

Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program

Guidance for Industry

Draft Guidance

This guidance document is being distributed for comment purposes only.

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov/>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Jenny Murphy, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-402-6246, e-mail: Jenny.Murphy@fda.hhs.gov.

Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <https://www.fda.gov/AnimalVeterinary/default.htm> or <https://www.regulations.gov/>.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
June 2018**

Contains Nonbinding Recommendations

Draft–Not for Implementation

Table of Contents

I.	PURPOSE.....	4
II.	CONSIDERATIONS TO KEEP IN MIND IF YOU ESTABLISH AND IMPLEMENT A SUPPLY-CHAIN PROGRAM.....	4
III.	OVERVIEW OF THE REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM.....	5
	A. Applicable Requirements of Part 507.....	5
	B. “Receiving Facilities” and “Suppliers”	5
	C. Produce Safety Regulation	6
	D. Foreign Supplier Verification Program Regulation	6
	E. Accredited Third-Party Certification Regulation.....	7
IV.	UNDERSTAND THE HAZARD.....	7
V.	REQUIREMENT TO ESTABLISH AND IMPLEMENT A SUPPLY-CHAIN PROGRAM (21 CFR 507.105).....	7
	A. Requirement to Establish and Implement a Supply-Chain Program	7
	B. How Your Corporate Parent Can Participate in Establishing and Implementing Your Supply-Chain Program.....	8
	C. Exceptions to the Requirement to Establish and Implement a Supply-Chain Program.....	9
	D. Requirement When a Supply-Chain-Applied Control is Applied by an Entity Other than the Receiving Facility’s Supplier	10
	E. Role of the Preventive Controls Qualified Individual in the Supply-Chain Program.....	11
VI.	GENERAL REQUIREMENTS APPLICABLE TO A SUPPLY-CHAIN PROGRAM (21 CFR 507.110).....	11
	A. What the Supply-Chain Program Must Include	11
	B. Appropriate Supplier Verification Activities	12
	C. Assurance that a Hazard Has Been Significantly Minimized or Prevented	13
	D. Considerations in Approving Suppliers and Determining the Appropriate Supplier Verification Activities and the Frequency with Which They Are Conducted	14
	E. Supplier Nonconformance.....	19
VII.	RESPONSIBILITIES OF THE RECEIVING FACILITY (21 CFR 507.115)	20
	A. Your Responsibility to Approve Suppliers	20
	B. Your Responsibility to Determine and Conduct Appropriate Supplier Verification Activities	20
	C. What You May Not Accept from a Supplier as a Supplier Verification Activity .	21
	D. Audit Provided by the Supplier	22
VIII.	USING APPROVED SUPPLIERS (21 CFR 507.120)	22

Contains Nonbinding Recommendations

Draft–Not for Implementation

A.	Approving Suppliers	22
B.	Written Procedures for Receiving Raw Materials and Other Ingredients.....	22
IX.	DETERMINING APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES (INCLUDING DETERMINING THE FREQUENCY OF CONDUCTING THE ACTIVITY) (21 CFR 507.125) ...	26
X.	CONDUCTING SUPPLIER VERIFICATION ACTIVITIES FOR RAW MATERIALS AND OTHER INGREDIENTS (21 CFR 507.130)	26
A.	Requirement to Conduct Supplier Verification Activities	26
B.	Specific Requirements When the Hazard Requiring a Preventive Control is a SAHCODHA Hazard.....	27
C.	Alternative Supplier Verification Activity If the Supplier Is a “Qualified Facility”	28
D.	Alternative Supplier Verification Activity If the Supplier is a Certain Type of Produce Farm	30
E.	Alternative Supplier Verification Activity If the Supplier Is a Shell Egg Producer That Is Not Subject to the Requirements of 21 CFR Part 118.....	31
F.	Financial Conflict of Interest	32
XI.	ONSITE AUDIT (21 CFR 507.135)	33
A.	Who Conducts an Onsite Audit?	33
B.	Consideration of Food Safety Regulations.....	35
C.	Substitution of an Inspection for an Audit.....	36
D.	Audits Conducted to Meet the Requirements of Subpart E Do Not Have to Comply with the Requirements of the Accredited Third-Party Regulation.....	37
XII.	RECORDS DOCUMENTING THE SUPPLY-CHAIN PROGRAM	37
XIII.	COMPLIANCE DATES	44
XIV.	REFERENCES	46
APPENDIX A –	GLOSSARY OF TERMS	48
Definitions	Established in 21 CFR 507.3	48
Other Terms	Used in This Guidance.....	51
APPENDIX B –	TABLE OF ABBREVIATIONS AND ACRONYMS USED IN THIS GUIDANCE.....	53

Contains Nonbinding Recommendations

Draft–Not for Implementation

**Hazard Analysis and Risk-Based Preventive Controls
for Food for Animals: Supply-Chain Program**

Draft Guidance for Industry

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Purpose

The purpose of this guidance is to help a receiving facility comply with the requirements of 21 CFR part 507, subpart E of the preventive controls for animal food (PCAF) regulation for establishing and implementing a supply-chain program for its suppliers. See section III.B and the list of terms in Appendix A for the definition of a “receiving facility.” This guidance 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 E to review and assess the entity’s applicable documentation, and document that review and assessment.

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

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

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

If you are an importer, see section V.C.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 E such that importers and receiving facilities do not have to duplicate verification activities. Importantly, 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 an animal food importer, and you choose to comply with the FSVP regulation and have appropriate documentation of that compliance rather than conducting supplier verification

Contains Nonbinding Recommendations

Draft–Not for Implementation

activities in accordance with subpart E (see 21 CFR 507.105(a)(2)), you should refer to our draft guidance on the FSVP regulation (Ref. 1).

