4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

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

RIN 0910-AG64

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is revising certain provisions of the proposed rule, issued in July 2013, on foreign supplier verification programs (FSVPs) for importers of food for humans and animals. We are primarily revising the proposed requirements concerning compliance status review of food and foreign suppliers, hazard analysis, and supplier verification activities. We are taking this action in response to the extensive public input we have received regarding these provisions and in coordination with revisions we are concurrently making to the proposed rule on current good manufacturing practice (CGMP) and hazard analysis and risk-based preventive controls for human food. We are seeking public comment on the revised proposed FSVP regulations. We are reopening the comment period on the proposed rule only with respect to the specific provisions identified in this Federal Register document.

DATES: Submit either electronic or written comments on the supplemental notice of proposed rulemaking by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 75 DAYS AFTER DATE OF

PUBLICATION IN THE FEDERAL REGISTER] (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions in the following ways:

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

Instructions: All submissions received must include the Docket No. (FDA-2011-N-0143) for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

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

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

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:

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Executive Summary

Purpose of the Supplemental Notice of Proposed Rulemaking

We are revising certain provisions of the proposed rule, issued in July 2013, on FSVPs for importers of food for humans and animals. The revisions primarily concern the proposed rule's requirements on compliance status review of food and foreign suppliers, hazard analysis, and supplier verification activities. We are issuing these revisions in response to extensive public input we have received regarding these provisions and in alignment with certain revisions we are concurrently making to the proposed rule on preventive controls for human food.

Summary of the Revisions to the Proposed Rule

One revision to the proposed rule would, consistent with many comments we received, delete the previously proposed section on compliance status review but incorporate some of the provisions into the requirements concerning hazard analysis and evaluation of certain risk factors in determining appropriate foreign supplier verification and related activities.

Another revision would modify some of the previously proposed hazard analysis requirements. In accordance with several comments we received, as well as the revised hazard analysis provisions and new supplier program provisions in the revised preventive controls proposal that we are concurrently issuing, the revised FSVP proposal changes the requirement to analyze hazards that are reasonably likely to occur to a requirement to analyze known or reasonably foreseeable hazards to determine if they are significant. Under the revised proposal, a significant hazard would be defined as a known or reasonably foreseeable hazard in a food 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 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.

Other changes related to the proposed hazard analysis requirements that are consistent with the proposed hazard analysis requirements in the preventive controls proposal include requiring analysis of hazards that may be intentionally introduced for purposes of economic gain, requiring evaluation of environmental pathogens in certain ready-to-eat food, and minor changes to other hazard evaluation factors.

Another revision to the previous proposed rule would specify that, along with the hazard analysis, the importer must consider other factors primarily related to supplier risks in determining appropriate supplier verification and related activities before importing a food from a particular foreign supplier and thereafter when the importer becomes aware of new information about these risks. These proposed changes respond to numerous comments stating that industry best practice is to base supplier verification activities on an assessment of information about the

risks presented by a food as well as by the supplier of the food, rather than focusing primarily on hazards inherent in food. Under the revised proposal, in addition to the hazard analysis, the importer would be required to consider the following in approving suppliers and determining appropriate verification activities:

- The entity that will be applying hazard controls, 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 are revising certain proposed requirements regarding supplier verification measures themselves and related activities. Instead of maintaining a list of their foreign suppliers, importers would be required to establish and follow procedures to ensure that they import foods only from foreign suppliers that they have approved (except, when necessary and appropriate, from unapproved suppliers on a temporary basis). Consistent with the revised proposal's focus on a broader evaluation of risks, we are proposing that, rather than being designed to ensure that identified hazards are adequately controlled, the purpose of importers'

supplier verification activities should be to provide adequate assurances that the foreign supplier produces the food in a manner consistent with FDA's regulations on preventive controls or produce safety, if either is applicable to the foreign supplier, and to assure that the food is not adulterated and not misbranded regarding allergen labeling. This approach is consistent with the purpose for foreign supplier verification specified in section 805(a)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 384a).

After considering comments on the alternative proposals we presented in the 2013 proposed rule regarding supplier verification activities, we are proposing an approach that gives importers the flexibility to determine appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods. Under the revised proposal, based on the risk evaluation the importer conducts, the importer would be required to determine and document what supplier verification activities are appropriate for a particular food and foreign supplier, as well as the frequency with which those activities should be conducted. Appropriate supplier verification activities could include onsite auditing of the foreign supplier, sampling and testing of food, review of the supplier's food safety records, or some other procedure determined to be appropriate based on the identified risks.

However, the revised proposal also specifies that, when there is a hazard in a food that could result in serious adverse health consequences or death to humans or animals (a "SAHCODHA" hazard), an importer would need 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 specifically determined that some other supplier verification activity and/or less frequent auditing would adequately address the identified risks. This

requirement would establish a clear verification standard for these most serious food hazards yet permit importers to employ a different approach if they can confirm that the alternative approach will provide adequate assurance that the identified risks are addressed.

We tentatively conclude that this revised proposal regarding supplier verification activities strikes an appropriate balance between granting importers the flexibility to adopt risk-based verification measures while increasing the likelihood that importers will apply the most rigorous verification measures to the most serious risks.

The revised proposal also would specify that if a foreign supplier is a farm that is not subject to the produce safety regulations, the importer of food from the supplier would not be subject to the "standard" verification requirements previously noted but would instead be required to obtain written assurance biennially that the supplier is producing the food in compliance with the FD&C Act. This proposed change reflects the different treatment of food from such farms under the produce safety regulations and would be consistent with the potential requirement for a supplier program in the preventive controls regulations.

In addition, we are proposing to add provisions stating that when importers or their customers are in compliance with the requirements on supplier programs in the proposed preventive controls regulations, the importers would be deemed in compliance with most of the FSVP requirements (in cases involving customer compliance with the supplier program requirements, the importer would need to obtain written assurance of compliance annually from the customer). This proposed change is consistent with our intent, stated in the FSVP and preventive controls proposed rules, to avoid imposing redundant regulatory requirements on food importers who also are food facilities subject to the preventive controls regulations.

Finally, we are increasing, from $500,000 to $1 million, the annual sales ceiling used in the proposed definition of "very small importer" and "very small foreign supplier" to be consistent with our revised approach to the proposed definition of "very small business" under the proposed preventive controls regulations.

Costs and Benefits

We summarize the annualized costs (over a 10-year time period discounted at both 3 percent and 7 percent) of the revised proposed rule in the following table.

	3 percent	7 percent
Annualized Cost	$396,780,114	$397,478,400
Reduction in Cost Relative to Original Option 1	$76, 191,228	$75,901,638
Reduction in Cost Relative to Original Option 2	$64,627,341	$64,343,306

The reduction in FSVP requirements for importers who also would be subject to the preventive controls regulations, and other proposed changes in the requirements, results in a cost savings of $76 million per year (compared to Option 1 of the 2013 proposed rule). The overall potential net benefit from the revised proposed rule is estimated at $714 million per year. These figures are based on a 3 percent discount rate, a scenario for inflation, over 10 years. (The figures are the same for a 7 percent discount rate.)

Although the FSVP proposed rule would not itself establish safety requirements for food manufacturing and processing, it would benefit the public health by helping to ensure that imported food is produced in a manner consistent with other applicable food safety regulations. The Preliminary Regulatory Impact Analyses for the proposed rules on preventive controls for human food and standards for produce safety consider and analyze the number of illnesses and deaths that the proposed regulations are aimed at reducing. The greater the compliance with those regulations, the greater the expected reduction in illnesses and deaths as well as the costs associated with them. The FSVP regulations would be an important mechanism for improving

and ensuring compliance with the previously noted food safety regulations as they apply to imported food. For this reason, we account for the public health benefits of the FSVP proposed rule in the preventive controls, produce safety, and other applicable food safety regulations instead of in this rule.

I. Background

A. Proposed Rule on FSVPs

On July 29, 2013, FDA published in the Federal Register a proposed rule entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" ("the 2013 FSVP proposed rule" or "the previous proposed rule") (78 FR 45730) to require importers to perform certain activities to help ensure that the food they bring into the United States is produced in a manner consistent with U.S. standards.

FDA proposed the FSVP regulations as part of our implementation of the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353). Section 301 of FSMA adds 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 raw agricultural commodities (RACs)) of the FD&C Act (21 U.S.C. 350g and 350h), as appropriate; (2) the food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and (3) the food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning food allergen labeling). Section 805(c) of the FD&C Act directs FDA to issues regulations on the content of importers' FSVPs.

The FSVP proposed rule would require food importers to adopt programs to ensure that the food they import meets the previously noted statutory standards. The previous proposed rule would have required importers to take the following actions as part of their FSVPs:

- Use a qualified individual to perform most FSVP activities.
- Review the compliance status of foods and foreign suppliers.
- Analyze the hazards reasonably likely to occur with foods.
- Determine and perform appropriate foreign supplier verification activities for foods. As discussed in more detail in section II.C.5, the proposal set forth two optional approaches to verification requirements that differ primarily with respect to the verification activities that importers must conduct when a SAHCODHA hazard is present in a food.
- 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.
- Maintain records of FSVP procedures and activities.

In addition to these "standard" FSVP requirements that would apply to most food importers, the previous 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 foreign suppliers.

- 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.

B. Public Comments

We requested comments on the FSVP proposed rule by November 26, 2013. We extended the comment period for the proposed rule and its information collection provisions (which are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520)) (78 FR 69602, November 20, 2013). The comment period for the proposed rule closed on January 27, 2014.

After we published the FSVP proposed rule in July 2013, we held two public meetings to solicit stakeholder and public comments on the proposed rule, inform the public about the rulemaking process, and respond to questions about the proposed rule (see 78 FR 57320, September 18, 2013). We also made other presentations, participated in Webinars, and met with stakeholders in the United States and abroad to discuss the FSVP proposed rule along with proposed rules implementing other FSMA provisions.

Over 350 comments were submitted to the docket on the FSVP proposed rule. We continue to review these comments as part of our development of the final rule on FSVPs. However, for the reasons discussed in sections I.C through I.E, we are issuing revisions to certain provisions in the previous proposed rule and requesting comment on the revisions.

C. Alignment of FSVP Regulations with Potential Supplier Verification Provisions in the Proposed Preventive Controls Regulations

In the FSVP proposed rule, we stated that we recognized the importance of coordinating the FSVP regulations 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 to 45741, 45747 to 45748). We had first expressed that intent in the proposed rule on "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (the "Preventive Controls proposed rule") (78 FR 3646, January 16, 2013). Although the Preventive Controls proposed rule did not include specific regulations on supplier verification, the Agency requested comment on when and how approval and verification of suppliers of raw materials and ingredients are an appropriate part of preventive controls, and sought comment on different aspects of supplier approval and verification programs (78 FR 3646 at 3665 to 3667). We also stated that we intended to align any supplier verification provisions in the preventive controls regulations with the FSVP regulations to avoid imposing duplicative requirements on entities that are subject to each of those sets of regulations because they are both registered food facilities and food importers. We expressed a similar intent regarding alignment with any supplier verification provisions that might be included in the proposed regulations on preventive controls for animal food (see "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals," 78 FR 64736 at 64808, October 29, 2013).

In the FSVP proposed rule, we requested comment on how to address foreign supplier verification by importers who could be subject to both the FSVP and preventive controls regulations to avoid imposing duplicative requirements on such firms. In particular, we requested comment on whether the FSVP regulations should state that if an importer was required to establish a supplier approval and verification program under the preventive controls regulations for a food, and was in compliance with those regulations, the importer would be

deemed to be in compliance with the FSVP regulations that address those matters (78 FR 45730 at 45748).

D. Decision to Issue Supplemental Notice of Proposed Rulemaking Regarding Certain Preventive Controls Requirements

In December 2013, we issued a statement (Ref. 1) noting the extensive input we had received from produce farmers and others in the agricultural sector on the Preventive Controls proposed rule and FDA's 2013 proposed rule on "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" ("the Produce Safety proposed rule") (78 FR 3504, January 16, 2013). We expressed our belief that significant changes would be needed in key provisions of the two proposed rules affecting small and large farmers, such as certain provisions affecting mixed-use facilities (i.e., facilities co-located on a farm). We also announced our intent to propose revised regulatory requirements and request comment on them, allowing the public the opportunity to provide input on our new thinking. We noted that there might be other revisions to these proposed rules that we would issue for public comment, and that we would determine the scope of the revised proposals as we completed our initial review of the submitted comments on the proposed rules.

