-entry basis because importers are required to establish FSVPs for each food that they import from a particular foreign supplier, and obtaining importer identification information on a line-

entry basis will help us assess compliance with the FSVP requirements in order to efficiently enforce section 805 of the FD&C Act.

(Comment 247) Some comments request that we specify the data elements that will be required at entry, when they must be provided, and in what format. However, the comments ask that we provide this information in guidance rather than the final rule because information systems can change over time.

(Response 247) To the extent that the comments request that we use guidance to provide information on the details of the exact manner and format in which importer identification information should be provided, we agree. Section 1.509(a) of the final rule establishes the requirements that importers ensure that their name, electronic mail address, and unique facility identifier are provided electronically to CBP for each line entry of food product they import. We anticipate that we will provide more detailed formatting and other information through guidance.

(Comment 248) One comment requests that we specify what information will be publicly available under CBP's confidentiality provisions.

(Response 248) For information about the disclosure of records created or obtained by CBP and under the control of CBP, we suggest contacting CBP directly. However, we note that CBP regards confidential commercial information appearing on entry documents as exempt from disclosure under Exemption 4 of the FOIA (5 U.S.C. 552(b)(4)).

(Comment 249) Some comments express concern about the proposed requirement that the importer's name and identification number be provided electronically when filing entry. One comment asserts that this information might be "hacked" or fall into the wrong hands through error, creating a risk of adulteration or potential terrorist acts. One comment suggests that we permit importers to file FSVP information before filing entry with CBP as part of the prior notice form. The comment also urges us to provide timely admissibility determinations about imports shipped under FSVP; the comment maintains that importers often do not file the CBP entry summary until after the arrival of imported products, and release of goods might be delayed if importers must wait to file FSVP-required information. The comment suggests that early submission of FSVP information would give FDA and the importer more time to make admissibility determinations, resolve any perceived failures to comply with FSVP, and, if admission is refused, give

the foreign supplier more time to react to the delivery disruption.

(Response 249) We do not agree that there is any need to change the requirement that FSVP importers be identified electronically when filing entry with CBP. With respect to the concerns about information being "hacked," CBP's electronic filing system is a secure system and CBP takes adequate steps to address security. With respect to the request to permit importers to file FSVP information before submitting entry, we decline this request. We believe that the requirement to submit importer identification information at entry is consistent with the definition of importer in section 805(a)(2)(A)–(B) of the FD&C Act (*i.e.*, the U.S. owner or consignee of an article of food "at the time of entry of such article into the United States" or, if there is no U.S. owner or consignee at the time of entry, the "United States agent or representative . . . at the time of entry"). To ensure that the identified importer is the person who meets this definition, we believe it is appropriate to require that importers file their FSVP information at entry.

With respect to the request to permit importers to file FSVP information as part of the prior notice form, we similarly do not think that doing so would be appropriate. Some entities who submit prior notice information for a food might lack information about the FSVP importer of the food. As a result, we anticipate that there would be technical challenges to allowing the submission of FSVP information during prior notice that could lead to delayed entries. However, we note that because some entities may make a business decision to file prior notice with the entry, there may be some cases in which FSVP information is provided at entry at the same time that prior notice is submitted.

We also do not agree that it is necessary to make any changes to § 1.509 to account for the fact that some importers delay the submission of CBP entry summary information. Although it might be the case that importers often do not file the CBP entry summary until after the arrival of imported products, importers can file entry earlier if they desire. There is no requirement that importers wait until after the arrival of imported products to file entry with CBP. Further, we do not think filing of importer identification information under § 1.509 will ordinarily trigger entry delays.

(Comment 250) Some comments request that we provide guidance to clarify FDA's and CBP's regulatory requirements regarding importer

responsibilities. Some comments ask that we provide a technology platform for industry to use to comply with the importer identification requirements.

(Response 250) The FSVP draft guidance will advise importers on how they can ensure that their name, electronic mail address, and unique facility identifier are provided to CBP when a food is offered for importation in accordance with § 1.509(a).

## 2. Designation of U.S. Agent or Representative

We proposed to require (in proposed § 1.509(a)) that, 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. As discussed in section III.A.13 of this document, we are adding a clarification to the definition of "importer" in § 1.500 stating that for the foreign owner or consignee of the article to validly designate a U.S. agent or representative for the purposes of the definition of "importer," the U.S. agent or representative's role must be confirmed in a signed statement of consent. The signed statement of consent must confirm that the U.S. agent or representative agrees to serve as the importer for the purposes of the FSVP regulation.

(Comment 251) Some comments suggest that we should have a better database of designated U.S. agents (for FSVP purposes) than exists for U.S. agents named in foreign facility registrations.

(Response 251) Section 415(a)(1)(B) of the FD&C Act provides in relevant part that the registration of a foreign food facility must include the name of the U.S. agent for the facility. As we have discussed in connection with a proposed rule to amend the Agency's regulation on food facility registration, we have learned that in some cases persons identified as U.S. agents in foreign food facility registrations were unaware that they had been so identified, and had not in fact agreed to serve as U.S. agents for foreign food facilities (80 FR 19160 at 19169, April 9, 2015). To the extent that the comment is concerned about the accuracy of designations of U.S. agents who would serve as FSVP importers in accordance with § 1.500, we conclude that the clarification we are making to the definition of "importer" in § 1.500 adequately addresses this concern. Specifically, we conclude that the clarification that any designation of a

U.S. agent or representative as the FSVP importer must be confirmed in a signed statement of consent will help ensure that the U.S. agents or representatives who are so designated have in fact agreed to serve in that role. As discussed in section III.A.13, we might request the foreign owner or consignee that is exporting the food to provide us with the signed statement when and if any questions arise about whether the person designated as the U.S. agent or representative agreed to serve in that role. Although we do not plan to establish a separate database for U.S. agents and representatives responsible for functioning as FSVP importers, we will include these entities in the list of all importers subject to the FSVP regulations that we will maintain on our Web site in accordance with section 805(g) of the FD&C Act, as discussed in section III.J.3 of this document.

(Comment 252) One comment asks that U.S. agents and representatives of foreign owners be excluded from the requirement to identify the importer at entry because agents and representatives have limited information available to them.

(Response 252) We do not agree. Under section 805(a)(2)(B) of the FD&C Act, the importer of a food for purposes of meeting the FSVP requirements must be the U.S. agent or representative of the foreign owner or consignee of the food when there is no U.S. owner or consignee at the time of entry of the food into the United States. Foreign owners or consignees will need to ensure that the persons who agree to serve as their U.S. agent or representative for purposes of functioning as the FSVP importer have or can obtain the information and capability needed to meet their obligations as importers subject to the FSVP regulation.

### 3. FDA List of Importers "Participating Under" the FSVP Regulation

In the preamble to the proposed rule, we stated that obtaining the identity of the importer at entry could help us meet the requirement, in section 805(g) of FD&C Act, to maintain on our Web site a list of "importers participating under this section," *i.e.*, section 805 regarding FSVPs. We stated that the meaning of the phrase "importers participating under this section" was ambiguous (*e.g.*, it might refer to all importers subject to section 805 or only those importers in compliance with section 805), and we sought comment on the meaning of the phrase and the purpose of section 805(g).

(Comment 253) Some comments suggest that we identify all importers

that are subject to the FSVP regulation. Some comments agree that the meaning of the phrase "participating under this section" is ambiguous but suggest that we focus on only those importers that are in compliance with the FSVP regulation. These comments assert that such a list would be helpful to retailers and others who seek to source from or otherwise employ the services of such importers. Some comments maintain that although section 805(g) was intended to produce a comprehensive list of all importers, FDA's intended use of the list and its plans for maintaining an accurate database are ambiguous. Some comments request clarity regarding what other information about importers we will "deem necessary" under section 805(g). Some comments encourage us to comply with the statute in a manner that does not conflict with CBP's confidentiality regulations, allowing companies to continue protecting sensitive shipping details such as those concerning product sourcing and distribution.

Some comments oppose any listing of importers "participating under" the FSVP regulation. Some comments question the meaning of the phrase "importers participating under this section" and the purpose of the list. Some comments contend that this provision does not belong in section 805 because that section creates requirements for all importers; these comments argue that maintaining a list of importers would be a huge task that would serve no purpose. One comment contends that publishing a list of names and locations of importers appears to be in direct conflict with section 415(a)(5) of the FD&C Act, which exempts facility registration records from public disclosure. Some comments suggest that, before publishing a list of "participating" importers, we should seek clarification from Congress regarding the meaning of section 805(g), or ask Congress to either delete the requirement or move it to the FSMA provisions concerning the VQIP for food importers (set forth in section 806 of the FD&C Act).

(Response 253) In publishing the list of importers "participating" in FSVP, we intend to develop a list that includes importers who are subject to the FSVP regulation (and not exempt from the requirements under § 1.501 of the final rule). Although we agree that a list of importers deemed to be in compliance with the FSVP regulation might be of interest to the public, even importers that are the subjects of enforcement actions for non-compliance with the FSVP regulation are "participating" under the regulations, given that

importer compliance with the FSVP regulation is not voluntary. Moreover, maintaining a list of importers deemed to be in compliance with the FSVP regulation would impose a substantial burden on the Agency. Maintaining a list of importers that are subject to the FSVP regulation, however, would be more administratively manageable, especially because we will be able to use the importer identification information provided under § 1.509(a) to establish and maintain the list.

Besides the name and location of importers, we are uncertain what other information, if any, we will include as part of our list of importers subject to the FSVP regulation. We plan to continue to consider whether we should include any additional information in the list. We will maintain the list on our Web site in accordance with the applicable public disclosure requirements, including the requirements in part 20.

### K. Records (§ 1.510)

We proposed several requirements concerning the manner in which FSVP records would be maintained and made available to FDA (proposed § 1.510). In response to comments received and to better align the FSVP records requirements with records provisions in other FSMA regulations, we have revised certain requirements regarding record availability (including offsite storage) and retention, and we have added provisions regarding electronic records, use of existing records, and public disclosure.

#### 1. Records Content and Format

We received some comments of a general nature regarding recordkeeping requirements.

(Comment 254) Some comments suggest that FDA educate itself about the content and format of records that importers and foreign suppliers maintain; the comments state that we should take into account the use of different systems in different countries and not impose a single, restrictive reporting rubric. One comment asks that the records importers are required to keep be based on an importer's risk assessment and not be specified in the regulation.

(Response 254) As discussed elsewhere in this document, we are requiring that importers document certain determinations they make and actions they take to meet the FSVP requirements, including regarding hazard analysis, evaluation of the risk posed by a food and the foreign supplier's performance, and supplier verification. In several areas, such as

onsite auditing of foreign suppliers, testing of imported food, and review of foreign supplier food safety records, we conclude that it is appropriate to require the documentation of specific information to ensure that importers can adequately assess whether their suppliers are producing food consistent with the applicable requirements. In addition, importer maintenance of certain records containing information required under the regulations will help us determine whether importers are taking adequate measures to ensure that they import safe food. However, as stated in section III.G.6 of this document with respect to documentation of foreign supplier verification activities, the regulation generally does not specify a particular form or format for required documentation. In addition, § 1.510(e) of the final rule allows importers to use existing records if they contain the information required by this part (see the response to the following comment).

(Comment 255) Some comments suggest that FDA train its investigators to understand that there will be a wide range of documentation approaches importers take that should be viewed as acceptable. The comments maintain that importers should be allowed to document their program as a whole (e.g., using a tiered or matrix approach to assessing supplier and ingredient risk and determining the corresponding verification activities) rather than maintaining a separate file for each individual supplier or food. The comments assert that importers should not be required to keep a narrative file explaining their reasoning as to which verification activities are appropriate for each supplier and food.

(Response 255) As previously stated, the FSVP regulation generally does not require the use of specific formats for the information that must be included in required records. However, the regulation requires importers to conduct a hazard analysis for each type of food they import, evaluate the risk associated with each food and the foreign supplier's performance, and use that evaluation to approve their foreign suppliers and determine appropriate supplier verification activities. Although importers may use a risk matrix or risk tier system to help them approve foreign suppliers and determine appropriate verification activities for particular foods and suppliers, importers must document, for each food and its foreign supplier, the evaluation of the food and the supplier and the determination of the appropriate type and frequency of supplier verification activities based on that evaluation. FDA investigators might

not be able to determine whether an importer had met these and other FSVP requirements for a particular food and foreign supplier simply by reviewing an importer's risk matrix or tier system, depending on the level of information and detail provided in the matrix or system. The maintenance of records on a food-and-supplier basis is essential to providing adequate assurance of the safety of foods obtained from each foreign supplier. This is especially important when an importer determines that a method other than annual onsite auditing can provide adequate assurance that SAHCODHA hazards in food are significantly minimized or prevented.

However, on our own initiative to align the FSVP regulation with other FSMA regulations, we have added to the final rule provisions allowing importers to use existing records under certain conditions to meet FSVP requirements. Section 1.510(e)(1) of the final rule states that existing records (e.g., records kept to comply with other Federal, State, or local regulations) do not need to be duplicated if they contain all of the information required under the FSVP regulation for each food and satisfy the FSVP requirements, including, as described above, that the records are specific to each food. Section 1.510(e)(1) further states that importers may supplement existing records as necessary to include all of the required information and satisfy the FSVP requirements. In addition, under § 1.510(e)(2), importers are not required to keep required information in one set of records. If existing records contain some of the required information, any new information required by the FSVP regulation may be kept separately or combined with existing records.

## 2. General Requirements

We proposed, in § 1.510(a), that importers be required to sign and date records concerning their FSVPs upon initial completion and subsequent modification.

(Comment 256) Some comments support not specifying which particular qualified individual must sign the FSVP records.

(Response 256) We agree that it is not necessary to specify a particular qualified individual who must sign and date all FSVP records for the importer. However, the qualified individual signing a record on behalf of the importer must have the authority to do so and be qualified to review and assess what he or she is signing.

(Comment 257) One comment suggests that only certain records should have to be signed and dated;

these records would primarily be those concerning the following: compliance status review (a proposed requirement that we deleted in the Supplemental Notice); hazard analysis; supplier verification activities; complaint review, investigations, and corrective actions; FSVP reassessment; dietary supplements; and very small importers and very small foreign suppliers.

(Response 257) We do not agree. The comment did not provide a reason as to why the other records do not need to be signed and dated, and we conclude that to aid in accountability and the efficient enforcement of the requirements in section 805 of the FD&C Act, importers must sign and date all records required under the FSVP regulation.

(Comment 258) One comment asks that we state in guidance that electronic signatures are acceptable.

(Response 258) We agree that electronic signatures are acceptable provided the importer maintains a system for ensuring that the signatures are trustworthy. We discuss electronic records generally in section III.K.5 of this document.

On our own initiative, we have added to § 1.510(a), consistent with other FSMA regulations, a requirement that importers keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. We have also moved the proposed requirement that all records be legible and stored to prevent deterioration or loss from proposed § 1.510(b) to § 1.510(a) of the final rule.

## 3. Records Availability

### a. Records in English

We proposed, in § 1.510(b), that importers retain records in English and make them available promptly to an authorized FDA representative, upon request, for inspection and copying.

(Comment 259) Some comments support the proposed requirement to retain records in English; however, most comments object to the proposal. Several comments state that foreign supplier records and supplier audit reports usually are created in the native language of the foreign supplier, which often is not English, and some importers do not speak English as their first language. The comments maintain that a requirement to translate all such records into English would be costly, burdensome, and could lead to confusion and misunderstandings that could adversely affect food safety when records are created for the foreign supplier or others in a language other

than English. One comment states that the proposed requirement could mean that native-language speaking foreign suppliers would need to recruit dual-language speaking personnel so they could provide English language records to their importers, or it might require importers to enlist specialized resources to engage in translations. Some comments contend that the proposed requirement is not authorized by FSMA or the FD&C Act. One comment states that translation is not needed to allow FDA to use its resources wisely and conduct efficient investigations. Some comments contend that a requirement to maintain records in English would be inconsistent with industry standards such as those in the British Retail Consortium and Safety Quality Food schemes. Two comments suggest that because the official languages of the WTO are French, Spanish, and English, importers should be allowed to keep records in these languages.

Some comments request that the regulations specify which records must be maintained in English; a few comments suggest that any English requirement should apply only to records created by the importer.

Some comments maintain that the English requirement is unnecessary because some importers have personnel who understand the languages of their foreign suppliers. Instead of requiring that FSVP records be maintained in English, several comments suggest that the regulation require that persons reviewing records for the importer be able to understand the language in which the records were written, including documents written by a foreign supplier or an auditor of a foreign supplier in a language other than English.

Several comments suggest that, as an alternative to the proposed requirement that records be maintained in English, the regulation could require importers to translate records upon FDA request in a reasonable time.

(Response 259) Although existing FDA regulations (§§ 120.14(c) and 123.12(c)) require importers of juice and seafood to maintain records in English, we conclude that it is not necessary to include such a requirement in the FSVP regulation. Although we believe that having records in English would facilitate efficient FDA inspection of importer records, we believe that we can address most of the concerns related to the language of records through other requirements. First, because an importer would not be able to meet its FSVP requirements (e.g., hazard analysis, review of results of supplier verification activities) if it could not understand the

documents that it was reviewing, we have added a requirement, in § 1.503(a) of the final rule, that a qualified individual must be able to read and understand the language of any records that the qualified individual must review in performing activities to meet FSVP requirements.

Second, the final rule requires, in § 1.510(b)(1), that, upon FDA request, importers must provide within a reasonable time an English translation of records maintained in a language other than English. We believe that a “reasonable” time in which to provide translated records would depend on the volume of the records requested but should not be so long as to impair the Agency’s ability to conduct record reviews and follow-up enforcement activities. Without the requirement to translate records in a reasonable time, we would not be able to efficiently enforce section 805 of the FD&C Act.

#### b. Place of Business or Reasonably Accessible Location

We proposed that importers be required to maintain records at their 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)).

(Comment 260) Some comments suggest that importers should have the flexibility to store records at any reasonably accessible location, including where the records are created or at a corporate office, import team facility, or offsite facility. Some comments suggest that we align the FSVP regulation with the proposed requirement in the preventive controls regulations permitting offsite storage of records provided that the records can be retrieved and made available onsite within 24 hours of FDA request. These comments maintain that the proposed FSVP approach would be too limiting because it would require importers to store all paper records onsite for the entire retention period because offsite paper documents would not be immediately retrievable by computer or other electronic means. On the other hand, some comments suggest that we apply the term “immediately retrieved” in a practical manner to allow for an employee at another location being in a meeting at the time of a request, and ask that we modify the preventive controls provisions for consistency to provide further flexibility for the storage location. One comment states that, rather than requiring that records be immediately retrieved from another

location, there should be a specific, reasonable interval, such as within 5 business days, but in no case less than 1 business day.

(Response 260) We conclude that it is appropriate, under § 1.510(b)(2) of the final rule, to permit offsite storage of records (including records retained by other entities) if such records can be retrieved and provided by the importer onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location. We believe that this approach, which is consistent with the approach under the preventive controls regulations, gives importers the flexibility to store records at whatever location they deem suitable provided that any records stored offsite can be made available onsite within 24 hours.

(Comment 261) Some comments object to the proposed requirement that retrieval from an offsite location could only be achieved “by computer or other electronic means” because some offsite locations might not have adequate resources and the provision might inadvertently require expensive computer system validation.

(Response 261) We agree. The final rule does not specify the manner in which offsite records must be retrieved and provided onsite, only that the records must be provided onsite within 24 hours.

#### c. Sending Records to FDA Electronically

We proposed that importers be required, when requested in writing by FDA, to send records to the Agency electronically rather than making the records available for review at the importer’s place of business. On our own initiative, we have modified the requirement so that § 1.510(b)(3) of the final rule states that if requested in writing by FDA, an importer must send records to us electronically, or through another means that delivers the records promptly, rather than making the records available for review at the importer’s place of business. Allowing use of another means that delivers the records promptly provides additional flexibility for all importers in the records review process. We also note that for records that will need to be translated into English, we expect to receive such records promptly after the reasonable time needed for translation.

(Comment 262) Several comments oppose the proposed requirement to send records to FDA electronically upon request. Some comments maintain that neither FSMA nor the FD&C Act (including FDA’s authority to issue



regulations for the efficient enforcement of the FD&C Act under section 701(a)) provides authority for the requirement and that such a requirement would be inconsistent with sections 414 and 704 of the FD&C Act. Some comments state that only one section of FSMA (section 808(c)(3)(B) of the FD&C Act) gives FDA remote records access; some comments contend that the proposed requirement would be inconsistent with FSMA's legislative history (because a similar requirement was included in a House of Representatives version of the FSMA legislation that Congress did not enact). Some comments maintain that the language of section 805(d) of the FD&C Act does not provide authority to require importers to send records to the Agency electronically because the provision only requires that records "be made available promptly" to an FDA representative. Some comments state that a requirement to submit records electronically would not be consistent with the HACCP regulation for juice or the proposed regulations on preventive controls or produce safety.

(Response 262) We disagree with the comments stating that FDA does not have the authority to require records to be sent to us electronically or through another means that delivers the records promptly upon request, as set forth in § 1.510(b)(3). Section 805(d) provides that FSVP records "be made available promptly to a duly authorized representative of the Secretary upon request." Section 805(c)(5)(B) states that the FSVP regulations must "include such other requirements as the Secretary 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 701(a) provides for the efficient enforcement of the FD&C Act. We conclude that we have the authority under these sections to require that records be made available to us electronically upon written request or through another means that delivers the records promptly. We conclude that this requirement is necessary for the efficient and effective enforcement of section 805 to ensure that importers are adequately verifying the safety of the food they import into the United States. It is important to note that the provisions in § 1.510(b)(1) and (2) describe FDA inspection of records at an importer's place of business, as authorized by section 805 and 701(a). Section 1.510(b)(3), however, provides an alternative means of efficiently reviewing records upon request—electronically or through another means that delivers the records to us promptly.

Several comments refer to the legislative history of FSMA and the "remote access" to records provisions that were included in a separate food safety bill, H.R. 2749, which was not incorporated into FSMA and was not ultimately enacted. The comments maintain that this legislative history indicates that Congress did not intend section 805(d) to mean that records could be reviewed electronically. S. 510, a separate bill with numerous distinct provisions, was passed by the Senate, enacted by both houses of Congress, and became FSMA. While H.R. 2749 does include specific provisions regarding "remote access" to records in certain circumstances, we conclude that the existence of the "remote access" provisions in that bill does not in any way indicate that Congress' decision to enact S. 510 was attributable to its disapproval of requests for records outside of the inspection context.

The decision to enact S. 510 could be attributable to any number of factors. Indeed, H.R. 2749 was a separate bill from S. 510 and differed in many critical respects. Although there is no mention of the term "remote access to records" in any section of S. 510, it is notable that H.R. 2749's section regarding imports did not refer to FSVP at all and consisted only of what became the VQIP program (section 806 of the FD&C Act). It is therefore impossible to draw the conclusion that, in enacting S. 510, Congress rejected the notion of FDA issuing written requests for FSVP records. Indeed, there is no evidence in the legislative record and no evidence provided by the comments that the "remote access" to records provision in H.R. 2749 was even a factor regarding which of the two bills would be enacted as FSMA. What actually occurred was the adoption of an entirely separate bill with many provisions that differed from H.R. 2749, including the requirements for foreign supplier verification.

We agree with the comments stating that the recordkeeping provisions in this rule differ from the recordkeeping provisions in FDA's HACCP regulations, the preventive controls regulations, and the produce safety regulation. Indeed, the difference is intentional. Unlike the recordkeeping provisions in those other regulations, the FSVP records requirements are designed to be specific to the imports context. As to the comments stating that the FSVP proposal is inconsistent with sections 414 and 704 of the FD&C Act, we disagree. We are not relying on those provisions as authority for the records requirements. In enacting section 805, we believe that Congress intended to provide FDA with a type of records

authority that is specific to the FSVP context. Consistent with that intent, we conclude that it is appropriate for the FSVP records provisions in this rule to differ from certain other Agency records provisions. We believe this is appropriate in light of the nature and purpose of FDA record review for the FSVP regulation. Our review of importers' FSVP records serves a distinct purpose from review of a manufacturing/processing facility's records in the context of an onsite inspection of activities at the facility. Importers do not necessarily manufacture, process, pack, or hold food. Instead, they must conduct activities to verify the food safety practices of their suppliers. The FSVP regulation requires that those verification activities be appropriately documented and that records be adequately maintained. Our enforcement of FSVP therefore ordinarily will not hinge on the observation of manufacturing/processing, packing, and holding activities. Rather, it ordinarily will be based on whether importers have conducted adequate verification activities, documented those activities, and maintained appropriate records. The nature of the FSVP requirements therefore allows us to more easily determine compliance by reviewing records. Thus, while several comments refer to being able to put records into context at a manufacturing location, § 1.510 refers only to the importer's FSVP records, and there might not be a manufacturing location to inspect for purposes of assessing FSVP compliance.

The fact that Congress did not intend to limit FSVP records requests to the context of onsite inspections is evidenced by comparing section 805(d) to other FD&C Act records provisions that clearly contemplate onsite inspections. For example, section 414(a)(2), which applies in certain circumstances involving use of or exposure to food of concern, specifies that each person to which the section applies "shall permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article . . . ." This is in contrast to the language in section 805(d), which states that FSVP records "shall be made available promptly to a duly authorized representative of the Secretary upon request." Notably, section 805(d) differs from section 414(a)(2) in that it does not refer to copying records, providing

access at reasonable times, or the presentation of credentials—all of which suggest that any records request be preceded by, or be part of, an onsite inspection. In contrast to the language in section 414(a)(2), the language in section 805(d) leaves flexibility regarding the conditions under which FSVP records requests are made.

