

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry¹

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Chapter 15: Supply-Chain Program for Human Food Products

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¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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15.1 Purpose of this Chapter

The purpose of this chapter is to help a receiving facility comply with the requirements of subpart G for establishing and implementing a supply-chain program for its suppliers. (See section 15.3.2 and the list of terms in section 15.5.1 for the definition of “receiving facility.”) This chapter also is intended to help an entity other than the receiving facility conduct certain activities on behalf of a receiving facility, provided that the receiving facility complies with applicable requirements in subpart G to review and assess the entity’s applicable documentation, and document that review and assessment.

15.2 Considerations to Keep in Mind if You Establish and Implement a Supply-Chain Program

If you are an importer, see section 15.6.2.1 for a discussion of how we have aligned the provisions for supplier verification in our regulation entitled “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” (21 CFR part 1, subpart L; the FSVP regulation) with the provisions for a supply-chain program in subpart G such that importers and receiving facilities do not have to duplicate verification activities. Importantly, this chapter of this guidance does not address the responsibilities of receiving facilities that import raw materials or other ingredients to comply with applicable requirements of the FSVP regulation. If you are a receiving facility that is also a food importer, and you choose to comply with the FSVP regulation rather than conduct supplier verification activities in accordance with subpart G (see 21 CFR 117.405(a)(2)), you should refer to our guidance on the FSVP regulation.

15.3 Overview of the Requirements for a Supply-Chain Program

15.3.1 Applicable Requirements of Part 117

Subpart C requires a facility to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (21 CFR 117.130) and identifies several types of possible preventive controls, including process controls (21 CFR 117.135(c)(1)), food allergen controls (21 CFR 117.135(c)(2)), sanitation controls (21 CFR 117.135(c)(3)), and supply-chain controls (21 CFR 117.135(c)(4)). The requirements for supply-chain controls are established in subpart G (Supply-Chain Program). We list the requirements of subpart G in Table 15-1. In the

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remainder of this chapter, we provide recommendations for how you can comply with each of these requirements.

Table 15-1 Requirements for a Supply-Chain Program in Subpart G

Section	Description
117.405	Requirement to establish and implement a supply-chain program
117.410	General requirements applicable to a supply-chain program
117.415	Responsibilities of the receiving facility
117.420	Using approved suppliers
117.425	Determining appropriate supplier verification activities (including determining the frequency of conducting the activity)
117.430	Conducting supplier verification activities for raw materials and other ingredients
117.435	Onsite audit
117.475	Records documenting the supply-chain program

15.3.2 “Receiving Facilities” and “Suppliers”

Subpart G applies to a “receiving facility.” Part 117 defines a “receiving facility” as a facility that is subject to subparts C and G of part 117 and that manufactures/processes a raw material or other ingredient that it receives from a supplier. (See 21 CFR 117.3.) Part 117 defines a “supplier” as the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature. (See 21 CFR 117.3.)

Under subpart G, entities such as brokers, produce aggregators, food distributors, and cold storage facilities are neither receiving facilities that are required to establish a supply-chain program nor suppliers, because such entities are not manufacturers/processors. However, part 117 provides that such entities can conduct certain activities specified in subpart G on behalf of a receiving facility. (See 21 CFR 117.415.)

Examples of receiving facilities are:

- A facility that manufactures/processes produce raw agricultural commodities (RACs) into bagged salads;
- A facility that mills grains such as wheat to make flour; and
- A facility that manufactures cookies using flour, sugar and other ingredients.

Examples of suppliers are:

- A farm that grows RACs such as lettuce that are supplied to a bagged salad manufacturer;
- A farm that grows wheat that is supplied to a miller; and
- A facility that mills grains and manufactures flour that is supplied to a cookie manufacturer.

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See also section 15.6.4 for a discussion of the special circumstance of when a preventive control is applied by an entity other than the receiving facility's supplier (e.g., when a harvesting or packing operation applies controls to certain produce (i.e., produce covered by part 112), because growing, harvesting, and packing activities are under different management).

15.3.3 Produce Safety Regulation

In part 112 (21 CFR part 112), we have established our regulation entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (the produce safety regulation; 80 FR 74354, November 27, 2015). The produce safety regulation sets forth in a new part 112 procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. The produce safety regulation applies to certain produce farms, and does not apply to activities of facilities that are subject to part 117.

Some provisions of subpart G (i.e., 21 CFR 117.405(c), 117.410(d)(2)(ii), 117.430(d), and 117.475(c)(13)) refer to the provisions of the produce safety regulation.

15.3.4 Foreign Supplier Verification Program Regulation

In part 1, subpart L (21 CFR part 1, subpart L), we have established our regulation entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (the FSVP regulation; 80 FR 74226, November 27, 2015). The FSVP regulation requires importers to establish foreign supplier verification programs to verify that their foreign suppliers are using processes and procedures that provide the same level of public health protection as those required under the provisions on hazard analysis and risk-based preventive controls and standards for produce safety in the FD&C Act, that the imported food is not adulterated, and that food is not misbranded with respect to food allergen labeling.

Some provisions of subpart G (i.e., 21 CFR 117.405(a)(2) and 117.475(c)(2)) refer to the provisions of the FSVP regulation.

15.3.5 Accredited Third-Party Certification Regulation

In part 1, subpart M (21 CFR part 1, subpart M), we have established our regulation entitled "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (the accredited third-party certification regulation; 80 FR 74570, November 27, 2015). The accredited third-party certification regulation provides for accreditation of third-party certification bodies to conduct food safety audits and to certify that eligible foreign entities (including registered foreign food facilities) and food produced by such entities meet applicable FDA requirements for purposes of sections 801(q)² and 806³ of the FD&C Act.

² Section 801(q) of the FD&C Act gives FDA the authority to make a risk-based determination to require, as a condition of admissibility, that a food imported or offered for import into the United States be accompanied by a certification or other assurance that the food meets the applicable requirements of the FD&C Act.

³ Section 302 of FSMA (Voluntary qualified importer program) amended the FD&C Act to create a new section 806 with the same name. Section 806 of the FD&C Act describes a voluntary, fee-based program for the expedited review and importation of foods from importers who achieve and maintain a high level of

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Some provisions of part 117 (i.e., the definition of “qualified auditor” in 21 CFR 117.3 and the requirements for onsite audits in 21 CFR 117.435(d)) refer to the provisions of the accredited third-party certification regulation.

15.3.6 How We Use the Term “You” in This Chapter

In this guidance, we use the term “you” to refer to a “receiving facility,” rather than to all facilities subject to the PCHF requirements, because the requirements of subpart G apply only to receiving facilities.

15.4 Understand the Potential Hazard

Part 117 defines “supply-chain-applied control” as a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt. (See 21 CFR 117.3 and the list of terms in section 15.5.1.) For background and details about hazards, including hazards that could require a supply-chain-applied control, see Chapter 3 – Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food.

15.5 Terms Used in This Chapter

15.5.1 Definitions Established in 21 CFR 117.3

Section III.A in the Introduction of this guidance includes a glossary of terms that are used in this guidance and that are defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 15-2 for additional terms that are defined in 21 CFR 117.3. We intend to include these terms in the glossary in section III.A in the Introduction of this guidance when we update the Introduction. When we do so, we intend to delete Table 15-2 from this chapter, because it would be duplicative.

Table 15-2 Applicable Terms Defined in Part 117 (See 21 CFR 117.3.)

Term	What the Term Means
Audit	The systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier’s food safety processes and procedures.
Manufacturing/ processing	Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

control over the safety and security of their supply chains. This control includes importation of food from facilities that have been certified under FDA’s third-party certification rule.

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Term	What the Term Means
Qualified auditor	A person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 117.180(c)(2). Examples of potential qualified auditors include: (1) A government employee, including a foreign government employee; and (2) An audit agent of a certification body that is accredited in accordance with regulations in 21 CFR part 1, subpart M (Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications).
Qualified facility	A facility (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) that is a very small business, or a facility to which both of the following apply: (1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.
Raw agricultural commodity (RAC)	Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.
Receiving facility	A facility that is subject to subparts C and G of part 117 and that manufactures/processes a raw material or other ingredient that it receives from a supplier.
Supplier	The establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a <i>de minimis</i> nature.
Supply-chain-applied control	A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.
Very small business	A business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).
Written procedures for receiving raw materials and other ingredients	Written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

15.5.2 Other Terms That FDA Uses in This Chapter

Section III.B in the Introduction of this guidance includes a glossary of terms that are used in this guidance but are not defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 15-3 for additional terms that we use in this chapter. We intend to include these terms in the glossary in section III.B in the Introduction of this guidance when we update the Introduction. When we do so, we intend to delete Table 15-3 from this chapter, because it would be duplicative.

Table 15-3 Terms Used in this Chapter

Term	What the Term Means
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Term	What the Term Means
Approved supplier	A supplier that has met the criteria of the receiving facility's supply chain program, is controlling the identified hazard, and has been approved by the receiving facility.
Certificate of analysis (CoA)	A document, provided by the supplier of a food prior to or upon receipt of the food, that documents certain characteristics and attributes of the food.
Customer	An entity that receives a product, raw material, or ingredient from a receiving facility.
Identified hazard	A hazard identified by the receiving facility as requiring a supply-chain-applied control.
Second-party audit	An audit conducted by an employee of a receiving facility.
SAHCODH hazard	A hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.
Third-party audit	An audit conducted by a qualified auditor that is not an employee of either the receiving facility or the supplier.

15.6 Requirement to Establish and Implement a Supply-Chain Program (21 CFR 117.405)

15.6.1 Requirement to Establish and Implement a Supply-chain Program

With some exceptions (see 21 CFR 117.405(a)(2) and (a)(3)), subpart G requires a receiving facility to establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. (See 21 CFR 117.405(a)(1).)

The supply-chain program must be written. (See 21 CFR 117.405(b).) There is no standardized or required format for the written supply-chain program or its records. You can use whatever format works best for your facility, provided that the records include all the required information.

You are not required to establish and implement a supply-chain program for a particular raw material or other ingredient if you will control the hazard at your own facility, regardless of whether your supplier has also applied one or more preventive controls for that hazard to raw materials and other ingredients that your supplier provides to you. (See 21 CFR 117.405(a)(1).) In addition, you are not required to implement a preventive control if you comply with certain requirements for ensuring a hazard will be controlled by your customer or subsequent entity in the distribution chain. (See 21 CFR 117.136.)

Subpart G does not require you to establish and implement a supply-chain program to control potential hazards associated with food contact substances. A long-standing CGMP provision requires that appropriate quality control operations be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. (See 21 CFR 117.80(a)(2).) Similar provisions address other circumstances where food contact substances may migrate to the raw materials and other ingredients obtained by a receiving facility from suppliers (e.g., 21 CFR 117.40 regarding food-contact surfaces). FDA has extensive premarket review processes for food contact substances under the food contact notification process (21 CFR part 170, subpart D) and the food additive petition process (21 CFR part 171). In light of FDA's premarket oversight of food contact substances and our experience with regulatory

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oversight of food-packaging material as a matter of CGMP, we consider following CGMPs by a receiving facility to be sufficient to address the safety of food contact substances in raw materials and other ingredients it obtains. Therefore, there are no hazards associated with food contact substances that are hazards requiring a supply-chain applied control under 21 CFR 117.405(a)(1).