E. Scope of FSVP Supplemental Notice of Proposed Rulemaking

In accordance with our December 2013 statement, elsewhere in this issue of the Federal Register we are issuing a supplemental notice of proposed rulemaking regarding the preventive controls for human food proposed rule ("Preventive Controls supplemental document") and a supplemental notice of proposed rulemaking regarding the rule on preventive controls for animal food. In addition to revisions to previously proposed requirements, the Preventive Controls supplemental document includes proposed provisions on supplier programs for food facilities

that receive raw materials and ingredients. To align the FSVP proposed regulations with the provisions on supplier programs in the revised Preventive Controls proposed rule, and in response to comments that we have received concerning certain related issues in the FSVP proposal, we are revising the FSVP proposed rule. As discussed in detail in section II, the principal changes to the FSVP proposal include the following:

- Deleting the previously proposed section requiring importers to conduct a compliance status review of the food and foreign supplier but incorporating some parts of this section into the previously proposed requirement to conduct a hazard analysis of the food and a newly proposed requirement to evaluate other risks associated with the food and foreign supplier.
- Replacing the previously proposed requirement to analyze hazards that are "reasonably likely to occur" with a proposed requirement to analyze "known or reasonably foreseeable" hazards to determine if they are significant (i.e., necessitate control measures).
- Giving importers the flexibility to conduct the supplier verification activities that they have determined, based on their evaluation of food and foreign supplier risks, can provide adequate assurance that the supplier is producing the food in a manner consistent with U.S. food safety requirements. For foods that are associated with a SAHCODHA hazard, the revised proposal specifically requires initial and subsequent annual onsite auditing of the foreign supplier unless the importer determines, based on its risk evaluation of the food and foreign supplier, that other verification activities are appropriate and adequate.

We discuss these revised proposed requirements in section II. We are reopening the comment period on the proposed rule only with respect to these matters. In the FSVP final rule, we will take into account public comments already received and any comments received in response to this document in finalizing the FSVP requirements.

The previous proposed rule and the revisions and new provisions in this supplemental notice of proposed rulemaking, taken together, constitute the entirety of the proposed rule on FSVPs. Throughout this document, we discuss revisions to the previously proposed subpart L of 21 CFR part 1 and, in the codified section of this supplemental notice of proposed rulemaking, we list each of the revised and new provisions of proposed subpart L. For the convenience of readers and ease of reference, we prepared a separate document (to be included in the public docket for this rulemaking) that identifies the changes to the previous codified provisions and provides the complete proposed subpart L of 21 CFR part 1, as revised through this document (Ref. 2).

II. Revisions to the Proposed Rule

As stated in section I.E, in response to comments we have received and as part of our effort to align the FSVP requirements with the supplier program provisions in the revised Preventive Controls proposed rule, we are making several revisions to the FSVP proposed rule. These changes focus primarily on importers' evaluation of the risks associated with the foods they import and the foreign suppliers of this food, along with the supplier verification activities that importers must conduct.

Although we have tried to align the supplier verification provisions in the FSVP and preventive controls regulations as much as possible, there are some differences between the two. These differences are largely due to statutory language and the fact that while supplier

verification is the principal focus of the FSVP regulations, it would only be a component of the preventive controls regulations if it is included in the final preventive controls regulations. These factors result in the two sets of proposed regulations being structured somewhat differently. We request comment, in light of the statutory provisions, on the manner and extent to which the FSVP and preventive controls supplier verification provisions--as well as other aspects of the FSVP and preventive controls regulations--should be aligned in the final rules.

A. Compliance Status Review

The previous FSVP proposed rule included two requirements concerning importers' review of information related to the risk associated with foods and/or foreign suppliers. These are:

- A requirement to review the compliance status of each food to be imported and each foreign supplier being considered (previously proposed § 1.504); and
- A requirement to analyze the hazards in each food (previously proposed § 1.505).

Regarding compliance status review, proposed § 1.504 would have required an importer, before importing a food from a foreign supplier, to assess the compliance status of the food and the foreign supplier, including whether either is the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the FD&C Act (21 U.S.C. 381(q)) relating to the safety of the food, to determine whether it would be appropriate to import the food from the foreign supplier. Proposed § 1.504 also would have required an importer to document this review and to continue to monitor and document the compliance status as long as the importer obtains the food from the foreign supplier.

1. Comments

We received many comments about the proposed compliance status review provisions. A frequent comment by food importers on the compliance status review requirements is that the proposal places too much emphasis on compliance status review, in particular on warning letters and import alerts, as a basis for determining appropriate supplier verification activities. Several comments maintain that compliance status review should be regarded as just one part of an analysis of the risks associated with a food and the foreign supplier of the food. However, several comments state that supplier verification activities should be based not solely on an analysis of the hazards in a food but also on the potential risks associated with a foreign supplier of the food.

Some comments state that an importer should consider both positive and negative compliance information about a foreign supplier. One comment states that each importer should determine on its own what information is relevant to review about a supplier's risk, which might include assessing a supplier's compliance status.

Some comments express concern that certain information about a firm's compliance status, such as FDA Form 483 inspection reports and consent decrees, could be too difficult to obtain because they might be available only through a request under the Freedom of Information Act. In addition, some comments maintain that the FDA Web site is insufficiently organized and would have to be updated to track food and foreign supplier compliance status. Some comments state that an importer should be free to determine on its own what information about the risk of a foreign supplier is relevant to consider.

Many comments express concern that the proposal did not specify how frequently an importer must conduct a compliance status review. Several comments recommend that importers be required to conduct these reviews annually. Some comments object to a continuous

monitoring requirement as unnecessary and suggest instead that an importer be required to reassess its supplier's compliance status as part of the importer's reassessment of its FSVP when the importer becomes aware of new information about potential hazards associated with the food or supplier.

2. Revisions Regarding Food and Foreign Supplier Risk Evaluation

Contrary to how some of the commenters read the proposed requirements, the previous proposal would not have required importers to consider only whether there was a relevant warning letter, import alert, or certification requirement under section 801(q) of the FD&C Act; rather, the importer would have needed to consider information relevant to the compliance status of the food and the foreign supplier, e.g., warning letters and import alerts. The preamble to the 2013 proposed rule discussed other types of information about a food or foreign supplier's compliance status, such as Form FDA 483s, Establishment Inspection Reports, and recall notices.

We agree, however, that importers should consider both food and supplier risks in developing their supplier verification plans. Therefore, we tentatively conclude that it is appropriate to more clearly specify that importers must consider certain information relevant to the risks associated with a food and the foreign supplier. Rather than have a separate section requiring importers to conduct a compliance status review of foods and potential foreign suppliers, we are incorporating these compliance concerns into the proposed risk evaluation requirements.

We now are proposing to establish provisions requiring importers to evaluate the risks associated with the food and the potential foreign supplier to determine whether it is appropriate to approve the importation of the food from the foreign supplier. In addition to requiring

importers to consider the hazards they determine to be significant under proposed § 1.504 in the revised regulatory text (discussed in section II.B), proposed § 1.505(a)(1) in the revised regulatory text would require importers to consider the following:

- The entity that will be applying controls for the identified hazards, such as the foreign supplier or the foreign supplier's raw material or ingredient supplier. As stated in the preamble to the 2013 proposed rule, we believe that the person who will be controlling a hazard in a food is an important, though not necessarily the only, factor in determining an appropriate supplier verification activity for the food.
- The foreign supplier's procedures, processes, and practices related to the safety of the food. Many comments state that various aspects associated with the manner in which a foreign supplier produces a food can affect the risk associated with the supplier.
- Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter or import alert. There is widespread acknowledgement among the comments that a foreign supplier's history of compliance with applicable FDA regulations is an important component (though not the only component) of supplier risk evaluation. Documents such as warning letters and import alerts are available on FDA's Web site; we tentatively conclude that we would not require importers to consider non-public information regarding compliance with FDA regulations unless such information was available to the importer (e.g., provided to the importer by the foreign supplier).
- 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. Several comments state that an importer typically considers a foreign supplier's performance in providing products that meet the importer's specifications, as verified through onsite auditing, testing, or other measures, in determining the form and frequency of verification activities to conduct.

- Any other factors as appropriate and necessary, such as storage and transportation practices. We believe that there might be factors not previously specified that in certain circumstances an importer should consider in evaluating food and supplier risks, such as storage and transportation practices or recent changes to the management of a foreign supplier.

Proposed § 1.505(a)(2) in the revised proposed regulatory text would require the importer to document each risk evaluation it conducts.

We tentatively conclude that this approach to risk evaluation requirements provides a more complete and specific listing (compared to the combined requirements in the previous proposal regarding compliance status review and hazard analysis) of the factors noted by many comments as being the issues that importers typically consider in evaluating food and foreign supplier risks. Under the revised proposal, importers would need to consider each of the previously listed factors in performing their food and foreign supplier risk evaluations. We intend to issue guidance on the specific information that we believe should be considered under each of these factors and how these factors might be weighed in evaluating overall risk.

These proposed risk evaluation factors closely align with the factors that receiving facilities must consider in determining appropriate raw material and ingredient supplier verification activities under the supplier program provisions of the revised Preventive Controls proposed rule.

We believe that it is not necessary to mandate a specific frequency (e.g., on an annual basis) for a complete reanalysis of the risks associated with a food or foreign supplier. Instead, we believe that an importer should reevaluate food and supplier risks when it obtains new information about these risks, either through the importer's own investigation or from the foreign supplier, FDA, or some other source. Therefore, proposed § 1.504(b) in the revised regulatory text would require an importer to promptly evaluate the risks associated with a food or foreign supplier when the importer becomes aware of new information about the risks. We intend to provide guidance on the circumstances under which importers should reevaluate food and supplier risks.

B. Hazard Analysis

The other requirement in the previous proposed rule that concerned evaluation of food and supplier risk was the requirement to conduct a hazard analysis. Previously proposed § 1.505(a) would require each importer (with certain exceptions) to determine, for each food imported, the hazards, if any, that are reasonably likely to occur with the food and, for each, the severity of the illness or injury if such a hazard were to occur. The importer would need to document this determination and use it to determine appropriate supplier verification activities.

Previously proposed § 1.505(b) states that an importer's evaluation of the hazards that are reasonably likely to occur with each food that is imported must consider the following potential hazards that may occur naturally or may be unintentionally introduced: Biological hazards, including microbiological hazards such as parasites and environmental pathogens, and other microorganisms of public health significance; chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; physical hazards; and radiological hazards.

Previously proposed § 1.505(c) states that, in evaluating the hazards in § 1.505(b), the importer must consider the effect of several factors on the safety of the finished food for the intended consumer. These factors are as follows: The ingredients of the food; the condition, function, and design of the foreign supplier's establishment and equipment; transportation practices; harvesting, raising, manufacturing, processing, and packing procedures; packaging and labeling activities; storage and distribution; intended or reasonably foreseeable use; sanitation, including employee hygiene; and any other relevant factors.

Previously proposed § 1.505(d) would permit an importer to identify the hazards that are reasonably likely to occur for a particular food by reviewing and evaluating the hazard analysis conducted by the foreign supplier (rather than conducting an entirely separate evaluation of hazards using information that the importer itself has obtained).

Finally, under previously proposed § 1.505(e), for a RAC that is a fruit or vegetable, an importer would not be required to conduct a hazard analysis regarding the microbiological hazards that might be reasonably likely to occur with this food. Instead, the importer would need to verify that this kind of food is produced in compliance with FDA's produce safety standards, once finalized, or equivalent standards.

As stated in section II.A.2, our revised proposal would continue to require an importer to analyze the hazards in a food that it imports, with the hazard analysis being one part of the food and foreign supplier risk evaluation that the importer must conduct under § 1.505 in the revised regulatory text. In this section, we discuss certain revisions we are making to the hazard analysis requirements in the proposed rule.