In addition, section 808(c)(3)(B) regarding accredited third-party audits has a records provision distinct from that for FSVP, requiring accredited third-party certification bodies to “submit to the Secretary” regulatory audit reports and associated documents required under the third-party program. While one comment regards this as evidence that this is the only provision under which FSMA granted “remote records” access, we conclude that this language reflects the nature of audits conducted in accordance with the third-party certification rule and the fact that such audits are conducted by entities other than FDA, thus creating the practical necessity for regulatory audit reports to be submitted to FDA. It does not in any way suggest that Congress did not intend to authorize FDA to review FSVP records electronically or through other prompt means.

In addition, we believe that our records requirements are consistent with section 805(c)(2)(B), which provides that the FSVP regulations must include other requirements as we deem necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold in the United States. Providing records to us electronically or otherwise promptly upon our written request will help ensure that imported food is as safe as domestically-produced food because it will enable us to more efficiently review importers’ FSVP records. More efficient review of FSVP records will allow us to review more FSVP records than would otherwise be possible, which will help us ensure that more importers are importing food that meets U.S. food safety standards. More efficient review of records also will allow us to identify importers that have adequate FSVP records, as well as those that do not. Consequently, our review of FSVP records will help us target our inspection resources towards those importers that present a greater risk to food safety because their records are inadequate and/or raise concerns about compliance with other FSVP requirements. Conversely, our review of records will help us determine which importers present a lower risk because they have adequate records, therefore lessening the need for follow-up inspection. Importers we identify as

lower risk will therefore be less likely to be burdened by an FDA inspection.

The comments’ references to inconsistency with records requirements outside of FSMA, such as section 704 of the FD&C Act and the HACCP regulations, are similarly misplaced. We are not relying on our authority under section 704 to require access to FSVP records. That provision lays out the general parameters for an inspection of a “factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction.” Because FSVP importers do not necessarily manufacture, process, pack, or hold food, section 704 is not necessarily applicable to an FSVP importer and, unlike section 805(d), was not specifically designed to apply to access to records maintained as part of the FSVP program. Further, unlike a facility inspection, where a critical component of the inspection may be viewing the physical plant and observing the conditions in person, we often can evaluate an FSVP importer entirely by reviewing the records that the importer provides to us. Further, the HACCP regulations, like the preventive controls regulations, concern the control of hazards, and viewing records in the context of an onsite inspection of the HACCP processing facility where the actions described in the records occur is similarly important.

(Comment 263) Several comments contend that reviewing records remotely would constitute a significant change from current FDA practice of reviewing records onsite during inspections of regulated entities. The comments maintain that the Agency could not adequately understand importer records except in the course of an onsite inspection, when company experts can answer questions and records can be viewed in the context of the importer’s facility and operations. Some comments express concern that we might make unreasonable and burdensome demands for records, and that the requirement would create the potential for inadvertent disclosure of confidential commercial information and security breaches (including the potential for terrorist acts). One comment states that the proposed provision would essentially require importers to maintain all records electronically, which would be overly burdensome to small businesses. Some comments state that maintaining records submitted electronically would impose a significant burden on FDA. Some comments contend that the proposed

requirement would create the potential for fraud because unscrupulous companies might submit fraudulent records to the Agency.

(Response 263) We disagree with these comments. As previously discussed, the context of record review for the purposes of determining an importer’s compliance with the FSVP regulation can be quite different from a facility inspection. In many cases, depending on the type of importer, we might find that it is more appropriate to perform onsite record inspection, where an FDA official can have in-person, back-and-forth discussions with the importer, and § 1.510(b)(1) and (b)(2) contemplate this type of record review. But § 1.510(b)(3) allows the importer and FDA to avoid the burden of performing that onsite record inspection if it does not make sense given the context. For example, an importer who maintains all records electronically and travels between ports of entry without a traditional “facility” might benefit from the flexibility of being able to demonstrate compliance with FSVP by making records available to us electronically. We also disagree that importers will not be able to provide sufficient and appropriate context for records submitted electronically. Nothing prevents importers from providing explanatory information to accompany requested records or discussing the request by email or telephone. Moreover, because FSVP records will not necessarily address manufacturing/processing, packing, or holding activities that take place at the entity being inspected, we believe that the potential benefits of reviewing FSVP records onsite would be reduced.

We understand concerns that unreasonable demands for records might adversely affect both importers and the Agency. Our need to use our enforcement resources in a risk-based, efficient manner provides incentive for us to limit our requests to those records that will provide sufficient information about an importer’s level of compliance with the FSVP regulation. Targeting our record requests in this way should minimize the burden of these requests on individual importers and avoid unnecessary expenditure of Agency resources, enabling us to evaluate more importers for FSVP compliance.

We do not agree that it would be more likely for importers to maintain or submit fraudulent records if the records are submitted electronically. There have been times when we have encountered fraudulent records located at physical facilities. Although we understand concerns about the security of data submitted electronically to the Agency,

as well as concerns about confidential commercial information and terrorism, we will take appropriate steps to secure communications with importers and to protect any data we receive, whether submitted electronically or otherwise.

We agree with the comment stating that small businesses should not be forced to maintain electronic records, as this might be a disproportionate burden on these importers. For that reason, and to provide more flexibility in the review of records under the FSVP regulation, importers will not be required to provide records electronically to FDA. The final rule allows all importers, regardless of size, to either provide requested records electronically to us or use another means that delivers the records promptly. Therefore, there is no burden on small importers to maintain or make their records available electronically; they will be in compliance as long as they are able to send their records promptly.

#### 4. Records Retention

Under proposed § 1.510(d), we proposed a two-part approach to the requirements for the length of time that records must be retained. For records that would be created and used for an extended or indefinite period, such as the hazard analysis that an importer conducts for a food or the procedures that an importer uses to determine appropriate supplier verification activities, we proposed that records be retained until at least 2 years after use of the records was discontinued (e.g., because the importer no longer imported a particular food, no longer used a particular foreign supplier, or changed its FSVP procedures). For certain records that involved documentation of the implementation of procedures and determinations, such as the performance of supplier verification activities, corrective actions, and FSVP reassessments, we proposed that records be retained for a period of at least 2 years after the records were created or obtained (with certain exceptions). We stated that these proposed requirements were consistent with section 805(d) of the FD&C Act, which requires that FSVP records be maintained for a period of not less than 2 years.

(Comment 264) One comment maintains that some sections of the proposed regulation were not mentioned as having a records retention requirement and asks that we clarify the requirements. Some comments maintain that having two separate record retention specifications would be unnecessarily complicated and confusing. Instead, the comments suggest having the regulation require

that all records be maintained for 2 years after use of the records is discontinued. One comment states that this approach would be consistent with FSMA. One comment suggests that the phrase “after their use is discontinued” be modified because “their” might be seen as referring to use of the foreign supplier or use of the records. If the former, according to the comment this would mean that all records regarding use of the supplier must be kept until 2 years after the supplier is no longer used. However, the comment suggests that “their” should refer to the records, which would mean that importers would be required to keep records 2 years after use of those records was discontinued.

(Response 264) We agree that referencing records retained in accordance with specific sections of the FSVP regulations was unnecessarily confusing. However, we conclude that it is appropriate to distinguish records that are created and remain in use for an extended time (e.g., records of procedures) from records that are created to document the performance of activities under established procedures and are not used on a continuing basis. Therefore, § 1.510(c)(1) of the final rule specifies that importers must retain FSVP records until at least 2 years after the importer creates or obtains the records. This requirement would apply, for example, to results of foreign supplier verification activities that the importer conducts (or obtains documentation of) and documentation of corrective actions taken. However, § 1.510(c)(2) states that importers must retain records that relate to their FSVP processes and procedures, including the results of evaluations and determinations the importer conducts, for 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, has reevaluated the risk posed by a food and the foreign supplier's performance, or has changed its supplier verification activities for a particular food and foreign supplier). In other words, if the importer continues to rely on certain records to meet an FSVP requirement more than 2 years after the records were created or obtained, the importer must retain those records for at least 2 years after their use is ultimately discontinued.

As stated previously, section 805(d) of the FD&C Act mandates that FSVP records be maintained for a period of not less than 2 years, and § 1.510(c) reflects this statutory timeframe. We note that some food products are stored for longer than 2 years before they are

exported (but after they leave the foreign supplier). In such cases, relevant supplier verification activities (e.g., onsite auditing) might occur long before the food is imported into the United States. Although not required by the final rule, it is good business practice for importers of these foods to retain the FSVP records for these foods at least until the foods are distributed in the United States.

As further discussed in section III.M.2 of this document, we conclude that it is necessary to include a specific requirement for records on which an importer relies to document its status as a very small importer (as defined in § 1.500) in accordance with § 1.512(b)(1) of the final rule. Therefore, § 1.512(b)(5)(iii)(C) specifies that records that an importer relies on during the 3-year period preceding the applicable calendar year to support its status as a very small importer must be retained for at least 3 years.

#### 5. Electronic Records

We did not specify requirements for the retention of electronic records in the proposed rule. However, we received several comments regarding the potential application of the requirements for electronic records in part 11 (21 CFR part 11) to FSVP records.

(Comment 265) Several comments ask that we not apply the part 11 requirements to FSVP records. Several comments maintain that requiring importers to comply with part 11 would be costly, burdensome, and discourage the use of electronic records without significantly benefitting public health. One comment states that most electronic systems currently used by importers do not meet the stringent requirements of part 11 and would need to be recreated or redesigned at considerable expense if importers were required to comply with part 11. Some comments note that FDA exempted from part 11 electronic records established or maintained to satisfy the requirements of the Bioterrorism Act records regulation (21 CFR 1.329(b)). Some comments suggest that, rather than require compliance with part 11, the FSVP regulation should include more simplified, practical requirements to have appropriate systems to ensure the integrity and security of electronic records.

(Response 265) We agree that it would be unnecessarily burdensome to require that FSVP records meet the requirements in part 11. Therefore, § 1.510(d) of the final rule states that records that are established or maintained to satisfy the FSVP

requirements and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. Section 1.510(d) further specifies that records that satisfy the FSVP requirements, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. Consistent with these provisions, we are making a conforming change in part 11 to specify in § 11.1(l) that part 11 does not apply to records required to be established or maintained under the FSVP regulation, and that records that satisfy the requirements of the FSVP regulation, but that also are required under other statutory provisions or regulations, remain subject to part 11.

Although FSVP records are not subject to part 11, we will expect importers to maintain a system for their electronic records to ensure that the records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

#### 6. Public Disclosure

In the proposed rule, we did not specify requirements regarding the public disclosure of records created and retained to meet FSVP requirements.

(Comment 266) Several comments request that the regulations include provisions to protect FSVP records from public disclosure. The comments maintain that FSVP records will contain much commercially sensitive information and information that terrorists could use to overcome an importer's or foreign supplier's food defense measures. Some comments assert that the regulation should regard all information about foreign suppliers as confidential commercial information by default. Some comments assert that viewing and redacting FSVP records would overburden FDA FOIA staff and result in inadvertent disclosure of trade secrets and confidential information. Several comments ask that the regulation specify that FSVP records have the same level of protection from public disclosure under FOIA as juice and seafood HACCP records (which, under §§ 120.12(f) and 123.9(d), are exempt from disclosure unless previously disclosed or the records relate to a product or ingredient that has been abandoned and the records no longer represent a trade secret or confidential commercial or financial information). One comment states that it prefers the HACCP disclosure language to the provision included in the proposed regulation on preventive controls for human food, which

specifies that records are subject to the disclosure requirements in part 20.

(Response 266) We agree that many FSVP records retained by importers will contain confidential commercial information and trade secrets that will be exempt from public disclosure under current law. Therefore, § 1.510(f) of the final rule specifies that records obtained by FDA pursuant to the FSVP regulation are subject to the disclosure requirements under part 20. This means, for example, that certain information in records such as evaluations of foreign supplier performance and the results of onsite audits of suppliers likely would be exempt from disclosure under FOIA because, under § 20.61(b), such information is likely to be regarded as commercial or financial information that is privileged or confidential that is submitted or divulged to FDA and therefore not available for public disclosure under § 20.61(b) and (c).

We conclude that it is not necessary to use the disclosure provision contained in the HACCP regulations. The regulations in part 20 regarding public information apply to all Agency records, regardless of whether a particular recordkeeping requirement says so. In the case of the recordkeeping requirements for our HACCP regulations for juice and seafood, we framed the public disclosure provisions by providing specific details about how particular provisions in part 20 (*i.e.*, § 20.61 (concerning trade secrets and commercial or financial information which is privileged or confidential) and § 20.81 (concerning data and information previously disclosed to the public)) would apply to the applicable records because we recognized that such details were of particular interest to the regulated industries. In the case of the recordkeeping requirements for this rule, we framed the provisions regarding public disclosure by more broadly referring to all the requirements of part 20, consistent with our approach in the recently issued preventive controls regulations. For example, provisions such as § 20.20 (concerning the policy on disclosure of FDA records) apply to all records that we have in our system, including HACCP records, even though the HACCP regulations do not specify that this is the case.

(Comment 267) Several comments request that we train our investigators and staff regarding FSVP information that is confidential commercial information or trade secrets and therefore should be protected from disclosure under the FOIA.

(Response 267) We agree. We intend to include disclosure issues in the FSVP training that we will provide to Agency

investigators. We will evaluate the training currently provided to our FOIA personnel and, if necessary, make modifications to address FSVP records.

#### 7. Relationship to Records Required Under Customs Regulations

(Comment 268) One comment asks whether any FSVP documents are considered "A1A" documents that must be maintained under CBP regulations, specifically 19 CFR 163.5(b)(2).

(Response 268) We encourage the commenter to contact CBP about whether and under what circumstances CBP regulations apply to FSVP documents.

(Comment 269) One comment asks whether FSVP documents will need to be accessible by entry number.

(Response 269) Documents that importers create and maintain to meet FSVP requirements, such as hazard analyses, evaluations of the risk posed by food and of foreign supplier performance, and documentation of supplier verification activities, will not have to be linked to a particular entry number for an imported food. However, FDA investigators might refer to entry documents for particular food products when requesting records concerning such products during an inspection to assess an importer's compliance with the FSVP requirements. (Comment 270) One comment recommends that FDA collaborate with CBP on the portion of the FSVP guidance that addresses importer identification at entry.

(Response 270) We intend to work with CBP on implementing the importer identification at entry provisions. We also intend to consult with CBP as appropriate in drafting FSVP guidance on compliance with these requirements.

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

We proposed to adopt modified FSVP requirements for dietary supplements and dietary supplement components in § 1.511 of the proposed rule. We noted that facilities making these foods are exempt from the preventive controls requirements in section 418 of the FD&C Act when the facilities are in compliance with statutory provisions concerning dietary supplement CGMP requirements (section 402(g)(2) of the FD&C Act) and adverse event reporting (section 761 of the FD&C Act (21 U.S.C. 379aa-1)). We stated that the proposed FSVP requirements for dietary supplements and dietary supplement components reflected the food safety regulations applicable to those products (*i.e.*, the dietary supplement CGMP regulation in part 111 (21 CFR part 111)), rather than focusing on

verification of hazard control, as we had proposed under the “standard” FSVP requirements.

#### 1. Dietary Supplements for Further Processing

We proposed certain limited FSVP requirements for dietary supplements and dietary supplement components that will undergo further processing by the importer or its customer in accordance with certain dietary supplement CGMP regulations. We did this because we believe that the dietary supplement CGMP regulation, through its specification requirements, contains provisions that already require supplier “verification” tailored to dietary supplements. Specifically, these provisions require a dietary supplement manufacturer to verify that the ingredients they are using are identified properly, have the appropriate purity, strength, and composition, and do not contain contaminants that adulterate or can lead to adulteration of the dietary supplement. Therefore, imposing additional verification requirements under the FSVP regulation would be redundant and unnecessary.

Under proposed § 1.511(a), if an importer was required to establish specifications under § 111.70(b), (d), or (f) of the dietary supplement CGMP regulation with respect to a food and the importer was in compliance with the regulations for determining whether the specifications had been met, the only FSVP requirements that the importer would have to meet would be those concerning identification of the importer at entry and recordkeeping. Section 111.70(b), (d), and (f) concern specification requirements for (1) dietary supplement components, (2) dietary supplement labels and packaging that may come into contact with dietary supplements, and (3) products received for packaging or labeling as a dietary supplement and subsequent distribution, respectively.

We proposed (in § 1.511(b)) similar requirements for importers whose customer was required to establish such specifications and was in compliance with the regulations for determining whether the specifications were met, except that the importer also would be required to annually obtain written assurance that the customer was in compliance with those requirements. We tentatively concluded that these specification and verification provisions in the dietary supplement CGMP regulation would provide adequate assurances that the foreign supplier of the dietary supplement or dietary supplement component produced the food in compliance with the FD&C Act.

We also proposed that importers of dietary supplements and dietary supplement components acting in accordance with § 1.511(a) or (b) would not be subject to the proposed requirement to use a qualified individual to perform FSVP activities. As discussed in section III.D of this document, we conclude that it is appropriate to require these importers to use a qualified individual to perform the tasks required under these provisions.

Several comment express support for the proposed modified approach for dietary supplements and dietary supplement components under proposed § 1.511(a) and (b). However, as discussed in the following paragraphs, some comments suggest changes to the proposed requirements and some request that the FSVP regulation not include these requirements. In the final rule, we have removed the reference to § 111.70(f), as discussed in response to those comments in the following paragraphs.

(Comment 271) One comment suggests that, instead of referring to a “food” that is imported, § 1.511(a) and (b) should refer to a “food that is a dietary supplement or dietary supplement component . . . import[ed] for further manufacturing, processing, packaging, and/or labeling as a dietary supplement.”

(Response 271) We agree and have revised § 1.511(a) and (b) of the final rule accordingly, except that we have not included the suggested reference to labeling, consistent with our deletion of the reference to § 111.70(f) from those provisions.

(Comment 272) One comment objects to exempting from most FSVP requirements importers of dietary supplement components that are determined to meet specifications established by the importer in accordance with § 111.70(b). The comment maintains that conformance to specifications under § 111.70(b) would not provide adequate assurance that the component was in compliance with part 111 and not adulterated. The comment requests that importation of such dietary supplement components be subject to the standard FSVP requirements for conventional food.

(Response 272) We do not agree. Section 111.70(b) of the dietary supplement CGMP regulation and the requirements in §§ 111.73 and 111.75 applicable to determining whether those specifications are met are intended to ensure that:

- A component used in the manufacture of a dietary supplement has the proper identity;

- A dietary supplement manufactured using the component has the appropriate purity, strength, and composition; and
- The limits on the types of contamination that may adulterate or lead to adulteration of a finished batch of a dietary supplement are not exceeded.

To import a dietary supplement component in accordance with § 1.511(a) of the final rule, the manufacturer of a dietary supplement using an imported component will be required to determine whether the specifications for the component that the manufacturer has established under § 111.70(b) are met in accordance with §§ 111.73 and 111.75. We conclude that compliance by the importer/manufacturer with these CGMP specification provisions would provide adequate verification that the imported dietary supplement component was produced in accordance with the relevant CGMP requirements. We also note that, in addition to determining whether specifications for the dietary supplement component are met in accordance with §§ 111.73 and 111.75, the manufacturer of the dietary supplement using the imported component must comply with all other applicable CGMP requirements in producing the dietary supplement.

On our own initiative, to provide clarity we have added to the regulation references to the specific CGMP provisions (*i.e.*, §§ 111.73 and 111.75) concerning determination of whether established specifications are met for an imported dietary supplement or dietary supplement component.

(Comment 273) One comment objects to exempting from most FSVP requirements importers of dietary supplements for whose labels or packaging the importer has established specifications in accordance with § 111.70(d) and determines whether the specifications are met. The comment finds the reference to § 111.70(d) confusing. The comment maintains that the reference might suggest that FDA regards labels and packaging as food; if this is the case, the comment does not believe that confirming that those materials meet specifications would provide adequate assurance of their safe manufacture. On the other hand, the comment asserts that if the Agency does not regard labels and packaging as food, the reference to § 111.70(d) is misplaced because confirming that labels or packaging met specifications would not provide adequate assurance that the imported food was produced in compliance with U.S. law. The comment states that we should not

consider labels and packaging to be food and asks that we delete the reference to § 111.70(d) from proposed § 1.511(a) and (b).

(Response 273) We do not agree with the comment that the reference to § 111.70(d) in § 1.511(a) and (b) is inappropriate. Section 111.70(d) is relevant to the extent that it covers packaging that may come in contact with dietary supplements. The definition of food under the FSVP regulation includes food contact substances and § 111.70(d) refers to establishing specifications for packaging that may come in contact with dietary supplements. Section 111.70(d) specifies that packaging that may come into contact with dietary supplements must be safe and suitable for its intended use and must not be reactive or absorptive or otherwise affect the safety or quality of the dietary supplement. This requirement makes the verification of specifications for these materials relevant for a dietary supplement manufacturer under § 1.511(a) and (b). The domestic manufacturer is responsible for appropriate labeling of the dietary supplement made from the imported component in accordance with its own obligations under part 111.

(Comment 274) Some comments oppose the proposed exemption from the standard FSVP requirements for importers of dietary supplements who, in accordance with § 111.70(f), establish specifications to provide assurance that the product they receive for packaging or labeling (such as bulk capsules or tablets) is adequately identified and is consistent with the purchase order, and who determine whether these specifications are met. The comments maintain that this provision would be inconsistent with FDA's statement, in the preamble to the final rule on dietary supplement CGMP (see 72 FR 34752 at 34851, June 25, 2007), that a firm that only packages and labels a product may rely on information about the content of the product that it receives from the manufacturer. The comments assert that under proposed § 1.511(a), an importer that packages or labels an imported dietary supplement would have no obligation to verify that the imported dietary supplement was produced in compliance with part 111. One of the comments contends that retaining the reference to § 111.70(f) in proposed § 1.511(a) and (b) would incentivize dietary supplement manufacturers to use foreign manufacturing followed by domestic labeling or packaging instead of having the complete manufacturing occur either inside or outside the United States.

(Response 274) We do not agree with the assertion in the comment that an importer that receives a dietary supplement from a supplier for packaging and labeling would not be obligated to verify that the imported dietary supplement was produced in compliance with part 111. We believe that this statement mischaracterizes the obligations that apply to a firm that packages and/or labels a finished dietary supplement to which § 111.70(f) applies. Section 111.70(f) applies when the product received by the packager or labeler has left the control of the person who manufactured the product. Although the packager/labeler does not manufacture the product, it is responsible for ensuring that the product it places into interstate commerce is not adulterated (see sections 402(g) and 301(a) of the FD&C Act). The specifications that a packager/labeler would establish under § 111.70(f) must provide sufficient assurance that the received finished dietary supplement product is adequately identified and is consistent with the purchase order (see 72 FR 34752 at 34844 to 34845). The level and nature of information a packager/labeler requires as "sufficient assurance" under § 111.70(f) may vary based, for example, on the finished dietary supplement and the supplier from which it is received.

The verification activities that a packager/labeler might conduct in accordance with § 111.70(f) may not need to include, for a given supplier, verification that the manufacturer of the dietary supplement complied with all applicable requirements related to the manufacture of a finished dietary supplement. However, the verification requirements contemplated by section 805 of the FD&C Act would require that level of verification of the manufacturer. Specifically, section 805(a)(1) of the FD&C Act requires importers of dietary supplements, like importers of all foods, to perform risk-based foreign supplier verification activities for the purpose of verifying that the food they import is not adulterated under section 402. For importers of dietary supplements, this means that they are required to perform supplier verification activities for the purpose of verifying that the dietary supplements they import are in compliance with section 402(g), which deems dietary supplements adulterated if they fail to meet the CGMP requirements established in part 111.

Given this potential difference in required verification activities, we conclude that it is not appropriate to apply the modified requirements in § 1.511(a) and (b) of the final rule to importers of dietary supplements who

establish (or whose customers establish) specifications under § 111.70(f) and ensure they are met. Instead, firms who import dietary supplements for packaging and labeling in the United States (by themselves or their customers) will need to comply with § 1.511(c) and verify that the imported product was produced in compliance with the applicable requirements of part 111 for the manufacture of the dietary supplement. These importers may be able to use documentation provided under § 111.70(f) (as well as §§ 111.73 and 111.75 regarding determination that specifications are met) to fulfill some of the requirements under § 1.511(c) (e.g., regarding the performance of supplier verification activities).

(Comment 275) Two comments request that we broaden proposed § 1.511(a) and (b) to include not just importers that are subject to, and in compliance with, the specified dietary supplement CGMP requirements, but also importers that are not required to comply with those requirements in manufacturing certain products but voluntarily do so. The comments maintain that some facilities that are not subject to part 111 choose to comply with the requirements in that part for various reasons (e.g., a facility that manufactures only dietary ingredients but does so in compliance with part 111 at the request of their customer or at FDA's recommendation). Therefore, the comments ask that we revise proposed § 1.511(a) and (b) to include importers who voluntarily comply with § 111.70(b), (d), or (f).

(Response 275) We decline this request. Attempting to enforce compliance with the dietary supplement CGMP regulation by firms that are not legally required to comply with the regulation could present problems for the Agency if we sought to take an enforcement action against an importer for failure to comply with § 1.511(a) of the final rule because we determined that the importer was not in compliance with § 111.70(b) or (d).