15.6.2 How Your Corporate Parent Can Participate in Establishing and Implementing Your Supply-chain Program

As discussed in the final rule establishing part 117, your corporate parent (as the owner, operator, or agent in charge) can be active in developing and implementing your food safety plan (see Response 371, Response 668, and Response 690 at 80 FR 56022, 56100, and 56111, respectively). For example, an individual at the corporate level may be the preventive controls qualified individual (PCQI). Further, the responsibilities of the receiving facility (such as approving suppliers) could be handled at the corporate level. For example, your corporate parent could have a team that establishes written procedures for supplier approval, determines supplier verification activities, conducts supplier verification activities, and maintains required documentation. In addition, your corporate parent could establish and implement a supply-chain program that takes into consideration its knowledge of the food safety programs in place at all of the facilities under its ownership. See also the example in section 15.11.2.2 in which a facility that is part of a larger corporation determines an alternative to an onsite audit when the supplier is a subsidiary of the same corporation. The records documenting the supply-chain program are subject to the requirements, in subpart F, applying to records that must be established and maintained. Under 21 CFR 117.315, offsite storage of records (such as storage at the place of business of your corporate parent of records documenting the supply-chain program) is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. If your corporate parent establishes and maintains the records for the supply-chain program electronically and you can access applicable records maintained at the corporate level electronically, we consider the records to be onsite.

15.6.3 Exceptions to the Requirement to Establish and Implement a Supply-chain Program

Subpart G provides for two exceptions to the requirement to establish and implement a supply-chain program.

15.6.3.1 Exception for importers

We have aligned the provisions for supplier verification in the FSVP regulation with the provisions for a supply-chain program in part 117. A receiving facility that is an importer, is in compliance with the FSVP regulation, and has documentation of verification activities conducted under 21 CFR 1.506(e) (which provides assurance that the hazards to be controlled before importation for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient. (See 21 CFR 117.405(a)(2).) We are providing separate guidance to help importers

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who are subject to the FSVP regulation to comply with the requirements of the FSVP regulation.⁴

15.6.3.2 Exception for food supplied for research or evaluation use

The requirements for a supply-chain program do not apply to food that is supplied for research or evaluation use, provided that such food:

- Is not intended for retail sale and is not sold or distributed to the public (21 CFR 117.405(a)(3)(i));
- Is labeled with the statement “Food for research or evaluation use” (21 CFR 117.405(a)(3)(ii));
- Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of (21 CFR 117.405(a)(3)(iii)); and
- Is accompanied with documents, in accordance with the practice of the trade, stating that the food will be used for research or evaluation purposes and cannot be sold or distributed to the public (21 CFR 117.405(a)(3)(iv)).

You should take steps to ensure that the label statement “Food for research or evaluation use” remains securely attached to the food until the food is used for research or evaluation.

The quantity of the food should be limited to the amount anticipated to be needed to perform the research, analysis, or quality assurance procedures, and any unused portion should be properly disposed of. The amount of food used in research or for evaluation can vary based on the type of food, the nature of the research or evaluation, and other factors such as the number of repetitions required for the research or evaluation process. For example, 10 pounds of a food could be a small quantity consistent with the amount needed to perform a laboratory analysis for pesticides, and 50 pounds of the food could be a small quantity consistent with the amount needed for a mycotoxin analysis. On the other hand, only a few ounces of a color additive might be needed for research.

The exemption for food for research or evaluation does not apply to food for consumption at trade shows, because such food would be “distributed to the public” (i.e., attendees of the trade show). (See 21 CFR 117.405(a)(3)(i).) This is the case regardless of whether it is a “Research and Development” (R&D) facility that directly provides the food for consumption to a trade show, or it is the R&D facility’s customer that provides the food for consumption to a trade show. However, the exemption for research or evaluation would apply to food used in a defined study, conducted during a trade show, of a food involving a discrete set of test subjects who have agreed to participate in the study, because it does not appear that such food would be sold or distributed to the general public. When the exemption does not apply, you must comply with the requirements of subpart G when your supplier applies a supply-chain-applied control even if you consider yourself an “R&D facility.”

⁴ Even if you implement a supply-chain program in accordance with subpart G for a raw material or other ingredient you import, you will need to ensure that you are identified as the FSVP importer of the raw material or other ingredient in accordance with 21 CFR 1.509.

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15.6.4 Requirement When a Supply-Chain-Applied Control Is Applied by an Entity Other than the Receiving Facility's Supplier

When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when such an entity applies controls to certain produce (i.e., produce covered by part 112)), because growing, harvesting, and packing activities are under different management), the receiving facility must: (1) Verify the supply-chain-applied control; or (2) obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment. (See 21 CFR 117.405(c).)

The most likely circumstance where this requirement applies is included as an example in the requirement – i.e., when the supplier is a farm and growing, harvesting, and packing activities are under different management. The definition of supplier specifies that the supplier is the establishment that grows the food. However, harvesting and packing operations that are conducted by a business entity separate from the grower do not fall within the definition of “supplier,” even though harvesting and packing operations include some supply-chain-applied controls, such as maintaining wash water temperature adequate to minimize infiltration of microorganisms and establishing and following water-change schedules for recirculated water. A receiving facility has an obligation to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act (21 U.S.C. 342) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). That obligation includes responsibilities for raw materials and other ingredients when a supply-chain-applied control is applied by an entity (such as a harvesting or packing operation) other than the receiving facility's supplier (the grower).

We do not expect the receiving facility to follow all of the requirements of subpart G applicable to “suppliers” when verifying control by another entity in the supply chain (e.g., a harvesting or packing operation). Instead, we expect the receiving facility will take steps such as a review of that entity's applicable food safety records. For example, if a receiving facility receives produce from a supply chain that includes a separate grower, harvester, and packer, the grower is the supplier and the requirements of subpart G applicable to “suppliers” apply to the grower. To verify controls applied by the harvester, the receiving facility could review the harvester's records, such as records of training for workers who hand harvest RTE produce. To verify controls applied by the packer, the receiving facility could review the packer's records, such as water-change schedules for recirculated water used in packing operations.

See also the discussion in sections 15.8.1 and 15.8.2 of provisions of part 117 that allow entities such as distributors, brokers, and aggregators to determine, conduct, and document verification activities that apply to suppliers as a service to you, provided that you review and assess applicable documentation provided by the other entity and document your review and assessment. (See 21 CFR 117.415(a)(3).) If a harvester determines, conducts, and documents verification activities that apply to the grower (your supplier), you could review and assess the harvester's documentation. Likewise, you could obtain documentation of review of applicable records maintained by the harvester or packer from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

15.6.5 Role of the Preventive Controls Qualified Individual in the Supply-Chain Program

The preventive controls are part of your food safety plan, and your food safety plan must be prepared, or its preparation overseen by, your PCQI. (See 21 CFR 117.126(a)(2), 21 CFR 117.126(b)(2), and 117.180(a)(1).) (See 21 CFR 117.3 and the Glossary in section III of the Introduction of this guidance for the definition of “PCQI.”)

15.7 General Requirements Applicable to a Supply-Chain Program (21 CFR 117.410)

15.7.1 What the Supply-Chain Program Must Include

Subpart G includes a list of the general requirements for what the supply-chain program must include, and provides a cross-reference to where you can find the specific requirements. As specified in 21 CFR 117.410(a), the general requirements are:

- Using approved suppliers as required by § 117.420 (21 CFR 117.410(a)(1));
- Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 117.425 (21 CFR 117.410(a)(2));
- Conducting supplier verification activities as required by §§ 117.430 and 117.435 (21 CFR 117.410(a)(3));
- Documenting supplier verification activities as required by § 117.475 (21 CFR 117.410(a)(4)); and
- When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility’s supplier and documenting that verification as required by § 117.475, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 117.475 (21 CFR 117.410(a)(5)).

See the discussion of the specific requirements of 21 CFR 117.405(c), 117.420, 117.425, 117.430, 117.435, and 117.475 in sections 15.6.4, 15.9, 15.10, 15.11, 15.12, and 15.13, respectively.

15.7.2 Appropriate Supplier Verification Activities

Section 21 CFR 117.410(b) of subpart G specifies four appropriate supplier verification activities for raw materials and other ingredients. We discuss these in sections 15.7.2.1 through 15.7.2.4.

15.7.2.1 Onsite audits (21 CFR 117.410(b)(1))

See 21 CFR 117.430(b), 21 CFR 117.435, 21 CFR 117.475(c)(7), and sections 15.11.2, 15.12, and 15.13 for details about the requirements for onsite audits and our recommendations for how to comply with those requirements.

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**15.7.2.2 Sampling and testing of the raw material or other ingredient
(21 CFR 117.410(b)(2))**

Subpart G provides that sampling and testing of a raw material or other ingredient is an appropriate supplier verification activity. (See 21 CFR 117.410(b)(2).) Such sampling and testing can be on a periodic basis or on a lot-by-lot basis. We recommend that you establish the frequency of such testing by first conducting the sampling and testing on a relatively frequent basis (e.g., monthly) until the supplier establishes a good history of supplying an acceptable raw material or other ingredient, after which time you could sample and test less frequently, such as quarterly.

If you choose to use sampling and testing as a supplier verification activity, you should use scientifically-based sampling plans that provide reasonable assurance that the hazard has been significantly minimized or prevented and that address known limitations of sampling and testing foods as a verification activity. For example, your sampling plan should take into consideration whether a hazard is homogeneously distributed throughout the lot, and your selection of an analytical method should consider whether food components could interfere with the method of analysis, as well as whether the method is sensitive enough to detect a hazard that is present at low concentrations. To address such limitations, we recommend that you obtain samples that are representative of the lot, use a testing method that has been shown to provide reliable results when the analyte of interest is within the food matrix you will be testing, and use a method that has a sensitivity appropriate to detect that hazard.

See 21 CFR 117.475(c)(8) and section 15.13 for a list of required documentation when you conduct sampling and testing as a supplier verification activity. See section 15.8.2.2 for a discussion of the flexibility the rule provides for your supplier to conduct and document sampling and testing of raw materials and other ingredients, for the hazard it controls, and provide such documentation (such as in a Certificate of Analysis (COA)) to you in lieu of you conducting such sampling and testing yourself.

**15.7.2.3 Review of the supplier's relevant food safety records (21 CFR
117.410(b)(3))**

In general, by "relevant food safety records" we mean any records that will provide sufficient documentation that your supplier is following the procedures your supplier established to control a hazard and that the hazard has been controlled. Many such records relate to a particular lot of a raw material or other ingredient provided to you, such as the record created when a preventive control measure was applied. For example, if you produce frozen mixed vegetables and rely on your supplier (the farm that grows the vegetables) to control pesticide residues in the raw vegetables that you will use to produce the frozen mixed vegetables, and you determine through supplier verification activities (e.g., periodic testing for pesticides) that your supplier provided a vegetable with a pesticide level in excess of the approved tolerance for that pesticide, you could obtain a copy of the pesticide application records from the farm that grows the vegetables for a period of time adequate to demonstrate that problems that could lead to excess pesticide levels have been resolved.