1. Nature of the Hazards That Importers Must Analyze

a. Comments.

Several comments object to the proposed requirement that importers' hazard analyses focus on hazards that are "reasonably likely to occur" with a food. We proposed to define a hazard reasonably likely to occur as one for which a prudent importer would establish controls or verify that the supplier controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being imported in the absence of those controls. One comment states that the "reasonably likely to occur" standard should not be used because it goes beyond and is inconsistent with the "known or reasonably foreseeable" statutory standard in FSMA's preventive controls provisions (section 418(b)(1) of the FD&C Act). Several comments maintain that the term reasonably likely to occur typically has been used to determine critical control points for hazard analysis and critical control points (HACCP) systems and is inappropriate for use in a program like supplier verification that is a "prerequisite," foundational food safety program. The comments recommend instead that importers be required to consider "known or reasonably foreseeable" hazards because determining such hazards requires knowledge of the facility in which the food is produced.

b. Revisions regarding nature of hazards to be evaluated.

The hazard analysis provisions in both the FSVP and preventive controls previously proposed rules would have required evaluation of hazards that are reasonably likely to occur. As we state in the Preventive Controls supplemental document, we acknowledge that it might be confusing to use the phrase "reasonably likely to occur" in both our HACCP regulations and in the preventive controls and FSVP regulations, because the phrase "reasonably likely to occur" has been used as the basis for determining hazards that need to be addressed in a HACCP plan at critical control points. In light of this concern, and consistent with our revision of the hazard

analysis provisions in the preventive controls proposed rule, we tentatively conclude that the potential hazards that importers should be required to consider in their risk analyses are hazards that are known or reasonably foreseeable rather than hazards that are reasonably likely to occur. We believe that it is appropriate to align the hazard analysis provisions in the FSVP regulations with those in the proposed preventive controls regulations because hazard analysis is an import component of supplier verification.

We now propose to define a "known or reasonably foreseeable hazard" as a potential biological, chemical (including radiological), or physical hazard that is known to, or has the potential to be, associated with a food or the facility in which it is manufactured/processed (§ 1.500 in the revised regulatory text). (We accordingly propose to add a definition of "facility," which would be defined as a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act (21 U.S.C. 350d), in accordance with the requirements of 21 CFR part 1, subpart H.) We also are revising the hazard analysis provisions to make clear that they apply to analysis of known or reasonably foreseeable hazards.

Section 1.504(a) in the revised regulatory text would require an importer to analyze the known or reasonably foreseeable hazards in a food, based on experience, illness data, scientific reports, and other information, to determine whether they are "significant" hazards. We propose 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 (§ 1.500 in the revised regulatory text). This means that importers must conduct hazard

analyses to determine whether any known or reasonably foreseeable hazard in a food poses such a risk to health that it is necessary to establish controls to significantly minimize or prevent the hazard. This definition of significant hazard and the proposed requirement to determine whether known or reasonably foreseeable hazards are significant are consistent with the approach that we are proposing in the supplier program provisions of the preventive controls regulations.

2. Biological Hazards

As previously stated, previously proposed § 1.505(b)(1) would require importers to consider whether there are biological hazards in the food they import, including microbiological hazards such as parasites and environmental pathogens, and other microorganisms of public health significance. In the Preventive Controls supplemental document, we are replacing the phrase "microorganism of public health significance" in the proposed preventive controls hazard analysis provisions with the phrase "pathogen" and proposing to define "pathogen" as a microorganism of public health significance. To better align the FSVP requirements with those proposed for preventive controls, we are proposing to describe biological hazards in the same way in § 1.504(b)(1)(i) in the revised regulatory text and adding a definition of "pathogen" to proposed § 1.500. In addition, we are including the same revised definition of "environmental pathogen" as is set forth in the Preventive Controls supplemental document, which proposes 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 definition also specifies that spores of pathogenic sporeformers are not environmental pathogens).

3. Radiological Hazards

As previously stated, the proposed rule included radiological hazards among the types of hazards (along with biological, chemical, and physical hazards) that importers must consider in their hazard analyses.

a. Comments.

Some comments maintain that radiological hazards should be included among the chemical hazards rather than in a separate category. One comment states that treating radiological hazards as a separate category would mean that FSMA regulations would differ from Codex and world-wide HACCP standards, which require evaluation only of biological, chemical, and physical hazards, and would create a potential for misunderstanding and lack of acceptance by foreign suppliers. The comment states that making radiological hazards a subset of chemical hazards would help mitigate concerns about a requirement to consider radiological hazards.

b. Revisions regarding radiological hazards.

We tentatively conclude that it is appropriate to consider radiological hazards as a type of chemical hazard. Therefore, we have revised the definition of "hazard" and the reference to radiological hazards in the revised hazard analysis provisions (§§ 1.500 and 1.504(b)(1)(ii), respectively, in the revised regulatory text). However, this does not mean that consideration of radiological hazards would be optional; rather, importers would be required to review such hazards when considering possible chemical hazards in a food.

4. Intentional Hazards

In the previous FSVP proposed rule, we stated our tentative conclusion that importers need only consider those hazards that occur naturally or might be unintentionally introduced (78 FR 45730 at 45749). We noted that we planned to address the issue of certain intentionally

introduced hazards as part of our rulemaking to implement section 106 of FSMA, which directs FDA to issue regulations to protect against the intentional adulteration of food. But we acknowledged that some kinds of intentional adulterants could be viewed as reasonably likely to occur, such as in foods for which there is a known risk of economically motivated adulteration. Therefore, we requested comment on whether to include in the FSVP requirements potential hazards that may be intentionally introduced for economic reasons.

a. Comments.

Comments were submitted both for and against requiring importers to consider hazards intentionally introduced for economic reasons. One comment states that although importers should consider economically motivated adulterants, most such adulterants should not be regarded as reasonably likely to occur and do not pose a food safety hazard. Some comments question the feasibility of determining which economically motivated adulterants should be viewed as reasonably likely to occur. Some comments state that economically motivated adulteration is best addressed through food defense plans. One comment states that importers should not be required to consider intentional hazards, including economically-motivated hazards, because such hazards require different kinds of preventive measures than those traditionally used in supplier verification programs.

b. Revisions regarding intentional hazards.

We are proposing to add hazards that may be intentionally introduced for purposes of economic gain to the types of known or reasonably foreseeable hazards that an importer would be required to consider in its hazard analysis (see § 1.504(b)(2)(iii) in the revised regulatory text). As discussed in the Preventive Controls supplemental document, several substances, such as melamine and dyes containing lead, have been used in economically motivated adulteration

schemes and have potential to harm public health. Because some economically motivated adulterants should be regarded as known or reasonably foreseeable hazards, we believe it is appropriate that importers consider them when conducting hazard analyses. We are no longer proposing that importers analyze hazards that are reasonably likely to occur, so the concerns related to applying that standard to economically motivated adulterants are no longer relevant. In addition, because the proposed regulations define a "hazard" as an agent that is reasonably likely to cause illness or injury in the absence of its control, importers need only consider those economically motivated adulterants that are reasonably likely to harm consumers' health, not economically motivated adulterants that solely affect quality or value.

We disagree with the comment that economically motivated adulteration requires different kinds of preventive measures than those traditionally used in supplier verification programs. Industry currently uses audits, sampling, and testing to verify that hazards are being controlled, including hazards from economic adulteration. Nevertheless, as discussed in section II.C.5, the revised proposed supplier verification requirements provide considerable flexibility to importers in conducting supplier verification, including the ability to determine and implement any appropriate supplier verification activity based on the risks associated with the food and foreign supplier.

5. Environmental Pathogens in Certain Ready-to-Eat Food

To better align the hazard analysis requirements in the FSVP regulations with those in the proposed preventive controls regulations, we are adding a proposed requirement, in § 1.504(c)(2) in the revised regulatory text, for importers to include in their hazard analysis of a food 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.

6. Factors Affecting the Safety of Finished Food

Also to better align the FSVP hazard analysis requirements with those in the proposed preventive controls regulations, we are making two minor revisions to the list of proposed items that importers must consider regarding their potential effect on the safety of finished food for the intended consumer. In § 1.504(c)(3)(i) in the revised regulatory text, we are replacing "ingredients of the food" with "formulation of the food," and in § 1.504(c)(3(iii) in the revised regulatory text we are adding a requirement to consider "raw materials and ingredients."

C. Supplier Verification

We are revising several aspects of the proposed requirements concerning foreign supplier verification procedures and related activities. The revisions include a revised proposal regarding the alternative options presented in the proposed rule concerning appropriate supplier verification activities when foreign suppliers control (or verify control of) hazards in food.

1. List of Foreign Suppliers

To help ensure that importers are obtaining food only from appropriate foreign suppliers, previously proposed § 1.506(a) would require each importer to maintain a written list of the foreign suppliers from which they are importing food. The list would also help importers to quickly and accurately identify their foreign suppliers for purposes of conducting FSVP activities such as supplier verification, investigations, and corrective actions, and help ensure consistent performance of these activities by importers' employees or other qualified individuals.

a. Comments.

Several comments express support for the proposed requirement that importers maintain a list of their foreign suppliers. However, some comments oppose this requirement on the basis that it would present logistical or administrative challenges. Some comments state that it would be burdensome to constantly update the list of foreign suppliers. Some comments suggest that importers instead be required to provide a list of suppliers upon the Agency's request. One comment states that the identity of suppliers is confidential business information that importers should not be required to disclose to FDA on a routine basis.

Some comments state that some importers might not maintain a single list of approved suppliers but use a corporate-wide or centralized system to confirm receipt of food from approved suppliers. These comments instead recommend that importers be required to establish a system that will allow them to confirm that imported food is from a foreign supplier that the importer has approved for use.

One comment states that in emergency situations to avoid production disruptions, an importer might need to obtain food from foreign suppliers that they have not audited. The comment maintains that use of food from such suppliers would be acceptable provided that the food is inspected or analyzed before use.

b. Revisions regarding process for confirming receipt of food from approved suppliers.

We are uncertain how an importer could verify that a food it receives is from an approved foreign supplier yet be unable to generate a list of such approved suppliers, especially when the importer uses a centralized, corporate-wide system. We understand that use of multiple supplier databases could necessitate some compilation procedure, but it does not appear to us that this would be significantly burdensome. Nevertheless, we tentatively conclude that requiring importers to establish a system or procedure to confirm that imported foods are from approved

suppliers, rather than maintain a list of foreign suppliers, would enhance the safety of imported food at least as much as merely maintaining a list of suppliers while reducing the apparent administrative burden on importers. Therefore, we have replaced the proposed requirement to maintain a list of foreign suppliers with a proposed requirement, in § 1.506(a) in the revised regulatory text, to establish and follow written procedures to ensure that foods are imported from foreign suppliers the importer has approved based on the risk evaluation it conducts under § 1.505 and to document use of these procedures. These procedures might address approval of suppliers, approval or rejection of particular shipments of foods, and documentation of receipt from approved suppliers. It is essential that such procedures be capable of accurately identifying foreign suppliers for purposes of meeting FSVP requirements.

However, we believe that, in limited circumstances, it might be appropriate for an importer to use a supplier for which the importer has not completed a full risk evaluation provided that the importer takes other steps to ensure that food from such a supplier is safe. For example, because of a problem with a long-time supplier due to an equipment breakdown, an environmental or weather-related crisis (e.g., severe drought or flooding), or some other unexpected circumstance, it might be necessary for an importer to obtain a food on a temporary basis from a new supplier. 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 that supplier was safe. Such verification measures might include sampling and testing individual shipments from the supplier. Therefore, revised § 1.506(a) would permit the use of unapproved foreign suppliers on a temporary basis when necessary and appropriate, provided that the importer subjects the food from such suppliers to adequate verification activities before using or distributing the food. The importer's written procedures regarding the use of approved

suppliers also would need to address the circumstances under which unapproved suppliers might be used, and the importer would need to document the verification activities it conducts when using unapproved suppliers. We request comment on circumstances under which it might be necessary and appropriate to receive food from unapproved foreign suppliers and on the types of verification activities that an importer should conduct on food from an unapproved supplier.