(Comment 276) One comment objects to the requirement in proposed § 1.511(b) that an importer of a dietary supplement or dietary supplement ingredient obtain written assurance of compliance when the importer's customer is required to establish specifications under § 111.70(b), (d), or (f) and the customer is in compliance with the requirements for determining whether the specifications are met. The comment maintains that the written assurance requirement would impose a significant burden on importers (because importers might have hundreds or even thousands of

customers) without protecting public health because importers would not be in a position to audit their customers or otherwise confirm their compliance with part 111. The comment suggests that the exemption from most of the FSVP requirements under proposed § 1.511(b) should apply if either of the following occurs:

- The importer annually obtains written assurance of its customer's compliance with § 111.70(b), (d), or (f) (as applicable); or
- The importer verifies (such as through publicly available information) that its customer manufacturers, packages, and/or labels dietary supplements and the importer provides a disclosure in labels or commercial documentation accompanying the dietary supplement or dietary supplement component stating that the food was not imported under the standard FSVP requirements and is intended only for use in the manufacture, processing, packaging, or labeling of dietary supplements in compliance with part 111 (except as may be allowed under the customer's food safety plan).

(Response 276) We decline to make the suggested change. We acknowledge that obtaining written assurance from the customer of compliance with the applicable specification requirements would provide less definitive assurance of the customer's compliance than some other measures (such as onsite auditing or review of records); however, annually obtaining the assurance would necessitate the importer's ongoing consideration of its customer's compliance status. On the other hand, the disclosure to the customer suggested by the comment likely would not communicate any additional information to the customer that the customer would not already have learned through providing the required assurance.

## 2. Other Importers of Dietary Supplements

For finished dietary supplements (packaged and labeled dietary supplements that will not be subject to further processing) and other dietary supplements not subject to proposed § 1.511(a) and (b), we proposed to establish FSVP requirements that were similar to the proposed "standard" FSVP requirements applicable to most imported foods. Under proposed § 1.511(c), if a dietary supplement was imported other than in accordance with proposed § 1.511(a) or (b), the importer would not be required to comply with the standard FSVP requirements concerning hazard analysis but it would

be required to comply with requirements concerning the following:

- Use of a qualified individual (proposed § 1.503);
- Evaluation of risks (except hazard analysis) (proposed § 1.505(a)(2) through (6) and (b));
- Certain supplier verification activities, including use of approved foreign suppliers, establishment of written procedures, and determination and performance of appropriate verification activities to provide adequate assurances that the foreign supplier produced the dietary supplement in compliance with part 111 (proposed § 1.511(c)(2) through (8));
- Complaint review, investigations, corrective actions (proposed § 1.507);
- FSVP reassessment (proposed § 1.508);
- Identification of importer at entry (proposed § 1.509); and
- Recordkeeping (proposed § 1.510).

The comments generally support the proposed FSVP requirements for finished dietary supplements and other dietary supplements not imported in accordance with proposed § 1.511(a) or (b). We respond to comments on these requirements in the following paragraphs. We also discuss the changes that we have made to these requirements in accordance with several changes to the standard FSVP requirements discussed previously in this document and the updated references to these other sections (and, as previously discussed, this provision now includes dietary supplements imported for packaging and labeling in the United States). Section 1.511(c)(1) of the final rule states that if the food imported is a dietary supplement and neither § 1.511(a) or (b) is applicable, the importer must comply with § 1.511(c) and the requirements in §§ 1.503, 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d), and 1.508 through 1.510, but is not required to comply with the requirements in §§ 1.504, 1.505(a)(1)(i), 1.506, and 1.507. In addition to the changes discussed in the following paragraphs, we have made minor wording changes to several subsections.

### a. Evaluation for Supplier Approval and Verification

Proposed § 1.511(c)(1) specified that importers of finished dietary supplements would be required to comply with the requirements in proposed § 1.505 related to consideration of the entity that will control the hazards in a food and evaluation of the foreign supplier's performance (but not evaluation of the risk posed by a food, *i.e.*, the hazard

analysis). The applicable provisions of § 1.505 are now § 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d) rather than § 1.505(a)(2) through (6) and (b). The changes that we have made to § 1.505(a) concerning the factors for the entity controlling the hazards and foreign supplier performance, discussed in section III.F.1 of this document, are also applicable to importers of finished dietary supplements under § 1.511(c)(1) of the final rule.

### b. Corrective Actions

Proposed § 1.511(c)(1) specified that importers of finished dietary supplements would be required to comply with the requirements in proposed § 1.507, including those concerning review of complaints, investigations, corrective actions, and modification of the FSVP (when necessary). As discussed in section III.I of this document, the section of the regulation regarding corrective actions, § 1.508 of the final rule, does not require importers to review complaints or conduct investigations into possible adulteration, and includes certain changes to the corrective action requirements. Finished dietary supplement importers will need to comply with these final provisions of § 1.508.

### c. Identification of Importer at Entry

As discussed in section III.J of this document, we have revised the requirements related to importer identification at entry in § 1.509 of the final rule; these changes apply to the importation of finished dietary supplements under § 1.511(c)(1).

### d. Recordkeeping

As discussed in section III.K of this document, we have revised several recordkeeping requirements in § 1.510 of the final rule; these changes apply to the importation of finished dietary supplements under § 1.511(c)(1) of the final rule.

### e. Use of Approved Foreign Suppliers

Section 1.511(c)(2) of the final rule finalizes the proposed requirement to establish and follow written procedures to ensure the importation of dietary supplements from approved foreign suppliers (and in limited circumstances from unapproved suppliers) and codifies the requirements taken from revised § 1.506 that allow an entity other than the finished dietary supplement importer's foreign supplier to establish and follow such procedures, provided the importer reviews and assesses the other entity's procedures and activities (see the discussion of



these matters with respect to foods other than dietary supplements in section III.G.1 of this document).

#### f. Determination of Appropriate Foreign Supplier Verification Activities

Section 1.511(c)(4) of the final rule finalizes the requirement (in proposed § 1.511(c)(5)) to determine appropriate foreign supplier verification activities before importing a dietary supplement from a foreign supplier, as well as the frequency with these activities must be conducted. (We deleted the separate reference to the “purpose” of supplier verification activities stated in proposed § 1.511(c)(4)—*i.e.*, to provide adequate assurances that the foreign supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111—and added it to the provision requiring determination of appropriate supplier verification activities (§ 1.511(c)(4) of the final rule.) Section 1.511(c)(4) specifies that this determination must be based on the evaluation conducted under § 1.505, lists the possible appropriate verification activities, and permits the importer to rely on a determination of appropriate verification activities made by an entity other than the foreign supplier, provided the importer reviews and assesses the entity’s determination (see the discussion of these matters with respect to foods other than dietary supplements in section III.G.4 of this document).

#### g. Performance of Foreign Supplier Verification Activities

Section 1.511(c)(5) of the final rule finalizes the proposed requirement to conduct verification activities for foreign suppliers of finished dietary supplements. Among the changes to the verification activity provisions that match changes to proposed § 1.506 are the following:

- Section 1.511(c)(5)(i)(A)(2) specifies that when the foreign supplier of a dietary supplement is in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, an onsite audit of the supplier may consider the relevant laws and regulations of that country instead of the requirements of part 111.

- Section 1.511(c)(5)(i)(A)(3) specifies that if an onsite audit of a foreign supplier of a dietary supplement is conducted solely to meet the FSVP supplier verification requirements by an audit agent of a certification body accredited in accordance with FDA’s regulations on the accreditation of third-

party certification bodies, the audit itself is not subject to the requirements for audits conducted under those regulations.

- Section 1.511(c)(5)(i)(A)(5) broadens the scope of inspections on which an importer of a dietary supplement may rely instead of an onsite audit of the foreign supplier to include appropriate inspections for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal agencies (such as the USDA), and representatives of State, local, tribal, or territorial agencies, in addition to 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 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 (see the discussion of these provisions with respect to foods other than dietary supplements in section III.N of this document).

(Comment 277) One comment suggests that, instead of allowing an importer to rely on the results of an inspection of a 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, the importer should be allowed to rely on the results of such an inspection conducted within “approximately” 1 year of when the audit would have been required. The comment maintains that it is not always possible to obtain audit documentation within an annual timeframe (asserting that it might take several weeks or more to obtain an updated certificate of compliance following completion of an audit).

(Response 277) We decline to make this change. We are concerned that extending beyond 1 year the time period for which an importer could rely on inspection results would substantially weaken the likelihood that those results would accurately reflect the foreign supplier’s current state of compliance with applicable regulations and therefore diminish the assurance of food safety that such inspection results might provide.

- Section 1.511(c)(5)(i) includes other relatively minor changes to the requirements for documentation of foreign supplier verification activities.

- Under § 1.511(c)(5)(ii) and (iii) of the final rule, an importer of a dietary supplement may rely on supplier verification activities conducted by an entity in its supply chain provided that it reviews and assesses the results of those activities. However, the importer may not rely on the foreign supplier to conduct these activities except with respect to sampling and testing of a dietary supplement.

#### h. Verification of Customers and Other Subsequent Entities

Section 1.507 of the final rule contains provisions regarding verification when an importer imports a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation. Section 1.511(c)(1) states that this section does not apply to dietary supplements. This is because § 1.507 is based on the hazard analysis performed by importers. Specifically, importers can only avail themselves of the distribution chain provisions in § 1.507 if they identify the specific hazards that require control, thus enabling them to ensure either that the food could not be consumed without the application of an appropriate control or that the hazard will be appropriately controlled after importation. Because the FSVP regulation does not require hazard analysis by importers of dietary supplements, the provisions of § 1.507 are not suitable for dietary supplements.

(Comment 278) One comment suggests that if we do not delete the proposed requirement to obtain written assurance from customers subject to certain dietary supplement CGMP requirements under proposed § 1.511(b), then proposed § 1.511(c) should specify that the requirements under that paragraph, rather than the standard FSVP requirements, will apply when an importer is “unable to obtain the required written assurance” from the customer.

(Response 278) Although we agree with the comment that an importer of a dietary supplement or dietary supplement component that fails to obtain written assurance from its customer in accordance with § 1.511(b) of the final rule would be subject to the requirements in § 1.511(c), we conclude that it is not necessary to change § 1.511(c) as requested. The FSVP draft guidance will reiterate that when a dietary supplement is imported and neither § 1.511(a) nor (b) is applicable (including because the importer elects not to annually obtain the appropriate written assurance from its customer), the importer must comply with § 1.511(c).

### 3. Mixed-Use Food/Drug Ingredients

(Comment 279) One comment asks that we exempt from the preventive controls regulations certain ingredients that are used in the manufacture of both food and drugs, and also asks that we establish separate modified FSVP requirements for these ingredients. The comment states that there are many ingredients that are used in the United States as conventional foods, dietary supplements, and drugs, and many ingredients that can be used as drugs in foreign countries but only as foods in the United States. The comment maintains that if an ingredient is made in compliance with the United States Pharmacopeia (USP)/National Formulary (NF) or other official monographs and internationally recognized drug CGMP standards, it would be superfluous for the facility to be required to comply with proposed subparts B and C of the regulation on preventive controls for human food (proposed part 117). (The comment suggests that we include in the preventive controls regulation a definition of “monograph ingredient,” defined as an ingredient that is allowed for food use in the United States, meets certain criteria related to compliance with certain official monographs, and is manufactured in accordance with certain pharmaceutical CGMP standards or guidelines.) The comment asserts that because the construction, equipment, recordkeeping, training, and quality control operations of an establishment making a “monograph ingredient” will already be conducted in a manner that meets or exceeds the standards for CGMP in subpart B of part 117, it would be unnecessary to require the establishment to comply with that subpart. The comment also asserts that hazard analysis and preventive controls requirements in subpart C of part 117 also should not apply to monograph ingredients because official monographs and pharmaceutical CGMPs already provide preventive controls for harmful contaminants in these ingredients.

The comment also requests that we establish separate modified FSVP requirements for monograph ingredients. These modified requirements, which would be mandatory for monograph ingredients used as a conventional food and optional for monograph ingredients used as a dietary supplement or dietary supplement component, would be tailored toward providing adequate assurances that the food is in compliance with the applicable monograph and/or that the monograph ingredient was produced in accordance

with the requirements of the applicable pharmaceutical CGMP standards.

The comment asserts that requiring manufacturers of “monograph ingredients” to comply with the preventive controls regulation and failing to adopt the comment’s suggested modified FSVP requirements for these ingredients would be inconsistent with U.S. obligations under WTO agreements. The comment also maintains that the suggested modified FSVP provisions would be consistent with the intent of Congress because they would help ensure that imported food is as safe as food produced in the United States and they take into account differences among types of imported food and their level of risk.

(Response 279) We are not responding to the comments suggesting revision of the proposed regulation on preventive controls for human food as those comments are beyond the scope of this rulemaking. We decline to establish separate FSVP requirements for “monograph ingredients” as defined by the comment. We do not believe that the proposed definition of “monograph ingredient” is feasible given its references to multiple and in some cases unspecified official monographs and CGMP standards and guidelines. In addition, because the FSVP regulation applies to importers of food, we conclude that it would not be appropriate to establish FSVP provisions that would require importers of certain products to conduct activities to provide assurances that the food is specifically in compliance with a pharmaceutical monograph and/or that the foreign supplier was in compliance with certain pharmaceutical CGMP requirements.

Importers of ingredients that are dietary supplements will be required to comply with § 1.511(c) of the final rule; importers of such ingredients that are dietary ingredients will be required to comply with the “standard” FSVP requirements. However, in either case, importers might be able to rely on records regarding conformance to a foreign country’s drug standards or compliance with a foreign country’s drug regulations if such records also contain the information required under § 1.511(c) or the standard FSVP provisions (as applicable). Those requirements are for verification of the same level of public health protection as required under part 111, not strict compliance with the regulation. In our records provision in § 1.510(e), we state that an importer does not need to duplicate existing records it has (e.g., records retained to comply with other Federal, State, or local regulations) if

they contain all of the information required by the FSVP regulation, and that an importer may supplement any such existing records as necessary to include all of the required information. If, as the comment states, these products are produced at higher standards than the relevant FDA requirements, then it should not pose a significant burden to demonstrate that the relevant FDA standards are met using existing records.

With respect to the comment’s WTO-related assertion, we do not agree that our WTO obligations compel us to establish special FSVP requirements for producers of “monograph ingredients.” As we stated in the preceding paragraph, the FSVP requirements are to obtain assurances that the foreign supplier is producing food in compliance with processes and procedures that provide the same level of public health protection as required by the relevant FDA regulations. To the extent that the information regarding the production of foods in compliance with foreign pharmaceutical monograph specifications is relevant, importers may be able to use that information.

### 4. Dietary Supplements Regulated in Foreign Countries as Drugs

(Comment 280) One comment requests that we exempt from the dietary supplement CGMP regulation and subparts B and C of the preventive controls for human food regulation certain finished food products that are imported as dietary supplements but regulated as drug products in the countries in which they are manufactured. The comment also requests that we adopt separate modified FSVP requirements for these products. The comment proposes to call such products “foreign registered products,” which it proposes to define as products that are allowed for sale in the United States as dietary supplements and that meet the following criteria:

- The product is manufactured in a foreign jurisdiction and is registered as a drug product, medicine, therapeutic good, or natural health product by the government of that jurisdiction.
- The product complies with a standard setting forth required physical, chemical, and/or biological characteristics, including limits on any harmful contaminants likely to occur, such as a product registration, market authorization, or official monograph in a national pharmacopeia, codex, or formulary.
- The product is manufactured at a facility that is registered with FDA as a food facility and registered with the

government of the jurisdiction in which it is located, and the facility is regularly inspected for compliance with applicable CGMP requirements.

- The product is manufactured in accordance with one or more of several specified drug CGMP regulations or guidelines.

The comment states that many finished products imported into the United States as dietary supplements are regulated as drugs in their country of manufacture and generally must comply with an official monograph, product registration, or market authorization that sets forth required attributes, and must be manufactured under CGMP requirements. The comment contends that application of parts 111 and 117 (or equivalent foreign regulations) to suppliers of foreign registered products would pose a burden without any benefit because the standards and CGMPs applicable to these suppliers exceed the U.S. requirements for dietary supplements. The comment therefore maintains that importers of such products should have the option to verify the product against any applicable monograph, product registration, or market authorization and/or to verify the supplier's compliance with the applicable CGMP requirements, rather than its compliance with part 111 or 117 (or equivalent foreign regulations). The comment also asks that importers of foreign registered products be provided the option of complying with the FSVP requirements in proposed § 1.511 or complying with separate modified FSVP requirements tailored toward providing adequate assurances that the food is in compliance with the requirements of the applicable monograph, product registration, or market authorization and/or that the supplier is producing the product in accordance with the applicable CGMP requirements of the foreign jurisdiction.

The comment asserts that requiring manufacturers of "foreign registered products" to comply with the dietary supplement CGMP or preventive controls regulations, and failing to adopt the comment's suggested modified FSVP requirements for these products, would be inconsistent with U.S. obligations under WTO agreements. The comment also maintains that the suggested modified FSVP provisions for foreign registered products would be consistent with the intent of Congress because the provisions would help ensure that imported food is as safe as food produced in the United States and they take into account differences among types of imported food and their level of risk.

(Response 280) We decline to establish separate FSVP requirements for "foreign registered products" as defined by the comment for the reasons we stated in declining to adopt separate FSVP requirements for monograph ingredients. In particular, because the FSVP regulation applies to importers of food, we conclude that it would not be appropriate to establish FSVP provisions requiring importers of certain products to conduct activities to provide assurances that the food is in compliance with the requirements of an applicable pharmaceutical monograph, product registration, or market authorization and/or that the supplier is producing the product in accordance with the applicable drug CGMP requirements or guidelines. Importers of finished dietary supplements that are used as drugs in foreign countries will be required to comply with § 1.511(c) of the final rule. However, importers of such products might be able to rely on records of conformance to drug standards or compliance with other drug regulations if such records contain the information required under § 1.511(c) or the standard FSVP provisions (as applicable). In the FSVP draft guidance, we intend to address how importers of such products might use information related to foreign supplier compliance with drug monographs, product registrations, market authorizations, and drug CGMP regulations and guidelines to meet their FSVP requirements.

For the reasons stated in our response to the comment regarding "monograph ingredients," we do not agree that the failure to adopt the suggested modified FSVP requirements for so-called "foreign registered products" would be inconsistent with U.S. obligations under WTO agreements.

#### 5. Location of FSVP Regulations Applicable to Dietary Supplements

In the proposed rule, we sought comment on whether we should add the proposed foreign supplier verification requirements applicable to dietary supplements to the regulation on dietary supplement CGMP in part 111, rather than include them in the FSVP regulation in subpart L of part 1.

(Comment 281) Two comments support including the FSVP requirements for importers of dietary supplements in the FSVP regulation because they believe that the FSVP regulation should be comprehensive, but they suggest that the dietary supplement CGMP regulation include a reference to the FSVP requirements applicable to dietary supplement importers. Two comments suggest that

taking the opposite approach would facilitate clarity and compliance with the requirements for verification of foreign suppliers of dietary supplements.

(Response 281) We conclude that it is appropriate to locate the FSVP requirements applicable to importers of dietary supplements and dietary supplement components in the FSVP regulation in part 1, subpart L, in part because the requirements for the importation of finished dietary supplements in § 1.511(c) are very similar to the "standard" FSVP requirements and include cross-references to some of those requirements. However, we are adding, to § 111.5 in the dietary supplement CGMP regulation, a statement that importers of dietary supplements and dietary supplement components can find the FSVP requirements in part 1, subpart L.

#### *M. Very Small Importers and Importers of Food From Certain Small Foreign Suppliers (§ 1.512)*

In the proposed rule, we proposed modified FSVP requirements for importers that are very small importers and for importers of food from very small foreign suppliers. We proposed some changes to these modified requirements in the Supplemental Notice. An importer following the proposed modified requirements would still be subject to the requirements in §§ 1.502 (concerning the scope of an FSVP), 1.503 (concerning the use of qualified individuals), and 1.509 (concerning identification of the importer at entry), but it would not be required to comply with the proposed requirements in §§ 1.504 through 1.508 or § 1.510. This means that very small importers and importers obtaining 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.

Under the proposed modified requirements, an importer would need to obtain written assurance, before importing the food and at least every 2 years thereafter, that its foreign suppliers are producing food in compliance with the 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, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. The written assurance would be required to include a brief description of the processes and procedures that the foreign supplier is following to ensure

the safety of the food. An importer would be required to promptly take appropriate corrective actions, as necessary, maintain relevant records, and make those records available to FDA upon request.

#### 1. Modified Requirements for Very Small Importers and Importers of Food From Certain Small Foreign Suppliers

We received many comments both for and against the proposed modified FSVP requirements for very small importers and importers of food from very small foreign suppliers. As discussed in the following paragraphs, we conclude that it is appropriate to include in the final rule modified requirements for very small importers as well as for importers of food from certain small foreign suppliers. We are making changes to the proposed requirements in response to comments and to align with requirements applicable to the verification of certain suppliers of raw materials and other ingredients under the supply-chain program provisions of the preventive controls regulations.

(Comment 282) Some comments agree with the proposal to have modified requirements for very small importers and importers of food from very small foreign suppliers. The comments assert that applying special and fewer requirements to these entities would assist small businesses that create jobs and innovate without creating public health concerns. These comments argue that application of the detailed and technical requirements of the FSVP regulation would be overly burdensome for very small businesses given the administrative and related costs. Some comments state that FDA should recognize that the vast majority of recent foodborne illness-related public health incidents were caused by large U.S. companies, not small businesses or foreign suppliers of processed food.

Other comments object to the proposed modified requirements, asserting that food safety risks are not limited to any particular business size and that food produced by very small foreign suppliers or imported by very small importers could still be high risk. Some comments argue that no producer of food, whether foreign or domestic, should be exempt from good food safety practices. Some comments assert that inherent risk factors associated with smaller farms due to economic challenges increase the likelihood of food safety compliance problems. Some comments maintain that foods imported from very small operations have been the source of significant illness outbreaks in the past. One comment

points to spices in particular, arguing that a single very small supplier can have a huge negative effect on the food supply. Another comment argues that certain microbial contamination issues in imported food most likely would involve a very small importer or very small supplier. Some comments contend that the costs of outbreaks, including the costs associated with a loss of consumer confidence that are borne by firms not responsible for the outbreak, would be greater than the costs to very small foreign suppliers and very small importers of complying with the full FSVP requirements. Some comments assert that adopting FSVP requirements based on the size of the importer or foreign supplier, rather than the hazards in the imported food, might be inconsistent with international trade agreements.

Some comments express concern that a significant percentage of imported food would be eligible for the modified requirements under our proposed definitions of very small importer and very small foreign supplier. These comments cite the PRIA of the original proposal, which estimated that 59 percent of processed food suppliers and 93 percent of raw produce suppliers would fall under the very small foreign supplier category.

Some comments maintain that the modified requirements should only be adopted if very small producers in the United States are treated in the same way. Other comments state that the definitions of very small importer and very small foreign supplier should correspond with the definitions of similar terms in the preventive controls regulations to align the requirements, comply with WTO obligations, and avoid confusion.

(Response 282) We agree with three main concerns expressed by the comments on very small importers and importers of food from very small suppliers. First, we recognize that some very small entities might have great financial difficulty complying with this rule. Second, while we recognize that small entities are not immune from food safety problems, their operations typically involve a relatively low volume of food, which, in most cases, should reduce consumers' exposure to, and thus potential risk from, such food. We are not aware of data conclusively demonstrating that small or large firms are more likely to be responsible for foodborne illness outbreaks. Third, we agree that the scope of any modified FSVP requirements for very small entities should align with the scope of modified requirements under the supply-chain program provisions of the

preventive controls regulations, to the extent appropriate and feasible.

With respect to the comments concerning the consistency of the modified requirements with U.S. international obligations, we believe that the requirements are proportionate to the risk posed by food imported by or from these smaller entities but will still provide adequate assurances of the safety of the food, and therefore are consistent with our international trade obligations. We also conclude that aligning the FSVP and preventive controls regulations to the extent feasible and appropriate regarding food from small suppliers helps provide parity in supplier verification requirements for domestic and foreign food producers and is therefore consistent with the national treatment provisions in international trade agreements to which the United States is a party.

In response to comments, we are finalizing modified requirements for certain very small entities, but we are changing the scope of the entities to which the modified requirements will apply. As discussed in section III.A.23 of this document, we have changed the definition of very small importer to better align with the definitions of very small business under the regulations on preventive controls for human food and for animal food.

In addition, we are convinced by the comments to reconsider whether all food from "very small foreign suppliers" as we defined the term in the Supplemental Notice (*i.e.*, suppliers with less than \$1 million in annual food sales) should be eligible for modified requirements. We agree that making a large percentage of imported produce not subject to the full FSVP requirements by adopting such a definition would be concerning. We also recognize that the produce safety regulation excludes from coverage farms with \$25,000 or less in annual produce sales (while also providing for qualified exemptions in certain other circumstances), which is clearly a lower monetary ceiling than the proposed \$1 million ceiling for very small foreign suppliers.

In addition, we note that there is no analogous "very small supplier" category in the supply-chain program provisions of the preventive controls regulations. However, those regulations include modified supplier verification requirements (in §§ 117.430(c), (d), and (e) (for human food) and 507.130(c), (d), and (e) (for animal food)) applicable to raw materials or other ingredients from the following suppliers (both domestic and foreign):

- Qualified facilities;
- Farms that grow produce and are not covered farms under the produce safety regulation in accordance with § 112.4(a) (the farm has 3-year average annual produce sales of \$25,000 or less) or in accordance with §§ 112.4(b) and 112.5 (the farm satisfies the requirements for a qualified exemption under the produce safety regulation and associated modified requirements in § 112.6); and

- Shell egg producers not subject to part 118 because the supplier has fewer than 3,000 laying hens.