Relevant food safety records also include, when applicable, records demonstrating that your supplier has verified control of a hazard by its own supplier. Such records could relate more broadly to a supplier's food safety procedures, such as records of your supplier's audit of its supplier's food safety activities. For example, if you produce deli salads and obtain chopped

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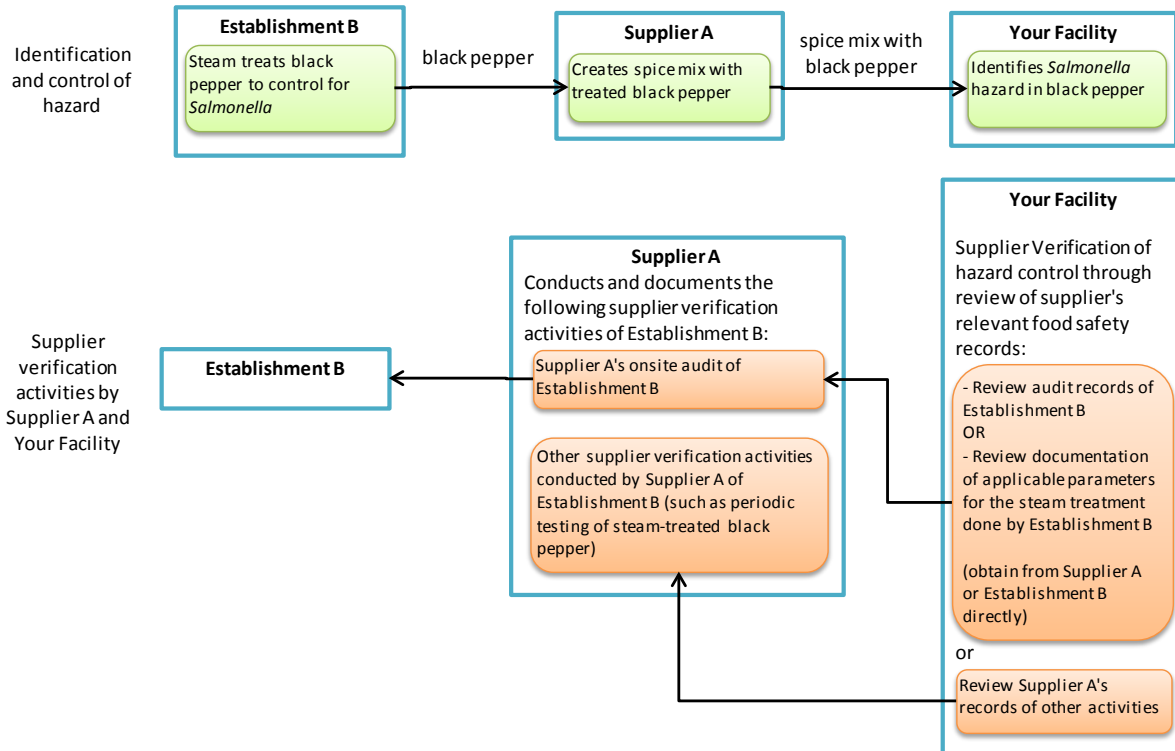
fresh vegetables from your supplier, you could obtain a copy of your supplier's records documenting his audits of the farms growing the vegetables.

Figure 1 shows an example of using relevant food safety records when the hazard requiring a supply-chain-applied control is *Salmonella* that could contaminate black pepper and your supplier (Supplier A) provides you with a spice mix containing black pepper that has been steam-treated by Establishment B (earlier in the supply chain) to control *Salmonella*. One relevant food safety record could be the applicable audit records resulting from an onsite audit of Establishment B, which you could obtain from Supplier A.⁵ The applicable audit records could include copies of audit procedures, dates, conclusions of the audits, and any corrective actions taken in response to significant deficiencies identified during the audit of Establishment B. If Supplier A conducts additional verification activities such as periodic testing of the steam-treated black pepper, you could also ask Supplier A to provide records of those activities to you for your review. If you want to see documentation of the applicable parameters for the steam treatment that Establishment B delivered to a lot of black pepper, you could obtain these records either directly from Establishment B or from Supplier A.

⁵ Alternatively, Supplier A may request that Establishment B obtain a third-party audit. Thus, Establishment B may also be able to provide applicable audit records for you to review.

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Figure 1. Applicable Records When Supplier A Provides You With a Spice Mix Containing Black Pepper That Has Been Steam-treated by Establishment B



See 21 CFR 117.475(c)(9) and section 15.13 for a list of required documentation when you conduct a review of the supplier's relevant food safety records as a supplier verification activity.

15.7.2.4 Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient (21 CFR 117.410(b)(4))

Subpart G provides that you could conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on your supplier's performance and the risk posed by the raw material or other ingredient. This means that you could specify and design risk-based activities (other than an onsite audit, sampling and testing, and review of relevant food safety records) that can provide effective supplier verification.

As one example, you could develop and use a fact-specific questionnaire or consider information applicable to a supplier's certification to a specific audit scheme, and you could use such activities alone or in combination with other supplier verification activities. As another example, if you determine and document that you would audit a supplier on a biennial rather

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than annual basis as provided by 21 CFR 117.430(b)(2), you could review the records demonstrating the results of the supplier's environmental monitoring program during the year that you do not conduct an audit.

See 21 CFR 117.475(c)(10) and section 15.13 for recommended documentation when you conduct a supplier verification activity other than an onsite audit, sampling and testing, or review of the supplier's relevant food safety records.

15.7.3 Assurance that a Hazard Has Been Significantly Minimized or Prevented

The supply-chain program in subpart G is a type of preventive control and, thus, must comply with the requirements applicable to preventive controls in 21 CFR 117.135. Under 21 CFR 117.135(a), a preventive control provides assurance that any hazards requiring a preventive control will be significantly minimized or prevented. To make this clear, 21 CFR 117.410(c) specifies that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. Suppliers that are subject to the PCHF requirements in part 117 are required to develop and implement a food safety plan that will significantly minimize or prevent hazards associated with the food manufactured, processed, packed or held by the facility (21 CFR 117.126) and to document they are following their plan (21 CFR 117.190). Suppliers subject to the produce safety requirements in part 112 must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. (See 21 CFR 112.11.)

15.7.4 Considerations in Approving Suppliers and Determining the Appropriate Supplier Verification Activities and the Frequency with Which They Are Conducted

As noted in section 15.7.1, subpart G specifies that you must approve suppliers and determine appropriate supplier verification activities (including determining the frequency of conducting the activity). (See 21 CFR 117.410(a)(1) and (a)(2).) Section 21 CFR 117.410(d)(1) specifies factors that you must consider in approving suppliers and determining appropriate supplier verification activities (including determining the frequency of conducting the activity). We discuss these factors in sections 15.7.4.1 through 15.7.4.4. With one exception, the requirement to consider each of these factors applies every time you approve a supplier for a raw material or other ingredient, and every time that you determine the appropriate supplier verification activity for a food received from that supplier. See a discussion of the exception, in 21 CFR 117.410(d)(2), in section 15.7.4.5.

As noted in sections 15.8.1 and 15.8.2, only you can approve suppliers, but subpart G provides some flexibility for another entity in the distribution chain to conduct certain other activities related to supplier verification, and to provide you with applicable documentation of those activities, to help you do so.

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15.7.4.1 Hazard analysis

The first factor that you must consider in (1) approving suppliers, (2) determining appropriate supplier verification activities, and (3) determining the frequency of conducting those activities is the hazard analysis of the food, conducted in accordance with 21 CFR 117.130. (See 21 CFR 117.410(d)(1)(i).) To do so, you must consider the nature of the hazard controlled before receipt of the raw material or other ingredient. (See 21 CFR 117.410(d)(1)(i).) Immediately below, we explain the requirements of part 117 for a hazard analysis and provide recommendations for how to consider the hazard analysis in approving suppliers, determining appropriate supplier verification activities, and determining the frequency of those activities.

Part 117 requires that you conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. (See 21 CFR 117.130(a).) If you determine that there are any hazards that require a preventive control, with few exceptions Part 117 further requires that you must identify and implement a preventive control. (See 21 CFR 117.135(a).) When the preventive control will be applied to a raw material or other ingredient before receipt, part 117 requires that you establish and implement a risk-based supply-chain program for that raw material or other ingredient. (See 21 CFR 117.405.)

As part of your hazard analysis, you would evaluate the hazard to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. (See 21 CFR 117.130(c)(1)(i).) The outcome of this aspect of the hazard evaluation impacts the type of verification activity you use (as well as the frequency of conducting the activity). For example, when the hazard is one for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death, in general you must conduct an annual onsite audit before using the raw material or other ingredient from the supplier and at least annually thereafter. (See 21 CFR 117.430(b) and the discussion in section 15.11.2.) For other hazards, the determination of supplier verification activities, and the frequency of conducting those activities, also should be risk-based – i.e., the greater the risk presented by the hazard, the more robust the verification activity, and the greater the frequency of the verification.

As part of your hazard analysis, you also would evaluate environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. (See 21 CFR 117.130(c)(1)(ii).) If, for example, you are purchasing a cheese to be used in an RTE product you make, and you expect that a sanitation control will be applied to address the environmental pathogen *Listeria monocytogenes*, you could ask to review the cheese producer's written procedures for the environmental monitoring it does to verify the sanitation controls. (See 21 CFR 117.165(b)(3).) You also could periodically verify your supplier's controls by sampling and testing the cheese for *L. monocytogenes*. Because *L. monocytogenes* is a hazard for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death, you also would conduct an annual onsite audit to verify that your supplier controls *L. monocytogenes* when it manufactures the cheese by using a "kill step" such as pasteurization of the milk used to make the cheese and sanitation controls to significantly minimize contamination from *L. monocytogenes* in the environment, with environmental monitoring to verify controls for *L. monocytogenes*.

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For all hazards that require a supply-chain-applied control, we recommend that you use the outcome of your hazard analysis to help you determine the extent of what you do to consider supplier performance as required by 21 CFR 117.117.410(d)(1)(iii) (see the discussion in section 15.7.4.3). The greater the risk presented by the hazard, the more stringently you should assess supplier performance as a mechanism to reduce the risk presented by the hazard.