2. Purpose of Supplier Verification

Section 1.506(c) of the 2013 proposed rule would have required the importer to conduct foreign supplier verification activities to provide adequate assurances that the hazards the importer had identified as reasonably likely to occur were adequately controlled. However, we tentatively concluded that this provision should not apply to microbiological hazards in RACs that are fruits or vegetables and that would be subject to the produce safety regulations in proposed part 112 (21 CFR part 112) because importers of these fruits or vegetables would not be required to conduct a hazard analysis regarding the microbiological hazards in this food. Instead, proposed § 1.506(h) stated that verification for these hazards should address whether foreign suppliers are producing these fruits and vegetables in accordance with the produce safety regulations.

a. Comments.

One comment maintains that directing that supplier verification activities be designed to provide assurances that hazards are adequately controlled is inconsistent with the statute and does not focus on the key issues affecting the safety of imported food. The comment states that supplier verification activities should consider not just the hazards in food but supplier-related risks. Some comments maintain that linking supplier verification activities solely to food

hazards incorrectly implies that verification controls the hazard and suggests that the supplier can pose no significant safety risks.

b. Revisions regarding purpose of supplier verification.

We do not believe, nor does the preamble to the 2013 proposed rule state, that supplier verification activities actually control hazards. Rather, a key purpose of verification is to provide assurance that hazards are being effectively controlled by the foreign supplier or some other entity. However, as stated in section II.A.2, we tentatively conclude that importers should consider both food and supplier risks in determining what supplier verification activities to conduct. In accordance with this approach, we believe that the purpose of supplier verification activities should not be limited to verifying control of hazards. Therefore, we now propose to require (in § 1.506(c) in the revised regulatory text) that supplier verification activities provide adequate assurances that the foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the FD&C Act (the preventive controls and produce safety provisions, respectively), if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. This more directly links supplier verification activities to the statutory purpose for FSVPs in section 805(a)(1) of the FD&C Act.

With this change to the proposed purpose of supplier verification activities, we tentatively conclude that there is no need for a separate requirement concerning supplier verification activities related to microbiological hazards in RACs that are fruits or vegetables subject to the produce safety regulations. With respect to microbiological hazards in such food, under revised § 1.506(c), the importer of the food would need to conduct activities to verify that: (1) The foreign supplier is using processes and procedures that provide at least the same level of

protection as those required under the produce safety regulations, when finalized and (2) the food is not adulterated or misbranded regarding allergen labeling.

3. No Hazards Identified

Under § 1.506(d) of the previous proposed rule, if an importer determines that no hazards are reasonably likely to occur with a food, the importer would not be required to conduct supplier verification activities. However, under the supplier program provisions in the revised preventive controls proposal, when there are no significant hazards in a raw material or ingredient, the receiving facility would not be required to have a supplier program for the food, including the requirement to determine appropriate verification activities by considering food and supplier risks. To better align the proposed FSVP regulations with the proposed preventive controls regulations, we propose to specify, in § 1.504(f) in the revised regulatory text, 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 it should conduct and would not be required to conduct any such activities. (As under the proposed rule, revised § 1.504(f) states that this exemption would not apply if the food is a RAC that is a fruit or vegetable and that is subject to the produce safety regulations.)

4. Hazards Controlled by the Importer or Its Customer

The preamble to the 2013 proposed rule noted that some hazards associated with an imported food are controlled through actions that the importer or its customer takes after the food is brought into the United States. We tentatively concluded that if an importer or its customer has established validated preventive controls to ensure that a hazard is adequately controlled through processing in the United States, there would be no need for the importer to conduct a

foreign supplier verification activity with respect to that hazard (78 FR 45730 at 45752). Therefore, when an importer is adequately controlling a hazard that it has identified, proposed § 1.506(e) would have required the importer to document, at least annually, that it had established and was following procedures that adequately controlled the hazard. Similarly, when an importer's customer was controlling a hazard, proposed § 1.506(f) would have required the importer to document that its customer controlled the hazard by obtaining written assurance, at least annually, from the customer that it had established and was following procedures (identified in the written assurance) that adequately controlled the hazard.

However, we also requested comment on whether it would be appropriate to deem importers who are in compliance with any applicable supplier verification provisions that are included in the preventive controls regulations to be in compliance with the FSVP requirements, to avoid duplicative regulation of importers who are also registered with FDA as food facilities. We tentatively concluded that, if a provision to this effect were included in the FSVP regulations, proposed § 1.506(e) would be unnecessary, as importers that control hazards in foods they import would be subject to the supplier verification provisions in the preventive controls regulations (78 FR 45730 at 45752). Similarly, we tentatively concluded that proposed § 1.506(f) would be unnecessary if the FSVP regulations were to include a provision stating that an importer whose customer was in compliance with any adopted preventive controls supplier verification provisions was deemed to be in compliance with the FSVP requirements. We requested comment on this proposed approach to supplier verification when the importer or its customer controls a hazard.

a. Comments.

Several comments agree with proposed § 1.506(e) requiring importers who control hazards in food they import to document their control of these hazards. In addition, several comments express support for avoiding imposing redundant verification requirements on importers that would be required to conduct supplier verification under the preventive controls regulations. One comment agrees that proposed § 1.506(e) would be unnecessary if importers who were in compliance with supplier verification provisions in the preventive controls regulations were deemed in compliance with the FSVP requirements.

One comment states that supplier verification activities should not turn on the entity that is controlling a hazard in a food. The comment states that verification activities may be needed even when the foreign supplier does not control the hazard, adding that importers should not be required to engage in a paperwork exercise to obtain assurances of their customers' food safety controls. Similarly, another comment opposes not requiring standard verification activities when a hazard is to be controlled by the importer or its customer, maintaining that nearly all suppliers should be subject to verification activities. The comment states that not requiring any supplier verification would overlook important issues such as the supplier's compliance with CGMP requirements and the need for programs to avoid introducing any unforeseen hazards. The comment also states that the proposal is problematic because the intended use of the food may not be known at the time of entry or different parts of a product batch might be destined for different customers with different processes. However, elsewhere in its submitted comments, the commenter maintains that FDA must harmonize the supplier verification provisions in the preventive controls regulations with the FSVP regulations so that imported ingredients need only be verified once.

b. Revisions regarding importers subject to the supplier program provisions in the preventive controls regulations.

As stated previously in this document, elsewhere in this issue of the Federal Register we are proposing a potential requirement for a supplier program in the proposed preventive controls regulations. Therefore, consistent with the discussion in the 2013 FSVP proposed rule, we propose to specify, in § 1.502(c) in the revised regulatory text, that if an importer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer is in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the United States). Similarly, under § 1.502(d) in the revised regulatory text, if an importer's customer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer annually obtains written assurance that its customer is in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulations (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). Because the importer or its customer would be performing supplier verification activities under the preventive controls regulations, we tentatively conclude that this approach addresses concerns about a lack of supplier verification when the importer or its customer controls a hazard, while also avoiding imposing redundant verification requirements.

However, even though we are proposing to add these provisions regarding importers who are facilities that are subject to the supplier program requirements in the preventive controls regulations, we tentatively conclude that it would not be appropriate to delete the previously

proposed provisions concerning foods with hazards to be controlled by the importer or its customer. The reason for this is that we tentatively conclude that it is appropriate to align the FSVP requirements with the potential supplier program provisions discussed in the preventive controls proposed rule, should they be adopted. The potential supplier program requirements would not apply under the following circumstances:

- When the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards in a raw material or ingredient; or
- When the receiving facility relies on its customer to control the 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.

In such circumstances, requiring an importer that also is a facility subject to the preventive controls regulations to conduct foreign supplier verification activities would not impose a redundant regulatory burden because such importer-facilities would not also be subject to the preventive controls supplier program requirements. Nevertheless, we tentatively conclude that it still would impose an unnecessary burden because the importer's (and/or its customer's) control of all significant hazards in the food would effectively resolve the food safety concerns that supplier verification is intended to address. Therefore, we propose to specify, in § 1.504(g) of the revised regulatory text (in the hazard analysis section of the proposed FSVP regulations), that if the preventive controls that an importer and/or its customer implements under the preventive controls regulations are adequate to significantly minimize or prevent all significant hazards in a food, the importer is not required to determine appropriate foreign supplier verification and related activities under § 1.505 and is not required to conduct such activities

under § 1.506. Proposed § 1.504(g) further states that if the importer's customer controls one or more significant hazards in a food, the importer must annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

5. Hazards Controlled by the Foreign Supplier

The previous proposed rule set forth two options for the requirements regarding supplier verification activities for hazards that are controlled, or for which control is verified, by the importer's foreign supplier (see previously proposed § 1.506(g), Options 1 and 2). 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. (The preamble to the 2013 proposed rule described a SAHCODHA hazard as one for which a recall of a violative product posing such hazard is designated as "Class I" under 21 CFR 7.3(m)(1).) 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 certain initial and subsequent periodic (at least annual) onsite audits of the foreign supplier. Onsite auditing also would be required under Option 1 for microbiological hazards in certain RACs that are fruits or vegetables. When onsite auditing alone could not provide adequate assurances that such a hazard was adequately controlled, the importer would have had to conduct one or more additional verification activities to provide such assurances. 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, upon consideration of the risk presented by the hazard and the food and foreign supplier's compliance status, one or more of the following verification activities before using or distributing the food and periodically thereafter:

- 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.
- Any other procedure established as being appropriate based on the risk associated with the hazard.

On the other hand, Option 2 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. In determining the appropriate verification activities and how frequently they should be conducted, Option 2 would have required the importer to consider the risk presented by the hazard, the probability that exposure to the hazard would result in serious adverse health consequences or death to humans or animals, and the food and foreign supplier's compliance status.

a. Comments.

We received many comments in support of Option 1 and many that favor Option 2. Comments in favor of Option 1 include the following:

- Option 1 would provide greater protection to consumers than Option 2.

- Option 1 is risk-based in that it would require the most rigorous form of supplier verification--onsite auditing--when the most serious hazards are present in food.
- Option 2 would provide too much discretion to importers, who would have an incentive to choose lower-cost and less effective verification methods, which could result in an increase in contaminated imported food.
- A single, streamlined requirement would be more easily enforced without confusion, and regulated entities often prefer such clarity.
- Option 1 would reduce industry costs by avoiding the need for importers to make verification decisions on a product-by-product basis.

Comments in favor of Option 2 include the following:

- Option 2 would provide importers with the flexibility needed to tailor the supplier verification to the particular food and supplier risk.
- Option 2 is more closely aligned with current industry practice, which often uses onsite audits but also relies on other verification methods depending on food and supplier risk.
- Option 2 is more risk-based and would result in a better allocation of resources by not requiring onsite auditing when it would not be justified by risk.
- Requiring different supplier verification activities for different types of hazards in a food is inconsistent with current industry practice.
- Option 1 could lead importers to simply "check the box" that a foreign supplier has been audited rather than analyze the audit results and consider whether additional verification activities are needed.

- The SAHCODHA standard is not well understood and might not be workable as a factor for determining supplier verification activities.

One comment recommends what it describes as a hybrid of the two options. The comment suggests that annual onsite auditing should be the default requirement for SAHCODHA hazards and for microbiological hazards for RACs that are fruits or vegetables, but an importer would be permitted to use alternative verification measures if it could justify, based on a comprehensive risk assessment, that risks are reduced and that the alternative measures would adequately verify that the foreign supplier adequately controlled the hazards.

b. Revisions regarding supplier verification activities.

Although we acknowledge the concerns regarding Option 2 expressed by supporters of Option 1, we tentatively conclude that allowing importers the flexibility to determine the appropriate supplier verification activity (or activities) based on the importer's evaluation of food and supplier risks would be a more risk-based approach. We believe that this would more closely align the verification requirements with Congress's directive that importers perform risk-based verification activities. In turn, this should result in safer imported food by allowing importers to optimize their verification efforts in accordance with the relative risks to public health posed by different foods and suppliers.