In each case, the underlying food safety regulations (*i.e.*, the regulations on preventive controls, produce safety, and the production, storage, and transportation of shell eggs) exclude or provide modified requirements for entities based at least in part on their size. To verify such suppliers, the receiving facility must obtain written assurance, at least every 2 years, of the supplier's compliance (or acknowledgement that it is subject to the adulteration provisions of the FD&C Act). The verification requirement varies depending on the type of small supplier as follows:

- Written assurance from a qualified facility must attest to the facility's compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States), and the assurance must include either a brief description of the supplier's preventive controls for a hazard or a statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

- Written assurance from a farm that grows produce and is not a covered farm in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5, or a shell egg producer with fewer than 3,000 laying hens, must attest that the farm or shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

In addition to these modified requirements for supplier verification activities, receiving facilities obtaining raw materials or other ingredients from these small suppliers are subject to other modified supply-chain program

requirements. Rather than having to conduct a full review of a supplier's performance in accordance with § 117.410(d)(1)(iii) or § 507.110(d)(1)(iii), these receiving facilities need only consider the small supplier's compliance history under § 117.410(d)(1)(iii)(B) or § 507.110(d)(1)(iii)(B). However, these receiving facilities still must approve these suppliers and include them in the procedures the receiving facilities establish and follow to ensure that they obtain raw materials and other ingredients from approved suppliers (see §§ 117.420 and 507.120).

We conclude that the FSVP regulation should include analogous modified requirements for food imported from these same types of small suppliers. (In § 1.506(d)(4) of the proposed rule as revised by the Supplemental Notice, we had already proposed parallel provisions for food from certain small farms; we respond to comments on proposed § 1.506(d)(4) later in this section of the document.) Therefore, under § 1.512(a)(2) of the final rule, the FSVP regulation includes modified requirements for importers of food from the following small foreign suppliers:

- Qualified facilities under the regulations on preventive controls for human food or for animal food (§ 117.3 or § 507.3, respectively);
- Farms that grow produce and are not covered farms under the produce safety regulation in accordance with § 112.4(a) (the farm has 3-year average annual sales of \$25,000 or less), or in accordance with §§ 112.4(b) and 112.5 (the farm satisfies the requirements for a qualified exemption under the produce safety regulation and associated modified requirements in § 112.6); and
- Shell egg producers that are not subject to part 118 because they have fewer than 3,000 laying hens.

For both human food (under § 117.3) and animal food (under § 507.3), a qualified facility is (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a "very small business," or a facility to which both of the following apply:

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

2. The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year

was less than \$500,000, adjusted for inflation.

For human food, under § 117.3, a very small business is a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee). For animal food, under § 507.3, a very small business is a business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale). More information about qualified facilities and very small businesses appears in the preventive controls final rules.

For produce, produce farms that are not "covered farms" under § 112.4 of the forthcoming produce safety rule have less than \$25,000 in annual sales averaged over the previous 3-year period, or satisfy the requirements for a qualified exemption in § 112.5 and associated modified requirements in § 112.6, based on average monetary value of all food sold (less than \$500,000) and direct farm marketing (during the previous 3-year period, the average annual monetary value of food sold directly to qualified end users exceeded the average annual monetary value of the food sold to all other buyers). In the Supplemental Notice, we erroneously referred to these farms as farms "not subject to the requirements in part 112." While produce farms that make less than \$25,000 annually are not subject to the requirements in part 112, produce farms that satisfy the requirements for a qualified exemption are not subject to the full requirements of part 112, but they do have certain modified requirements that they must meet, as described in § 112.6. In the Supplemental Notice we further erroneously described the types of farms that are not subject to the requirements in part 112 under § 112.4 as including farms that do not grow and harvest "produce" and certain farms that grow and harvest produce that is not covered under the proposed produce safety regulation (*i.e.*, produce that is rarely consumed raw and produce for personal consumption or consumption on the farm). Although the produce rule does not apply to food from such farms, § 112.4 does not establish this. Rather, §§ 112.3 and 112.2 of the produce safety

final rule define what constitutes produce and specify what produce is not covered by part 112, respectively.

For shell eggs, we considered the regulations on production, storage, and transportation of shell eggs in part 118. Section 118.1(a) states that the regulations in part 118 apply only to shell egg producers with 3,000 or more laying hens at a particular farm that do not sell all of their eggs directly to consumers and that produce shell eggs for the table market. Therefore, any shell egg producer with fewer than 3,000 laying hens is not subject to the requirements in part 118. The reasoning behind this cutoff, that producers with fewer than 3,000 layers do not contribute significantly to the table egg market (see the final rule on the production, storage, and transportation of shell eggs, 74 FR 33030 at 33036, July 9, 2009), is consistent with our basis for establishing modified requirements when suppliers are farms that are not covered farms under the produce safety regulation or qualified facilities under the preventive controls regulations. As a result, we are including shell egg producers with fewer than 3,000 laying hens among the small foreign suppliers from which an importer could import food subject to the modified requirements in § 1.512.

As with the importation of food by very small importers, we conclude that modified FSVP requirements are appropriate for the importation of food from these small foreign suppliers because they provide a relatively low volume of food imported into the United States, resulting in less consumer exposure and potential risk. To align the FSVP regulation with the supply-chain program provisions of the preventive controls regulations, the modified requirements in § 1.512 include certain different requirements for importers of food from the specified small foreign suppliers compared to the requirements for very small importers.

One such difference concerns the applicable standard of compliance for written assurance from the foreign supplier. Under § 1.512(b)(3)(i) of the final rule, a very small importer must obtain written assurance, before importing a food and at least every 2 years thereafter, that its foreign supplier is producing 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, and implementing regulations, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the FD&C Act. However, consistent with the analogous

requirements in the supply-chain program provisions of the preventive controls regulations, importers of food from small foreign suppliers must obtain written assurances as follows:

- If the foreign supplier is a qualified facility as defined by § 117.3 or § 503, the written assurance must attest that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States). The written assurance must include either (1) a brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food or (2) a statement that the supplier is in compliance with State, local, county, tribal or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries (§ 1.512(b)(3)(ii)).

- If the foreign supplier is a farm that grows produce and is not a covered farm under part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the written assurance must attest that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) (§ 1.512(b)(3)(iii)).

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

We believe that these requirements for supplier verification appropriately reflect the laws and regulations applicable to the relevant type of foreign supplier in the different circumstances, such that the specified foreign suppliers need only provide assurances that their food is in compliance with, or is subject to, applicable food safety requirements. With respect to the written assurances from certain farms that are not covered farms (as specified in § 1.512(b)(3)(iii)) and shell egg producers with fewer than 3,000 laying hens, we believe that the

acknowledgement that the producer's food is subject to the adulteration provisions of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) provides adequate and proportional assurance of safety given the lower risk to U.S. consumers posed by the lesser volume of food from such suppliers. Any business that introduces food into interstate commerce, including these small suppliers, is subject to the prohibited acts provisions in section 301 of the FD&C Act and is accountable if it produces food that is adulterated under section 402. We therefore conclude that the written assurances required from such suppliers provide adequate assurance of safety while minimizing the burden that providing the assurances to importers may indirectly impose on these suppliers.

Consistent with these requirements, we have correspondingly revised the requirement (§ 1.512(b)(4) of the final rule) for a very small importer or importer of food from one of the specified types of small foreign suppliers to take corrective actions if the foreign supplier does not produce the food in accordance with the applicable standards just discussed to make clear that corrective action is only required if an importer determines that the foreign supplier of the imported food does not produce the food consistent with the assurance provided under § 1.512(b)(3)(i) through (iv).

Paragraph (c) of § 1.512 of the final rule sets forth certain requirements that apply to importers of food from the specified small foreign suppliers but not to very small importers. We believe that these provisions provide an additional level of food safety assurance that should be part of the standard operations for most food importers, except for very small importers. This approach to FSVP requirements for importers of food from certain small suppliers is consistent with the supply-chain requirements applicable to receiving facilities that obtain raw materials or other ingredients from these types of suppliers under the preventive controls regulations.

Section 1.512(c)(1)(i) requires that in approving foreign suppliers, importers of food from the specified small foreign suppliers must conduct (and document) a limited evaluation of a potential foreign supplier by considering the applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those

regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety. Section 1.512(c)(1)(i) also states that the importer may also consider other factors relevant to a foreign supplier's performance, including those specified in § 1.505(a)(1)(iii)(A) and (a)(1)(iii)(C) (*i.e.*, a foreign supplier's food safety processes, procedures, and practices and its food safety history).

Section 1.512(c)(1)(ii)(A) requires the importer to promptly reevaluate the concerns associated with the foreign supplier's compliance history when the importer becomes aware of new information about the supplier's compliance history and to document the reevaluation. If the importer determines as a result of the reevaluation that the concerns associated with importing a food from a foreign supplier have changed, the importer must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier. However, § 1.512(c)(1)(ii)(B) requires that if, at the end of any 3-year period, an importer has not reevaluated the concerns associated with the foreign supplier's compliance history, the importer must reevaluate those concerns and take other appropriate actions, if necessary, and document the reevaluation and any subsequent actions taken.

The potential burden of reviewing a small foreign supplier's compliance history may be reduced because the regulation permits the importer to review another entity's evaluation or reevaluation of a foreign supplier's compliance history. Under § 1.512(c)(1)(iii) of the final rule, if another entity (other than the foreign supplier) has, using a qualified individual, performed the supplier compliance evaluation or the reevaluation, the importer may meet its requirements by reviewing and assessing the evaluation or reevaluation conducted by that entity. If an importer chooses to do this, it must document its review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

Under § 1.512(c)(2) of the final rule, importers of food from certain small foreign suppliers must approve these suppliers on the basis of the compliance history evaluation the importer either conducts or reviews and assesses, and the importer must document the approval.

Finally, § 1.512(c)(3)(i) requires these importers of food from certain small foreign suppliers to establish and follow

written procedures to ensure that they import foods only from foreign suppliers approved based on the compliance history evaluation (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods the importer subjects to adequate verification activities before importing the food). The importer must document its use of these procedures. However, under § 1.512(c)(3)(ii), the importer may rely on another entity (other than its foreign supplier) to establish these procedures and perform and document the required activities, provided that the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer documents its review and assessment.

Having discussed the principal changes the final rule makes to the proposed modified requirements for very small importers and importers of food from very small foreign suppliers, in the following paragraphs we respond to comments on various aspects of the proposed requirements and, in doing so, note other changes included in the final rule.

#### a. Comments Regarding the Proposed Modified Verification Requirements for Certain Farms

(Comment 283) Some comments state that the produce safety regulation excludes farms with annual sales of \$25,000 or less but the FSVP regulation does not include an analogous exclusion. The comments ask that we delete the exclusion from the produce safety regulation because they believe that mandating importers to hold foreign operations to standards that domestic operations are not required to meet would invite a WTO challenge.

(Response 283) As previously stated, importers obtaining produce from farms with annual sales of \$25,000 or less are subject to modified requirements under the FSVP regulation. While these requirements do not constitute an exclusion from FSVP, they significantly decrease the burden of the regulation for these importers. Because farms with \$25,000 or less in annual sales are not subject to the produce safety regulation, the modified requirements do not mandate that an importer of produce from such a farm obtain assurance that the farm is in compliance with section 419 of the FD&C Act, as the produce safety regulation would not apply.

In addition, we have aligned the supplier verification provisions in the FSVP regulation with the supply-chain program provisions of the preventive controls regulations, to the extent

appropriate and feasible, including the eligibility criteria for the modified requirements for produce imported from suppliers that are farms that are not covered farms under the produce safety regulation in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5. Therefore, receiving facilities subject to the preventive controls regulations that obtain produce from domestic farms are not subject to less burdensome supplier verification requirements for that produce than importers importing produce from foreign farms.

(Comment 284) One comment suggests that we not provide modified requirements for certain farm suppliers and delete proposed § 1.506(d)(4) because modified requirements would not give importers the tools they need to assure that they are addressing safety issues with food from such farms. On the other hand, one comment asks that we apply the proposed modified requirements to all farms that are not subject to the produce safety regulations.

(Response 284) We stated in the preamble to the Supplemental Notice that proposed § 1.506(d)(4) would have provided modified verification requirements with respect to food from the following:

- Farms that grow or harvest crops such as grains that are not "produce," as defined in § 112.3(c) of the proposed produce safety regulation.
- Farms that grow and harvest produce that is not covered by the proposed produce safety regulation in accordance with proposed § 112.1. Such "non-covered produce" includes produce that is rarely consumed raw, produce that is produced for personal consumption or for consumption on the farm or another farm under the same ownership.
- Farms that are not "covered farms" because they produce an average annual monetary value of produce of no more than \$25,000.

- Farms that are not covered farms because they satisfy the requirements for a qualified exemption from the proposed produce safety regulation under proposed § 112.5 and the exemption has not been withdrawn.

Although § 1.512 of the final rule provides modified verification requirements for the latter two types of farms, it does not provide modified verification requirements for the former two types of farms. That is, final § 1.512 does not provide modified verification requirements for farms that grow and harvest crops such as grains that are not "produce" as defined in proposed § 112.3(c), and does not provide



modified requirements for farms that grow or harvest produce that is not covered by the proposed produce safety regulation in accordance with proposed § 112.1 (e.g., because such produce is rarely consumed raw or is produced for personal or on-farm consumption). We believe that this approach is appropriate.

With respect to crops such as grains that are not “produce” as defined in the produce safety regulation (and thus are not subject to the regulation), much of this imported food likely will not be consumed without processing that provides for the application of an appropriate kill step or control. Rather than provide for modified verification requirements for such food under § 1.512, we think it is more appropriate to allow importers to rely on the provisions of § 1.507 discussed in section III.H of this document, as applicable. Under those provisions, if the hazards have not been significantly minimized or prevented before importation, an importer may determine and document that the food could not be consumed without application of an appropriate control (e.g., cooking or other treatment of the food for grains for human consumption) or could obtain assurances from its customer that the customer or a subsequent entity in the distribution chain will process the food for food safety. This approach allows the hazard control to be applied after importation while also providing the importer with flexibility as to which entity will apply the appropriate control. In addition, importers of some grains may appropriately determine through their hazard analysis that there are no hazards requiring control. In such cases, the importer would document that determination in its written hazard analysis but would not be required to conduct an evaluation for foreign supplier approval and verification under § 1.505 and would not be required to conduct foreign supplier verification activities under § 1.506. Importers of other grains might determine that the only way to ensure that identified hazards are significantly minimized or prevented would be to conduct verification activities in accordance with § 1.506.

For similar reasons, the final rule requires importers of produce rarely consumed raw to comply with the provisions in §§ 1.505, 1.506, and 1.507, as applicable, instead of providing modified provisions for such produce. For some produce rarely consumed raw, an importer might determine it is appropriate to conduct supplier verification activities to ensure that hazards in the food have been

significantly minimized or prevented before importation. For other produce in this category, we believe that the requirements in § 1.507 are suitable to ensuring the safety of such produce because the food will be subject to the application of a control after importation, and § 1.507 provides flexibility as to which entity will apply the control. With respect to produce for personal or on-farm consumption, this produce would either never be exported to the United States (because it is consumed on the farm) or could be eligible for the personal consumption exemption from the FSVP regulation under § 1.501(d). We therefore do not see any need to establish modified requirements applicable to this category.

We are not certain whether the comment requesting that the modified requirements apply to all farms not subject to the produce safety regulation contemplates any other food or farms being subject to the modified verification requirements in § 1.512. To the extent that the comment requests that food produced by such operations as dairy farms be covered by the modified requirements in § 1.512, we do not agree. Safety problems may arise in food produced by such operations. Providing modified requirements for such operations would increase the volume of imported food subject to modified requirements, and would therefore also increase consumers’ risk of exposure to such food. Consistent with Congress’ intent that we implement the FSVP requirements based on the level of risk posed by the imported food (see section 805(c)(3) of the FD&C Act), we believe it is appropriate that importers of food from such farms be subject to the standard supplier verification requirements. Indeed, we have designed the modified verification requirements in § 1.512 so they apply only to operations that expose consumers to less risk because the operations export a relatively small volume of food to the United States. We also believe that our treatment of produce and food from other farms not subject to the produce safety regulation is consistent with the coverage of the supply-chain program provisions in the preventive controls regulations.

In the context of the nature of the imports for which we are providing modified verification requirements in § 1.512, we continue to believe that the modified requirements would be adequate to provide assurances from these particular suppliers that the food is produced in compliance with the applicable standards in this rule. In addition, the foods covered by the modified requirements in § 1.512 are

and will continue to be covered under the adulteration provisions of the FD&C Act and applicable implementing regulations, irrespective of the modified verification requirements under the FSVP regulation.

(Comment 285) Several comments request that importers not be required to obtain written assurance of compliance with the FD&C Act from the farms specified in proposed § 1.506(d)(4). The comments assert that obtaining written assurance would be unnecessary or inappropriate because FDA has already determined that these foods are of minimal or no risk. The comments also state that, with respect to a RAC that is not subject to the produce safety regulations, the importer might not know the identity of the farmer who grows the RAC (e.g., RACs that are consolidated before export to the United States).

(Response 285) As stated previously, the fact that we are allowing importers to obtain written assurance, instead of requiring importers to determine and conduct what might be more burdensome supplier verification activities, reflects our view of the risk to public health attributable to produce from these farms. To the extent that the comments believe that requiring assurances is inconsistent with the risk to public health posed by these suppliers, we disagree. Obtaining assurances is an appropriate verification activity because it requires importers to obtain from suppliers information about the safety of the imported food. For produce RACs consolidated before export to the United States from farms described in § 1.512(a)(2)(ii) of the final rule, the regulation does not prohibit an importer from enlisting the consolidator to help obtain the necessary written assurances.

(Comment 286) One comment contends that obtaining written assurances from grain farmers is not feasible because FDA has not established safety standards for grain.

(Response 286) As finalized and as previously discussed, § 1.512 does not establish any modified requirements specific to the importation of grain. However, we expect that the risk-based framework of this rule will still generally result in a relatively low verification burden for the importation of grain. As described in the previous paragraphs, importers may be able to take advantage of the flexibility in § 1.507 for imported grains for which hazards will be controlled after importation.

b. Other Comments Related to the Appropriateness or Implementation of Modified Provisions for Small Entities

(Comment 287) Some comments assert that Congress did not provide an exemption for very small importers and food from very small foreign suppliers and FDA should not create one.

(Response 287) As discussed in the proposed rule, section 805(c)(3) of the FD&C Act directed 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. We have not created an exemption from the FSVP regulation for very small importers or very small foreign suppliers. Instead, as discussed previously, we are adopting modified requirements that generally apply to situations that involve a relatively low volume of imported food, which should reduce consumers' exposure to, and thus potential risk from, the food (see 78 FR 45730 at 45765). We think this approach is commensurate with the risk to public health posed by these importers and suppliers, consistent with section 805(c)(3), because the food affected by these provisions constitutes a relatively low volume of imported food, which should reduce the risk to consumers posed by this food.

(Comment 288) Some comments agree with the idea of having modified requirements for very small importers and very small foreign suppliers, but state that the modified requirements should be different from what we proposed. Some comments maintain that we should require a third-party audit by a qualified individual for very small importers and importers of food from very small foreign suppliers. Some comments argue that these importers should be subject to the full requirements of the FSVP regulation, but that we should address the challenges for these entities in complying by giving them additional time to comply.

(Response 288) Although an importer may determine that a third-party audit is the most appropriate verification activity for a given food and foreign supplier, the FSVP regulation does not mandate a third-party audit of a foreign supplier for any imported food. We do not see the logic in creating more stringent requirements for very small importers and importers of food from small suppliers than for all other importers subject to the FSVP regulations.

(Comment 289) Some comments support modified requirements for very small foreign suppliers but state that

importers' requirements should be the same regardless of the size of the importer or its supplier.

(Response 289) The FSVP regulations apply to importers; they do not impose direct requirements on foreign suppliers. The size of the importer is relevant to its ability to comply with the FSVP requirements and to the volume of food imported by the importer (and thus consumers' exposure to the food). We therefore believe it is appropriate to adopt modified requirements for very small importers.

(Comment 290) Some comments state that very small foreign suppliers may already be exempt from the preventive controls or produce safety regulations and do not need a duplicative exemption from importers' verification requirements.

(Response 290) We did not propose and are not finalizing an exemption for food from qualified facilities or certain small farms. We are establishing modified, risk-based verification requirements for importers of such food.

(Comment 291) Some comments express concern that these provisions will allow businesses to alter their structures to ensure that the imported food is exempt from the regulation. Some comments assert that businesses would assign the FSVP importer responsibility to the entity most likely to be exempt. Comments also maintain that large exporters of food to the United States might break shipments into smaller units to avoid application of the full FSVP requirements.

(Response 291) While this rule does not prevent various business arrangements from developing, we do not believe that it would be cost-effective for an importer to alter its entire supply chain to only import food from many small facilities or farms to meet its needs instead of from its usual large suppliers. We understand that many large importers that import food from large suppliers are already performing supplier verification activities of some kind. We believe they are much more likely to simply modify their current practices, if such modification is needed, rather than adopt entirely new supply structures to evade application of the full requirements of the rule.

We do not agree that large exporters of food to the United States are likely to break shipments into smaller units to avoid the full FSVP requirements. An importer of food from a large exporter would not be eligible for modified requirements just because the particular shipment the importer received happened to be small. To make its products eligible for application of the

modified requirements, an exporter would have to divide itself into smaller, distinct businesses, which could create significant costs for the underlying business.

(Comment 292) Some comments assert that if FDA believes the modified requirements are sufficient, those requirements should apply to all importers regardless of size.

(Response 292) As previously stated, FSMA directed 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 are designed to specify verification activities that take into account the risk to overall public health posed by the low volume of food from these entities imported into the United States. The modified requirements would not be appropriate for all importers regardless of risk.

(Comment 293) Some comments express concern that eligibility reporting and verification activities will create additional work for FDA. They assert that verification of sales data might be possible for importers through interagency cooperation with the Internal Revenue Service but not for foreign suppliers. The comments maintain that without verification, importers might fraudulently document that an entity meets the very small foreign supplier definition as well as assurances of compliance.

(Response 293) When we review records of importers who are following modified requirements in accordance with § 1.512, we will expect to review documentation supporting their determination that the food they import is eligible for the modified requirements. Importers should expect that we will use information available to us to verify the truthfulness and accuracy of this information. Falsely reporting eligibility criteria to FDA could subject importers to penalties under 18 U.S.C. 1001.

(Comment 294) Some comments ask what course of action FDA would have in the event of a foodborne illness outbreak if an outbreak is traced back to a very small foreign supplier or food imported by a very small importer.

(Response 294) If a foodborne illness outbreak is traced back to food subject to modified requirements under the FSVP regulation, we will be able to use our enforcement tools to address the issue in the same manner as we would with importers subject to the "standard" FSVP requirements, including, if appropriate, placing the foreign supplier or importer on import alert.

(Comment 295) Some comments state that the modified requirements do not solve the problems associated with having to verify thousands of farms, including maintaining a list of approved suppliers, conducting compliance status reviews, and documenting the entities' eligibility for the modified requirements. Some comments question whether compliance status review for thousands of small farms that do not directly sell food to the United States is a good use of resources.

(Response 295) The final modified requirements do not include maintaining a list of approved suppliers; they do include documenting eligibility for the modified requirements and, for importers of food from the specified small foreign suppliers, evaluating their potential suppliers' compliance history. If an importer wants to follow the modified requirements, it must make a determination about its eligibility through reviewing its own annual sales information or obtaining written assurance from a foreign supplier. Maintaining the record of that determination allows the importer to show that it meets the eligibility criteria and enables us to verify the importer's eligibility.

Regarding the comments on compliance status review, § 1.512 of the final rule does not require very small importers to conduct a compliance status review of potential foreign suppliers, as we had originally proposed. As previously discussed, § 1.512(c)(1) does require importers of food from certain small foreign suppliers to evaluate their foreign suppliers' compliance history. With respect to produce imported from a farm that grows produce and is not a covered farm in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5, under § 1.512(c)(1)(iii), an importer of such produce could rely on another entity (other than the foreign supplier) to evaluate the compliance history of a potential foreign supplier.

## 2. Provisions of the Modified Requirements for Very Small Importers and Importers of Food From Certain Small Suppliers

Some comments address particular aspects of the proposed modified requirements for very small importers and importers of food from very small foreign suppliers. We respond to these concerns in the following paragraphs.

### a. Calculating Eligibility

Under proposed § 1.512(b)(1), an importer seeking to import food under the modified requirements would have to 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. For the purpose of determining whether the definitions were satisfied, the baseline year for calculating the adjustment for inflation would be 2012. Proposed § 1.512(b)(1) further states that if the importer or foreign supplier conducts food sales in currency other than U.S. dollars, the importer would have to 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.

The final rule includes changes to § 1.512(b)(1) to clarify how importers must determine their eligibility for the modified provisions for very small importers and importers of food from certain small foreign suppliers. To import food as a very small importer, an importer must document its eligibility as a "very small importer" (as defined in § 1.500) with respect to human food and/or animal food before initially importing food and thereafter on an annual basis by December 31 of each calendar year (§ 1.512(b)(1)(i)(A)). For the purpose of determining whether the importer satisfies the definition of very small importer with respect to human food and/or animal food for a given calendar year, the relevant 3-year period of sales (and U.S. market value of human or animal food, as appropriate) is the period ending 1 year before the calendar year for which the importer intends to import food as a very small importer (§ 1.512(b)(1)(i)(B)). To align the very small importer requirements with the requirements for qualified facilities in the preventive controls regulations, the baseline year for calculating the adjustment for inflation is 2011 rather than 2012 as proposed. If the importer conducts any food sales in currency other than U.S. dollars, it 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.

To import food under the modified provisions for food from small foreign suppliers, an importer must obtain written assurance that its foreign supplier meets the criteria for one of the types of small suppliers in § 1.512(a)(2)(i), (ii), or (iii) before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year.