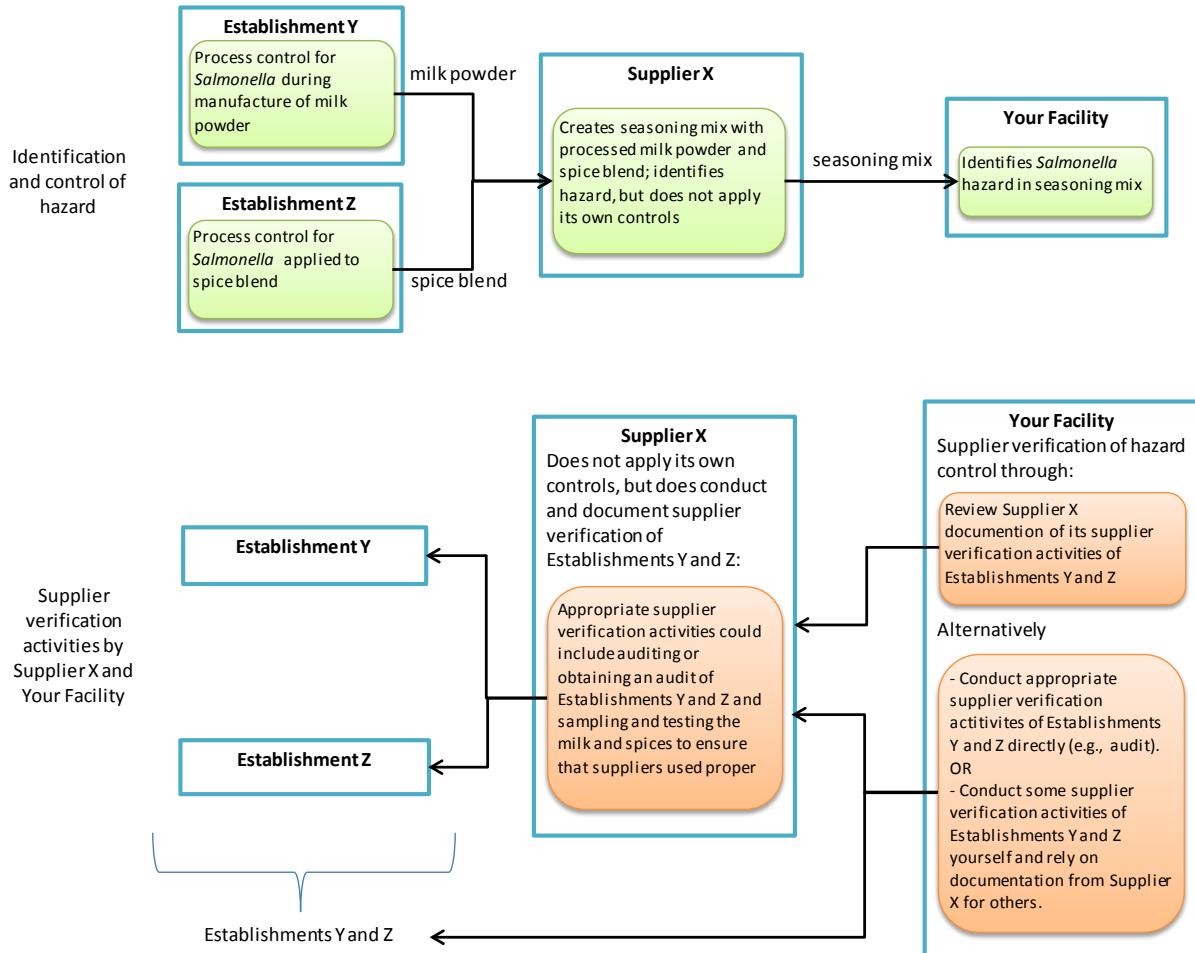
15.7.4.2 Entity controlling the hazard

The second factor that you must consider in (1) approving suppliers, (2) determining appropriate supplier verification activities, and (3) determining the frequency of conducting those activities is the entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control. (See 21 CFR 117.410(d)(1)(ii).) For example, the entity that applies the appropriate preventive control could be your direct supplier or your supplier's supplier. If the control is not applied by your direct supplier, you would direct your supplier verification activities to your supplier's supplier, but there is some flexibility in how you could do this.

Figure 2 shows an example in which you obtain a seasoning mix from Supplier X. Supplier X made the seasoning mix by blending milk powder (produced by Establishment Y) and a spice blend (produced by Establishment Z). You identify *Salmonella* as a hazard in the seasoning mix, and you learn from Supplier X (your direct supplier) that it does not apply a control for *Salmonella* in its blending operation. Instead, Establishment Y applies a process control for *Salmonella* in the milk powder and Establishment Z applies a process control for *Salmonella* in the spice blend. Although Supplier X is your "supplier," Supplier X also is a receiving facility (because Supplier X is a manufacturer) and, thus, would have conducted appropriate supplier verification activities, such as auditing its suppliers (or obtaining audits) and sampling and testing the milk and the spices, to ensure that they have used proper controls. (See section 15.11.1 for a discussion of when an audit is required for certain hazards and the exception to that requirement.) With respect to supplier verification activities for Establishments Y and Z, Subpart G provides that you could rely on documentation provided by Supplier X to you regarding Supplier X's supplier verification activities. (See 21 CFR 117.415(a)(3).) Alternatively, you could conduct the appropriate supplier verification activities with respect to Establishments Y and Z yourself, or you could rely on documentation from Supplier X for some supplier verification activities with respect to Establishments Y and Z and conduct other supplier verification activities with respect to Establishments Y and Z yourself. You also would determine an appropriate supplier verification activity and associated frequency for Supplier X.

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Figure 2. Supplier X makes a seasoning mix by blending milk powder (produced by Establishment Y) and a spice blend (produced by Establishment Z)



In determining whether to approve a supplier that relies on its own supplier to control the hazard requiring a supply-chain-applied control, we recommend you consider the robustness of the entity's supplier approval process and supplier verification activities.

15.7.4.3 Supplier performance

The third factor that you must consider in approving suppliers, determining appropriate supplier verification activities, and determining the frequency of conducting those activities is supplier performance. (See 21 CFR 117.410(d)(1)(iii).) Considering supplier performance includes:

- The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients (21 CFR 117.410(d)(1)(iii)(A));
- Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of food and other FDA compliance actions related to food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially

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recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations) (21 CFR 117.410(d)(1)(iii)(B)); and

- The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems (21 CFR 117.410(d)(1)(iii)(C)).

As noted in section 15.7.4.1 regarding your hazard analysis as the first factor to consider, the greater the risk presented by the hazard, the more stringently you should assess supplier performance as a mechanism to reduce the risk presented by the hazard.

15.7.4.3.1 Supplier's procedures, processes, and practices

Understanding the supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients can help you understand the supplier's strengths and weaknesses. Mechanisms to do so include:

- Conducting a supplier "pre-assessment" questionnaire or survey to gather information about the supplier's operation, covering topics such as product information (e.g., regulatory compliance information and allergen information) and the supplier's food safety programs (e.g., a Hazard Analysis and Critical Control Point (HACCP) program, a sanitation control program, and an allergen control program);
- Asking the supplier to provide documents such as a food safety plan or HACCP plan (if applicable) and third-party food safety and good manufacturing practice audit results;
- Conducting a pre-approval site visit to assess programs and process capabilities; and
- Using a system with defined metrics to evaluate supplier performance, including compliance to specifications, third-party audit scores, number of recalls, mock recall performance, material rejections/complaints, and issue response time (e.g., the supplier's timeframe for resolving a food safety issue).

15.7.4.3.2 Applicable food safety regulations

You should determine what FDA food safety regulations a potential supplier is subject to, such as the CGMP and PCHF requirements (21 CFR part 117), the produce safety regulation (21 CFR part 112), the requirements applicable to low-acid canned foods (21 CFR parts 108 and 113), the requirements applicable to acidified foods (21 CFR parts 108 and 114), or other relevant food safety provisions. In evaluating the supplier's compliance with the relevant regulations, you should consider whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (e.g., mandatory recall). See our Web site "Supplier Evaluation Resources" (FDA, 2016d) for resources that are available to help you evaluate the supplier's compliance with relevant FDA regulations.

Having an understanding of applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations can help you determine whether the supplier has a demonstrable history of supplying acceptable products and meeting all industry and regulatory requirements. Mechanisms to do so include:

- Asking the supplier to provide documentation of any recent regulatory inspections on file;

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- Searching our online databases for warning letters, import alerts, import refusals, recalls, and inspections. All of these databases are available to the public from our Web site “Supplier Evaluation Resources” (FDA, 2016d).
- Searching for actions that we publicize, such as food outbreak investigations and suspension of a facility’s registration. We generally make these available from the homepage for our human food program at <http://www.fda.gov/Food/default.htm>.

You should use this information to inform your decisions about whether you will approve a supplier, the type of verification activity you would use if you do approve the supplier, and the frequency of conducting the verification activity. Being subject to an FDA enforcement action such as a warning letter or an import alert should not necessarily disqualify a supplier. However, you should consider carefully the actions a supplier has taken as a result of regulatory compliance issues along with how it impacts your approval of that supplier and your verification activities.

Part 117 includes several provisions that reflect that some suppliers operate in a foreign country. (See, e.g., the definition of “qualified auditor in 21 CFR 117.3 and the provisions of 21 CFR 117.405(a)(2), 117.430(c), 117.435(c)(1)(ii), 117.435(c)(2), and 117.475(c)(15).) When the supplier is in a foreign country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, you may consider relevant laws and regulations of that country, and information relevant to the supplier’s compliance with those laws and regulations. (See 21 CFR 117.410(d)(1)(iii)(B).) Thus, having an understanding of applicable laws and regulations in a foreign country can help you consider supplier performance when FDA has officially recognized that country’s food safety system as comparable or determined it is equivalent to that of the United States. For example, just as you could ask a domestic supplier to provide documentation of any recent regulatory inspections on file, you could ask a foreign supplier that is in a foreign country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States to provide documentation of an inspection conducted by the applicable food safety authority. As of the date of this guidance, FDA has a Food Safety Systems Recognition Arrangement with Australia (FDA, 2017), Canada (FDA, 2016b), and New Zealand (FDA, 2015a). To determine whether we have a Food Safety Systems Recognition Arrangement or other cooperative arrangement with a foreign country, you can search the “Cooperative Arrangements” Web page (FDA, 2016a) of our “International Arrangements” Web page (FDA, 2015b) of our internet site directed to International Programs (FDA, 2016c).

15.7.4.3.3 Supplier’s food safety history

Before you became subject to the requirements of subpart G, you could already have established a relationship with your suppliers and have information related to audits or have the results of sampling and testing that provide a history of how the supplier has met your specifications. If so, you already could be aware of past problems with raw materials or other ingredients provided by the supplier, and the steps the supplier took to address such problems. You may consider such prior relationships as part of your consideration of the supplier’s food safety history. Likewise, as time goes on and you conduct appropriate supplier verification activities to comply with the requirements of subpart G, you would consider this same type of information for suppliers that you approve in compliance with subpart G.

You should focus your consideration of the supplier’s food safety history on the hazard that the supplier is controlling because that is the most relevant information. However, you should also consider other information about the supplier, e.g., information regarding recalls or regulatory

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actions. For example, if you are obtaining a product from a supplier that is controlling a microbial hazard (e.g., *Salmonella* in a spice blend) and food from this supplier has been associated with a chemical hazard (e.g., excess sulfites in another spice blend it produces), you should consider whether you should implement verification activities related to control of sulfites to prevent excess sulfites in the spice blend you receive for a period of time adequate to demonstrate that problems that could lead to excess sulfites levels have been resolved.

15.7.4.4 Other factors

Section 117.410(d)(1)(iv) specifies that you must consider any other factors as appropriate and necessary, such as storage and transportation practices, in approving suppliers, determining appropriate supplier verification activities, and determining the frequency of conducting those activities. For example, if you are receiving raw materials or other ingredients that support the growth of mold that could produce mycotoxins during storage if temperature and moisture are not controlled, you should consider the procedures that the supplier uses to control factors impacting growth of mold during the time the supplier stores the raw materials or other ingredients being supplied. As another example, if you are receiving raw materials or other ingredients that need temperature control during transportation to ensure their safety, you should consider the ability of the supplier to ensure control of temperature during transportation if the supplier will be responsible for that activity. As another example, if you are obtaining a raw material or other ingredient from a facility that is owned by your corporate parent you may consider your knowledge of corporate-wide food safety procedures, processes, and practices in determining the type of supplier verification activity and the frequency with which it is conducted. See also the discussion in section 15.6.2 of a circumstance where an individual at the corporate level is the PCQI for the purposes of the supply-chain program.

15.7.4.5 Exception to the full requirements for considerations for approving suppliers and determining appropriate supplier verification activities

Section 117.410(d)(2) provides that considering supplier performance can be limited to the supplier's compliance history (as required by 21 CFR 117.410(d)(1)(iii)(B)), if the supplier is: (i) A qualified facility as defined by 21 CFR 117.3; (ii) a farm that grows produce and is not a covered farm under 21 CFR part 112 in accordance with 21 CFR 112.4(a), or in accordance with 21 CFR 112.4(b) and 112.5; or (iii) a shell egg producer that is not subject to the requirements of 21 CFR part 118 because it has less than 3,000 laying hens.