Therefore, we are proposing, in § 1.506(d)(1) in the revised regulatory text, that importers be required to conduct and document one or more of four supplier verification activities--onsite auditing, sampling and testing of food, review of the foreign supplier's food safety records, or some other appropriate risk-based verification activity--before initially importing a food and periodically thereafter. The importer would be required to determine and document which verification activity or activities are appropriate, as well as the frequency with

which the activities must be conducted, based on the risk evaluation that the importer conducts for the food and supplier under proposed § 1.505. As in both Option 1 and Option 2 under the previous proposed rule, the revised proposal recognizes that for some foods or foreign suppliers it might be necessary to conduct more than one verification activity to provide the required assurances (see § 1.506(d)(3) in the revised regulatory text).

The revised proposal states that an onsite audit of a foreign supplier must be conducted by a qualified auditor (§ 1.506(d)(1)(i)(A) in the revised regulatory text), who is defined as a person who is a qualified individual and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function (§ 1.500 in the revised regulatory text). (The proposed definition also specifies that a foreign government employee could be a qualified auditor.) The revised proposal also states that sampling and testing of a food may be conducted by either the importer or the foreign supplier (§ 1.506(d)(1)(ii)(A) in the revised regulatory text).

We are proposing a slight modification to this general rule regarding verification activities in the case of foods with SAHCODHA hazards, similar to the "hybrid" approach suggested by one comment. As expressed by some Option 1 supporters, we believe that requiring onsite auditing when there is a SAHCODHA hazard in a food is risk-based because it would require what is arguably the most robust supplier verification activity--annual onsite auditing--for the most serious hazards in foods. However, we acknowledge the possibility that: (1) Use of some other verification activity, (2) less frequent onsite auditing, or (3) some combination of those two approaches could provide adequate assurances regarding the safety of the food. We also recognize that although some importers might prefer the ease of not having to make a determination of appropriate supplier verification activities when a SAHCODHA hazard

is present in a food, others would prefer being able to tailor verification activities (and the frequency with which they are conducted) to a particular food and supplier risk profile.

For these reasons, we are proposing to require, in § 1.506(d)(2) in the revised regulatory text, that when a SAHCODHA hazard in a food will be controlled by the foreign supplier, the importer must conduct (or obtain documentation of) initial and subsequent annual onsite auditing of the foreign suppler unless the importer determines that other supplier verification activities and/or less frequent onsite auditing are appropriate to provide adequate assurances regarding the safety of a particular food and foreign supplier based on the risk evaluation conducted under § 1.505. This would provide importers with the certainty of knowing that use of initial and subsequent annual onsite auditing would satisfy the verification requirement when a SAHCODHA hazard is present in a food, while allowing importers to use an alternative verification mechanism(s) if they determine that such mechanism(s) provide adequate safety assurances.

We do not believe, as some comments suggest, that making onsite auditing mandatory when there is a SAHCODHA hazard in a food or, in the case of our revised proposal, establishing onsite auditing as the "default" verification activity in such circumstances, would result in importers failing to analyze audit results or consider whether additional verification activities are needed. Both the previous proposed rule (§ 1.506(g)(5) under Option 1) and the revised proposal (§ 1.506(d)(6) in the revised regulatory text) would require importers to promptly review the results of their verification activities and, if necessary, take appropriate corrective action. In addition, under both the previous proposed rule (§ 1.506(g)(1) under Option 1) and the revised proposal (§ 1.506(d)(3) in the revised regulatory text), even when an importer conducts an onsite audit or obtains an onsite audit report to verify control of a SAHCODHA

hazard in a food, it might be necessary in some circumstances for the importer to conduct some additional verification.

We also do not believe that purported uncertainty about the SAHCODHA standard would make it difficult for importers to comply with this provision. FDA's Reportable Food Registry Questions and Answers document discusses the types of violative products that should be addressed through a Class I recall, which uses the SAHCODHA standard. In addition, the Agency's weekly FDA Enforcement Report, which is available at FDA's Web site (http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm), provides more information about foods that have been the subject of a Class I recall and the reasons for the recall. We will consider providing additional guidance to industry to help clarify what food hazards constitute SAHCODHA hazards under the FSVP regulations.

We acknowledge that there may be concerns that the revised proposed approach to foreign supplier verification activity requirements could lead some importers to rely on verification activities that might be inadequate to provide sufficient assurances about the safety of the imported food. We believe that there are some circumstances, such as when a SAHCODHA hazard is present in a food, in which onsite auditing on an annual basis likely would be needed to ensure proper verification of suppliers. However, in some cases, including even when a SAHCODHA hazard is present, we believe it is possible that alternative supplier verification activities would provide adequate assurances of food safety. An importer who chose to conduct such an alternative activity would need to maintain documentation that the activity provides adequate assurances of safety; this documentation would be available for FDA review during any inspection of the importer. To address concerns that the revised proposal may allow too much discretion, and to assist importers in meeting the verification requirements, we

anticipate that we will provide guidance to industry on the circumstances (incorporating both food and supplier risks) under which onsite auditing of foreign suppliers and/or other supplier verification approaches are appropriate for providing adequate assurances regarding the safety of the food produced by a foreign supplier.

6. Food From Farms That Are Not Covered Farms Under the Proposed Produce Safety Regulations

In addition to the just-discussed revisions concerning supplier verification activities, we are proposing to include a revision regarding food from foreign suppliers that are farms but not "covered farms" subject to the produce safety regulations. We are making this change to reflect the different treatment of food from such farms under the proposed produce safety regulations and to be consistent with the potential requirement for a supplier program in the proposed preventive controls regulations.

Under § 1.506(d)(4) in the revised regulatory text, if a foreign supplier of a food is a farm that is not subject to the requirements in part 112 (the produce safety regulations) in accordance with § 112.4 regarding the food being imported, the importer would not be subject to the FSVP supplier verification activity requirements in revised § 1.506(d)(1) and (d)(2) if the importer:

- Documented, at the end of each calendar year, that the food provided by the foreign supplier was not subject to part 112; and
- obtained written assurance, at least every 2 years, that the foreign supplier was producing the food in compliance with the FD&C Act.

These alternative verification requirements would apply to importers of food from the following:

- Farms that do not grow and harvest "produce," as defined in § 112.3(c) of the proposed produce safety regulations. For example, because food grains are not produce, the alternative verification requirements would apply to importers of food grain.
- Farms that grow and harvest produce that is not covered by the proposed produce safety regulations 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, and produce that is not a RAC.
- Farms that are not "covered farms" because they produce an average annual monetary value of produce of no more than $25,000 (see proposed § 112.4(a)).
- Farms that are not covered farms because they satisfy the requirements for a qualified exemption from the proposed produce safety regulations under proposed § 112.5 (including requirements concerning direct sale to qualified end-users) and the exemption has not been withdrawn.

Because FDA has determined that these farms either: (1) Should not be subject to the produce safety regulations or (2) should not be required to comply with the "standard" requirements applicable to covered activities conducted for covered produce, we tentatively conclude that it is appropriate to similarly not require importers of food from such farms to conduct the "standard" supplier verification activities. We request comment on the proposed alternative method of supplier verification of obtaining written assurance of compliance with the FD&C Act by these farms.

7. Documentation of Foreign Supplier Verification Activities

The proposed rule does not specify what documentation of onsite audits of foreign suppliers importers must maintain. At the public meetings on the FSVP proposed rule and in other meetings with stakeholders, we invited comment on what documentation of onsite audits importers should be required to have. We also stated that for onsite audits conducted for FSVP purposes, importers would not be required to obtain a regulatory audit report as required for audits conducted by accredited auditors/certification bodies under FDA's proposed rule on "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (78 FR 45782, July 29, 2013).

With respect to documentation of sampling and testing of an imported food, the proposed rule (§ 1.506(g)(2)(ii) under Option 1) specified a certificate of analysis (COA) containing the results of testing as an example of appropriate documentation but did not require a particular form or forms of documentation. The preamble to the proposed rule suggested certain information that might be included in a COA (78 FR 45730 at 45757). Similarly, the proposed rule (§ 1.506(g)(2)(iii) under Option 1) included records of a foreign supplier's audit of its supplier's hazard control activities as an example of appropriate documentation of review of a foreign supplier's food safety records but did not require a specific form of documentation. The preamble to the proposed rule states that food safety records are records documenting that the hazard control procedures established by the supplier are being followed and are adequately controlling the hazards (78 FR 45730 at 45756). The proposed rule provided no example of appropriate documentation of other verification procedures determined by the importer to be appropriate.

a. Comments.

Several comments state that importers should not be required to share foreign supplier audit reports with FDA. The comments state that because such reports often include confidential business information and findings of flaws in safety systems, requiring that the reports be made available to the Agency might make suppliers less likely to allow audits or result in less robust audits. Some comments suggest that importers be required to maintain documentation that an audit was conducted (the date of the audit and the name of the auditor) and documentation of the completion of any corrective actions in response to significant deficiencies.

Regarding documentation of sampling and testing, one comment encourages us not to specify requirements for the content of COAs because this could change over time and is better left to industry to determine.

b. Revisions regarding documentation of supplier verification activities.

We acknowledge the concerns about requiring importers to document onsite audits of foreign suppliers with the full reports of those audits. We do not believe that importers should be required to make full audit reports available to us in an FSVP inspection. We understand that a foreign supplier might be reluctant to submit to onsite auditing if the full report of the audit would be made available to us, and we do not believe that we need to review the full audit report to determine whether an appropriate audit was conducted and any significant problems were corrected. Accordingly, we now are revising the proposed provisions regarding onsite auditing of foreign suppliers to require importers to retain documentation of the following: 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 (§ 1.506(d)(1)(i)(C) in the revised regulatory text). We tentatively conclude that this requirement would enable us to

determine whether an appropriate audit of the foreign supplier was conducted and whether the importer used the audit results appropriately, while preserving the benefits of the confidentiality of the audit reports.

We also are proposing to specify documentation requirements for other supplier verification activities. The revised proposal (§ 1.506(d)(1)(ii)(B) in the revised regulatory text) states that documentation of an incidence of sampling and testing (which under § 1.506(d)(1)(ii)(A) may be conducted either by the importer or the foreign supplier) must include the following: Identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical methods(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.

The revised proposal (§ 1.506(d)(1)(iii) in the revised regulatory text) states that documentation of each review of foreign supplier safety records must include 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.

The revised proposal does not specify how importers must document other appropriate supplier verification activities that they conduct. We request comment on whether the regulations should specify the form of such documentation and, if so, what form such documentation should take.

8. Independence of Qualified Individuals Conducting Verification Activities

The previous proposed rule specifies that a qualified individual who conducts any of the supplier verification activities must not have a financial interest in the foreign supplier and

payment of the qualified individual must not be related to the results of the activity (proposed § 1.506(g)(6) (under Option 1)). The proposal states that this requirement would not prohibit an importer or one of its employees from conducting the verification activity. In the preamble to the 2013 proposed rule, we requested comment on whether and, if so, how the regulations should specify what constitutes a financial interest (78 FR 45730 at 45759).

a. Comments.

Many comments express support for prohibiting persons who conduct supplier verification activities from having a financial interest in the foreign supplier whose operations they are evaluating, as well as support for the ban on linking remuneration to the results of verification activity (i.e., payment for a favorable assessment). One comment states that we should specify what constitutes a financial interest to ensure that audits are not performed by persons with a financial interest in the foreign supplier, and requests that we provide a standard disclosure form regarding financial interests.

b. Request for further comment.

At this time, we are not making any revisions to the proposed requirement that persons conducting supplier verification activities not have a financial interest in the foreign supplier and that payment to such a person must not be related to the results of the activity they have performed. However, in the Preventive Controls supplemental document, we are requesting comment on whether the potential supplier program requirements, should they be included in the final rule, include provisions to address the independence of persons who conduct supplier verification activities. We ask in that document whether such conflict of interest requirements should be directed to a subset of persons who conduct verification activities (such as auditors) or whether they should encompass all persons who conduct verification activities. We also ask

whether requirements such as those in the FSVP proposed rule would be appropriate or whether we should instead adopt different requirements, such as a requirement that persons be free of conflicts of interest that are relevant to the outcome of the verification activity conducted. In addition, we ask what should constitute a financial interest, including whether owning stock in a company should constitute a financial interest.