(Comment 296) One comment seeks clarification as to who will determine the monetary value of an importer and how such criteria will be enforceable.

(Response 296) Under § 1.512(b)(1)(i) of the final rule, the importer itself must determine the dollar amount of its sales of human or animal food and the market value of any human or animal food imported, manufactured, processed, packed, or held without sale. Importers must retain documentation of eligibility for the modified requirements and make it available for FDA review.

### b. Written Assurances

We proposed (in § 1.512(b)(3)) that an importer seeking to import food under the modified requirements be required to obtain written assurance, before importing a food and at least every 2 years thereafter, that the foreign supplier is producing 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, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. The written assurance would have to include a brief description of the processes and procedures that the foreign supplier is following to ensure the safety of the food.

As previously discussed, the final rule contains revised written assurance requirements for very small importers and importers of food from certain small foreign suppliers.

(Comment 297) Some comments agree with the proposed requirement to obtain written assurances from foreign suppliers. Other comments argue that we should allow greater flexibility by allowing a very small supplier to provide records, like a commercial invoice, a certification of safety by the supplier's regulatory authority, a HACCP plan/certification, or a private certification, to meet the verification requirements. These comments also state that if a food is specifically named as high risk by FDA, or food from the foreign supplier was rejected twice at the border for its food safety performance, then additional proof of safety could be demanded according to FDA guidance developed in consultation with small food companies.

(Response 297) We believe that the requirement to obtain written assurances from foreign suppliers will not be more burdensome than obtaining records from those suppliers. Recognizing the variety of business practices that currently produce safe food, the final rule provides a significant amount of flexibility concerning the form of written assurances. The modified requirements do not specify the particular form of

documentation that must be used as written assurance for FSVP purposes. Some records suggested by the comments, such as a certification of safety by a supplier's regulatory authority or a private certification, might be sufficient for written assurance purposes if they satisfy the applicable requirements for written assurance in § 1.512(b)(3). However, for food from qualified facilities, the written assurance must include the information required by § 1.512(b)(3)(ii).

We believe that basing supplier verification requirements for a particular food on whether it had been refused admission, as suggested by some comments, would be too administratively burdensome for both importers and the Agency. As to the issue of basing the level of supplier verification on whether a food is high risk, we generally agree that supplier verification should be risk-based and this rule applies a risk-based framework. In general, the rule allows importers to tailor the supplier verification activities they conduct based on the hazards applicable to the food and the characteristics of the supplier. For very small importers, however, we believe that the modified requirements, including the requirement to obtain supplier assurances, are appropriate given the reduced risk to consumers posed by the relatively low volume of food imported by these firms.

#### c. Corrective Actions

We proposed (in § 1.512(b)(4)) that very small importers be required to promptly take corrective actions if they determine that a foreign supplier of food they import does 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 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 of non-compliance, adulteration, or misbranding have been adequately addressed. We further proposed that importers be required to document any corrective actions they take to meet this requirement.

We have revised the corrective action requirements in § 1.512(b)(4) to reflect the revised requirements for written assurances for very small importers and importers of food from certain small foreign suppliers by specifying that appropriate corrective actions would be

required if the importer determines that its foreign supplier does not produce food consistent with the assurance provided in accordance with § 1.512(b)(3).

(Comment 298) Some comments ask that the provision be revised to specify that corrective actions are only necessary when non-compliance causes a risk to public health. The comments assert that this would be consistent with FDA's statement in the preamble to the proposed rule that regulations should 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.

(Response 298) For the reasons stated with respect to the corrective action provisions in § 1.508 of the final rule (see section III.L.4 of this document), we disagree that corrective actions are only necessary when non-compliance causes a risk to public health.

#### d. Records

We proposed certain requirements (in § 1.512(b)(5)) related to the availability, quality, and retention of records of activities under the modified requirements for very small importers and importers of food from very small foreign suppliers. We proposed to require importers to maintain records, in English, and to make them available promptly to an authorized FDA representative, upon request, for inspection and copying. We also proposed that importers be required to maintain records at their places 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.

The final rule includes several changes to the proposed requirements to align the recordkeeping requirements in § 1.512(b)(5) of the final rule with the changed recordkeeping requirements in § 1.510 (discussed in section III.K of this document) as well as for consistency with the supply-chain program provisions in the preventive controls regulations. Section 1.512(b)(5)(ii)(A) of the final rule does not require that records be maintained in English. Instead, upon FDA request, importers must provide within a reasonable time an English translation of records maintained in a language other than English.

The record retention provisions in § 1.512(b)(5)(iii) require importers to retain records for at least 2 years after records are created or obtained. However, records of importers who

obtain food from certain small foreign suppliers that relate to the importers' processes and procedures (e.g., evaluations of supplier compliance history under § 1.512(c)(1), approvals of suppliers under § 1.512(c)(2)) must be retained for at least 2 years after their use is discontinued. Also, records relied on to support an importer's status as a very small importer must be retained for at least 3 years.

Section 1.512(b)(5)(iv) specifies that records of very small importers and importers of food from certain small foreign suppliers obtained by FDA in accordance with the FSVP regulations are subject to the disclosure requirements under part 20. In addition, under § 1.512(b)(5)(v)(A), these importers do not need to duplicate their existing records if they contain all of the information required under the FSVP regulation, and importers may supplement any existing records as necessary to include all required information. Under § 1.512(b)(5)(v)(B), importers are not required to keep required information in one set of records; if existing records contain some of the required information, any new information required by the FSVP regulation may be kept separately or combined with existing records.

(Comment 299) Some comments suggest that records should be considered to be at a reasonably accessible location if they can be retrieved within 5 business days from another location, rather than immediately retrieved by computer or other means. The comments state that "immediately" is subject to misinterpretation, and FDA should replace the term with a specific, reasonable time interval. The comments suggest that 5 days is adequate, but in no case should FDA impose an interval of less than 1 business day. Some comments object to the requirement that only computer or other electronic means are suitable for record retrieval because some locations of offsite records might not have adequate resources, and a requirement to use electronic means might inadvertently require expensive computer system validation.

(Response 299) Consistent with changes to proposed § 1.510 discussed in section III.K.3.b of this document, we have changed § 1.512(b)(5)(ii)(B) to specify that offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Under the final rule, electronic records are considered to be onsite if they are accessible from an onsite location. We believe that the 24-hour deadline is important because records must be

available to FDA investigators during inspections. We do not believe it is reasonable for an inspection to be put on hold for 5 business days so that an importer can acquire the necessary records. However, the provision no longer specifies retrieval by computer or other electronic means; an importer could use a non-electronic means (e.g., courier service) to retrieve and provide records onsite.

(Comment 300) Some comments request that the regulations specify that there is no requirement for compliance with any part of part 11.

(Response 300) The final rule includes a provision (§ 1.512(b)(5)(iv)) specifying that electronic records that are established or maintained to satisfy the requirements of § 1.512 are exempt from the requirements of part 11.

### 3. Other Concerns Regarding the Modified Requirements

#### a. Withdrawal of Eligibility

(Comment 301) One comment expresses concern that the modified requirements for very small importers do not include a provision on withdrawal of eligibility for the exemption, as there is in the preventive controls regulations. The comment asks that we consider adding the ability to withdraw eligibility from an importer that imports food that causes an illness outbreak.

(Response 301) We do not believe such a provision is necessary, given the risk-based nature of the eligibility criteria for these modified requirements and our existing enforcement tools in the imports arena. For example, if an importer imports food that causes an illness outbreak, we can place the importer on import alert, as appropriate, among other options to ensure the safety of the food.

#### b. Identifying Very Small Importer Eligibility at the Time of Entry

(Comment 302) Some comments say that exemptions and exceptions to the FSVP requirements, including the proposed modified requirements for very small importers and importers of food from very small foreign suppliers, should be identified at the time of entry by using an exemption/exception code, similar to the structure in place under the prior notice regulations.

(Response 302) We are planning to establish data elements that can be submitted at the time of entry to identify shipments that are exempt from the FSVP regulation or, as with very small importers and importers of food from certain small foreign suppliers, subject to modified FSVP requirements.

#### c. Compliance Period

(Comment 303) Some comments ask that we consider giving very small importers and importers of food from very small foreign suppliers more time, beyond the 3 years proposed, to comply with the requirements. Some comments suggest 5 years.

(Response 303) We do not believe that the modified requirements are sufficiently onerous to justify a longer compliance period for very small importers or importers of food from small suppliers. With respect to the compliance period for all importers, we are aligning the FSVP regulation with the compliance dates of the supply-chain program provisions in the preventive controls regulations, to the extent feasible. For more discussion about the applicable compliance dates, see section IV of this document.

#### d. Outreach

(Comment 304) Some comments ask that we commit to engaging in capacity building and education to help improve the knowledge and performance of very small entities, particularly for very small importers.

(Response 304) We are committed to stakeholder engagement throughout the implementation of FSMA. We plan to issue several guidance documents to assist entities in complying with the new FSMA regulations, including a general guidance document on FSVPs. We intend for this guidance to include recommendations on compliance with the modified requirements for very small importers and importers of food from small foreign suppliers. We will develop and issue these guidances in accordance with our good guidance practice regulation, which establishes criteria for when we issue a guidance document as an initial draft, invite public comment, and prepare a final version of the guidance document that incorporates suggested changes, when appropriate (21 CFR 10.115(g)). In addition, we plan to develop training materials to assist importers in complying with the requirements of this rule.

With respect to capacity building, we issued a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries in countries from which foods are exported to the United States in accordance with section 305 of FSMA in 2013 (Ref. 15). We anticipate that this plan will provide a strategic framework for our capacity-building efforts over the next several years.

#### *N. Importing a Food From a Foreign Supplier in a Country With an Officially Recognized or Equivalent Food Safety System (§ 1.513)*

We proposed to establish alternative FSVP requirements for food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States, when certain conditions are met. These provisions would allow the importation of such food without being subject to most of the standard FSVP requirements.

Proposed § 1.513(a) specified that 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, 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. The proposed conditions (stated in proposed § 1.513(b)(1)) were the following:

- 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 to that of the United States; and
- The food must be within the scope of the relevant official recognition or equivalency determination.

Proposed § 1.513(b)(1) also specified that these conditions be documented before importing a food from the foreign supplier and annually thereafter.

Under proposed § 1.513(b)(2), when those conditions were met, the importer would have the option of complying with modified FSVP requirements. Under such modified requirements, the importer would be required to determine and document whether the foreign supplier of the food was in good compliance standing with the food safety authority of the country in which the foreign supplier is located. Importers 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 are not being adequately controlled, we proposed that the importer would be required to take prompt corrective action, which would depend on the circumstances but could include discontinuing use of the foreign supplier. We also proposed to require that these importers document any corrective actions. If an importer met

those conditions and requirements for a food, the importer would not be required to comply with most of the proposed FSVP requirements (e.g., for hazard analysis, compliance status review, supplier verification activities). (However, for the reasons stated in section III.D of this document, we conclude that it is appropriate to require these importers to use a qualified individual to perform the tasks required under § 1.513 of the final rule.) But we proposed that these importers would be required to comply with the requirements concerning identification of the importer at entry and recordkeeping.

In the preamble to the proposed rule, we discussed how these proposed modified requirements were consistent with a risk-based approach to food safety, which includes leveraging the regulatory efforts of food safety authorities in foreign countries. We discussed our systems recognition initiative, under which we are conducting assessments of foreign food safety systems to determine whether they provide similar protections to those offered under the U.S. system and a similar level of oversight and monitoring. The systems recognition process, which is described on our Web site at <http://www.fda.gov/food/internationalinteragencycoordination/ucm367400.htm> (Ref. 16), involves a comprehensive review of a country's food safety system by FDA scientists, auditors, and investigators, along with use of a food safety authority self-assessment tool (currently in draft form) called the International Comparability Assessment Tool (ICAT), to determine whether a country has a food safety system that is comparable to that of the United States.

As stated in the preamble to the proposed rule, the systems recognition review process consists of two principal stages. After satisfactory completion of a 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 assessment provides an objective and comprehensive means of assessing the foreign food safety system. FDA will only enter into a systems recognition arrangement with a foreign government if we are confident that the oversight of the foreign food safety authority is sufficiently rigorous and reliable that it can ensure that food produced in that country is as safe as food produced in the United States.

After FDA enters into a systems recognition arrangement with another food safety authority, we will maintain an ongoing dialogue and hold annual consultations to determine whether any substantial changes in the country's food safety system have developed to ensure that the country's food safety system continues to be comparable. Although we are still developing the systems recognition process, we plan to reevaluate the operation and status of each arrangement every 5 years, including reviewing changes in a country's food safety system and conducting system audits as needed.

We requested comment on the appropriateness of our proposed modified FSVP requirements for food imported from a country with a comparable or equivalent food safety system, including the proposed conditions and modified FSVP requirements that would be applicable to such imported food. In addition, in light of the possible inclusion of supplier verification provisions for raw materials and other ingredients in the preventive controls regulations, we requested comment on whether the modified requirements should apply to the importation of raw materials and other ingredients.

#### 1. Appropriateness of the Modified Requirements

We received comments supporting and opposing the proposed modified FSVP requirements for food from foreign suppliers in countries with comparable or equivalent food safety systems. As discussed in the following paragraphs, we conclude that the modified provisions are an appropriate component of risk-based foreign supplier verification requirements. However, for the reasons described in the following paragraphs, we conclude that it is appropriate to limit the scope of the modified provisions to imported food that will not be further manufactured/processed in the United States, including packaged food products and fresh produce intended for consumption without further commercial manufacturing/processing. This change will ensure that food from foreign suppliers in countries whose food safety systems we have officially recognized as comparable or determined to be equivalent to that of the United States will be subject to supplier verification under the FSVP regulation in the same circumstances that food from domestic suppliers will be subject to supplier verification under the preventive controls regulations.

(Comment 305) Several comments express support for the application of

modified FSVP requirements for importing a food from a country with a comparable or equivalent food safety system. These comments maintain that the requirements are consistent with a risk-based approach to food safety that avoids unnecessary expenditure of verification resources by incorporating the regulatory efforts of foreign food safety authorities. With respect to the importation of raw materials and other ingredients, some comments support applying the modified requirements to these products.

On the other hand, some comments oppose the modified provisions, asserting that supplier verification is needed to provide adequate assurance of safety regardless of the regulatory environment in the country in which a food is produced. The comments assert that just because a country's food safety system has been deemed comparable does not mean that the system operates perfectly all the time. The comments express concern that under the modified provisions not all foreign suppliers would be held to the same standards that apply to domestic producers.

(Response 305) We conclude that the application of the modified FSVP requirements for imports of food from foreign suppliers in countries with a food safety system officially recognized as comparable or determined to be equivalent is consistent with a modern, risk-based approach to food safety. As previously stated, the systems recognition process provides for a thorough and rigorous assessment of whether the food safety system in a foreign country provides similar protection to that provided to consumers under the U.S. system. We believe that the production of food by a foreign supplier in good compliance standing with a food safety authority implementing a system that FDA has deemed comparable or equivalent to the U.S. system will provide adequate assurance of safety and make supplier verification by importers unnecessary. Thus, importation of food under these modified provisions should reduce the regulatory burden on importers while still providing assurance that the food will be produced consistent with U.S. standards.

However, we conclude that the scope of the modified requirements for food from countries with comparable or equivalent food safety systems must be revised with respect to raw materials and other ingredients. Supplier verification for raw materials and other ingredients is an important part of a preventive approach to food safety. Through supplier verification, the entity receiving raw materials or other

ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented controls to significantly minimize or prevent known or reasonably foreseeable hazards in the raw material or other ingredients. As a result of these considerations, we have finalized requirements for supplier verification in the preventive controls regulations—even for suppliers that operate under the U.S. food safety system. Under the preventive controls regulations, receiving facilities that obtain raw materials or other ingredients from either domestic or foreign suppliers will, under certain circumstances, need to have a supply-chain program that includes the performance of supplier verification activities.

We believe that verifying foreign suppliers of raw materials and other ingredients is as important to food safety as verifying domestic suppliers, and that where the supplier operates and the nature of government oversight does not change the need for supplier verification requirements. In other words, supplier requirements are important when food is produced in the United States, when it is produced in foreign countries whose food safety systems FDA has not officially recognized as comparable or determined to be equivalent, and when it is produced under food safety systems that FDA has found to be comparable or equivalent. When a supplier has not controlled a hazard requiring a control, the entity receiving that food can help ensure that the hazard is controlled before there is a finished product to be distributed to consumers—regardless of whether the supplier is located domestically or in a foreign country.

The U.S. food safety system requires that hazards be significantly minimized or prevented in finished food products, and the same will be the case for the food safety system in any country that FDA officially recognizes as comparable or determines to be equivalent. When food that does not require further manufacturing/processing is imported from foreign suppliers in good compliance standing in those countries, we do not believe that there will be significant public health benefit in an importer conducting verification that the supplier's hazards have been significantly minimized or prevented. In those circumstances, we will have confidence that the food safety system of the foreign supplier's country adequately requires the control of hazards for which controls are needed. Furthermore, we do not see a reason for the FSVP regulation to permit imports of raw materials and other ingredients

under the modified requirements for food from countries with comparable or equivalent food safety systems while raw materials and other ingredients would be subject to supplier verification under the preventive controls regulations. Therefore, § 1.513(a)(2) of the final rule specifies that the modified provisions apply only to food that is not intended for further manufacturing/processing, including packaged finished food products and RACs that will not be commercially processed further before consumption.

(Comment 306) Several comments maintain that we should exempt U.S. producers that are in good compliance standing with FDA from the supplier verification requirements in the preventive controls regulations. These comments assert that if domestic manufacturers are subject to supplier verification requirements under the preventive controls regulations while importers of food from countries with comparable or equivalent food safety systems are exempt from most FSVP requirements, this would result in imported food being subject to less oversight than domestic food.

(Response 306) As discussed previously, § 1.513(a)(2) of the final rule provides that supplier verification of raw materials and other ingredients is treated the same under the FSVP and preventive controls regulations by limiting the applicability of the modified provisions on food from countries with comparable or equivalent food safety systems to food that will not be subject to further manufacturing/processing. Further, we believe, as stated previously, that supplier verification of raw materials or other ingredients is important regardless of whether the food is produced by domestic or foreign suppliers. Such verification allows the facility receiving the raw material or other ingredient to take steps, when necessary, to control hazards requiring a control that have not been controlled by the supplier.

(Comment 307) Some comments suggest that there is an inconsistency with the provisions of proposed §§ 1.513 and 1.506(d)(5). As discussed in section III.G.4 of this document, proposed § 1.506(d)(5) would permit an importer to rely on an inspection of a foreign supplier that is conducted by the food safety authority of a country whose food safety system we had officially recognized as comparable or determined to be equivalent, as a substitute for conducting a required onsite audit of the foreign supplier. The comments assert that this provision is superfluous because proposed § 1.513 would relieve

the importer of the obligation to conduct an onsite audit of the foreign supplier.

(Response 307) We do not agree. As stated previously, the modified provisions in § 1.513 of the final rule apply only to food that will not be commercially processed further in the United States. However, under § 1.506(e)(1)(i)(E)(2) of the final rule, an importer of a raw material or other ingredient from a country with a comparable or equivalent food safety system may substitute an inspection by the food safety authority for an onsite audit of the foreign supplier of the raw material or other ingredient provided that certain conditions are met. In addition, the provisions allowing substitution of an inspection for an onsite audit do not require documentation that the foreign supplier is in good compliance standing with the food safety authority in a country with a comparable or equivalent food safety system, which is required for importing food under the modified provisions in § 1.513. Consequently, we conclude that there are circumstances under which an importer of food from a country with a comparable or equivalent food safety system might wish to rely on the results of an inspection conducted by the food safety authority of that country in accordance with § 1.506(e)(1)(i)(E)(2).

## 2. Systems Recognition Process

Several comments request changes to, or clarification of, our systems recognition process, while some comments request a change to proposed § 1.513 to address a concern about the systems recognition process.

(Comment 308) Some comments request that we clarify and simplify the process of making systems recognition determinations. Some comments, noting their understanding that the systems recognition approach will allow FDA to prioritize its inspection and surveillance activities according to risk, ask that we more clearly show the benefits for exporting countries under the approach to increase the incentive for participation in systems recognition.

(Response 308) The systems recognition initiative is a food safety regulatory cooperation program and it is not intended to be a program for the promotion of trade or market access. Systems recognition is a regulator-to-regulator program that allows FDA to take into account the role of food safety systems of exporting countries in our risk-based decision making regarding inspections, monitoring, admissibility, and follow-up when food safety incidents occur. As a regulatory coordination program, systems recognition embraces cooperation in



many areas such as research, capacity building with third countries, and outbreak response.

We are using systems recognition as a tool to determine when we can rely on the implementation of science-based food safety programs by foreign regulatory authorities and take action based on information provided by such authorities. However, we note that the systems recognition program is based on the principle that foreign food producers can meet U.S. food safety requirements by providing assurances that these foods are produced according to the food safety standards of a country whose food safety system we have found to be comparable or equivalent. Therefore, it is appropriate, under § 1.513 of the final rule, to exempt from the application of most FSVP requirements certain food from foreign suppliers that are in good compliance standing with the food safety authority of a country whose food safety system we have found to be comparable to ours as a result of a systems recognition assessment.

(Comment 309) One comment requests that we revise proposed § 1.513(b) to replace “country” with “country or entity” in the phrase “country with an officially recognized or equivalent food safety system” to recognize that, in addition to individual countries, entities such as the EU might also be the subject of a food safety systems recognition agreement. This comment also asks that we establish a transition program or grace period for countries that are undergoing systems recognition evaluation so that exports from those countries are not subject to the full range of FSVP requirements while FDA conducts its evaluation.

(Response 309) We appreciate that the EU plays an important role in coordinating the food safety policy of its Member States. However, within the EU the food safety agencies of the national governments of the Member States are responsible for enforcing the feed and food safety laws and implementing official controls for food safety through all stages of production, processing, and distribution (Ref. 17). In that context, we are continuing to evaluate and consider how to best address the functions and processes of both the EU and its Member States. We do not believe that it is necessary to revise § 1.513(b)(1) as requested to address this aspect of our systems recognition review.

We also decline to apply modified FSVP requirements to importers of food from countries that are undergoing, but have not completed, a systems recognition assessment. Applying such requirements to systems recognition

candidates before we have completed the evaluation process would prejudice the outcome of the process.

(Comment 310) Some comments request that we rapidly expand the list of countries participating in the systems recognition program so that it includes the major trading partners of the United States. These comments assert that a systems recognition program covering the United States’ largest trading partners would significantly reduce burdens on food importers.

(Response 310) We are transitioning the systems recognition program from the pilot phase to the implementation phase. During this transition we will be addressing modifications of our internal procedures and training of FDA personnel involved in systems recognition determinations. As a result, we will be applying more resources to the program in response to requests for recognition from additional countries. As we gain more experience with the systems recognition program, we expect to improve the efficiency of the review process. However, because there is variation in the level of maturity of food safety systems in countries around the world, not all countries are likely to qualify to participate in the systems recognition program.

(Comment 311) One comment asserts that in selecting countries to review under the systems recognition process, FDA will be biased towards countries with legal systems and official languages that are similar to those of the United States, making it difficult for other countries to obtain systems recognition status.

(Response 311) We do not agree. We are administering the systems recognition pilot program through a transparent and objective science-based evaluation of the food safety systems of the candidate countries. We will continue to provide information and opportunities for stakeholder input as the program transitions from the pilot stage to the full implementation stage.

(Comment 312) Some comments assert that FDA should only make equivalency determinations and not systems recognition determinations. One of these comments maintains that equivalency determination is a more robust approach than systems recognition for determining whether the United States can rely on another country’s food safety system.

(Response 312) We do not agree. Both equivalence and systems recognition have unique aspects, but both can be considered robust enough to satisfy the objectives of the FSVP regulations, which include several methods for an importer to achieve compliance.

Systems recognition, in particular, involves a sufficiently rigorous analysis of the food safety system of the foreign country so that it is appropriate to include it as an alternative.

### 3. Commodity-Specific Arrangements With FDA

In the proposed rule, we requested 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.

(Comment 313) Several comments support the idea of having commodity-specific systems recognition arrangements. These comments assert that there are certain countries with excellent food safety systems for specific products. The comments suggest that limiting compliance assurance to these specific products rather than requesting equivalence for all food products should be sufficient and appropriate in certain cases. The comments ask that we publish a listing of all commodity/country arrangements for specific food sectors within countries that can demonstrate equivalent public health protection with respect to the listed commodities. Some comments ask that we consider products that are already covered under bilateral memoranda of understanding (MOUs), such as FDA’s agreement with Mexico regarding cantaloupe, as subjects for future commodity-specific systems recognition agreements.

(Response 313) We are considering whether and how best to develop commodity-specific recognition programs. In considering the best path forward, we are aware that, although a country’s overall food safety system may not be comparable to that of the United States for FDA-regulated products, the country might be able to successfully demonstrate that a specific production practice or set of practices for a particular food or foods provides the same level of public health protection for a specific measure or a set of measures as described in FDA regulations. At the same time, we know that an evaluation of an overall food control system allows for intensive and extensive review of many components of that safety system. We will provide opportunities for stakeholder input as we continue to consider whether and how to recognize programs for specific commodities when a country demonstrates that their programs provide the same level of public health protection as those being applied to food production in the United States. If we establish commodity-specific

arrangements in the future, we will provide information about such arrangements on our Web site.

(Comment 314) One comment suggests that FDA base an equivalence determination on an evaluation of the official food safety control system of the exporting country by investigating the food safety control systems of a specific number of suppliers in the exporting country.