15.7.5 Supplier Nonconformance

Section 117.410(e) specifies that if you determine through auditing; verification testing; document review; relevant consumer, customer or other complaints; or otherwise that the supplier is not controlling hazards that you have identified as requiring a supply-chain-applied control, you must take and document prompt action in accordance with 21 CFR 117.150 (Corrective actions and corrections) to ensure that raw materials or other ingredients from the supplier do not cause food that you manufacture or process to be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

We recommend that you establish processes and procedures to handle supplier nonconformance situations. The appropriate actions you take in response to nonconformance will depend on the circumstances and the specific root cause of the nonconformance and could include:

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- Discontinuing use of the supplier until the cause or causes of nonconformance, adulteration, or misbranding are adequately addressed;
- Notifying the supplier of the problem and requesting documentation of corrective actions taken by the supplier;
- Assisting the supplier's efforts to correct and prevent recurrence of the problem;
- Revising your supply-chain program; and
- Conducting, or working with your supplier to conduct, a recall of an adulterated or misbranded food.

15.8 Responsibilities of the Receiving Facility (21 CFR 117.415)

Section 117.415 describes your responsibilities as a receiving facility. As noted in section 15.3.2, subpart G includes provisions that provide for an entity other than you to conduct certain activities, provided that you review and assess the entity's applicable documentation, and document that review and assessment. Section 117.415 both specifies this flexibility provided by subpart G and places some bounds on that flexibility. We discuss this flexibility and its bounds in sections 15.8.1 through 15.8.4.

15.8.1 Your Responsibility to Approve Suppliers

Section 117.415(a)(1) specifies that the receiving facility must approve suppliers. Although 21 CFR 117.415(a)(2) through (a)(4) provide some flexibility for other entities to determine and conduct appropriate supplier verification activities (see section 15.8.2), ultimately the receiving facility is responsible for its supply-chain program (see the discussion in the final rule establishing part 117, 80 FR 55908 at 56097). See section 15.7.4 for considerations in approving suppliers and section 15.9 for the requirements to approve suppliers before receiving raw materials and other ingredients from those suppliers and have written procedures for receiving raw materials and other ingredients.

As noted in section 15.6.1, the definition of "supplier" in part 117 means that a broker or distributor is not a supplier; the supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food. Thus, if you buy raw materials or other ingredients from a broker or distributor, you should ask the broker or distributor to provide you with information that allows you to approve the establishment that manufactures/processes the food, raises the animal, or grows the food as a supplier of the food that you purchase from that broker or distributor. Likewise, if you purchase raw materials or other ingredients from a retail establishment (e.g., a warehouse-style establishment that sells to consumers), some applicable information (e.g., name and place of business of the manufacturer, packer, or distributor) would be on the product label as required by food labeling regulations. (See 21 CFR 101.5.) Also, you could ask the retail establishment to provide you with information that allows you to evaluate the establishment that manufactures/processes the food, raises the animal, or grows the food.

15.8.2 Your Responsibility to Determine and Conduct Appropriate Supplier Verification Activities

Section 117.415(a)(2) specifies that the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of subpart

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G. However, sections 117.415(a)(3) and (4) provide some flexibility for other entities to determine and conduct supplier verification activities on behalf of the receiving facility. See section 15.7.4 for considerations in determining appropriate supplier verification activities and the frequency of conducting them.

15.8.2.1 Flexibility for another entity to determine, conduct, and document appropriate supplier verification activities

Under 21 CFR 117.415(a)(3), an entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

- Establish written procedures for receiving raw materials and other ingredients by the entity (21 CFR 117.415(a)(3)(i));
- Document that written procedures for receiving raw materials and other ingredients are being followed by the entity (21 CFR 117.415(a)(3)(ii)); and
- Determine, conduct, or both determine and conduct the appropriate supplier verification activities (21 CFR 117.415(a)(3)(iii)), with appropriate documentation.

Although we specify that these activities are your responsibility, subpart G accounts for one or more entities in the supply chain between you and “the supplier” by providing some flexibility for these entities to perform certain activities.

15.8.2.2 Supplier verification activities that the supplier can conduct and document

Under 21 CFR 117.415(a)(4), the supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility. However, 21 CFR 117.415(a)(4) also requires that you review and assess that documentation, and document that review and assessment. An example of documentation of the results of sampling and testing is a COA, whether of periodic testing or lot-by-lot testing of the raw material or ingredient.

We recommend that a COA document that major analytical parameters for the specific foods, or lots, contained in a specific shipment have been met (see, e.g., GMA, 2008). Testing can be performed by the supplier's in-house laboratory or contracted to an outside testing laboratory. The laboratory conducting the testing should use scientifically valid laboratory methods and procedures that can provide reliable, accurate test results.

15.8.3 What You May Not Accept from a Supplier as a Supplier Verification Activity

Section 117.415(b) specifies that a receiving facility may not accept any of the following as a supplier verification activity from its supplier:

- A determination by its supplier of the appropriate supplier verification activities for that supplier (21 CFR 117.415(b)(1));
- An audit conducted by its supplier of that supplier (21 CFR 117.415(b)(2));

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- A review by its supplier of that supplier's own relevant food safety records (21 CFR 117.415(b)(3)); or
- The conduct by its supplier of other appropriate supplier verification activities for that supplier (21 CFR 117.415(b)(4)).

The only supplier verification activities in which the supplier can play a role are sampling and testing (see section 15.8.2.2) and providing an audit of the supplier conducted by a third party (see section 15.8.4).

15.8.4 Audit Provided by the Supplier

Under 21 CFR 117.415(c), your responsibilities as a receiving facility do not prohibit you from relying on an audit provided by your supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with the requirements of subpart G applicable to audits (i.e., 21 CFR 117.430(f) and 117.435). We discuss these requirements applicable to audits in sections 15.11.6 and 15.12, respectively.

15.9 Using Approved Suppliers (21 CFR 117.420)

As noted in sections 15.7.1 and 15.8.1, subpart G requires that a receiving facility approve suppliers. (See 21 CFR 117.410(a)(1) and 117.415(a)(1).)

15.9.1 Approving Suppliers

Section 117.420(a) specifies that the receiving facility must approve suppliers in accordance with the requirements of 21 CFR 117.410(d), and document that approval, before receiving raw materials and other ingredients from those suppliers. As discussed in section 15.7.4, 21 CFR 117.410(d) both specifies factors that you must consider in approving suppliers and determining appropriate supplier verification activities and provides for an exception to the full requirements for considering these factors.

15.9.2 Written Procedures for Receiving Raw materials and Other Ingredients

Section 117.420(b) specifies that:

- Written procedures for receiving raw materials and other ingredients⁶ must be established and followed (21 CFR 117.420(b)(1));
- The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use) (21 CFR 117.420(b)(2)); and

⁶ As noted in the list of terms in section 15.5, part 117 defines the term "written procedures for receiving raw materials and other ingredients" to mean written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use). We defined this term to simplify the provisions discussing these procedures.

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- Use of the written procedures for receiving raw materials and other ingredients must be documented (21 CFR 117.420(b)(3)).

You have flexibility to design appropriate written procedures that are tailored to your facility and operations for receiving raw materials and other ingredients. The goal of these written procedures is to ensure that you can accurately identify approved suppliers and incorporate changes to your suppliers in a timely and accurate way (e.g., addition of new approved suppliers, deletion of suppliers no longer deemed approved, criteria for approving temporary suppliers). Procedures to ensure that raw materials or other ingredients are only received from approved suppliers allow consistent implementation of the supplier program by personnel who order raw materials and other ingredients, personnel who receive raw materials and other ingredients, and personnel who conduct supplier verification activities. Such procedures also can be part of training of personnel who will have responsibility for receiving raw materials and other ingredients.

The use of written procedures for receiving raw materials and other ingredients is particularly important in light of the flexibility subpart G provides for an entity other than you (such as an entity in the supply chain between you and the supplier) to conduct this activity. (See 21 CFR 117.415(a)(2).) Although such an entity can do this as a service to you, a written procedure is appropriate to ensure a robust and meaningful verification. If you purchase from a broker or distributor, you must approve the suppliers of the raw materials or other ingredients you buy from the broker/distributor (see sections 15.8.1 and 15.9.1), but the broker/distributor could document that written procedures are being followed to ensure that the raw materials and other ingredients provided to you only come from suppliers that you have approved. The broker/distributor would provide this documentation to you (e.g., in documents accompanying the shipment) for you to review and assess. Thus, if you rely on a broker/distributor to ensure that the raw materials and other ingredients provided to you only come from suppliers that you have approved, you and the broker/distributor you buy from should agree on the written procedures for how the broker/distributor will document that raw materials or other ingredients are received only from suppliers approved by you. For example, the broker/distributor could have a checklist that an employee dates and initials after reviewing the invoice from the supplier, and send a copy of that dated checklist to you together with the invoice for the raw materials or other ingredients. You could use an electronic system or specific supply chain management software to document receipt of the raw material or other ingredient and review of checklist from the broker/distributor at the time of receipt. Below, we discuss the use of checklists and computer systems in more detail.

One approach to a written procedure for ensuring that raw materials and other ingredients are only received from approved suppliers is to maintain and use an actual “approved supplier list” to ensure that only suppliers from the lists are used for the purchase of raw materials or other ingredients (Zaura, 2005). One example of this approach is a simple paper system where the receiving personnel or quality control/assurance personnel check the origin of the purchased materials (IFS, 2012) and refer to a list of approved suppliers to verify that the raw material or ingredient is received from an approved supplier (SQFI, 2014) (e.g., put a check mark on the receiving document if the supplier is an approved supplier).

Another approach to a written procedure for ensuring that raw materials and other ingredients are only received from approved suppliers is a computer system or specific supply chain management software that manages the procurement, receipt, and usage of raw materials and

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other ingredients. An example of this approach is for authorized personnel from the receiving facility or its corporate headquarters to enter approved suppliers and approved raw materials and other ingredients into the computerized system. When raw materials and other ingredients are delivered to a facility, the receiving personnel cross reference the purchase order number, supplier name, and material received with the information previously entered into the computer system to verify the materials are from an approved supplier and the order is correct. Typically the computer system would also have a safeguard mechanism to prevent the acceptance of a raw material or other ingredient from an unapproved supplier. On an as needed basis, a facility or its corporate headquarters can use the computer system to generate a list of the approved suppliers and approved raw materials or ingredients in real time.

Another approach to a written procedure for ensuring that raw materials and other ingredients are only received from approved suppliers is use of computer programs that link inputs on items received with the list of approved suppliers for that item and flag discrepancies. You could either use your existing receiving record system or modify your existing receiving record system to record information regarding receipt from approved suppliers.

Subpart G accounts for emergency situations in which you would need to receive raw materials or other ingredients on a temporary basis from an unapproved supplier (See 21 CFR 117.420(b)(2) and SQFI, 2014.) Examples of such situations are disruptions in delivery of raw materials and other ingredients from approved suppliers due to:

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

For an unapproved supplier that you plan to use on a temporary basis, we recommend that you conduct at least a minimal review of the supplier. For example, we suggest that you review FDA's Web site to determine whether the potential supplier has received a warning letter or is listed on an import alert. In addition, if you need to use an unapproved supplier under such unexpected circumstances, you must subject the applicable raw materials or other ingredients to adequate verification activities before acceptance for use. (See 21 CFR 117.420(b)(2).) For example, if you are receiving a raw material or ingredient such as black pepper and your supplier controls *Salmonella*, you could sample and test each shipment of food from the supplier for *Salmonella* using a statistically-based sampling plan. Alternatively, you could obtain and review records of the process that the temporary supplier uses to kill *Salmonella* in the black pepper.