In light of our statements in the Preventive Controls supplemental document, we renew our request for comment on the provisions in the FSVP proposed rule on the independence of qualified individuals conducting verification activities and invite comment (in the context of the FSVP regulations) on the additional conflict of interest issues raised in the Preventive Controls supplemental document.

D. Definitions of Very Small Importer and Very Small Foreign Supplier

The 2013 proposed rule specified certain modified FSVP requirements for very small importers and importers of food from very small foreign suppliers. Proposed § 1.500 defined a "very small importer" as an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation. Proposed § 1.500 defined a "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 $500,000, adjusted for inflation.

We stated in the preamble to the proposed rule that the limitation of $500,000 in annual food sales was consistent with the sales limitation in the definition of "qualified facility" in the

Preventive Controls proposed rule and "small business" in the Produce Safety proposed rule. We requested comment on this proposed approach to the definitions of very small importer and very small foreign supplier (78 FR 45730 at 45744). We also requested comment on whether and, if so, how these definitions should take into account the proposed definition of "very small business" in the Preventive Controls proposed rule, for which we posed three alternative dollar-value ceilings: $250,000, $500,000, and $1 million.

1. Comments

Several comments oppose modified requirements for very small importers and importers of food from very small foreign suppliers regardless of the sales dollar-value ceiling. Reasons specified for such opposition include the following: Congress did not exempt very small importers from the FSVP requirements; smaller operations may be more likely than larger ones to lack adequate verification or control systems because they have fewer resources; the effect of the FSVP regulations could be undermined if importers and foreign suppliers tried to manipulate their facilities or operations to avoid the "standard" requirements; and many small foreign suppliers would already be exempt from the preventive controls or produce safety regulations and should not benefit from an exemption from verification for their U.S. importers.

Several comments support the proposed $500,000 annual food sales ceiling as a reasonable limit on eligibility for the "very small" modified FSVP requirements. Other comments maintain that a $1 million ceiling would better reflect the types of very small importers and foreign suppliers operating today. One comment proposes that FDA set the annual sales ceiling at $2 million to be consistent with how "small companies" are defined in Japan.

Some comments state that other factors, either instead of, or in addition to, the monetary value of food sales, should be considered in defining very small importers and very small foreign

suppliers. Some comments maintain that a more appropriate eligibility standard would be volume of food handled or sold, reflecting the fact that sales revenues vary by type of food, origin, quantity, price, and inflation rates. One comment states that a very small foreign supplier should be defined as one that has fewer than 100 employees, contending that use of a monetary value ceiling would provide an unfair advantage to foreign firms because many foreign suppliers are located in countries with currencies valued lower than the U.S. dollar.

Several comments state that the definitions of very small importer and very small foreign supplier should align with the definition of very small business under the preventive controls regulations. The comments state that such alignment is needed to reduce unnecessary confusion, help FDA achieve its stated goal of aligning the FSVP provisions with the supplier verification provisions in the preventive controls regulations, and ensure that the regulations are consistent with U.S. international trade obligations.

2. Revisions Regarding Definitions of Very Small Importer and Very Small Foreign Supplier

We are revising the proposed definitions of very small importer and very small foreign supplier by increasing the annual food sales ceiling from $500,000 to $1 million, consistent with the revised proposed definition of very small business set forth in the Preventive Controls supplemental document published elsewhere in this issue of the Federal Register. The preamble to the Preventive Controls supplemental document states that defining a very small business as a business that has less than $1 million in total annual sales of human food adjusted for inflation would simplify a food facility's determination of whether it is a qualified facility under the preventive controls regulations because the facility would only need to calculate its total sales of human food rather than determine how much food was sold to qualified end users. The preamble to the Preventive Controls supplemental document also notes that FDA estimates that businesses

with less than $1 million in total annual food sales produce less than one percent of the dollar value of food that is produced in the United States that would be covered by the preventive controls regulations in the absence of special provisions for very small businesses. The preamble further states that we are not basing the proposed definition of very small business on the number of employees or the volume of food sold because the statutory criteria for qualified facilities (of which very small businesses are a subset) focus on monetary value of sales, rather than volume of sales or number of employees.

To more appropriately reflect the risk to public health posed by the volume of food imported by very small importers and importers of food from very small foreign suppliers, as well as to align the proposed FSVP regulations with the proposed preventive controls regulations, we tentatively conclude that the monetary value ceiling in the definitions of very small importer and very small foreign supplier should be $1 million, adjusted for inflation. Consistency with the monetary value ceiling in the proposed definition of very small business under the proposed Preventive Controls for Human Food regulations, rather than the monetary value ceiling in the so-called Tester Amendment criteria for the definition of qualified facility (under section 418(l)(1) of the FD&C Act, is appropriate because use of the $1 million ceiling (instead of, for example, a ceiling of $250,000) means that any facility with sales below the ceiling would meet the definition of a qualified facility. We request comment on whether the revised proposed monetary value ceiling of $1 million, adjusted for inflation, for very small importers and very small foreign suppliers is appropriate, as well as on whether it is appropriate that the ceiling be the same as that specified in the definition of very small business under the preventive controls regulations.

As previously noted, the produce safety proposed rule includes provisions applicable to "small businesses," which are defined as having annual produce sales of no more than $500,000; the proposed rule also includes provisions for "very small businesses," which are defined as having annual produce sales of no more than $250,000. In addition, farms with produce sales of no more than $25,000 would not be covered under the proposed produce safety regulations. We also note that the revised proposed regulations on preventive controls for food for animals define "very small business" as having annual sales of animal food of less than $2,500,000. We request comment on whether and, if so, how the FSVP regulations should take into account these definitions and provisions applicable to smaller entities under the regulations on produce safety and preventive controls for animal food.

As with all other matters not specifically addressed in this supplemental notice of proposed rulemaking, we are still considering the comments that we have received concerning other aspects of the proposed modified provisions for very small importers and importers of food from very small foreign suppliers. These issues include, but are not limited to, whether the regulations should include any such modified provisions and, if so, what the modified requirements should be and whether the food sales to be considered for determination of eligibility should be limited to sales in or to the United States, rather than all food sales of an importer or foreign supplier. We will address comments on these issues and finalize any requirements for very small importers and importers of food from very small foreign suppliers in the FSVP final rule.

E. Other Related Revisions

We are making other revisions to the proposed rule to incorporate the changes that we are making regarding food and foreign supplier risk evaluations and supplier verification activities.

1. FSVP Reassessments

We are revising the proposed requirement in § 1.508 of the previous proposal for importers to reassess the effectiveness of their FSVPs to be consistent with our amended proposal requiring importers to evaluate food and foreign supplier risks. Section 1.508(a)(2) in the revised regulatory text would require an importer to promptly reassess the effectiveness of its FSVP for a food when it becomes aware of new information about potential risks associated with the food or foreign supplier of the food, instead of when the importer becomes aware of information about potential food hazards, as under previous § 1.508(a)(2).

Similarly, § 1.508(b) in the revised regulatory text would require that, in conducting an FSVP reassessment, an importer update its risk evaluation for a food and foreign supplier rather than, as under previous § 1.508(b), updating only the hazard analysis the importer conducted. If the reassessment led to a change in the identified risks, the importer would need to determine whether it needed to change its verification activities.

2. Records

We are revising the proposed recordkeeping requirements to reflect the previously discussed proposed amendments regarding: (1) Importers whose customers are in compliance with the supplier program requirements of the preventive controls regulations, (2) importers whose customers are controlling a significant hazard in a food, and (3) documentation requirements for supplier verification activities. Under previous § 1.510(d)(2), importers would have been required to maintain for at least 2 years (after the records were created or obtained) records of certain supplier verification activities, investigations and corrective actions, FSVP reassessments, food subject to certain dietary supplement CGMP regulations, and food imported from a country with an officially recognized or equivalent food safety system (except that

records of changes to FSVPs in accordance with the corrective actions or reassessment provisions would have had to be maintained until at least 2 years after their use was discontinued).

Under § 1.510(d)(2) in the revised regulatory text, importers would be required to maintain for at least 2 years (after the records were created or obtained) records of, among other things, written assurances from their customers that are in compliance with the supplier program requirements of the preventive controls regulations and documentation of supplier verification activities that importers conduct. Also subject to this requirement would be written assurances from importers' customers that the customer has established and is following procedures that will significantly minimize or prevent a hazard. With respect to records concerning the importation of dietary supplements, § 1.510(d)(2) in the revised regulatory text makes clear that this 2-year requirement would apply to written assurances of compliance with the dietary supplement CGMPs obtained from importers' customers and documentation of supplier verification activities conducted by importers of dietary supplements (discussed in section II.E.3).

3. Dietary Supplements

We are revising the proposed modified FSVP requirements for importers of dietary supplements in § 1.511 of the proposed rule to reflect previously discussed revisions to the proposed rule. We are revising previously proposed § 1.511(a) and (b) to specify that importers of dietary supplements and dietary supplement components that are subject to certain dietary supplement CGMP regulations in part 111 (21 CFR part 111) (or whose customers are subject to those regulations) would not be required to comply with revised § 1.506(a), concerning the requirement to establish and follow written procedures to ensure the use of approved suppliers

(which replaces the previously proposed requirement to maintain a written list of foreign suppliers). This change is appropriate because these importers would not be required to conduct risk evaluations, which provide the basis for supplier approval. However, we request comment on whether some other requirement concerning identification of foreign suppliers would be appropriate for these importers, such as a requirement, as originally proposed, to maintain a list of the foreign suppliers of the dietary supplements and dietary supplement components they import.

We also are revising several of the provisions in previously proposed § 1.511(c) regarding importers of dietary supplements that will not be further processed. First, we are revising § 1.511(c)(1) to specify that although importers of these "finished" dietary supplements would not be required to analyze the hazards in the dietary supplements they import, they would be required to evaluate the other food safety risks set forth in § 1.505(a) in the revised regulatory text. Second, under § 1.511(c)(2) in the revised regulatory text, importers of these dietary supplements would be required to establish and follow written procedures to ensure that foods are imported only from approved suppliers (except in the limited circumstances when unapproved suppliers may be used), rather than having to maintain a list of their foreign suppliers. Third, § 1.511(c)(4) in the revised regulatory text now specifies that the purpose of supplier verification activities with respect to these dietary supplements is to provide assurances that the 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. Finally, in § 1.511(c)(5)(i) through (c)(5)(iv) in the revised regulatory text, we are proposing requirements for documentation of foreign supplier verification activities by these importers that match those discussed in section II.C.5.

4. Very Small Importers and Importers of Food From Very Small Foreign Suppliers

We are revising, in § 1.512 in the revised regulatory text, the proposed modified FSVP requirements for very small importers and importers of food from very small foreign suppliers by deleting the proposed requirement to maintain a list of foreign suppliers. Consistent with our approach to requirements for very small businesses under the potential supplier program provisions in the preventive controls proposed rule, we are not proposing to require very small importers and importers of food from very small foreign suppliers to institute procedures to verify receipt of food from approved foreign suppliers.

5. Food From Countries With Officially Recognized or Equivalent Food Safety Systems

We are revising, in § 1.513 in the revised regulatory text, the proposed modified FSVP requirements for importers of food from foreign suppliers in countries whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States by renumbering references to sections of the regulations and by deleting the requirement to maintain a list of foreign suppliers. We tentatively conclude that, given the nature of the food that may be imported in accordance with these modified provisions (e.g., that the food is from a foreign supplier in good compliance standing with the food safety authority in a country with a comparable or equivalent food safety system), it is not necessary to apply a requirement to establish a procedure to verify receipt of food from approved suppliers to importers of such food.

6. Qualified Individuals

We are revising previously proposed § 1.503, "Who must develop my FSVP and perform FSVP activities?", to revise a reference to proposed § 1.512, regarding the modified requirements for very small importers and importers of food from very small foreign suppliers. Previously proposed § 1.503 states that except with respect to the requirements in §§ 1.506(a),

1.509, 1.510, 1.511(c)(2), and 1.512(b)(3) and (b)(6), a qualified individual must develop their FSVP and perform each of the activities required under the subpart. Previously proposed § 1.512(b)(3) stated the proposed requirement to maintain a written list of foreign suppliers, a requirement that is being deleted by this supplemental document. Previously proposed § 1.512(b)(6) referred to records requirements, which have been renumbered as § 1.512(b)(5) in the revised regulatory text. Therefore, § 1.503 should be modified to refer only to § 1.512(b)(5).