(Response 314) We agree that consideration of the food safety control systems of exporting suppliers might be a relevant factor in an equivalence determination. However, more important to this determination would be the quality and strength of the foreign authority's food safety operations.

*O. Consequences of Failure To Comply With FSVP Requirements (§ 1.514)*

We proposed to codify in the FSVP regulation certain FSMA provisions related to the consequences of failing to comply with the FSVP requirements. In accordance with section 801(a) of the FD&C Act, we proposed to specify, in § 1.514(a), 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 the food fails to comply with the FSVP regulations with respect to that food. 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. In accordance with section 301(b) of FSMA, we proposed to specify, in § 1.514(b), 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 FSVP regulation, is prohibited under section 301(zz) of the FD&C Act.

In the final rule, we are making certain changes to the regulatory text for these provisions. Specifically, in § 1.514(a) we are changing the phrase "has not been sold . . . to" to "is not owned by" in accordance with the changes we made to the definition of "importer" in § 1.500. Another change we are making to § 1.500 also is relevant to these provisions. As discussed in section III.A.11 of this document, we are adding a clarification to the definition of importer in § 1.500 stating that a designation of a U.S. agent or representative by a foreign owner or

consignee of a food (when there is no U.S. owner or consignee at the time of entry) must be confirmed in a signed statement of consent that the U.S. agent or representative agrees to serve as the importer under the FSVP regulation. In cases where there is no such signed statement of consent, there would not be a valid designation of a U.S. agent or representative for purposes of the definition of importer in § 1.500. In those circumstances, food offered for entry into the United States may be refused admission under § 1.514(a). We might ask the foreign owner or consignee that is exporting the food to provide us with the signed statement if any questions arise about whether the person designated as the U.S. agent or representative in fact agreed to serve in that role.

(Comment 315) One comment states that FDA should share with port officials from relevant agencies information on refusals of admission due to an importer's failure to comply with the FSVP regulation. The comment also suggests that we take steps to ensure that importers do not "port shop" to gain entry after previously being denied.

(Response 315) We currently post information related to all admission refusals on our Web site. In addition, we share information on refusals with CBP, relevant partner government agencies (PGAs), and State officials as appropriate. Once compliance with the FSVP regulation is required, this information might include refusals related to non-compliance with the regulation.

In addition, we believe that the FSVP regulation will provide us with tools to respond to any inappropriate "port shopping." Under § 1.509(a) of the final rule, the name, electronic mail address, and unique facility identifier identifying the importer must be provided electronically when filing entry with CBP for each line entry of food product offered for importation into the United States. Because we will have information about individual importers, we will be able to identify shipments linked to those importers. We plan to use this information to respond to any inappropriate "port shopping" that importers might attempt. In addition, in appropriate situations, when we identify violations with respect to products, shippers, and/or importers, we may place the products, shippers, and/or importers on import alert. Import alerts provide guidance to FDA field staff that future shipments appear violative within the meaning of applicable FD&C Act provisions. Based on information in an import alert, field

staff might detain products in shipments without physical examination.

Detention without physical examination places the burden on the importer to demonstrate that each shipment is in compliance. When products, shippers, and/or importers are included on an import alert, this prompts the FDA district office to flag relevant shipments involving these products and entities. Flagging such shipments makes "port shopping" less likely to be successful.

(Comment 316) One comment asks that we provide importers with a means to pose questions or request secondary consideration of shipment refusal due to FSVP non-compliance. One comment suggests that we develop procedures for informing foreign suppliers (and presumably importers) how they can obtain entry for future shipments following an admission refusal.

(Response 316) Importers will be able to use existing procedures to resolve matters related to non-compliance with the FSVP regulation. Under § 1.514(a), 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 the FSVP regulation with respect to that food. If there appears to be a violation, we might issue a Notice of Detention and Hearing specifying a place and period of time in which testimony may be introduced either verbally or in writing concerning the detention to prove compliance with the regulatory requirements. Throughout this process, the importer may contact the local District compliance office to ask questions.

To the extent that the second comment is asking about procedures for removal of food from detention without physical examination under an import alert due to FSVP non-compliance, existing procedures are likely to be applicable. An importer is placed on detention without physical examination because information indicates the appearance of a violation of an applicable provision of the FD&C Act. Our decisions to remove an importer from an import alert are based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and we have confidence that future entries will be in compliance with the relevant FD&C Act requirements. FDA import alerts often provide guidance about removal from the import alert, in particular how to remove the appearance of a violation. If we place any importers on import alert for FSVP violations, we plan to provide information in the import alert about achieving removal from the alert.

Depending on the nature of the violations at issue, that guidance may specify that we might require reviewing the records of the importer before granting removal. However, this review might not always be necessary.

(Comment 317) One comment states that FDA might sample an imported food and determine that it is adulterated or misbranded even though the importer is meeting all FSVP requirements. The comment states that although the food itself would be subject to detention or refusal, it is not clear what action the Agency would pursue regarding the importer's FSVP. The comment suggests that we explain what action we might take, such as conducting a follow-up inspection of the importer or directing the importer to revise its FSVP as needed to address inadequacies.

(Response 317) We agree that it is possible that we might find, based on an examination of samples or otherwise, that an importer's food appears to be adulterated, even in circumstances in which we had found the importer to be in compliance with the FSVP requirements during our most recent review of the importer's records. In such circumstances, we may take appropriate action in response to any such finding of an appearance of a violation, including, where appropriate, detention and subsequent refusal of admission of the food. Any finding that imported food appears to be adulterated may require the importer to take appropriate corrective action under § 1.508 to ensure that its foreign supplier produces food consistent with the applicable requirements of the FD&C Act. The importer also might need to modify its FSVP for the food to provide adequate assurance of the food's safety. Depending on the circumstances, we might determine that we should inspect the importer to assess its compliance with the FSVP regulation and, potentially, place the importer, the food, and/or its foreign supplier on import alert. However, we realize that there are circumstances in which the finding of adulteration in any particular shipment might not necessarily mean that the importer is in violation of the FSVP regulation.

To the extent that the comment is addressing circumstances in which the hazards in a food are controlled after importation, those circumstances are addressed, in part, in section III.H.2 of this document. As explained in that section, under § 1.507 in the final rule, importers are not required to conduct an evaluation under § 1.505 or supplier verification activities under § 1.506 under specified circumstances. For instance, importers are not required to

conduct § 1.505 evaluations or § 1.506 activities if they demonstrate and document that they rely on their customer to ensure that the identified hazard will be significantly minimized or prevented, or that they rely on a customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer, and that other specified requirements are satisfied (§ 1.507(a)(2) through (4)). In addition, § 1.502(c)(1) deems in compliance with most of the FSVP requirements an importer that is a facility subject to the preventive controls regulations that is implementing preventive controls for the hazards in the food in accordance with those regulations.

(Comment 318) One comment suggests that food from a foreign supplier for which FDA has refused admission under § 1.514(a) should be located and placed under embargo or "stop sale," adding that FDA should work with State and local government authorities in this effort whenever possible.

(Response 318) Under section 801(a)(3) of the FD&C Act, food that is refused admission under section 801(a) must be exported or destroyed within 90 days after its refusal. If, after a reasonable time, FDA has not received notification of exportation or destruction of articles refused admission, FDA guidance for import operations recommends that FDA district offices investigate the status of the disposition. Because of the requirement to either export or destroy such food, we do not agree that there is any general need to embargo the food or place it on "stop sale." However, if the need arises, we may work with State counterparts in connection with use of their "embargo" authority under State and/or local law. Our ability to work with States in this manner is one of the reasons we agree with the suggestion that we work with State and local government authorities when appropriate.

(Comment 319) Some comments state that, although it will be very easy for FDA to find technical infractions of the FSVP regulation, the Agency should focus more on infractions that may be linked to food safety problems rather than violations related to paperwork or recordkeeping procedures.

(Response 319) As with all of our FSMA-related enforcement efforts, we intend to apply our FSVP enforcement resources in a risk-based manner, placing greater emphasis on violations of the regulation that are more likely to result in harm to the public health. In

considering what enforcement actions, if any, are appropriate, we expect to consider factors including the severity of the violation, the risk to public health, and the willingness of the importer to cooperate and take corrective actions. In addition, we plan to provide guidance and technical assistance to assist importers in achieving compliance.

(Comment 320) Some comments request that we establish an appeals process for disputes regarding compliance with the FSVP regulation.

(Response 320) Importers will be able to use existing procedures to challenge FDA findings regarding non-compliance with the FSVP regulation. If we cite violations of the FSVP regulation upon inspection of an importer, the importer will have the opportunity to respond to the inspectional observations, and any such inspectional observations will not represent a final Agency determination regarding compliance. In addition, if we issue a warning letter to an importer, the importer will likewise have the opportunity to respond. Generally, FDA warning letters request corrective actions and a written response within a specified period of time after the date of receipt of the letter, usually 15 working days. At our discretion, the recipient of a warning letter may be offered an opportunity to discuss the letter with FDA district officials or, when appropriate, with other FDA officials.

(Comment 321) Some comments request that we provide information on the measures we will use to assess an importer's compliance with the FSVP regulation.

(Response 321) FDA investigators may conduct inspections of importers and review importers' records. In conducting such inspections and reviews, we might consult any information and/or Agency guidance that is relevant and appropriate.

#### *P. Other Issues*

We received comments on several matters related to FDA implementation and enforcement of the FSVP regulation as well as Agency outreach and training. We respond to the comments in the following paragraphs.

##### *1. Implementation and Enforcement*

As discussed in the following paragraphs, we received comments concerning FDA inspections of importers, the role of States in enforcing the FSVP regulation, and other implementation and enforcement issues.

a. How should FDA conduct FSVP inspections?

(Comment 322) We received many comments addressing how we should conduct FSVP inspections. Several comments ask that we provide companies with flexibility to develop their supplier verification programs. Some comments assert that FDA inspections of supplier verification programs should focus on ensuring that importers establish strong, risk-based programs that are consistently implemented and documented.

Some comments assert that FDA inspectors should focus on whether the qualified individuals responsible for developing the FSVPs have the necessary education and experience.

Some comments recommend that we assess the evaluation of hazards and suppliers, consider whether the importer properly used the evaluation to determine the appropriate supplier verification activities, and verify that the importer conducted the appropriate activities. Some comments assert that unless there is cause, we should not routinely question an importer's determinations about individual suppliers or review the food and supplier evaluations and determinations of appropriate verification activities. One comment suggests that we defer to importers in our inspection and enforcement relating to supplier verification activities.

(Response 322) We understand the need for both flexibility and accountability when conducting records reviews for compliance with the FSVP regulation. The regulation is written to provide importers with flexibility in meeting the requirements, including by determining appropriate supplier verification activities based on the risk posed by a food and the foreign supplier's performance. However, the regulation requires importers to document their procedures, determinations, and activities to allow us to assess importers' compliance.

We disagree that we should not review any particular aspect of an importer's FSVP. Because the final rule allows importers flexibility in meeting the requirements, we must assess the choices the importer makes to ensure that its FSVP adequately protects U.S. consumers from unsafe imported products. It is not our practice to defer to regulated entities in our implementation and enforcement of regulations.

However, we realize that no method of supplier verification can provide complete assurance against the emergence of foodborne illness, and

there might be circumstances in which the failure to detect or control a hazard might not necessarily mean that the importer has incorrectly analyzed the hazards, selected a "wrong" method of verification, or has otherwise violated the FSVP regulation. In such circumstances, however, an importer might be required to revise its procedures to be in compliance with the requirements.

(Comment 323) Some comments recommend that we conduct our inspections of FSVP activities at the central locations where such activities are carried out. Some comments suggest that we conduct targeted inspections at corporate headquarters that focus only on the importer's FSVP, because most supplier verification programs are managed at the corporate level.

(Response 323) Because the FSVP regulation requires documentation of an importer's implementation of its FSVP, our inspections will be records-based. Therefore, in the event of an in-person inspection, the inspection generally will take place where the majority of FSVP records are kept. That might be at the importer's corporate headquarters or another central location. Although § 1.509(b)(2) permits offsite storage of records, those records must be retrieved and provided onsite within 24 hours of FDA's request for review.

b. Role of States in Enforcement

(Comment 324) Some comments ask how we will coordinate our FSVP enforcement activities with State and local agencies. Some comments assert that State and local authorities can play an important role in ensuring the effectiveness of this verification system through the inspection and surveillance of imported food products marketed to establishments routinely inspected by State and local agencies. Some comments ask that we communicate early and often with States and local authorities regarding anticipated roles, options, and resources that will be available for the implementation of this rule. Other comments suggest that we establish cooperative agreements with States explaining what type of enforcement actions we will support, how States should respond to discovered food hazards, and how we will use information reported by States. Some comments ask whether we will provide funding to State agencies to assist them in meeting inspection mandates.

(Response 324) We agree that State and local food safety regulatory authorities play an important role in helping to protect consumers from unsafe food. As previously stated, we

are working through the Partnership for Food Protection to develop and implement the IFSS consistent with FSMA's emphasis on establishing partnerships for achieving compliance (see section 209(b) of FSMA). We are currently developing our compliance strategy for the FSVP regulation and are considering the role that State and local authorities can play in helping to achieve compliance.

(Comment 325) Many comments ask us to be more open and transparent with records of imported foods distributed within the States. Some comments assert that State agencies must have access to all relevant import records when a State agency discovers an adulterated product. Some comments ask that we develop a formal mechanism through which States can supply surveillance information to us so that we can better target import inspections and review problem products, companies, and countries. Other comments ask us to develop a method to allow States to efficiently access FDA records.

(Response 325) In general, we work with our State partners in enforcement actions, including coordinating actions or deferring to each other when one department has authority to act swiftly to protect the consumer. As previously stated, we are still determining the appropriate role of our State partners in FSVP implementation and enforcement.

c. Decreased Border Sampling for Food Subject to FSVP

(Comment 326) Some comments ask that we consider decreasing the sampling frequency of regular border inspections for chemical, physical, and radiological contamination of imported foods if the importer is in compliance with the FSVP regulation. These comments assert that chemical, physical, and radiological hazards are not increased during transport, unlike biological hazards.

(Response 326) We agree that the results of FSVP inspections should factor into our operations at ports of entry. We plan on incorporating data from the inspections into our PREDICT system to help better target food imports based on risk, which could include risks associated with different types of hazards.

2. Outreach and Training

(Comment 327) Some comments support the efforts of the FSPCA and encourage supplier verification-specific training as part of Alliance programs. Some comments offer recommendations for the content, delivery, and timing of education and training for FDA and

industry. These comments suggest that materials be designed for simplicity of understanding but also completely address all requirements, that FDA take advantage of the wide range of methods available for distribution and dissemination of educational and instructional materials (e.g., workshops, webinars, publications/media, and onsite trainings/consultations), and that we begin training efforts as soon as the final rule is published.

(Response 327) We agree that the FSVP materials we develop for industry need to be comprehensive and understandable to importers and other stakeholders. We also agree that our outreach methods for distribution and dissemination of educational and instructional materials should vary and be easily accessible. We have solicited input on how to best reach all affected stakeholders and will continue to do so. We intend to begin external outreach soon after we issue the final rule.

(Comment 328) Some comments request that we provide “special and differential treatment” along with technical assistance to help exporters from developing countries meet the requirements of the FSVP regulation. One comment also states that providing training will be particularly useful for addressing how implementation of FSMA will impact developing countries.

(Response 328) The concept of special and differential treatment is incorporated in the WTO agreements. Article 10.2 of the SPS Agreement states: “Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction . . . longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports” (Ref. 4). At the 2001 WTO Ministerial Conference in Doha, WTO Members issued a Ministerial Decision that interpreted the special and differential obligations of the SPS Agreement (Ref. 18). The Ministerial Decision defined “longer time-frame for compliance” with regulatory measures to normally mean a period of not less than 6 months.

As discussed in section VI.B of this document, we proposed that importers generally would be required to come into compliance with the FSVP regulation 18 months after the publication date of the final rule. For importation of foods subject to the preventive controls or produce safety regulations, importers would be required to comply with the FSVP regulation 6 months after their foreign

suppliers were required to comply with the applicable regulations.

However, recognizing that smaller businesses may need more time to comply with the requirements, the preventive controls and produce safety regulations contain extended compliance deadlines for very small businesses and small businesses. For example, in the final rule on preventive controls for human food, we are allowing 2 years for small businesses and 3 years for very small businesses to comply with that regulation. We anticipate that these extended implementation periods for small businesses and very small businesses will apply to many firms that would be foreign suppliers for FSVP purposes, including suppliers in developing countries. We believe these implementation periods are sufficient to address the needs of producers in developing countries, particularly for small and very small producers in such countries.

In addition to the extended time periods for compliance for small and very small businesses, we have also established modified supplier verification requirements for importers of food from three types of small foreign suppliers. These foreign suppliers are: (1) Qualified facilities under the preventive controls regulations for human food or animal food, (2) certain smaller farms that grow produce and are not covered farms under the produce safety regulation in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5, and (3) shell egg producers not subject to the shell egg production regulation because they have fewer than 3,000 laying hens. Each of these types of suppliers is either exempt from their underlying FDA food safety regulations or subject to modified requirements, mostly if not wholly because of the size of the entity.

In addition to the 18-month time periods for compliance for all firms, extended compliance dates for small and very small businesses subject to the preventive controls and produce safety regulations, and modified requirements for very small businesses, we intend to work with the food industry, educational organizations, the USDA, the United States Agency for International Development, and foreign governments to develop the tools and training programs needed to facilitate compliance with these new food safety regulations by exporters, including those from developing countries. In addition, as previously stated, we have issued a comprehensive plan to expand the technical, scientific and regulatory food safety capacity of foreign

governments and their respective food industries in countries from which foods are exported to the United States.

(Comment 329) Some comments assert that effective implementation of the FSVP regulation will require comprehensive FDA inspector training, and they recommend that we begin developing such a training program. Some comments ask us to establish a dedicated cadre of supplier verification inspectors who are specially trained to efficiently and effectively ensure that importers’ FSVPs are subject to careful and thoughtful inspections. These comments assert that inspectors who are only familiar with food facility operations will lack the necessary insight and understanding to effectively inspect supplier verification programs unless they are given considerable training. Some comments maintain that inspectors should be trained to understand what is required of the FSVP regulation, how inspections should be conducted, and what types of observations are appropriate to include on FDA-Form 483s issued to importers.

Some comments assert that inspector calibration will be essential to ensure that the regulations are enforced consistently from one region to another by both Federal and State officials. These comments suggest that internal guidance and measures as well as extensive training and education will help ensure that Federal and State inspection and enforcement programs are applied consistently.

(Response 329) We agree that training is an important component of implementation of the FSVP regulation. We are currently developing a comprehensive training program for our inspectional and compliance staff with the goal of ensuring that our FSVP inspections are effective, efficient, and consistent. Our goal is to provide real-time communication between our field investigators and our subject matter experts at Agency headquarters so that questions can be resolved quickly and consistently. This will be important not only for the FSVP regulation but also for the supplier verification components of the preventive controls regulations.

While we agree that our FSVP inspections, which will be records based, will be different from our food facility inspections, we believe that many of the skills needed to conduct these inspections will overlap. For example, an investigator looking at an importer’s FSVP will have to understand the hazard analysis and food and supplier evaluation on which the importer relies to assess the effectiveness of the importer’s FSVP. We are currently exploring ways to leverage

the work done by the FSPCA to aid FSVP compliance efforts.

(Comment 330) Some comments assert that border agents should be appropriately trained in applying FSVP requirements to avoid delays in entry of imported food.

(Response 330) We intend to provide education and training on the FSVP regulation to all FDA staff. We note, however, that FSVP inspections will not occur at entry. These inspections will more likely occur at the offices of importers, their corporate headquarters, or other places where FSVP records are kept. Entry decisions will only be affected if we find problems with an importer's FSVP that remain uncorrected or pose a risk to public health.

(Comment 331) One comment expresses concern that we may not have adequate knowledge and appreciation of foreign food safety practices and asks that we train our inspectors to take these differences into account and adopt a flexible approach to inspections. The comment asserts that this concern is heightened by the FSMA mandate to increase inspections of foreign food facilities.

(Response 331) Because the FSVP regulation applies to importers, we generally will not be inspecting foreign facilities as part of our implementation and enforcement of this regulation. However, we appreciate the differences in food safety practices among different countries and will take them into account when implementing the FSVP regulation. FSMA mandates that importers provide adequate assurances that their foreign suppliers produce food using processes and procedures that provide the same level of public health protection as those required under applicable regulations in the United States. We will need to train our investigators and compliance staff to properly apply this standard when inspecting importers. Ensuring real-time communication between our field staff and subject matter experts at FDA headquarters will help provide consistency in interpretation and judgment.

(Comment 332) Some comments assert that we should design and develop a functional scheme to ensure that States receive needed funds and training to assist in implementing the FSVP regulation if they decide to do so. Some comments assert that we should pursue funding to invest in State agencies that can assist in meeting inspection mandates.

(Response 332) As stated previously, we are currently developing our compliance strategy for FSVP and are

considering the role that State and local authorities can play in helping to achieve compliance.

#### IV. Effective and Compliance Dates

##### A. Effective Date

We proposed that any final rule on FSVPs would become effective 60 days after the date on which it is published in the **Federal Register**.

(Comment 333) Some comments support the proposed effective date while others assert that the effective date should be a minimum of 6 months to 1 year after the publication of the final FSVP guidance.

(Response 333) We decline the request to extend the effective date for this rule beyond 60 days after publication. Sixty days is a customary effective date period for significant rules. To the extent that the comments would like importers to have additional time to comply with the final rule, compliance dates are more relevant than the rule's effective date. As discussed in section IV.B of this document, we are providing more time for importers to comply with the FSVP regulation. We intend to issue guidance in a timely manner to facilitate compliance with the new requirements.

##### B. Compliance Dates

We proposed that generally importers would be required to come into compliance with the FSVP regulation 18 months after the publication date of the final rule. We believed that 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 proposed. We proposed exceptions to this approach to take into account the different compliance dates suggested in the proposed rules on preventive controls for human food, preventive controls for animal food, and produce safety.

We proposed that with respect to foods subject to the preventive controls regulations, the importer would be required to comply with the FSVP regulation 6 months after the foreign supplier of the food is required to comply with the preventive controls regulations.

With regard to foreign suppliers that are farms, we proposed 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 regulation 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 regulation, whichever is later.

- If the foreign supplier is not subject to the produce safety regulation, the compliance date for the importer to comply with the FSVP regulation 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 safety final rule, whichever is later. This approach would ensure that the receiving facility would be able to know whether the farm supplier was subject to the produce safety regulation before choosing any appropriate verification activities.

(Comment 334) Some comments support the proposed general compliance date of 18 months after publication of the final rule. Some comments assert that the proposed compliance period is too short and ask that the compliance date be extended to 30 months, 3 years, or 5 years after the publication of the final rule. Some comments ask us to coordinate uniform compliance dates for all the FSMA implementing rules to provide certainty and allow businesses to plan for the extensive changes that will be mandated.

(Response 334) We agree that we should coordinate compliance dates for the FSMA implementing rules that are interrelated. We continue to believe that 18 months is a reasonable timeframe for certain importers to begin complying with the requirements. In addition, we continue to strive to minimize the likelihood that an importer will be required to comply with the FSVP regulation before its supplier is required to comply with other FSMA food safety regulations. Finally, we see value in having the compliance dates of this rulemaking align with the compliance dates of the supply-chain program provisions in the preventive controls regulations, to the extent feasible. Therefore, we conclude that the date that importers must comply with the FSVP regulation is the latest of the following dates:

- 18 months after the publication of this final rule;
- For the importation of food from a supplier that is subject to the preventive controls regulations for human food or animal food or the produce safety regulation, 6 months after the foreign supplier of the food is required to comply with the relevant regulations; or
- For an importer that is also subject to the supply-chain program provisions in the preventive controls regulations for human food or animal food, the date the importer, as a receiving facility, is

required to comply with the supply-chain program provisions of the relevant regulation.

(Comment 335) Some comments assert that there should be an informed compliance or transition period after the end of the pre-compliance period during which importers would be expected to comply gradually with the FSVP regulation without the threat of full enforcement and associated penalties. Some comments specify 12 months as the appropriate time for such an informed compliance or transition period. Some comments ask that we give developing countries longer transition periods.

(Response 335) We decline these requests for an informed compliance period because we conclude that we are providing importers with adequate time in which to come into compliance with the FSVP regulation. However, we intend to conduct outreach, training, and engagement activities to help importers understand the new requirements and enable them to comply with the requirements by the applicable compliance dates.

#### V. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal governmental officials regarding this rulemaking. We have prepared a Tribal Summary Impact Statement that includes a summary of tribal officials' concerns and how we have addressed them (Ref. 19). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at <http://www.fda.gov/fsvprule> or at <http://www.regulations.gov>. Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### VI. Economic Analysis of Impacts

FDA has examined the impacts of the final 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, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is a significant regulatory action under Executive Order 12866.

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 conclude that the final rule will have a significant economic impact on a substantial number of small entities.

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 \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. We expect this final rule to result in a 1-year expenditure that would meet or exceed this amount.

The final analyses conducted in accordance with these Executive Orders and statutes will be made available in the docket for this rulemaking and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/> (Ref. 20).

#### VII. Analysis of Environmental Impact

We have 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.

#### VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the paragraphs that follow with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

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

*Description:* FDA is finalizing its regulation on FSVPs for food for humans and animals. The regulation is intended 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 the processes and procedures required for production of food in compliance with section 418 or 419 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g or 350h), if either is applicable, and in compliance with sections 402 and 403(w) (if applicable) of the FD&C Act (21 U.S.C. 342 and 343(w)).