You should use unapproved suppliers only on a temporary basis until you are able to fully evaluate and approve a new supplier, or until the problem with your previously approved supplier has been corrected and, as appropriate, you reevaluate your approval of that supplier. An appropriate time period for use of an unapproved supplier on a temporary basis might vary, depending on the circumstances, from a few weeks to a few months. For example, if your approved supplier ceases operations and you intend to continue to use a temporary supplier, you should promptly evaluate the new supplier and revise your supply-chain program accordingly. If you are considering multiple new suppliers to replace your approved supplier,

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you may need some additional time to evaluate and approve the additional suppliers. As another example, it could be the case that you expect to be able to obtain the food from the approved supplier in a few weeks, but you subsequently determine that it may take several months or an indefinite period of time before you can obtain the food from the approved supplier because of an equipment breakdown or a weather-related incident. In that circumstance, you may determine that you want to use your temporary supplier or another supplier on a more permanent basis. If that occurs, you should promptly evaluate and approve the new supplier and revise your supply-chain program to reflect this. Having multiple suppliers approved for each raw material or ingredient you receive can reduce the use of temporary suppliers when one supplier becomes unavailable.

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

If you receive raw materials or other ingredients on a temporary basis from an unapproved supplier, remember that subpart G requires you to subject raw materials or other ingredients from that unapproved supplier to adequate verification activities before you accept the raw materials or other ingredients for use. (See 21 CFR 117.420(b)(3).) To satisfy this requirement, you should document the verification activities that you conducted before accepting raw materials or other ingredients from a temporary supplier.

15.10 Determining Appropriate Supplier Verification Activities (Including Determining the Frequency of Conducting the Activity) (21 CFR 117.425)

Section 21 CFR 117.425 requires that appropriate supplier verification activities (including the frequency of conducting the activity) be determined in accordance with the requirements of 21 CFR 117.410(d). Section 21 CFR 117.410(d) specifies the considerations in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted. For details about the requirements of 21 CFR 117.410(d) and our recommendations for complying with those requirements, see section 15.7.4.

15.11 Conducting Supplier Verification Activities for Raw Materials and Other Ingredients (21 CFR 117.430)

Section 21 CFR 117.430 specifies requirements to conduct one or more of the supplier verification activities specified in 21 CFR 117.410(b), provides for alternative supplier verification activities in certain circumstances, and prohibits certain financial conflicts of interest. We discuss these provisions in sections 15.11.1 through 15.11.6.

15.11.1 Requirement to Conduct Supplier Verification Activities

With some exceptions, 21 CFR 117.430(a) requires that one or more supplier verification activities (i.e., onsite audit, sampling and testing, review of food safety records, and other supplier verification activities)⁷ must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter. The exceptions to this requirement are specified in 21 CFR 117.430(c), (d), and (e). See the discussion of the exceptions to this requirement in sections 15.11.3 through 15.11.5.

A successful supplier program includes supplier verification activities both before the use of the raw material or other ingredient and periodically thereafter to evaluate ongoing compliance (ASTA, 2011; Edleman, 2012; Eldridge, 2012; ERG, 2004; Neumann, 2009; Zaura, 2005). Periodic verification provides routine feedback on the supplier's performance, rather than only when a problem arises (Zaura, 2005).

Subpart G includes specific requirements for conducting onsite audits (21 CFR 117.435) and for documenting the conduct of supplier verification activities (21 CFR 117.475). See sections 15.11.2 and 15.12 for discussions of conducting an onsite audit as a supplier verification activity. See section 15.13 for a discussion of documenting of supplier verification activities.

15.11.2 Specific Requirements When the Hazard Requiring a Preventive Control is a SAHCODH Hazard

15.11.2.1 Requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODH hazard

With one exception (see section 15.11.2), 21 CFR 117.430(b)(1) requires that when a hazard in a raw material or other ingredient will be controlled by the 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 (SAHCODH hazard):

- The appropriate supplier verification activity is an onsite audit of the supplier (21 CFR 117.430(b)(1)(i)); and
- The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter (21 CFR 117.430(b)(1)(ii)).

SAHCODH hazards are those for which a recall of a violative product posing such a hazard is designated as "Class 1" under 21 CFR 7.3(m)(1) (i.e., a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death). Examples of such hazards that, in some circumstances, have resulted in serious adverse health consequences or death to humans include pathogens or their toxins in RTE foods and undeclared food allergens. Foods (other than dietary supplements or infant formula) containing a SAHCODH hazard are considered "reportable foods," subject to the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007. See our "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration

⁷ The list of appropriate supplier verification activities is specified in 21 CFR 117.410(b). The receiving facility determines which activity to conduct in accordance with 21 CFR 117.410(d). See the discussion of the appropriate supplier verification activities in section 15.4.2. See the discussion of determining appropriate supplier verification activities in section 15.4.4.

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Amendments Act of 2007” (FDA, 2009 and FDA, 2010), and the annual reports of the Reportable Food Registry (e.g., FDA, 2016e.) for examples of foods that we have considered to be SAHCODH hazards.

Onsite audits provide the opportunity to review the food safety plan and written procedures and to observe the implementation of food safety procedures, as well as to review the records related to the past application of control measures, including laboratory test results. Audits also provide the opportunity to interview employees to assess their understanding of the food safety measures for which they are responsible.

The goal of conducting an audit “at least annually thereafter” is to receive the results of an audit with sufficient frequency to provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. We realize there could be practical reasons which preclude meeting this timeframe, e.g., if a third-party auditor needs to delay a previously scheduled audit. We do not expect to take action if the timeframe between annual audits is reasonably close to one year (e.g., within 13-14 months).

For specific requirements that apply to an audit, see 21 CFR 117.435 and section 15.12. For a discussion of documentation associated with an audit, see section 15.13.

15.11.2.2 Exception to the requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODH hazard

The exception to the requirement to conduct an annual onsite audit when the hazard requiring a preventive control is a SAHCODH hazard is when there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. (See 21 CFR 117.430(b)(2).) The written determination is part of your food safety plan and, thus, must be prepared by (or under the oversight of) your PCQI (see the discussion in section 15.6.5).

As an example of using an alternative approach to an annual onsite audit, consider the situation in which you are part of a larger corporation, are making trail mix, and obtain roasted peanuts from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as you. You could determine that the food safety requirements established by the parent company and applied at the subsidiary provide the needed assurance that *Salmonella* in raw peanuts is adequately controlled. You could support your decision by documenting this determination, including the supplier’s procedures and the corporation’s activities to verify that the subsidiary operates in accordance with corporate food safety policies to ensure that hazards are adequately controlled. See also the discussion in section 15.6.2 of a circumstance where an individual at the corporate level is the PCQI for the purposes of the supply-chain program.

However, if a SAHCODH hazard is identified for the food and you conclude that annual onsite auditing is not required, we recommend that your supplier verification activities generally include some frequency of onsite auditing, such as every 2 or 3 years for most suppliers not in your same corporate structure. For example, consider the situation in which you have many years of experience with the same supplier. You could document the history of the supplier’s compliance with control of the hazard (including summarizing test results, audit findings and other information) to support your decision that an annual onsite audit is not needed. You would identify appropriate supplier verification activities and document these in your supply-chain program, e.g., you could determine and describe in your written program that you will require an audit every two years and sample and test for the hazard each quarter in the intervening year.

15.11.3 Alternative Supplier Verification Activity If the Supplier Is a “Qualified Facility”

Section 21 CFR 117.430(c) provides for an alternative supplier verification activity if a supplier is a qualified facility as defined by 21 CFR 117.3. If this is the case, you do not need to comply with the requirements to conduct one of the supplier verification activities specified in 21 CFR 117.410(b) (i.e., audit, sampling and testing, review of the supplier’s relevant food safety records, or other appropriate supplier verification activity), or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODH hazard, if you:

- Obtain written assurance that the supplier is a qualified facility as defined by § 117.3:
 - Before first approving the supplier for an applicable calendar year; and
 - On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and
- Obtain written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:
 - A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or
 - A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

A facility is a qualified facility if it is a very small business as that term is defined in part 117. See the definitions for “qualified facility” and “very small business” in 21 CFR 117.3 and in the list of terms in section 15.5. A qualified facility is not subject to the PCHF requirements for hazard analysis and risk-based preventive controls, including the requirement to have a supply-chain program. It is the responsibility of the supplier to determine whether it is a qualified facility; it is your responsibility to obtain written assurance from the supplier that it is a qualified facility.

By specifying “by December 31” for the annual written assurance that the supplier is a qualified facility, the provision provides some flexibility for you to work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify you about its status. You and your suppliers have some flexibility to approach the potential for the status of a facility to shift between “qualified facility” and “not a qualified facility” (or vice versa) in a way that works best for your specific business relationship.

The biennial written assurance aligns with the responsibilities of a qualified facility to submit an attestation to FDA every two years.⁸ (See 21 CFR 117.201(a).) In its attestation, the qualified facility attests that: (1) It meets the definition of a qualified facility; and (2) either it has established and is following certain food safety practices, or it is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and

⁸ For a facility that begins manufacturing, processing, packing or holding food before September 17, 2018, the facility must make its first submission by December 17, 2018. For a facility that begins manufacturing, processing, packing or holding food after September 17, 2018, the facility must make its first submission before beginning operations.

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regulations of foreign countries. See section 15.7.4.3 for a discussion of the applicability of relevant laws and regulations 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. A qualified facility submits its attestation to FDA on Form FDA 3942a. A supplier that is a qualified facility could provide a copy of that form to its customers to help them comply with 21 CFR 117.430(c)(1). (A qualified facility that submits the attestation electronically could print a copy for this purpose.) Subpart G also requires that a receiving facility obtain a written assurance that includes a brief written description of the preventive controls that the qualified facility is implementing to control the applicable hazard in the food, or a statement that the qualified facility is in compliance with an applicable non-Federal food safety law. For example, a qualified facility that supplies honey-roasted pecans could include a brief written description of its preventive controls to control *Salmonella* on the pecans (e.g., roasting the pecans at a specified temperature for a specified time period); alternatively, a qualified facility that supplies honey-roasted pecans could provide a statement that it complies with the food safety laws of the state in which it is located.

15.11.4 Alternative Supplier Verification Activity If the Supplier is a Certain Type of Produce Farm

Section 21 CFR 117.430(d) provides for an alternative supplier verification activity if a supplier is a farm that grows produce and is not a covered farm under the produce safety regulation in 21 CFR part 112 in accordance with 21 CFR 112.4(a), or in accordance with 21 CFR 112.4(b) and 112.5. If this is the case, you do not need to comply with the requirements to conduct one of the supplier verification activities specified in 21 CFR 117.410(b), or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODH hazard, for produce that the receiving facility receives from the farm as a raw material or other ingredient if you:

- Obtain written assurance that the raw material or other ingredient provided by the supplier is not subject to the produce safety regulation in 21 CFR part 112 in accordance with 21 CFR 112.4(a), or in accordance with 21 CFR 112.4(b) and 112.5:
 - Before first approving the supplier for an applicable calendar year; and
 - On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and
- Obtain written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

Under 21 CFR 112.4(a), a farm or farm mixed-type facility that has less than \$25,000 in annual sales of produce averaged over the previous 3-year period is not a covered farm under the produce safety regulation. Under 21 CFR 112.4(b) and 112.5, a farm is not a covered farm if the farm is eligible for a qualified exemption and associated modified requirements based on the average monetary value of all food sold and the relative value of food sold directly to qualified end users as compared to all other buyers⁹, and FDA has not withdrawn the farm's exemption. It is the responsibility of the supplier to determine whether it is not subject to the produce safety regulation; it is your responsibility to obtain written assurance from the supplier that it is not subject to the produce safety regulation.