III. Preliminary Regulatory Impact Analysis

As explained in the 2013 FSVP proposed rule, we performed the necessary analyses to examine the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), and the PRA (44 U.S.C. 3501-3520). We provided a preliminary regulatory impact analysis (PRIA) of the proposed rule (see Ref. 13 of the proposed rule) for public input (78 FR 45730 at 45770).

We performed additional analyses to examine the impacts of the revised proposed provisions described in this Federal Register document under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act of 1995, and the PRA. We present our additional analyses, including the total estimated costs and benefits of the FSVP proposed rule as revised, in our supplemental PRIA for this proposed rule (Ref. 3). We seek comment on our additional analyses.

IV. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the OMB under the PRA (44 U.S.C. 3501-3520). A description of these provisions is given in the Description section with an estimate of the annual reporting, recordkeeping, and

third-party disclosure 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.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

Description: FDA is revising its proposed regulations on FSVPs for food for humans and animals. The proposed regulations are 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) of the FD&C Act (21 U.S.C. 342 and 343(w)). The revisions to the proposed rule include the following: (1) Specifying a revised approach to proposed requirements for supplier verification activities (the previous proposal contained two alternative approaches); (2) stating that importers who are in

compliance with the potential supplier program provisions of the preventive controls regulations would be deemed in compliance with most of the FSVP requirements; (3) deleting the proposed requirement that importers conduct a food and foreign supplier compliance status review but adding a proposed requirement that importers consider, in addition to the hazards in the food they import, certain factors related to supplier risks; (4) proposing to require importers to follow written procedures for ensuring the use of suppliers that they have approved based on their evaluation of supplier risks, rather than require importers to maintain a list of suppliers; (5) proposing to require importers of food from farms not subject to the produce safety regulations to obtain written assurance of compliance from their suppliers rather than conduct standard verification activities; and (6) revising the definitions of very small importer and very small foreign supplier by increasing the annual food sales limit from $500,000 to $1 million.

Description of Respondents: Generally, persons who import food into the United States. We estimate that there are approximately 56,800 persons who meet the definition of importer set forth in the proposed rule. However, the proposed rule would exempt from the FSVP requirements the importation of certain foods, including certain juice and seafood products, food for research or evaluation (exempt but subject to a third-party disclosure requirement), food for personal consumption, certain alcoholic beverages, food that is transshipped, and food that is imported for further processing and future export. The proposed rule also would specify that importers who are in compliance with any supplier program provisions that the preventive controls final regulations may include would be 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 or its customer controls the hazards and to importers of food from farms

not subject to the produce safety regulations. In addition, the proposed rule would establish modified FSVP requirements for importers of dietary supplements, very small importers, importers of food from very small foreign suppliers, and importers of 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.

The information collection estimate for the FSVP proposed rule has decreased due to revisions to the proposed rule requirements. The information collection burden was previously estimated to be 3,303,988 hours; the revised estimate is 2,917,603 hours, a reduction of 386,385 hours. For more information on the original calculation of the information burden estimate, refer to the PRA for the previous proposed rule (Docket No. FDA-2011-N-0143).

Information Collection Burden Estimate

Supplemental Notice of Proposed Rulemaking Burden

FDA estimates the burden for this information collection as follows:

A. Reporting Burden

1. Exemption for Food for Research or Evaluation

Under proposed § 1.501(c), the FSVP regulations would not apply to 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."
- When filing entry for the food with U.S. Customs and Border Protection (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 1, 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. There is no change from the previous estimated burden.

2. Importer Identification at Entry

Proposed § 1.509(c) would require importers to ensure that, for each line entry of food product offered for importation into the United States, its name and Dun and Bradstreet Data Universal Numbering System (DUNS) number is provided electronically when filing entry with CBP. As shown in table 1, 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. There is no change from the previous estimated burden.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Exemption for food for research 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
DUNS number for filing with CBP 1.509(c), 1.511(c), 1.512(b)(2)	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total					299,067

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

B. Recordkeeping Burden

1. Documentation of Production of Low-Acid Canned Foods in Accordance With 21 CFR Part 113

Proposed § 1.502(b) would require importers of thermally processed low-acid canned foods (LACF) packaged in hermetically sealed containers to verify and document that, with respect to microbiological hazards that are controlled under part 113 (21 CFR 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 2, 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. There is no change from the previous estimated burden.

2. Hazard Analysis

Revised proposed § 1.504(a) would require importers, for each food they import or offer for import, to have a written hazard analysis. We estimate that 13,389 importers would need to spend an average of 10.5 hours each determining and documenting hazard analyses for imported foods, resulting in an estimated burden of 140,584.5 hours (46,862 hours annualized).

Revised proposed § 1.504(d) would permit importers to identify the hazards that are reasonably likely to occur with a food by reviewing and evaluating the hazard analysis conducted by the foreign supplier of the food. 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 2, we estimate that 13,389 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 93,723 hours (30,929 hours annualized).

3. Risk Evaluation

Revised proposed § 1.505(a)(2) would require importers to document their evaluation of food and supplier risks. As shown in table 2, we estimate that it will take 12 hours for each of an estimated 13,389 importers to conduct and document their risk evaluation and approval of suppliers, resulting in a total burden of 160,668 hours (53,556 hours annualized). In addition, revised proposed § 1.505(b) requires that the importer reevaluate risk factors associated with 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 1,221,746 hours annually.

4. Foreign Supplier Verification and Related Activities

Under revised proposed § 1.506(a), 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 risk evaluation they conduct 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 distributing, and document the use of those procedures. As shown in table 2, we estimate that it would take each of 13,389 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 53,556 hours for a grand total of 89,305 hours annually.

Under revised proposed § 1.506(b), importers must establish and follow adequate written procedures for conducting foreign supplier verification activities. As shown in table 2, we estimate that it would take each of 13,389 importers 2 hours to establish procedures for about 4

hazards/products per importer resulting in a total annual burden of 107,112 hours (35,883 hours annualized).

Revised proposed § 1.506(d) would require importers to determine and document which supplier verification activities are appropriate in order to provide adequate assurances that the 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, as applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. Under revised proposed § 1.506(d)(1)(i), an importer may conduct (and document) or obtain documentation of a periodic onsite audit of the foreign supplier. As shown in table 2, we estimate that 2,369 such audits would be conducted or documentation obtained for, with each audit requiring an average of 14 hours each, resulting in a total annual burden of 33,166 hours.

Under revised proposed § 1.506(d)(1)(ii), an importer may conduct (and document) or obtain documentation from a foreign supplier of lot-by-lot or periodic sampling and testing of a food for a hazard. As shown in table 2, we estimate that 11,396 importers each year would determine that this approach to verification is appropriate an average of 5 times per year. We further estimate that each incidence of sampling and testing and corresponding documentation will require 4 hours. This results in a total annual burden of 227,920 hours.

Under revised proposed § 1.506(d)(1)(iii), 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 2, we estimate that 11,396 importers each year would determine that this approach to verification is appropriate an average of 5 times per year. We further estimate that documentation of food safety record review would require 1.6 hours, resulting in a total annual burden of 91,168 hours.

Under revised proposed § 1.506(d)(1)(iv), an importer may use a different verification procedure that it has established as being appropriate based on the risk associated with the food and foreign supplier; the importer must document such use. We have not identified any alternative verification procedure nor included such costs in the PRIA; therefore, we do not identify any associated burden here for revised proposed § 1.506(d)(1)(iv).

Revised proposed § 1.506(d)(4) requires that if a foreign supplier of a food is a farm that is not subject to the requirements in part 112, the importer need only to: (1) Document, at the end of each calendar year, that the food from the foreign supplier is not subject to the produce safety regulations and (2) obtain written assurance, at least every 2 years, that the foreign supplier is producing the food in compliance with the FD&C Act. We estimate that these requirements would affect 22,333 importers annually and that each importer would need to conduct this documentation for 8 such suppliers each year, with documentation of each determination requiring, on average, 0.75 hours. This would result in a total annual burden of 133,998 hours.

Revised proposed § 1.506(d)(5) would allow an importer, instead of conducting an onsite audit, to rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. We do not estimate a PRA burden associated with this option because FDA has only officially recognized one country's food safety system to date and the Agency inspects only a small percentage of foreign food facilities each year.

5. Review of Complaints, Investigations, and Corrective Actions

Proposed § 1.507(b) would require 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 shown in table 2, we estimate that 10,658 importers would need to conduct 1 such investigation each year, and that conducting and documenting an investigation will require 14 hours. This would result in a total annual burden of 149,212 hours. There is no change from the previous estimated burden.

Revised proposed § 1.507(c) would require 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 the requirements of 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. 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. In the PRIA we postulated that most importers probably already take some type of corrective actions if they determine that a food they import is not in compliance with appropriate regulations and that they probably document those corrective actions. Therefore, because we assume that most importers already take these types of corrective actions, we did not estimate the cost of additional corrective actions in the PRIA nor calculate a burden associated with corrective actions in the PRA.

Revised proposed § 1.507(d) would require an importer, if it determines by means other than its verification activities conducted under § 1.506 or § 1.511(c) or its FSVP reassessment conducted under § 1.508, that one of its foreign suppliers does not produce food in compliance with the requirements of 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,

to promptly investigate to determine whether the importer's FSVP is adequate and, when appropriate, to modify the FSVP. This provision also would require importers to document any such investigations and FSVP changes. As shown in table 2, we estimate that, on average, 10,658 importers will need to conduct an investigation once a year to determine the adequacy of their FSVP in accordance with proposed § 1.507(d) and that conducting and documenting the investigation will require 5 hours. This would result in a total annual burden of 53,290 hours. There is no change from the previous estimated burden.

6. FSVP Reassessment

Revised proposed § 1.508(b) would require an importer to document each reassessment of its FSVP that it conducts under § 1.508 and any resulting changes to the FSVP. Reassessment would be required every 3 years or more frequently if an importer becomes aware of new information about potential risks associated with a food or foreign supplier. We did not estimate a cost for reassessing an importer's FSVP under this requirement in the PRIA because we have already incorporated the costs of reassessment into the costs for maintaining the various elements of the FSVP in other provisions. Therefore we do not calculate an associated PRA burden here.

7. Food Subject to Certain Dietary Supplement CGMP Regulations

Revised proposed § 1.511 sets forth modified FSVP requirements for food that is subject to certain dietary supplement CGMP regulations. Under revised proposed § 1.511(a), importers who are required to establish specifications under § 111.70(b), (d), or (f) (21 CFR 111.70(b), (d), or (f)) with respect to a food, and are in compliance with the requirements of part 111 applicable to determining whether those specifications are met, must comply with the requirements in proposed §§ 1.509 and 1.510, but are not required to comply with the requirements of proposed

§§ 1.502 through 1.508. These importers are included in the estimated reporting burden for proposed § 1.509(c).

Under revised proposed § 1.511(b), if an importer's customer is required to establish specifications under § 111.70(b), (d), or (f) with respect to a food, the customer is in compliance with the requirements of part 111 applicable to determining whether those specifications are met, and the importer annually obtains from its customer written assurance that the customer is in compliance with those requirements, then for that food the importer must comply with the requirements in §§ 1.509 and 1.510, but is not required to comply with the requirements of §§ 1.502 through 1.508. As shown in table 2, we estimate that 5,574 importers would need to obtain written assurance from an average of 6 customers in accordance with revised § 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 proposed § 1.509(c).

Under revised proposed § 1.511(c), importers of "finished" dietary supplements (i.e., packaged and labeled dietary supplements that are not subject to further processing) would be subject to different FSVP requirements. Revised proposed § 1.511(c)(2) would require 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 risk evaluation conducted under § 1.505. This burden to importers of "finished" dietary supplements is captured in the burden calculated for proposed § 1.506(a). Proposed § 1.511(c)(3) would require importers of finished dietary supplements to establish and follow procedures for conducting foreign supplier verification activities. This burden is included in the burden of revised proposed § 1.506(b).