*Description of Respondents:* We estimate that currently there are approximately 56,800 persons who meet the definition of importer set forth in this final rule (and are not exempt from the rule) and are therefore subject to its information collection requirements. The rule exempts from these requirements the importation of certain foods, including the following: Certain juice and seafood products and ingredients; food for research or evaluation; food for personal consumption; certain alcoholic beverages and ingredients imported for use in alcoholic beverages; food that is transshipped through the United States; food that is imported for processing and future export; food that is produced in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country; and meat, poultry, and egg products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). The final rule also specifies that importers who are in compliance with the supply-chain program provisions in the preventive controls regulations, who implement preventive controls for the hazards in the food they import, or who are not required to implement a preventive control under certain provisions of the preventive controls regulations, are deemed in compliance with most of the FSVP requirements. Certain exceptions to the standard FSVP requirements would apply to importers of food for which the importer's customer or a subsequent entity in the distribution chain controls a hazard. In addition, the final rule establishes modified FSVP requirements for importers of dietary supplements, very small importers, importers of food from certain small foreign manufacturers/processors and farms, and importers of



certain food from suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

In the **Federal Register** of July 29, 2013 (78 FR 45729), we published a notice of proposed rulemaking including a Paperwork Reduction Act (PRA) analysis of the information collection provisions found in the proposed regulation. In the **Federal Register** of September 29, 2014 (79 FR 58573), we published a supplemental notice of proposed rulemaking also including a PRA analysis. While we received some comments regarding

recordkeeping requirements generally, which are discussed in section III.K of this document, we did not receive specific comments addressing the four information collection topics solicited in both the original and supplemental proposed rules. We are, therefore, retaining the estimates provided in our supplemental notice of proposed rulemaking, except to the extent that revisions are necessary to address changes to the proposed regulation included in the final rule, as discussed in the following paragraphs. For more information on our original calculations of the information collection burden associated with this rulemaking, you

may refer to the PRA analyses found under Docket No. FDA-2011-N-0143 at [www.regulations.gov](http://www.regulations.gov).

We estimate the burden for this information collection as follows:

#### Reporting Burden

Table 4 shows the total estimated annual reporting burden associated with this final rule. This estimate is consistent with the reporting estimates found in the supplemental notice of proposed rulemaking published on September 29, 2014 (79 FR 58573 at 58590), except where revisions are necessary to reflect new requirements included in the final rule.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.501(c); exemption for food for research .....	36,360	40	1,454,400	0.083 (5 minutes) .....	120,715
1.509(a), 1.511(c), 1.512(b)(2); importer identification information for filing with CBP.	56,800	157	8,917,600	0.02 (1.2 minutes) .....	178,352
Total .....	.....	.....	.....	.....	299,067

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

#### A. Exemption for Food for Research or Evaluation

Section 1.501(c) of the FSVP regulation exempts food that is imported for research or evaluation purposes, provided that:

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

As shown in Table 4, we estimate that annually there will be 36,360 persons for whom a declaration that a food will be used for research or evaluation purposes will be submitted, and that about 40 declarations will be submitted for each such person annually. We further estimate that submission of this declaration should take approximately 0.083 hours, resulting in a total annual burden of 120,715 hours.

#### B. Importer Identification at Entry

Section 1.509(a) requires importers to ensure that, for each line entry of food product offered for importation into the United States, its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA is provided electronically when filing

entry with CBP. As shown in Table 4, we estimate that each of the estimated 56,800 importers would need to ensure that this information is provided for an average of 157 line entries each year. We further estimate that each such submission would require 0.02 hours, resulting in a total annual burden of 178,352 hours.

#### Recordkeeping Burden

Table 5 shows the total estimated annual recordkeeping burden associated with this final rule. While this estimate is consistent with many of the recordkeeping estimates found in our previous analyses, we have revised certain estimates to reflect changes to the proposed requirements included in the final rule and adopted additional requirements under § 1.507(a) and have revised our calculations accordingly.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Controls for LACF—1.502(b) .....	2,443	4	9,772	1	9,772
Determine and document hazards—1.504(a) .....	11,701	1	11,701	3.5	40,954
Review hazard analysis—1.504(d) .....	11,701	7	81,907	0.33	27,029
Evaluation of food and foreign supplier—1.505(a)(2), 1.511(c)(1) .....	11,701	1	11,701	4	46,804
Approval of suppliers—1.505(b), 1.512(c)(1)(iii) .....	8,191	1	8,191	12	98,292
Reevaluation of food and foreign supplier—1.505(c), 1.512(c)(1)(ii)(A) .....	11,701	365	4,270,865	0.25	1,067,716

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Confirm or change requirements of foreign supplier verification activity—1.505(c), 1.512(c)(1)(ii)(A) .....	2,340	1	2,340	2	4,680
Review of other entities assessments—1.505(d), 1.512(c)(1)(iii) .....	3,510	1	3,510	1.2	4,212
Written procedures for use of approved foreign suppliers—1.506(a)(1), 1.511(c)(2), 1.512(c)(3)(i) .....	11,701	1	11,701	8	93,608
Review of written procedures—1.506(a)(2), 1.511(c)(2)(ii), 1.512(c)(3)(ii) .....	11,701	1	11,701	1	11,701
Written procedures for conducting verification activities—1.506(b), 1.511(c)(3) .....	11,701	1	11,701	2	23,402
Determination and documentation of appropriate supplier verification activities—1.506(d)(1)–(2) 1.511(c)(4)(i) .....	11,701	4	46,804	3.25	152,113
Review of appropriate supplier verification activities determination by another entity—1.506(d)(3) 1.511(c)(4)(iii) ...	11,701	2	23,402	0.33	7,723
Conduct/review audits—1.506(e)(1)(i), 1.511(c)(5)(i)(A) .....	11,701	2	23,402	3	70,206
Conduct periodic sampling/testing—1.506(e)(1)(ii), 1.511(c)(5)(i)(B) .....	11,701	2	23,402	1	23,402
Review records—1.506(e)(1)(iii), 1.511(c)(5)(i)(C) .....	11,701	2	23,402	1.6	37,443
Document your review of supplier verification activity records—1.506(e)(3), 1.511(c)(5)(iii) .....	11,701	6	70,206	0.25	17,552
1.507(a)(1) .....	11,701	3.17	37,082	1.25	46,353
Written assurances—1.507(a)(2), 1.507(a)(3), and 1.507(a)(4) .....	11,701	8.72	102,038	0.50	51,019
Disclosures that accompany assurances—1.507(a)(2), 1.507(a)(3), and 1.507(a)(4) .....	102,038	1	102,038	0.50	51,019
Document assurances from customers—1.507(c) .....	36,522	2.8	102,262	0.25	25,566
Document corrective actions—1.508(a) and 1.512(b)(4) ....	2,340	1	2,340	2	4,680
Investigate and determine FSVP adequacy—1.508(b), 1.511(c)(1) .....	2,340	1	2,340	5	11,700
Written assurances for food produced under dietary supplement CGMPs—1.511(b) .....	11,701	2.88	33,664	2.25	75,744
Document very small importer/certain small foreign supplier status—1.512(b)(1) .....	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier—1.512(b)(3) .....	50,450	2.8	141,084	2.25	317,439
Total					

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

#### A. Documentation of Production of LACF in Accordance With Part 113

Section 1.502(b)(1) requires importers of LACF to verify and document that, with respect to microbiological hazards that are controlled under part 113, the food was produced in accordance with those regulations, and for all matters not controlled under part 113, to have an FSVP as specified in § 1.502(a). As shown in Table 5, we estimate that there are 2,443 importers of LACF importing an estimated 4 LACF products annually. We further estimate that it would take each LACF importer 1 hour to document that a food was produced in accordance with part 113. This results in a total annual burden of 9,772 hours.

#### B. Hazard Analysis

Section 1.504(a) requires importers, for each food they import or offer for import, to have a written hazard analysis. We have updated our estimates. We estimate that 11,701

importers would need to spend an average of 3.5 hours each determining and documenting hazard analyses for imported foods, resulting in an estimated burden of 40,954 hours (13,651 hours annualized).

Section 1.504(d) permits importers to identify the hazards that are reasonably likely to occur with a food by reviewing and evaluating the hazard analysis conducted by another entity (including the foreign supplier). If the importer selects this approach to hazard analysis it must document the determination it makes based on its review and evaluation of the foreign supplier's hazard analysis. As shown in table 5, we estimate that 11,701 importers would take this approach to hazard analysis for about 7 products each, and that evaluating the supplier's hazard analysis and documenting each evaluation would require about 1 hour on average. This results in a total

burden of 27,029 hours (9,010 hours annualized).

#### C. Evaluation for Supplier Approval and Verification

Section 1.505(a)(2) requires importers to document their evaluation of the risk posed by a food and the foreign supplier's performance. As shown in table 5, we estimate that it will take 12 hours for each of an estimated 11,701 importers to conduct and document their evaluation under §§ 1.505(a) and 1.511(c), resulting in a total burden of 46,804 hours (15,601 hours annualized).

Section 1.505(b) requires importers to document the approval of their foreign suppliers on the basis of the food and supplier evaluation the importer conducts under § 1.505(a). As shown in table 5, we estimate that it will take 12 hours for each of an estimated 8,191 importers to approve their foreign suppliers and document their approval of the suppliers, resulting in a total

burden of 98,292 hours (32,764 hours annualized).

Section 1.505(c) requires that the importer reevaluate factors associated with the food and foreign suppliers when the importer becomes aware of new information. Recognizing that some importers may choose to spend more time less often, we estimate it would take about 15 minutes per day to maintain and follow these procedures by reviewing information regarding hazards and suppliers. This results in a burden of 1,067,716 hours annually.

Section 1.505(c) also requires that if an importer determines that the concerns associated with importing a food from a foreign supplier have changed, the importer must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier and whether the supplier verification activities conducted need to be changed. We estimate that 2,340 importers will need to determine and document whether they need to change their supplier verification activities 1 time per year, resulting in a total burden of 4,680 hours.

Section 1.505(d) allows importers to review another entity's evaluation or reevaluation of the risk posed by a food and the foreign supplier's performance and requires the importer document the review and assessment or reassessment. As shown in table 5, we estimate that it will take 1.2 hours for each of an estimated 3,510 importers to review and assess or reassess documentation provided by another entity, resulting in a total burden of 4,212 hours (1,404 hours annualized).

#### *D. Foreign Supplier Verification and Related Activities*

Under § 1.506(a)(1), importers must establish and follow adequate written procedures to ensure that they import foods only from foreign suppliers that they have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods importers subject to adequate verification activities before using or distributing), and document the use of those procedures. As shown in table 5, we estimate that it would take each of 11,701 importers 8 hours to establish procedures resulting in a burden of 107,112 hours (35,749 hours annualized) and 4 hours annually to document the use of such procedures resulting in an annual burden of 93,608 hours, for a grand total of 31,203 hours annualized.

Under § 1.506(a)(2), an importer may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under § 1.506(a)(1) provided that the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer document its review and assessment. As shown in table 5, we estimate that it would take each of 11,701 importers 1 hour to review and assess another entity's procedures, resulting in a burden of 11,701 hours (3,900 hours annualized).

Under §§ 1.506(b) and 1.511(c)(3), importers must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted. As shown in table 5, we estimate that it would take each of 11,701 importers 2 hours to establish procedures resulting in a total burden of 23,402 hours (7,801 hours annualized).

Section 1.506(d) requires importers to determine and document which supplier verification activities are appropriate in order to provide adequate assurances that the hazards requiring a control in the food the importer bring into the United States have been significantly minimized or prevented. Under § 1.506(d)(2), when a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the importer must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer makes an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities and/or less frequent onsite auditing are appropriate to provide adequate assurances that the hazards requiring a control in the food are significantly minimized or prevented. As shown in table 5, we estimate that it would take an estimated 11,701 importers 3.25 hours to determine and document appropriate supplier verification activities under either § 1.506(d)(1) or (2) or § 1.511(c)(4)(i) for 4 food and foreign supplier combinations per importer, resulting in a total burden of 152,113 hours (50,704 hours annualized).

Under §§ 1.506(d)(3) and 1.511(c)(4)(iii), instead of determining the verification activities themselves, importers can review and document that they have reviewed and assessed the supplier activities determinations made

by another entity. As shown in table 5, we estimate that it would take an estimated 11,701 importers 0.33 hours to review and document review of another entity's determination of the appropriate supplier verification activities 2 food and foreign supplier combinations per importer, resulting in a total burden of 7,723 hours (2,574 hours annualized).

Under § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A), an importer may conduct (and document) or obtain documentation of an onsite audit of the foreign supplier. As shown in table 5, we estimate that 32,402 such audits would be conducted (or documentation obtained for) annually, with each audit requiring an average of 3 hours each, resulting in a total annual burden of 70,206 hours.

Under § 1.506(e)(1)(ii) or § 1.511(c)(5)(i)(B), an importer may conduct (and document) or obtain documentation of sampling and testing of a food for a hazard. As shown in table 5, we estimate that 11,701 importers each year would determine that this approach to verification is appropriate for an average of two products they import. We further estimate that each incidence of sampling and testing and corresponding documentation will require 1 hour. This results in an estimated annual burden of 23,402 hours.

Under § 1.506(e)(1)(iii) or § 1.511(c)(5)(i)(C), an importer may conduct (and document) or obtain documentation of a review of its foreign supplier's food safety records to verify control of a hazard. As shown in table 5, we estimate that 11,701 importers each year would determine that this approach to verification is appropriate for an average of two products they import. We further estimate that documentation of food safety record review would require 1.6 hours, resulting in a total annual burden of 37,443 hours.

Under § 1.506(e)(1)(iv) or § 1.511(c)(5)(i)(D), an importer may use a different verification procedure that it has established as being appropriate based on an evaluation of the risk posed by a food and the foreign supplier's performance; the importer must document such use. We have not identified any alternative verification procedure nor included an estimated cost, nor have we estimated any associated burden for revised § 1.506(e)(1)(iv).

Section 1.506(e)(3) requires importers to promptly review and assess the results of the verification activities that they conduct or obtain documentation of under § 1.506(e)(1), or that are

conducted by other entities in accordance with § 1.506(e)(2), and to document the review and assessment of the results. However, importers are not required to retain documentation of supplier verification activities conducted by other entities, provided that the importer can obtain the documentation and make it available to FDA in accordance with § 1.510(b). As shown in table 5, we estimate that 11,701 importers will review and assess the results of 70,206 supplier verification activities annually, and that each review and assessment will take 0.25 hours. This results in a total annual burden of 17,552 hours.

*E. Requirements for Food That Cannot Be Consumed Without Hazards Being Controlled or for Which Hazards Are Controlled After Importation*

Section 1.507 of the final rule includes provisions for activities that were partially addressed under the proposed rule and the supplemental notice of proposed rulemaking. Under § 1.507(a)(1) of the final rule, an importer is not required to conduct a food and foreign supplier evaluation under § 1.505 or conduct supplier verification activities under § 1.506 if it determines and documents that the type of food it is importing could not be consumed without application of an appropriate control. As shown in table 5, we estimate that each year 11,701 importers will determine that 37,082 foods cannot be consumed without application of a control and that it will take 1.25 hours, on average, to make the determination, resulting in a total annual burden of 46,353 hours.

Under § 1.507(a)(2), an importer is not required to conduct an evaluation under § 1.505 or verification activities under § 1.506 if it relies on its customer who is subject to subpart C of part 117 or part 507 (the regulations on hazard analysis and risk-based preventive controls) to ensure that the identified hazard will be significantly minimized or prevented, and the importer:

- Discloses in documents accompanying the food that the food is “not processed to control [identified hazard]”; and
- Annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

Under § 1.507(a)(3), an importer is not required to conduct an evaluation under § 1.505 or verification activities under § 1.506 if it relies on its customer who is not required to implement preventive controls under part 117 or part 507 to

provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and the importer:

- Discloses in documents accompanying the food that the food is “not processed to control [identified hazard]”; and
- Annually obtains from its customer written assurance that the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.

Under § 1.507(a)(4), an importer is not required to conduct an evaluation under § 1.505 or verification activities under § 1.506 if it relies on its customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and the importer:

- Discloses in documents accompanying the food that the food is “not processed to control [identified hazard]” and
- Annually obtains from its customer written assurance that the customer will disclose in documents accompanying the food that the food is “not processed to control [identified hazard]” and will only sell to another entity that agrees, in writing, it will: (1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to subpart C of part 117 or part 507) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not required to implement preventive controls under part 117 or part 507); or (2) obtain a similar written assurance from the entity’s customer as required under § 1.507(a)(4)(ii)(A) or (B).

As shown in table 5, we estimate that 11,701 importers will obtain such a written assurance from 102,038 customers annually in accordance with § 1.507(a)(2), (3), and (4), collectively, and that it will take 0.50 hours to document the written assurance. This results in an estimated annual burden of 51,019 hours. We estimate that the disclosure burdens under these provisions will also take 0.50 hours each and will be done for each of the 102,038 assurances identified resulting in an annual burden of 51,019 hours.

Under § 1.507(a)(5), an importer is not required to conduct an evaluation under § 1.505 or verification activities under § 1.506 if it establishes, documents, and implements a system that ensures control, at a subsequent distribution step, of the hazards in a food and the importer documents its implementation of that system. We did not include an estimate for compliance with this

provision because we do not know any examples of such a system for hazard control.

Under § 1.507(c), the customer of an importer or some other subsequent entity in the distribution chain for a food that provides a written assurance under § 1.507(a)(2), or (3), or (4) must document its actions taken to satisfy the written assurance. As shown in table 5, we estimate that 36,522 customers of importers or other subsequent entities in the distribution chain will need to document its actions in accordance with § 1.507(c) 2.8 times annually and that this documentation will require 0.25 hours, resulting in a total annual burden of 25,566 hours.

*F. Investigations, Corrective Actions, and Investigations Into FSVP Adequacy*

Proposed § 1.507(b) would have required an importer, if it became aware that an article of food that it imported was adulterated or misbranded, to promptly investigate the cause or causes of such adulteration or misbranding and to document any such investigation. As previously discussed, this requirement was not included in the final rule and we have therefore removed the burden previously calculated for its implementation and revised our estimate accordingly.

Section 1.508(a) of the final rule requires an importer to take corrective actions if it determines that one of its foreign suppliers of a food does 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, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act. Such 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. As shown in table 5, we estimate that 2,340 importers will need to take a corrective action 1 time annually, and that the corrective action will require 2 hours to complete, resulting in a total annual burden of 4,680 hours.

Section 1.508(b) requires an importer, if it determines by means other than its verification activities conducted under § 1.506 or § 1.511(c) or a reevaluation conducted under § 1.505(c) or (d), that one of its foreign suppliers does not produce food using 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, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act, to promptly investigate to determine whether the importer's FSVP is adequate and, when appropriate, to modify the FSVP. This provision also requires importers to document any such investigations and FSVP changes. As shown in table 5, we estimate that, on average, 2,340 importers will need to conduct an investigation once a year to determine the adequacy of their FSVP in accordance with § 1.508(b) and that conducting and documenting the investigation will require 5 hours. This results in an estimated annual burden of 11,700 hours.

#### *G. Food Subject to Certain Dietary Supplement CGMP Requirements*

Section 1.511 sets forth modified FSVP requirements for food that is subject to certain dietary supplement CGMP requirements. Under § 1.511(a), importers who are required to establish specifications under § 111.70(b) or (d) with respect to a food that is a dietary supplement or dietary supplement component it imports for further manufacturing or processing as a dietary supplement, and are in compliance with the requirements in §§ 111.73 and 111.75 applicable to determining whether those specifications are met, must comply with the requirements under §§ 1.503 and 1.509, but are not required to comply with the requirements in §§ 1.502, § 1.504 through 1.508, or § 1.510. These importers are included in the estimated reporting burden for § 1.509(a).

Under § 1.511(b), if an importer's customer is required to establish specifications under § 111.70(b) or (d) with respect to a food that is a dietary supplement or dietary supplement component it imports for further manufacturing or processing as a dietary supplement, the customer is in compliance with the requirements in §§ 111.73 and 111.75 applicable to determining whether those specifications are met, and the importer annually obtains from its customer written assurance that the customer is in compliance with those requirements, then for that food the importer must comply with the requirements in §§ 1.503, 1.509, and 1.510, but is not required to comply with the requirements in §§ 1.502 and §§ 1.504 through 1.508. As shown in table 5, we estimate that 5,574 importers would need to obtain written assurance from

an average of 6 customers in accordance with § 1.511(b) and that documentation of each assurance would take 2.25 hours, resulting in a total annual burden of 75,249 hours. In addition, these importers are included in the estimated annual reporting burden for § 1.509(a).

Under § 1.511(c), importers of other dietary supplements, including "finished" dietary supplements (*i.e.*, packaged and labeled dietary supplements that are not subject to further processing) and dietary supplements imported only for packaging and labeling are subject to different FSVP requirements.

Section 1.511(c)(2)(i) requires importers of finished dietary supplements to establish and follow written procedures to ensure that food is imported only from foreign suppliers that have been approved for use based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods the importer subjects to adequate verification activities). This burden to importers of "finished" dietary supplements and dietary supplements imported only for packaging and labeling is captured in the burden calculated for § 1.506(a)(1).

Under § 1.511(c)(2)(ii), an importer of a dietary supplement may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under § 1.511(c)(2)(i) provided that the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer document its review and assessment. This burden is captured in the burden calculated for § 1.506(a)(2).

Section 1.511(c)(3) requires importers of finished dietary supplements to establish and follow procedures for conducting foreign supplier verification activities. This burden is included in the burden calculated for § 1.506(b).

Section 1.511(c)(4)(i) requires importers of finished dietary supplements to determine and document which appropriate verification activities should be conducted, and the frequency with which they should be conducted. The estimated burden for this provision is included in the burden calculated for § 1.506(d)(1) and (2).

Under § 1.511(c)(4)(iii), a dietary supplement importer may rely on a determination of appropriate foreign supplier verification activities made by an entity other than the foreign supplier if the importer reviews and assesses whether the entity's determination regarding appropriate activities is

appropriate and documents the review and assessment. This burden is included in the burden calculated for § 1.506(d)(3).

For each dietary supplement imported in accordance with § 1.511(c), the importer would need to conduct one or more of the verification activities listed in § 1.511(c)(5)(i)(A) through (D) before using or distributing the dietary supplement and periodically thereafter. Estimates associated with these activities are included in the burdens presented in table 5 for § 1.506(e)(1)(i) through (e)(1)(iv), respectively.

Section 1.511(c)(5)(iii) requires importers to promptly review and assess the results of the verification activities that they conduct or obtain documentation of under § 1.511(c)(5)(i), or that are conducted by other entities in accordance with § 1.511(c)(5)(ii), and to document the review and assessment of the results. However, importers are not required to retain documentation of supplier verification activities conducted by other entities, provided that the importer can obtain the documentation and make it available to FDA in accordance with § 1.510(b). This burden is included in the burden calculated for § 1.506(e)(3).

Section 1.511(c) also requires importers of finished dietary supplements to conduct evaluations of the foreign supplier, conduct investigations (in certain circumstances) to determine the adequacy of their FSVPs, and ensure that information identifying them as the importer is provided at entry. These importers have been included in the estimated record keeping and reporting burdens for these activities under §§ 1.505, 1.508, and 1.509(a), respectively.

#### *H. Food Imported by Very Small Importers and From Certain Small Foreign Suppliers*

Section 1.512 sets forth modified proposed FSVP requirements for very small importers as defined in § 1.500; food from a foreign supplier that is a qualified facility as defined by § 117.3 or § 507.3; produce from a farm that is not a covered farm under the produce safety regulation in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or shell eggs from an egg producer with fewer than 3000 laying hens. Under § 1.512(b)(1), if a very small importer or an importer of food from such a foreign supplier chooses to comply with the requirements in § 1.512, the importer would be required to 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 criteria in § 1.512(a)(2)(i), (ii), or (iii), as applicable. As shown in table 5, we estimate that 37,206 very small importers and importers of food from foreign suppliers and importers of food from certain small foreign suppliers involved with 13,244 certain small suppliers would need to document eligibility each year for themselves and their small suppliers and that such documentation would require 1 hour. The resulting annual burden is 50,450 hours.

Under § 1.512(b)(3), each very small importer or importer of food from foreign suppliers that meet the criteria in § 1.512(a)(2)(i), (ii), or (iii) needs to obtain written assurance, before importing the food and at least every 2 years thereafter, that its foreign supplier is producing the food in accordance with applicable statutory and regulatory standards. Importers of food from the specified foreign suppliers must obtain written assurance that the supplier is producing food in compliance with applicable requirements or acknowledges that it is subject to applicable standards (as specified in § 1.512(b)(3)(ii) through (iv)). As shown in table 5, we estimate that 50,450 very small importers and importers of food from certain small suppliers would need to obtain an average of 2.8 such written assurances each year and that documentation of each assurance would require 2.25 hours, resulting in a total annual burden of 317,439 hours.

Section 1.512(b)(4) requires very small importers and importers of food from certain small foreign suppliers to take corrective actions. This burden is included in the burden calculated for § 1.508(a).

Section 1.512(c) sets forth requirements that apply to importers of food from the specified types of small foreign suppliers, but not to very small importers. Under § 1.512(c)(1)(i), in approving their foreign suppliers, these importers must consider the applicable FDA food safety regulations and evaluate information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. We include this burden in our calculation of the burden associated with § 1.505(a)(2) in table 5.

Under § 1.512(c)(1)(ii)(A), these importers must promptly reevaluate the concerns associated with the foreign supplier's compliance history when the importer becomes aware of new information about supplier compliance history, and the reevaluation must be documented. Section 1.512(c)(1)(ii)(A) further requires that if the importer

determines that the concerns associated with importing a food from a foreign supplier have changed, the importer must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier. We include these burdens in our calculation of the burdens associated with § 1.505(c) in table 5.