⁹ See 21 CFR 112.5(a) for the requirements of the qualified exemption and 21 CFR 112.3 for the definition of "qualified end users."

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By specifying “by December 31” for the annual written assurance that the supplier is a farm that grows produce and is not a covered farm under the produce safety regulation, the provision provides some flexibility for you to work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify you about its status. You and your suppliers have some flexibility to approach the potential for the status of a facility to shift between “not a covered farm” and “covered farm” (or vice versa) in a way that works best for your specific business relationship.

See section 15.7.4.3 for a discussion of the applicability of relevant laws and regulations 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.

15.11.5 Alternative Supplier Verification Activity If the Supplier Is a Shell Egg Producer That Is Not Subject to the Requirements of 21 CFR Part 118

Section 21 CFR 117.430(e) provides for an alternative supplier verification activity if a supplier is a shell egg producer that is not subject to the requirements of 21 CFR part 118 for the production, storage, and transportation of shell eggs because it has less than 3,000 laying hens. If this is the case, you do not need to comply with the requirements to conduct one of the supplier verification activities specified in 21 CFR 117.410(b), or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODH hazard, if you:

- Obtain written assurance that the shell eggs produced by the supplier are not subject to 21 CFR part 118 because the shell egg producer has less than 3,000 laying hens:
 - Before first approving the supplier for an applicable calendar year; and
 - On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and
- Obtain written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

A shell egg producer is not subject to the requirements for the production, storage, and transportation of shell eggs if it has less than 3,000 laying hens. It is the responsibility of the supplier to determine whether it is not subject to the requirements for the production, storage, and transportation of shell eggs; it is your responsibility to obtain written assurance from the supplier that it is not subject to those requirements.

By specifying “by December 31” for the annual written assurance that the supplier is a shell egg producer that is not subject to 21 CFR part 118, the provision provides some flexibility for you to work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify the receiving facility about its status. You and your suppliers have some flexibility to approach the potential for the status of a facility to shift between “not subject to 21 CFR part 118” and “subject to 21 CFR part 118” (or vice versa) in a way that works best for your specific business relationship.

See section 15.7.4.3 for a discussion of the applicability of relevant laws and regulations 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.

15.11.6 Financial Conflict of Interest

Section 21 CFR 117.430(f) specifies that there must not be any financial conflicts of interests that influence the results of the verification activities listed in 21 CFR 117.410(b). For example, if a qualified individual has a financial conflict of interest that influences the results of supplier verification activities, the qualified individual would be precluded from being able to independently conduct supplier verification activities. You can avoid this possibility when conducting supplier verification activities by only using individuals or firms that do not have conflicts of interest.

In addition, 21 CFR 117.430(f) specifies that payment must not be related to the results of the activity. For example, you may not give a qualified auditor who conducts an onsite audit, or a qualified individual who reviews supplier food safety records, greater compensation for determining that a supplier is in compliance with applicable FDA requirements. Also, you may not reduce the compensation of a qualified auditor or qualified individual or assess financial penalties because the qualified auditor or qualified individual identified areas of supplier non-compliance. Similarly, a supplier may not make such payments.

The requirements of 21 CFR 117.430(f) do not prohibit employees of a supplier from performing the functions specified in 21 CFR 117.415 in accordance with 21 CFR 117.415. (See the discussion of functions that a supplier can perform in accordance with 21 CFR 117.415(a)(4) in section 15.8.2.2). For example, this provision would not prohibit an employee of a supplier from conducting sampling and testing so that the supplier could provide the results in documentation provided to the receiving facility; it is common for suppliers to include COAs for tests conducted on specific lots of product along with the shipment to the receiving facility. The requirements of 21 CFR 117.430(f) also do not prohibit you from relying on an audit provided by your supplier when the audit of the supplier was conducted by a third-party qualified auditor. (See the discussion of 21 CFR 117.415(c) in section 15.8.4.)

15.12 Onsite Audit (21 CFR 117.435)

Section 21 CFR 117.435 specifies requirements applicable to onsite audits, including who must conduct an onsite audit; consideration of applicable food safety regulations; and when the written results of an inspection can be substituted for an audit. We discuss these provisions in sections 15.12.1 through 15.12.3.

15.12.1 Who Conducts an Onsite Audit

Section 21 CFR 117.435(a) requires that an onsite audit of a supplier be performed by a qualified auditor. Part 117 defines “qualified auditor” as a person who is a qualified individual as defined in part 117 and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by 21 CFR 117.180(c)(2). Examples of potential qualified auditors include:

- A government employee, including a foreign government employee; and
- An audit agent of a certification body that is accredited in accordance with the accredited third-party certification regulation.

Part 117 defines “qualified individual” as a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean

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and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

See the definitions of "qualified auditor" and "qualified individual" in 21 CFR 117.3 and in the list of terms in section 15.5.) The requirements applicable to a qualified auditor are set forth in 21 CFR 117.180(c)(2), which specifies that to be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. A qualified auditor may be, but is not required to be, an employee of the receiving facility.

We have not established specific courses, programs, or certifications, or defined the type of experiences that would be required to satisfy the requirements applicable to a qualified auditor as defined in part 117. However, consistent with the requirements for competent audit agents in 21 CFR 1.650 and the guidance entitled "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff" (Guidance on Accredited Third-Party Certification) (FDA, 2016f), we expect a qualified auditor to have education, training, or experience that provides the person with knowledge and skills necessary to evaluate whether the equipment, processes, and procedures in a food facility or on a farm ensure that the hazards associated with the food have been controlled. For example, an individual who has previously conducted food safety inspections for a food safety authority may be a qualified auditor, provided that the individual has the knowledge and experience to assess compliance with the applicable provisions of the FD&C Act. A person should have at least some actual experience in auditing (including assisting in audits or observing audits) to meet the definition of a qualified auditor, because the necessary technical expertise likely cannot be obtained solely through education and/or training that does not involve assisting or observing others in the performance of an audit.

The example of an audit agent of a certification body that has been accredited in accordance with regulations in our accredited third-party certification regulation (21 CFR part 1, subpart M) adds context about the standard for such individuals. The requirements in 21 CFR 1.650 address how an accredited third-party certification body must ensure its audit agents are competent and objective. Although an onsite audit that is solely conducted to meet the requirements of part 117 by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M, is not subject to the requirements in those regulations (see section 15.12.4), the requirements for audit agents and the Guidance on Accredited Third-Party Certification with respect to competency are useful in determining appropriate education, training, or experience for a qualified auditor. For example, competency requirements for audit agents in the accredited third-party certification regulation include that they:

- Have relevant knowledge and experience that provides an adequate basis for the audit agent to evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations;
- Be competent to conduct food safety audits; and
- Have completed annual food safety training (FDA 2016f).

The Guidance on Accredited Third-Party Certification (FDA 2016f) further recommends education and/or experience for entry level auditors and lead auditors, as well as auditor skills such as observational, reasoning, analytical and communication skills (FDA 2016f). Auditors should be trained to understand and properly apply FDA's food safety requirements under the

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FD&C Act and FDA regulations for purposes of auditing (FDA 2016f). Technical training may vary depending on the processes and products being audited (FDA 2016f). Training methods may include classroom training, annual food safety training, and joint audits with a qualified trainer to help the audit agent apply classroom learning (FDA 2016f).

The GFSI provisions for auditor competency in “GFSI Food Safety Auditor Competencies” (GFSI, 2013) are also useful in determining the knowledge, experience, and skills for a qualified auditor. The GFSI’s auditor competency model lists three main components for auditor competencies: (1) Auditing skills and knowledge; (2) technical skills and knowledge; and (3) behavior and systems thinking (GFSI, 2013). Within each main component, GFSI provides details of specific tasks and the required auditor knowledge and skills to perform the specific tasks (GFSI, 2013).

You or one of your employees may conduct the audit as long as you are or your employee is a qualified auditor, based on education, training, or experience, or a combination thereof.

15.12.2 Consideration of Food Safety Regulations

Section 21 CFR 117.435(b) requires that if the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

The qualified auditor who audits your supplier may be your own employee (“second-party audit”) or an independent third party (i.e., a qualified auditor who is neither your employee nor an employee of the supplier) (third-party audit). Both second-party audits and third-party audits allow first-hand review of the critical food safety programs in place at a supplier’s establishment and can help you to obtain a sense of how effective programs are by diligently reviewing program records, observing activities, and interviewing workers.

Because FDA food safety regulations vary in scope and detail, the parameters and key components of an onsite audit conducted under section 21 CFR 117.435(a) would vary depending on what regulations apply to the supplier.

A supplier that is subject to the PCHF requirements must have a food safety plan. (See 21 CFR 117.126.) If your supplier is subject to the PCHF requirements, the onsite audit would focus on the supplier’s food safety plan and assess the implementation of the preventive controls applied by the supplier to address the known or reasonably foreseeable hazards that you have determined to require a supply-chain-applied control. For example, before you obtain roasted peanuts for which you had identified *Salmonella* as a hazard from a supplier subject to the PCHF requirements, you would audit the supplier (or obtain documentation of an audit performed by a third party) to determine whether the supplier’s roasting process adequately controlled the *Salmonella*. Because the supplier was subject to the PCHF requirements, the audit should include a review of the supplier’s food safety plan. The auditor should review whether the roasting process had been validated to significantly minimize *Salmonella* in peanuts and should examine whether the supplier had implemented the roasting procedures in accordance with its food safety plan (e.g., through observing the establishment’s procedures and reviewing records).

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A supplier that is not subject to the PCHF requirements, but is subject to HACCP requirements, would have a “HACCP plan” rather than a “food safety plan.” If, for example, you use juice as an ingredient in a refrigerated fruit salad, and your supplier is subject to the process control requirements in 21 CFR 120.24, the onsite audit of the juice supplier would assess the validation and implementation of the process controls in your supplier’s HACCP plan.

The produce safety regulation in 21 CFR part 112 does not require farms that are subject to that regulation to have food safety plans. However, in some cases, a supplier (such as a large farming operation) might voluntarily elect to establish a food safety plan. In that case, the onsite audit of the supplier should include a review of the supplier’s written plan, and its implementation of the plan, to ensure that identified hazards are being adequately controlled.

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

There are several national and international auditing schemes widely used to assess food safety practices in manufacturing facilities and on farms. You could rely on the results of audits conducted in accordance with such schemes provided that the audits evaluate the farm or facility’s compliance with applicable FDA regulations, review the supplier’s food safety plan (if any) and its implementation, and otherwise meet the requirements for onsite audits in 21 CFR 117.435. Before relying on the results of a third-party onsite audit, you should determine whether the auditing scheme used can help you to conclude whether the supplier uses processes and procedures that comply with applicable regulations. Audit schemes that consider FDA food safety regulations and include a review of the supplier’s written food safety plan (including a HACCP plan), if any, and its implementation, with respect to the hazard being controlled are likely to satisfy the requirements for an onsite audit.

15.12.3 Substitution of an Inspection for an Audit

Section 21 CFR 117.435(c) allows for the following inspections to substitute for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:

- The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture (USDA)), or by representatives of State, local, tribal, or territorial agencies (21 CFR 117.435(c)(1)(i)); or
- For a foreign supplier, the written results of an inspection 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. (See 21 CFR 117.435(c)(1)(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. (See 21 CFR 117.435(c)(2).)