Revised proposed § 1.511(c)(5) would require 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. As shown in table 2, we estimate that this provision would affect 1,822 importers annually and that each importer would need to make and document about 2 determinations (regarding both the appropriate verification activity and its frequency) each year, with making and documenting of each determination requiring 2.5 hours. This would result in a total annual burden of 9,110 hours. There is no change from the previous estimated burden.

For each "finished" dietary supplement imported, the importer would need to conduct one or more of the verification activities listed in proposed § 1.511(c)(5)(i) through (c)(5)(iv) before using or distributing the dietary supplement and periodically thereafter. The estimates associated with these activities are included in the burdens presented in table 2 for § 1.506(d)(1)(i) through (d)(1)(iv), respectively.

Revised proposed § 1.511(c) also would require importers of finished dietary supplements to conduct risk evaluations, conduct investigations and corrective actions, reassess the effectiveness of their FSVP, and ensure that information identifying them as the importer is provided at entry. These importers have been included in the estimated recordkeeping and reporting burdens for these activities under proposed §§ 1.505, 1.507(b), 1.508(b), and 1.509(c), respectively. We do not estimate any specific burden associated with corrective actions (§ 1.507(c)) as previously discussed.

8. Food Imported by Very Small Importers and From Very Small Foreign Suppliers

Revised proposed § 1.512 sets forth modified proposed FSVP requirements for very small importers (i.e., importers with annual food sales of not more than $1 million) and food

from very small foreign suppliers (i.e., foreign suppliers with annual food sales of not more than $1 million).

Under proposed § 1.512(b)(1), if a very small importer or an importer of food from a very small 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 definition of very small foreign supplier in § 1.500, whichever is applicable. As shown in table 2, we estimate that 56,800 importers would need to document eligibility each year (either that they are a very small importer or that they are obtaining food from a very small foreign supplier) and that such documentation would require 1 hour. While very small importers would only need to document this once per year, importers importing from very small suppliers may need to do it more than once, so we use an average of 1.79 records per importer, resulting in a total annual burden of 101,770 hours.

Under revised proposed § 1.512(b)(3), each very small importer or importer of food from a very small foreign supplier would need to obtain written assurance, before importing the food and at least every 2 years thereafter, that its foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as that required under section 418 or 419 of the FD&C Act, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. As shown in table 2, we estimate that 56,800 importers would need to obtain an average of 2 such written assurances each year and that documentation of each assurance would require 2.25 hours, resulting in a total annual burden of 255,600 hours.

Revised proposed § 1.512(b)(4) also would require very small importers and importers of food from very small foreign suppliers to document corrective actions; as previously stated, we do not estimate any specific burden associated with corrective actions.

9. Food Imported From a Country With an Officially Recognized or Equivalent Food Safety System

Revised proposed § 1.513 would establish modified FSVP requirements for importers of 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 met certain conditions or requirements, they would not be required to comply with the requirements in proposed §§ 1.503 through 1.508, but they would be required to comply with §§ 1.509 and 1.510.

Proposed § 1.513(b)(1) would require an importer, before importing a food from the foreign supplier and annually thereafter, to document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent 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.

Proposed § 1.513(b)(2) would require an importer, before importing a food from the foreign supplier, to determine and document whether the foreign supplier of the food is in good compliance standing, as defined in proposed § 1.500, with the food safety authority of the country in which the foreign supplier is located. The importer would be required to continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicated that food safety hazards associated with the

food were not being adequately controlled, the importer would be required to take prompt corrective action 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; we have not yet determined any food safety systems to be equivalent. Because we have only recently entered into a systems recognition arrangement with New Zealand, we have not been able to assess the effect of the arrangement on the importation of food from that country. Therefore, we have not included estimates for the recordkeeping burdens associated with proposed § 1.513. There is no change from the previous estimated burden.

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (hours)	Total Hours	Total Operating and Maintenance Costs
Controls for LACF 1.502(b)	2,443	4	9,772	1	9,772	
Determine and document hazards 1.504(a)	13,389	1	13,389	3.5	46,862	
Review hazard analysis 1.504(d)	13,389	7	93,723	0.33	30,929	
Risk evaluation 1.505(a) and (b), 1.511(c)(2)	13,389	1	13,389	4	53,556	
Reevaluation of risks 1.505(c)	13,389	365	4,886,985	0.25	1,221,746	
Written procedures for use of approved foreign suppliers 1.506(a), 1.511(c)(2)	13,389	1	13,389	6.67	89,305	
Written procedures for conducting verification activities 1.506(b), 1.511(c)(3)	13,389	4	53,556	0.67	35,883	

Conduct/review audits 1.506(d)(1)(i), 1.511(c)(5)(i)	2,369	1	2,369	14	33,166	$1,480,625
Conduct periodic sampling/testing 1.506(d)(1)(ii), 1.511(c)(5)(ii)	11,396	5	56,980	4	227,920	$75,954,340
Review records 1.506(d)(1)(iii), 1.511(c)(5)(iii)	11,396	5	56,890	1.6	91,168	
Written assurances from foreign suppliers 1.506(d)(4)	22,333	8	178,664	0.75	133,998	
Investigate adulteration or misbranding 1.507(b), 1.511(c)(1)	10,658	1	10,658	14	149,212	$6,661,250
Investigate and determine FSVP adequacy 1.507(d), 1.511(c)(1)	10,658	1	10,658	5	53,290	
Written assurances for food produced under dietary supplement CGMPs 1.511(b)	5,574	6	33,444	2.25	75,249	
Determine and document verification activities for importers of dietary supplements 1.511(c)(5)	1,822	2	3,644	2.50	9,110	
Document very small importer/very small foreign supplier status 1.512(b)(1)	56,800	1.79	101,770	1	101,770	
Written assurances associated with very small importer/very small foreign supplier 1.512(b)(3)	56,800	2	113,600	2.25	255,600	
Total					2,618,536	$84,096,215

[1] There are no capital costs associated with this collection of information.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. Interested persons are requested to send comments regarding information collection by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the title, "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals."

V. Analysis of Environmental Impact

We did not prepare an environmental assessment or an environmental impact statement for the 2013 FSVP proposed rule because we 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. Because we have reached the same determination with respect to these revisions to the proposed rule included in this supplemental notice of proposed rulemaking, neither an environmental assessment nor an environmental impact statement is required for this document.

VI. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

VII. 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. These references are also available electronically at http://regulations.gov. We have verified the Web site addresses in this section, but we are not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.

1. FDA, Statement from FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers, December 19, 2013 (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm379397.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery).

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

3. FDA, "Supplemental Preliminary Regulatory Impact Analysis," Docket Nos. FDA-2011-N-0143, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, and FDA-2011-N-0146, Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 2014

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

List of Subjects in 21 CFR Part 1

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1, as proposed to be added on July 29, 2013 (78 FR 45730), be amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

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

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

Subpart L--[Amended]

2. In § 1.500, remove the definition for "Hazard reasonably likely to occur," add in alphabetical order definitions for "Environmental pathogen," "Facility," "Known or reasonably foreseeable hazard," "Pathogen," "Qualified auditor," and "Significant hazard," and revise the definitions for "Hazard," "Very small foreign supplier," and "Very small importer" to read as follows:

§ 1.500 What definitions apply to this subpart?

* * * * *

Environmental pathogen means a pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be

contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

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

* * * * *

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

* * * * *

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

* * * * *

Pathogen means a microorganism of public health significance.

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

* * * * *

Significant hazard means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections

and corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

* * * * *

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

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

* * * * *

3. In § 1.502, add paragraphs (c) and (d) to read as follows:

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

* * * * *

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

(d) Importers whose customer is subject to section 418 of the Federal Food, Drug, and Cosmetic Act. If your customer is required to establish and implement a risk-based supplier program under § 117.136 or § 507.43 of this chapter for a food you import, and you annually

obtain from your customer written assurance that it is in compliance with that section, then you are deemed to be in compliance with the requirements of this subpart, except for the requirements in §§ 1.509 and 1.510.

4. Revise § 1.503 to read as follows:

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

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

5. Revise § 1.504 to read as follows:

§ 1.504 What hazard analysis must I conduct?

(a) Requirement for a hazard analysis. You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each food you import to determine whether there are any significant hazards. Your hazard analysis must be written.

(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, and food allergens; and

(iii) Physical hazards.

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

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced;

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

(c) Hazard evaluation. (1) Your hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to 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 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 foreign supplier's establishment and equipment;

(iii) Raw materials and 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.

(d) Review of the foreign supplier's hazard analysis. If your foreign supplier has analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any significant hazards, you may meet your requirement to determine whether there are any significant hazards in a food by reviewing and assessing the analysis conducted by the foreign supplier.

(e) Microbiological hazards in raw agricultural commodities that are fruits or vegetables. If you are importing a raw agricultural commodity that is a fruit or vegetable, you are not required to determine whether there are any significant microbiological hazards in such food.

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

(g) Significant hazards controlled by you and/or your customer. If the preventive controls that you and/or your customer implement in accordance with subpart C of part 117 of this chapter are adequate to significantly minimize or prevent all significant hazards in a food you import, you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. If your customer controls one or more such hazards, you must annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

6. Revise § 1.505 to read as follows:

§ 1.505 What risk evaluation must I conduct?

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

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

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

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

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

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

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

(2) You must document your evaluation of risks.

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

to import the food from the foreign supplier, you must document the reevaluation and your determination.

7. Revise § 1.506 to read as follows:

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

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

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

(c) Purpose of supplier verification. Your foreign supplier verification activities must provide adequate assurances that the foreign supplier produces the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g, 350h, 342, and 343(w)).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8. Amend § 1.508 by revising paragraphs (a)(2) and (b) to read as follows:

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

(a) * * *

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

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

9. Amend § 1.510 by revising paragraph (d)(2) to read as follows:

§ 1.510 How must I maintain records of my FSVP?

* * * * *

(d) Record retention. * * *

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

maintain records of any changes to your FSVP in accordance with § 1.507(d) or § 1.508(b) until at least 2 years after their use is discontinued.

10. Amend § 1.511 by:

a. Revising the first sentence of paragraph (a);

b. Revising paragraph (b);

c. Revising paragraphs (c)(1), (2), and (4);

d. Revising the second sentence of paragraph (c)(5) introductory text;

e. Revising paragraphs (c)(5)(i) through (iv), (6), (7), and (8); and

f. Removing paragraph (c)(9).

The revisions read as follows:

§ 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 practice regulations. If you are required to establish specifications under § 111.70(b), (d), or (f) of this chapter with respect to a food you import and you are in compliance with the requirements of part 111 of this chapter applicable to determining whether the specifications you established are met for such food, then for that food you must comply with the requirements in §§ 1.509 and 1.510, but you are not required to comply with the requirements in §§ 1.502 through 1.508. * * *

(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), (d), or (f) of this chapter with respect to a food you import, your customer is in compliance with the requirements of part 111 of this chapter applicable 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 §§ 1.509 and 1.510, but you are not required to comply with the requirements in §§ 1.502 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)(2) through (a)(6) and (b), and 1.507 through 1.510, but you are not required to comply with the requirements in §§ 1.504 and 1.505(a)(1). This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

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

* * * * *

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

(5) Supplier verification activities. * * * You must determine and document which verification activity or activities are appropriate to provide adequate assurances in accordance with paragraph (c)(4) of this section. * * *

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

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

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

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

(ii) Periodic or lot-by-lot sampling and testing of the food. (A) Sampling and testing of the dietary supplement may be conducted by you or the foreign supplier.

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

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

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

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

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

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

11. Amend § 1.512 by:

a. Revising paragraph (b)(2);

b. Removing paragraph (b)(3);

c. Redesignating paragraphs (b)(4) and (5) as paragraphs (b)(3) and (4), respectively;

d. Revising newly redesignated paragraph (b)(4); and

d. Removing paragraph (b)(6).

The revisions read as follows:

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

* * * * *

(b) Applicable requirements. * * *

(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.

* * * * *

(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 in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the

cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

12. Amend § 1.513 by revising paragraph (a) to read as follows:

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

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

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Dated: September 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014-22448 Filed 09/19/2014 at 8:45 am; Publication Date: 09/29/2014]