Section 1.512(c)(1)(ii)(A) further requires that if the importer determines that the concerns associated with importing a food from a foreign supplier have changed, the importer must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier. This burden is included in the estimate for § 1.505(c) in table 5.

Under § 1.512(c)(1)(iii), if an entity other than the foreign supplier has, using a qualified individual, performed the evaluation or reevaluation of foreign supplier compliance history, the importer may review and assess the evaluation or reevaluation conducted by that entity, and document its review and assessment. We include this burden in our calculation of the burden associated with § 1.505(d) in table 5.

Under § 1.512(c)(2), the importer of a food from certain small foreign suppliers must approve the foreign suppliers on the basis of the evaluation the importer conducts (or reviews and assesses) and document its approval. We include this burden in our calculation of the burden associated with § 1.505(b).

Under § 1.512(c)(3)(i), importers of food from certain small foreign suppliers must establish and follow written procedures to ensure that they import foods only from approved foreign suppliers (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods are subjected to adequate verification activities before using or distributing). Importers must document their use of these procedures. We include this burden in our calculation of the burden associated with § 1.506(a)(1).

Under § 1.512(c)(3)(ii), an importer may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under § 1.512(c)(3)(i) provided that the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer documents its review and assessment. We include this burden in our calculation of the burden associated with § 1.506(a)(2).

### *I. Food Imported From a Country With an Officially Recognized or Equivalent Food Safety System*

Section 1.513 establishes modified FSVP requirements for importers of certain food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States. If such importers meet certain conditions or requirements, they will not be required to comply with the requirements in §§ 1.504 through 1.508, but they will be required to comply with §§ 1.503, 1.509, and 1.510.

Section 1.513(b)(1) requires 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 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.

Section 1.513(b)(2) requires an importer, before importing a food from the foreign supplier, to determine and document whether the foreign supplier of the food is in good compliance standing, as defined in § 1.500, with the food safety authority of the country in which the foreign supplier is located. The importer 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 significantly minimized or prevented, the importer is then required to take prompt corrective action and to document any such action.

FDA has officially recognized New Zealand as having a food safety system that is comparable to that of the United States; however, we have not recognized any other food safety systems as comparable or determined them to be equivalent. Because we have only recently entered into a systems recognition arrangement with New Zealand recognizing that country's food safety system as being comparable to that of the United States, we are not able to assess the effect of the arrangement on the importation of food from that country. Therefore, we are not including estimates for the recordkeeping burdens associated with § 1.513.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective

date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

## IX. Federalism

We have analyzed the final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that 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 conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. We have verified the Web site addresses provided for certain documents, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. FDA, "Transcript: FSMA Proposed Rules on Foreign Supplier Verification Programs and the Accreditation of Third-Party Auditors/Certification Bodies, Public Meeting, Day One," September 19, 2013, available in Docket No. FDA-2011-N-0143.
2. FDA, "Transcript: FSMA Proposed Rules on Foreign Supplier Verification Programs and the Accreditation of Third-Party Auditors/Certification Bodies, Public Meeting, Day Two," September 20, 2013, available in Docket No. FDA-2011-N-0143.
3. FDA, "Record of Outreach Sessions on FDA Proposed Rules," 2013, available in Docket No. FDA-2011-N-0143.
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## List of Subjects

### 21 CFR Part 1

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

### 21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

### 21 CFR Part 111

Dietary foods, Drugs, Foods, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 11, and 111 are 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. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271.

- 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 hazard analysis must I conduct?



- 1.505 What evaluation for foreign supplier approval and verification must I conduct?
- 1.506 What foreign supplier verification and related activities must I conduct?
- 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?
- 1.508 What corrective actions must I take under 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 if I am importing certain food from certain small foreign suppliers?
- 1.513 What FSVP may I have if I am importing certain 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, discussions with employees of the audited entity, records review, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

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

*Dietary supplement component* 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) and other ingredients.

*Environmental pathogen* means a pathogen that is capable of surviving and persisting within the

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

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

*Farm* means farm as defined in § 1.227.

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

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

*Food allergen* 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 grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

*Good compliance standing with a foreign food safety authority* 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 producers that are in good compliance standing with the food safety authority; or

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

*Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural

commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

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

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

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

*Importer* means the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.

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

*Lot* means the food produced during a period of time and identified by an establishment's 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 include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

*Microorganisms* means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

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

*Pathogen* means a microorganism of public health significance.

*Qualified auditor* means a person who is a qualified individual as defined in this section and has technical expertise

obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). Examples of potential qualified auditors include:

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

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

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

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

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

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

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

*Very small importer* means:

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

(2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed,

packed, or held without sale (e.g., imported for a fee).

*You* 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 requirements in this subpart apply to all food imported or offered for import into the United States and to the importers of such food.

(b) *Exemptions for juice and seafood—*(1) *Importers of certain juice and seafood products.* This subpart does 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 requirements in part 120 or part 123 of this chapter. If you import juice or fish and fishery products that are subject to part 120 or part 123, respectively, you must comply with the requirements applicable to importers of those products under § 120.14 or § 123.12 of this chapter, respectively.

(2) *Certain importers of juice or seafood raw materials or other ingredients subject to part 120 or part 123 of this chapter.* This subpart does not apply with respect to any raw materials or other ingredients that you import and use in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided that you are in compliance with the requirements in part 120 or part 123 with respect to the juice or fish or fishery product that you manufacture or process from the imported raw materials or other ingredients.

(c) *Exemption for food imported for research or evaluation.* This subpart does not apply to food that is imported for research or evaluation use, provided that such food:

(1) Is not intended for retail sale and is not sold or distributed to the public;

(2) Is labeled with the statement "Food for research or evaluation use";

(3) Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and

(4) Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

(d) *Exemption for food imported for personal consumption.* This subpart does 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) This subpart does 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, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(2) This subpart does not apply with respect to food that is not an alcoholic beverage 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.

(3) This subpart does not apply with respect to raw materials and other ingredients that are imported for use in alcoholic beverages provided that:

(i) The imported raw materials and other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(ii) Such manufacturing/processing, packing, or holding is performed by the importer;

(iii) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(iv) The importer is exempt from the regulations in part 117 of this chapter in accordance with § 117.5(i) of this chapter.

(f) *Inapplicability to food that is transshipped or imported for processing and export.* This subpart does not apply to food:

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

not sold or distributed to the public in the United States; or

(2) That is imported for processing and future export and that is not sold or distributed to the public in the United States.

(g) *Inapplicability to U.S. food returned.* This subpart does not apply to food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country.

(h) *Inapplicability to certain meat, poultry, and egg products.* This subpart does not apply with respect to:

(1) Meat food products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(2) Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(3) Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

#### **§ 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 the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act.

(b) *Low-acid canned foods*—(1) *Importers of low-acid canned foods not subject to further manufacturing or processing.* With respect to those microbiological hazards that are controlled by part 113 of this chapter, if you import a thermally processed low-acid food packaged in a hermetically sealed container (low-acid canned food), you must verify and document that the food was produced in accordance with part 113. With respect to all matters that

are not controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section.

(2) *Certain importers of raw materials or other ingredients subject to part 113 of this chapter.* With respect to microbiological hazards that are controlled by part 113, you are not required to comply with the requirements of this subpart for raw materials or other ingredients that you import and use in the manufacturing or processing of low-acid canned food provided that you are in compliance with part 113 with respect to the low-acid canned food that you manufacture or process from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section for the imported raw materials and other ingredients that you use in the manufacture or processing of low-acid canned foods.

(c) *Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act.* You are deemed to be in compliance with the requirements of this subpart for a food you import, except for the requirements in § 1.509, if you are a receiving facility as defined in § 117.3 or § 507.3 of this chapter and you are in compliance with the following requirements of part 117 or part 507 of this chapter, as applicable:

(1) You implement preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34 of this chapter;

(2) You are not required to implement a preventive control under § 117.136 or § 507.36 of this chapter with respect to the food; or

(3) You have established and implemented a risk-based supply-chain program in compliance with subpart G of part 117 or subpart E of part 507 of this chapter with respect to the food.

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

(a) *Qualified individual.* A qualified individual must develop your FSVP and perform each of the activities required under this subpart. A qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.

(b) *Qualified auditor.* A qualified auditor must conduct any audit conducted in accordance with § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). A qualified auditor must have technical

expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

**§ 1.504 What hazard analysis must I conduct?**

(a) *Requirement for a hazard analysis.* Except as specified in paragraph (d) of this section, you must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food you import to determine whether there are any hazards requiring a control. Your hazard analysis must be written regardless of its outcome.

(b) *Hazard identification.* (1) Your analysis of the known or reasonably foreseeable hazards in each food must include the following types of hazards:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and

(iii) Physical hazards (such as stones, glass, and metal fragments).

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

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

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

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

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

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

(i) The formulation of the food;

(ii) The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food;

(iii) Raw materials and other ingredients;

(iv) Transportation practices;

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

(vi) Packaging and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of natural toxins).

(d) *Review of another entity's hazard analysis.* If another entity (including your foreign supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any hazards requiring a control, you may meet your requirement to determine whether there are any hazards requiring a control in a food by reviewing and assessing the hazard analysis conducted by that entity. You must document your review and assessment of that hazard analysis, including documenting that the hazard analysis was conducted by a qualified individual.

(e) *Hazards in raw agricultural commodities that are fruits or vegetables.* If you are importing a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined in § 112.3 of this chapter, you are not required to determine whether there are any biological hazards requiring a control in such food because the biological hazards in such fruits or vegetables require a control and compliance with the requirements in part 112 of this chapter significantly minimizes or prevents the biological hazards. However, you must determine whether there are any other types of hazards requiring a control in such food.

(f) *No hazards requiring a control.* If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no hazards requiring a control, you are not required to conduct an evaluation for foreign supplier approval and verification under § 1.505 and you are not required to conduct foreign supplier verification activities under § 1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined in § 112.3 of this chapter.

**§ 1.505 What evaluation for foreign supplier approval and verification must I conduct?**

(a) *Evaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified in paragraphs (d) and (e) of this section, in approving your foreign suppliers and determining the appropriate supplier verification activities that must be conducted for a foreign supplier of a type of food you import, you must consider the following:

(i) The hazard analysis of the food conducted in accordance with § 1.504, including the nature of the hazard requiring a control.

(ii) The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.

(iii) Foreign supplier performance, including:

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

(B) Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

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

(2) You must document the evaluation you conduct under paragraph (a)(1) of this section.

(b) *Approval of foreign suppliers.* You must approve your foreign suppliers on the basis of the evaluation that you conducted under paragraph (a) of this section or that you review and assess under paragraph (d) of this section, and document your approval.

(c) *Reevaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified

in paragraph (d) of this section, you must promptly reevaluate the concerns associated with the factors in paragraph (a)(1) of this section when you become aware of new information about these factors, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier and whether the supplier verification activities conducted under § 1.506 or § 1.511(c) need to be changed.

(2) If at the end of any 3-year period you have not reevaluated the concerns associated with the factors in paragraph (a)(1) of this section in accordance with paragraph (c)(1) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1).

(d) *Review of another entity's evaluation or reevaluation of a foreign supplier's performance and the risk posed by a food.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (a) of this section or the reevaluation described in paragraph (c) of this section, you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(e) *Inapplicability to certain circumstances.* You are not required to conduct an evaluation under this section or to conduct foreign supplier verification activities under § 1.506 if one of the circumstances described in § 1.507 applies to your importation of a food and you are in compliance with that section.

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

(a) *Use of approved foreign suppliers.* (1) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(2) You may rely on an entity other than your foreign supplier to establish the procedures and perform and document the activities required under paragraph (a)(1) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(b) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(c) *Requirement of supplier verification.* The foreign supplier verification activities must provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented.

(d) *Determination of appropriate foreign supplier verification activities—*(1)(i) *General.* Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food you obtain from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under § 1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (e)(1)(i) of this section;

(B) Sampling and testing of a food as specified in paragraph (e)(1)(ii) of this section;

(C) Review of the foreign supplier's relevant food safety records as specified in paragraph (e)(1)(iii) of this section; and

(D) Other appropriate supplier verification activities as specified in paragraph (e)(1)(iv) of this section.

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

(3) *Reliance on a determination by another entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (d)(1) or (2) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(e) *Performance of foreign supplier verification activities—*(1) *Verification activities.* Except as provided in paragraph (e)(2) of this section, based on the determination made in accordance with paragraph (d) of this section, you must conduct (and document) or obtain documentation of one or more of the supplier verification activities listed in paragraphs (e)(1)(i) through (iv) of this section for each foreign supplier before importing the food and periodically thereafter.

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

(B) If the food is subject to one or more FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations and include a review of the supplier's written food safety plan, if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws

and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(C) If the onsite audit is conducted solely to meet the requirements of paragraph (e) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

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

(E) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(1) The written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(2) The written results of an inspection of the foreign supplier by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

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

(iii) *Review of the foreign supplier's relevant food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records

reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) *Other appropriate activity.* (A) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(B) You must retain documentation of each activity conducted in accordance with paragraph (e)(1)(iv) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(2) *Reliance upon performance of activities by other entities.* (i) Except as specified in paragraph (e)(2)(ii) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (e)(1) of this section by another entity provided that you review and assess the results of these activities in accordance with paragraph (e)(3) of this section.

(ii) You may not rely on the foreign supplier itself or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (e)(1)(ii) of this section.

(3) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (e)(1) of this section, or that are conducted by other entities in accordance with paragraph (e)(2) of this section. You must document your review and assessment of the results of verification activities. If the results do not provide adequate assurances that the hazards requiring a control in the food you obtain from the foreign supplier have been significantly minimized or prevented, you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(4) *Independence of qualified individuals conducting verification activities.* There must not be any financial conflicts of interests that influence the results of the verification activities set forth in paragraph (e)(1) of

this section, and payment must not be related to the results of the activity.

**§ 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?**

(a) *Circumstances.* You are not required to conduct an evaluation of a food and foreign supplier under § 1.505 or supplier verification activities under § 1.506 when you identify a hazard requiring a control (identified hazard) in a food and any of the following circumstances apply:

(1) You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard;

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to provide assurance it is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements;

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(B) Will only sell the food to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507); or

(2) Obtain a similar written assurance from the entity's customer, subject to the requirements of paragraph (c) of this section, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document your implementation of that system.

(b) *Written assurances.* Any written assurances required under this section must contain the following:

(1) Effective date;

(2) Printed names and signatures of authorized officials; and

(3) The assurance specified in the applicable paragraph.

(c) *Provision of assurances.* The customer or other subsequent entity in the distribution chain for a food that provides a written assurance under paragraph (a)(2), (3), or (4) of this section must act consistently with the assurance and document its actions taken to satisfy the written assurance.

#### **§ 1.508 What corrective actions must I take under my FSVP?**

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

those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act. This determination could be based on a review of consumer, customer, or other complaints related to food safety, the verification activities conducted under § 1.506 or § 1.511(c), a reevaluation of the risks posed by the food and the foreign supplier's performance conducted under § 1.505(c) or (d), or any other relevant information you obtain. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph.

(b) If you determine, by means other than the verification activities conducted under § 1.506 or § 1.511(c) or a reevaluation conducted under § 1.505(c) or (d), 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, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) 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.

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

#### **§ 1.509 How must the importer be identified at entry?**

(a) You must ensure that, for each line entry of food product offered for importation into the United States, your name, electronic mail address, and unique facility identifier recognized as acceptable by FDA, identifying you as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.

(b) 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.

#### **§ 1.510 How must I maintain records of my FSVP?**

(a) *General requirements for records.*

(1) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

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

(3) All records must be legible and stored to prevent deterioration or loss.

(b) *Record availability.* (1) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(2) Offsite storage of records, including records maintained by other entities in accordance with § 1.504, § 1.505, or § 1.506, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(c) *Record retention.* (1) Except as specified in paragraph (c)(2) of this section, you must retain records referenced in this subpart until at least 2 years after you created or obtained the records.

(2) You must retain records that relate to your processes and procedures, including the results of evaluations and determinations you conduct, for 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, you have reevaluated the risks associated with a food and the foreign supplier, or you have changed your supplier verification activities for a particular food and foreign supplier).

(d) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic



records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(e) *Use of existing records.* (1) You do not need to duplicate existing records you have (e.g., records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(2) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(f) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

**§ 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) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, and you are in compliance with the requirements in §§ 111.73 and 111.75 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 §§ 1.503 and 1.509, but you are not required to comply with the requirements in § 1.502, §§ 1.504 through 1.508, or § 1.510. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(b) *Importers whose customer is subject to certain dietary supplement current good manufacturing practice regulations.* If your customer is required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging

as a dietary supplement, your customer is in compliance with the requirements of §§ 111.73 and 111.75 of this chapter applicable to 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 §§ 1.503, 1.509, and 1.510, but you are not required to comply with the requirements in § 1.502 or §§ 1.504 through 1.508.

(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, 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d), and 1.508 through 1.510, but you are not required to comply with the requirements in §§ 1.504, 1.505(a)(1)(i), 1.506, and 1.507. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

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

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(2)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(3) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(4) *Determination of appropriate foreign supplier verification activities—*(i) *General.* Except as provided in paragraph (c)(4)(iii) of this section, before importing a dietary supplement from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (c)(4)(ii)(A) through (D) of this section, as well as the frequency

with which the activity or activities must be conducted, are needed to provide adequate assurances that the foreign supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter. This determination must be based on the evaluation conducted under § 1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (c)(5)(i)(A) of this section;  
(B) Sampling and testing of a food as specified in paragraph (c)(5)(i)(B) of this section;

(C) Review of the foreign supplier's relevant food safety records as specified in paragraph (c)(5)(i)(C) of this section; and

(D) Other appropriate supplier verification activities as specified in paragraph (c)(5)(i)(D) of this section.

(iii) *Reliance upon determination by other entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (c)(4)(i) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate based on the evaluation conducted in accordance with § 1.505. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(5) *Performance of foreign supplier verification activities.* (i) Except as provided in paragraph (c)(5)(ii) of this section, for each dietary supplement you import under paragraph (c) of this section, you must conduct (and document) or obtain documentation of one or more of the verification activities listed in paragraphs (c)(5)(i)(A) through (D) of this section before importing the dietary supplement and periodically thereafter.

(A) *Onsite auditing.* You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

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

(2) The onsite audit must consider the applicable requirements of part 111 of this chapter and include a review of the foreign supplier's written food safety plan, if any, and its implementation (or, when applicable, an onsite audit may

consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(3) If the onsite audit is conducted solely to meet the requirements of paragraph (c)(5) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

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

(5) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(i) The written results of appropriate inspection of the foreign supplier for compliance with the applicable requirements in part 111 of this chapter conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(ii) The written results of an inspection by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

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

(C) *Review of the foreign supplier's food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed,

the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(D) *Other appropriate activity.* (1) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(2) You must retain documentation of each activity conducted in accordance with paragraph (c)(5)(i)(D)(1) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(ii) *Reliance upon performance of activities by other entities.* (A) Except as specified in paragraph (c)(5)(ii)(B) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (c)(5)(i) by another entity provided that you review and assess the results of these activities in accordance with paragraph (c)(5)(iii) of this section.

(B) You may not rely on the foreign supplier or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (c)(5)(i)(B) of this section.

(iii) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5)(i) of this section, or that are conducted by other entities in accordance with paragraph (c)(5)(ii) of this section. You must document your review and assessment of the results of verification activities. If the results show that the foreign supplier is not producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter, you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(iv) *Independence of qualified individuals conducting verification activities.* There must not be any

financial conflicts of interest that influence the results of the verification activities set forth in paragraph (c)(5)(i) of this section, and payment must not be related to the results of the activity.

**§ 1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?**

(a) *Eligibility.* This section applies only if:

(1) You are a very small importer; or  
(2) You are importing certain food from certain small foreign suppliers as follows:

(i) The foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter;

(ii) You are importing produce from a foreign supplier that is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter; or

(iii) You are importing shell eggs from a foreign supplier that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens.

(b) *Applicable requirements—(1) Documentation of eligibility—(i) Very small importer status.* (A) If you are a very small importer and you choose to comply with the requirements in this section, you must document that you meet the definition of very small importer in § 1.500 with respect to human food and/or animal food before initially importing food as a very small importer and thereafter on an annual basis by December 31 of each calendar year.

(B) For the purpose of determining whether you satisfy the definition of very small importer with respect to human food and/or animal food for a given calendar year, the relevant 3-year period of sales (and U.S. market value of human or animal food, as appropriate) is the period ending 1 year before the calendar year for which you intend to import food as a very small importer. The baseline year for calculating the adjustment for inflation is 2011. If you conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

(ii) *Small foreign supplier status.* If you are a importing food from a small foreign supplier as specified in paragraph (a)(2) of this section and you choose to comply with the requirements in this section, you must obtain written assurance that your foreign supplier

meets the criteria in paragraph (a)(2)(i), (ii), or (iii) of this section before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year.

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

(3) *Foreign supplier verification activities.* (i) If you are a very small importer, for each food you import, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act.

(ii) If your foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter and you choose to comply with the requirements in this section, you must obtain written assurance before importing the food and at least every 2 years thereafter that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States). The written assurance must include either:

(A) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(B) A statement that the supplier is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(iii) If your foreign supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter, and you choose to comply with the requirements in this section, you must obtain written assurance before importing the produce and at least every

2 years thereafter that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

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

(4) *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 consistent with the assurance provided in accordance with § 1.512(b)(3)(i) through (iv). The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

(5) *Records*—(i) *General requirements for records.* (A) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

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

(C) All records must be legible and stored to prevent deterioration or loss.

(ii) *Availability.* (A) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation

of records maintained in a language other than English.

(B) Offsite storage of records, including records retained by other entities in accordance with paragraph (c) of this section, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(C) If requested in writing by FDA, you must send records to the Agency electronically or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(iii) *Record retention.* (A) Except as specified in paragraph (b)(5)(iii)(B) or (C) of this section, you must retain records required under this subpart for a period of at least 2 years after you created or obtained the records.

(B) If you are subject to paragraph (c) of this section, you must retain records that relate to your processes and procedures, including the results of evaluations of foreign suppliers and procedures to ensure the use of approved suppliers, for at least 2 years after their use is discontinued (e.g., because you have reevaluated a foreign supplier's compliance history or changed your procedures to ensure the use of approved suppliers).

(C) You must retain for at least 3 years records that you rely on during the 3-year period preceding the applicable calendar year to support your status as a very small importer.

(iv) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(v) *Use of existing records.* (A) You do not need to duplicate existing records you have (e.g., records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(B) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(vi) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

(c) *Requirements for importers of food from certain small foreign suppliers.* The following additional requirements apply if you are importing food from certain small foreign suppliers as specified in paragraph (a)(2) of this section and you are not a very small importer:

(1) *Evaluation of foreign supplier compliance history—(i) Initial evaluation.* In approving your foreign suppliers, you must evaluate the applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. You may also consider other factors relevant to a foreign supplier's performance, including those specified in § 1.505(a)(1)(iii)(A) and (C).

(ii) *Reevaluation of foreign supplier compliance history.* (A) Except as specified in paragraph (c)(1)(iii) of this section, you must promptly reevaluate the concerns associated with the foreign supplier's compliance history when you become aware of new information about the matters in paragraph (c)(1)(i) of this section, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier.

(B) If at the end of any 3-year period you have not reevaluated the concerns associated with the foreign supplier's compliance history in accordance with paragraph (c)(1)(ii)(A) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1)(ii)(A). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1)(ii)(A).

(iii) *Review of another entity's evaluation or reevaluation of foreign supplier compliance history.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (c)(1)(i) of this section or the reevaluation described in paragraph (c)(1)(ii), you may meet the

requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(2) *Approval of foreign supplier.* You must approve your foreign suppliers on the basis of the evaluation you conducted under paragraph (c)(1)(i) of this section or that you review and assess under paragraph (c)(1)(iii) of this section, and document your approval.

(3) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under paragraph (c)(1)(i) of this section (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(3)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

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

(a) *General.* (1) If you meet the conditions and requirements of paragraph (b) of this section for a food of the type specified in paragraph (a)(2) of this section that you are importing, then you are not required to comply with the requirements in §§ 1.504 through 1.508. You would still be required to comply with the requirements in §§ 1.503, 1.509, and 1.510.

(2) This section applies to food that is not intended for further manufacturing/processing, including packaged food products and raw agricultural commodities that will not be commercially processed further before consumption.

(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 that official recognition or equivalency determination.

(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 significantly minimized or prevented, 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 (b)(2).

**§ 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 if it appears that the importer of that food fails to comply with this subpart with respect to that food. If there is no U.S. owner or consignee of an article of food 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 appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.

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

**PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES**

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

**Authority:** 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 4. In § 11.1, add and reserve paragraph (h) and (k) and add paragraph (l) to read as follows:

**§ 11.1 Scope.**

\* \* \* \* \*

(l) This part does not apply to records required to be established or maintained by subpart L of part 1 of this chapter. Records that satisfy the requirements of subpart L of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

**PART 111—CURRENT GOOD  
MANUFACTURING PRACTICE IN  
MANUFACTURING, PACKAGING,  
LABELING, OR HOLDING  
OPERATIONS FOR DIETARY  
SUPPLEMENTS**

■ 5. The authority citation for 21 CFR part 111 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 371, 374, 381, 393; 42 U.S.C. 264.

■ 6. In § 111.5, add a sentence after the existing sentence to read as follows:

**§ 111.5 Do other statutory provisions and regulations apply?**

\* \* \* For importers of dietary supplements and dietary supplement components, the regulation on foreign supplier verification programs can be found in subpart L of part 1 of this chapter.

Dated: October 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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