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For an inspection conducted by FDA, other Federal Agencies, or State, local, tribal, or territorial agencies, an “appropriate” inspection conducted for compliance “with applicable FDA regulations” means that the inspection must be sufficiently relevant to compliance with applicable FDA food safety regulations to credibly substitute for an onsite audit. For example, inspection by USDA to determine whether a farm satisfies the requirements of the produce safety regulation could constitute an appropriate inspection that could substitute for an audit, but an inspection by USDA to determine whether a farm satisfies the requirements of the National Organic Program could not.

In the case of a foreign supplier, a country whose food safety system FDA has officially recognized as “comparable” to that of the United States would be one for which there is a signed systems recognition arrangement or other agreement between FDA and the country establishing official recognition of the foreign food safety system. See section 15.7.4.3.2 for information on countries for which we have a Food Safety Systems Recognition Arrangement or other cooperative arrangement with a foreign country.

Some countries issue certifications or recognitions to facilities for compliance with certain requirements such as for HACCP systems. We would not accept a HACCP certificate issued by a foreign government as a substitute for an onsite audit because HACCP requirements are not identical to the PCHF requirements, and it would not be clear as to what basis was used to issue a HACCP certificate. However, a receiving facility could consider whether such a certificate could be part of its justification for conducting another supplier verification activity in lieu of an annual onsite audit, or for conducting an audit on a less frequent basis than annually (see section 15.11.2.2).

15.12.4 Audits Conducted to Meet the Requirements of Subpart G Do Not Have to Comply with the Requirements of the Accredited Third-Party Regulation

Section 21 CFR 117.435(d) specifies that if an onsite audit is solely conducted to meet the requirements of part 117 by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M, the audit is not subject to the requirements in those regulations.

Audits conducted under the accredited third-party certification regulation are done for specific purposes, e.g., for compliance with the requirements of the Voluntary Qualified Importer Program. Audits conducted to meet the requirements of 21 CFR 117.435 may be conducted by a person who had been accredited under these provisions; however, the requirements for audits conducted under the accredited third-party certification regulation (e.g., specific information that must be included in an audit and submission of regulatory audit reports to FDA under 21 CFR 1.652) would not apply to an audit even when the auditor is accredited to do such audits unless they are also conducted for purposes under the accredited third-party certification regulation.

15.13 Records Documenting the Supply-Chain Program

Section 21 CFR 117.475 specifies that the records documenting the supply-chain program are subject to the requirements of subpart F of part 117. (See 21 CFR 117.475(a).) Subpart F sets forth general requirements applicable to all records, such as the use of either paper or electronic records and the need for records to be accurate, indelible, and legible. Subpart F also sets forth requirements for record retention and official review. Section 117.330 in subpart F explains how you can use existing records to satisfy the recordkeeping requirements of part 117.

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Section 21 CFR 117.475 requires that you must review the records of the supply-chain program in accordance with § 117.165(a)(4). (See 21 CFR 117.475(b).) Under 21 CFR 117.165(a)(4(ii)), records of the supply-chain program must be reviewed within a reasonable time after the records are made by (or under the oversight of) a PCQI to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions.

Table 15-4 lists the records required (as applicable) for the supply-chain program. (See 21 CFR 117.475(c).)

Table 15-4 List of Records Required for the Supply-Chain Program

Section	Description	Discussion
117.475(c)(1)	The written supply-chain program	There is no standardized or required format for the written supply chain program or its records. You can use whatever format works best for your facility, provided that the records include all the required information. Also, the written supply-chain program is part of the food safety plan, which must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification. (See 21 CFR 117.310.)
117.475(c)(2)	If you are an importer, documentation that you are in compliance with the FSVP requirements under part 1, subpart L, including documentation of verification activities conducted under §1.506(e)	If you are an importer, and you have records documenting the supplier verification activities you conducted to comply with the FSVP regulation, you can rely on those records as documentation of verification activities to comply with the supply-chain program requirements of subpart G.
117.475(c)(3)	Documentation of the approval of a supplier	<ul style="list-style-type: none"> • Your written determination of the basis for approving the supplier; and • The approved suppliers – e.g., a paper list of approved suppliers or an electronic system that can generate a list of approved suppliers as needed

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Section	Description	Discussion
17.475(c)(4)	Written procedures for receiving raw materials and other ingredients	Examples are a paper checklist and a computer system that manages the procurement, receipt, and usage of raw materials and other ingredients.
117.475(c)(5)	Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients	Examples are a paper checklist that was marked to demonstrate receipt and electronic records produced by a computer system that manages the procurement, receipt, and usage of raw materials and other ingredients.
117.475(c)(6)	Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients	Your written determination should explain why you chose your particular supplier verification activities. See the discussion in section 15.7.4.
117.475(c)(7)	Documentation of the conduct of an onsite audit, including (i) The name of the supplier subject to the onsite audit; (ii) Documentation of audit procedures; (iii) The dates the audit was conducted; (iv) The conclusions of the audit; (v) Corrective actions taken in response to significant deficiencies identified during the audit; and (vi) Documentation that the audit was conducted by a qualified auditor	<p>Examples of documentation of audit procedures include the process(es) and food(s) observed, types of records reviewed, and whether the audit included interviews or laboratory testing. Examples of the conclusions of an audit include whether the audit did, or did not, result in any significant deficiencies.</p> <p>You have some flexibility to work with the qualified auditor, or with a supplier who arranges for a third-party audit, on appropriate documentation that the auditor has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. Examples of such documentation are a list of applicable training and examples of relevant audits conducted by the auditor.</p>

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Section	Description	Discussion
117.475(c)(8)	Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include: (i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested; (ii) Identification of the test(s) conducted, including the analytical method(s) used; (iii) The date(s) on which the test(s) were conducted and the date of the report; (iv) The results of the testing; (v) Corrective actions taken in response to detection of hazards; and (vi) Information identifying the laboratory conducting the testing	You have some flexibility in the format of appropriate documentation of sampling and testing, such as on a CoA. Documentation of corrective actions would apply to the steps you take when you (or a third party acting on your behalf) detect the hazard in raw materials or other ingredients that you received, including what you do with the raw material or other ingredient and the steps you take to address the problem with the supplier.
117.475(c)(9)	Documentation of the review of the supplier's relevant food safety records. This documentation must include: (i) The name of the supplier whose records were reviewed; (ii) The date(s) of review; (iii) The general nature of the records reviewed; (iv) The conclusions of the review; and (v) Corrective actions taken in response to significant deficiencies identified during the review	Records of the supply-chain program must be reviewed within a reasonable time after the records are made by (or under the oversight of) a PCQI to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the supplier's preventive controls are effective, and appropriate decisions were made about corrective actions. (See 21 CFR 117.165(a)(4).)
117.475(c)(10)	Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient	Your documentation of other appropriate supplier verification activities would depend on the nature of the activity. For example, if you use a fact-specific questionnaire you would have a record of the questionnaire applied to a particular supplier. If you considered information applicable to a supplier's certification to a specific audit scheme, you would have a record of the information you considered.

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Section	Description	Discussion
117.475(c)(11)	Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the 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	Because your written supply-chain program is part of your food safety plan, the written determination must be prepared by (or under the oversight of) your PCQI. See the discussion in section 15.11.2.2 for examples of what such a written determination could address.
117.475(c)(12)	The following documentation of an alternative verification activity for a supplier that is a qualified facility: (i) The written assurance that the supplier is a qualified facility as defined by §117.3, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States)	You and your suppliers have some flexibility to determine the appropriate documentation in a way that works best for your specific business relationship. For example, for documentation of its status, a qualified facility could provide you with documentation of its submission of the qualified facilities form (Form FDA 3942a). For the other assurance, you and your supplier can choose which of two options to use, based on the specific circumstances of the supplier. See the discussion in section 15.11.3 of the two different types of attestation.

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Section	Description	Discussion
117.475(c)(13)	<p>The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter: (i) The written assurance that the supplier is not a covered farm under part 112 of this chapter in accordance with §112.4(a), or in accordance with §§112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States)</p>	<p>You and your suppliers have some flexibility to determine the appropriate documentation in a way that works best for your specific business relationship.</p>
117.475(c)(14)	<p>The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens: (i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States)</p>	<p>You and your suppliers have some flexibility to determine the appropriate documentation in a way that works best for your specific business relationship.</p>

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Section	Description	Discussion
117.475(c)(15)	The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the U.S. Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection are substituted for an onsite audit	The written results of an appropriate inspection would depend on the inspection and how the entity conducting the inspection reports its results.
117.475(c)(16)	Documentation of actions taken with respect to supplier nonconformance	Your documentation of supplier nonconformance would depend on the nature of the nonconformance. See the examples of potential supplier nonconformance in section 15.7.5.
117.475(c)(17)	Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier	The documentation you receive from another entity should be similar to the documentation you would have if you had conducted the activity yourself.

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Section	Description	Discussion
117.475(c)(18)	<p>When applicable, documentation of the receiving facility's review and assessment of: (i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed; (ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients; (iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients; (iv) Applicable documentation, from its supplier, of: (A) The results of sampling and testing conducted by the supplier; or (B) The results of an audit conducted by a third-party qualified auditor in accordance with 21 CFR 117.430(f) and 117.435; and (v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier</p>	<p>You have some flexibility for how to appropriately document that you reviewed and assessed the documentation from another entity. For example, appropriate staff in your facility could date and sign the documentation received from the other entity, or you could attach a signed, dated statement, from appropriate staff in your facility, specifying that the documentation had been reviewed and assessed.</p>

15.14 Compliance Dates

In the preamble of the final rule establishing part 117, we provided compliance dates for the requirements of the supply-chain program in subpart G. (See Table 54 in the final rule, 80 FR 55908 at 56128). The compliance dates for implementing your supply-chain program apply with respect to each of your suppliers, not to your supply-chain program as a whole, because the compliance dates depend on whether your suppliers will be subject to part 117, the produce safety regulation, or neither regulation. For those suppliers subject to part 117 or the produce safety regulation, you are not required to conduct supplier verification activities until after your supplier's compliance date is reached.

For your convenience, Table 15-5 provides the information from Table 54 in the preamble of the final rule establishing part 117.

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Table 15-5 Compliance Dates for the Requirements of the Supply-Chain Program

Situation	Compliance date:
You are a small business and your supplier will not be subject to the PCHF requirements of part 117 or the produce safety regulation	September 18, 2017
You are a small business and your supplier is subject to the PCHF requirements of part 117 or the produce safety regulation	The later of September 18, 2017, or 6 months after your supplier of that raw material or other ingredient is required to comply with the applicable requirements
You are neither a small business nor a very small business and your supplier will not be subject to the PCHF requirements of part 117 or the produce safety regulation	March 17, 2017
You are neither a small business nor a very small business and your supplier will be subject to the PCHF requirements of part 117 or the produce safety regulation	6 months after your supplier of that raw material or other ingredient is required to comply with the applicable requirements

15.15 Table of Abbreviations

Section IV in the Introduction of this guidance includes a table of abbreviations that are used in this guidance. At this time, that Table of Abbreviations does not include all abbreviations that are used in this chapter. See Table 15-6 for an additional abbreviation that we use in this chapter. For the convenience of the reader, Table 15-6 also describes what we mean by “PCHF,” even though this abbreviation is already in section IV in the Introduction of this guidance. We intend to compile all abbreviations in section IV in the Introduction of this guidance when we update the Introduction. When we do so, we intend to delete Table 15-6 from this chapter, because it would be duplicative.

Table 15-6 Table of Abbreviations

Abbreviation	What It Means
PCHF	“Preventive Controls for Human Food” (requirements in 21 CFR part 117 for hazard analysis and risk-based preventive controls for human food in accordance with section 418 of the FD&C Act)
SAHCODH Hazard	Hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans

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