III. Overview of the Requirements for a Supply-Chain Program

A. Applicable Requirements of Part 507

Subpart C of part 507 requires a facility to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (21 CFR 507.33). Subpart C of part 507 also identifies several types of possible preventive controls, including process controls (21 CFR 507.34(c)(1)), sanitation controls (21 CFR 507.34(c)(2)), and supply-chain controls (21 CFR 507.34(c)(3)). The requirements for supply-chain controls are established in subpart E (Supply-Chain Program). We list the requirements of subpart E for a supply-chain program in Table 1. In the remainder of this guidance, we provide recommendations for how you can comply with each of these requirements.

Table 1. Requirements for a Supply-Chain Program in Subpart E

Section	Description
507.105	Requirement to establish and implement a supply-chain program
507.110	General requirements applicable to a supply-chain program
507.115	Responsibilities of the receiving facility
507.120	Using approved suppliers
507.125	Determining appropriate supplier verification activities (including determining the frequency of conducting the activity)
507.130	Conducting supplier verification activities for raw materials and other ingredients
507.135	Onsite audit
507.175	Records documenting the supply-chain program

B. “Receiving Facilities” and “Suppliers”

Subpart E applies to a “receiving facility.” Part 507 defines a “receiving facility” as a facility that is subject to subparts C and E of part 507 and that manufactures/processes a raw material or other ingredient that it receives from a supplier. (See 21 CFR 507.3). Part 507 defines a “supplier” as the establishment that manufactures/processes the animal 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 507.3).

Under subpart E, entities such as brokers, 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 507 provides that such entities can conduct certain activities specified in subpart E on behalf of a receiving facility. (See 21 CFR 507.115).

Contains Nonbinding Recommendations

Draft–Not for Implementation

Examples of receiving facilities are:

- A facility that receives raw agricultural commodities (RACs) such as corn and then manufactures/processes swine food
- A facility that manufactures a complete and balanced extruded dog food using beef, rice, vitamin premix, and other ingredients
- A facility that manufactures a vitamin-mineral top dress for livestock food using vitamins, minerals, and other ingredients

Examples of suppliers are:

- A farm that grows RACs such as corn that are supplied to a feed mill
- A facility that manufactures a vitamin premix that is supplied to a facility that manufactures a complete and balanced extruded dog food
- A facility that manufactures vitamins that are supplied to a facility that manufactures a vitamin-mineral top dress for livestock food

See also section V.D 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 21 CFR part 112), because growing, harvesting, and packing activities are under different management).

C. 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 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 507.

Some provisions of subpart E (i.e., 21 CFR 507.105(c), 507.110(d)(2)(ii), 507.130(d), and 507.175(c)(13)) refer to the provisions of the produce safety regulation.

D. 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

Contains Nonbinding Recommendations

Draft–Not for Implementation

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.

Some provisions of subpart E (i.e., 21 CFR 507.105(a)(2) and 507.175(c)(2)) refer to the provisions of the FSVP regulation.

E. 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)¹ and 806² of the FD&C Act (certifications concerning imported foods and voluntary qualified importer program, respectively).

Some provisions of part 507 (i.e., the definition of “qualified auditor” in 21 CFR 507.3 and the requirements for onsite audits in 21 CFR 507.135(d)) refer to the provisions of the accredited third-party certification regulation.

IV. Understand the Hazard

Part 507 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 507.3 and the glossary of terms in Appendix A. For background and details about hazards, including hazards that could require a supply-chain-applied control, see Chapter 3 of draft guidance #245 – Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Ref. 2).

V. Requirement to Establish and Implement a Supply-Chain Program (21 CFR 507.105)

A. Requirement to Establish and Implement a Supply-Chain Program

With some exceptions (see 21 CFR 507.105(a)(2) and (a)(3)), subpart E requires a receiving facility to establish and implement a risk-based supply-chain program for those raw materials

¹ 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.

² 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 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.

Contains Nonbinding Recommendations

Draft–Not for Implementation

and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. See 21 CFR 507.105(a)(1).

The supply-chain program must be written (21 CFR 507.105(b)). The written supply-chain program is part of a receiving facility's food safety plan (see 21 CFR 507.31(c)(3)). 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, see section XII.

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 supplier has also applied one or more preventive controls for that hazard to raw materials or other ingredients that your supplier provides to you. In addition, you are not required to implement a preventive control, including a supply-chain applied 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 507.36).

Subpart E does not require you to establish and implement a supply-chain program to control hazards associated with animal food-contact substances. A current good manufacturing practice (CGMP) provision requires that animal food-packaging materials are safe and suitable. See 21 CFR 507.25(a)(3).

B. How Your Corporate Parent Can Participate in Establishing and Implementing Your Supply-Chain Program

As discussed in the final rule establishing part 507, your corporate parent (as the owner, operator, or agent in charge) can be active in developing and implementing your food safety plan (see Responses 239, 439, and 461 in 80 FR 56170 at 56240, 56297, and 56308, respectively). For example, an individual at the corporate level may be the preventive controls qualified individual (PCQI). See 21 CFR 507.3 and Appendix A for the definition of "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 X.B.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 507.208, 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

Contains Nonbinding Recommendations

Draft–Not for Implementation

electronically and you can access applicable records maintained at the corporate level electronically, we consider the records to be onsite.

C. Exceptions to the Requirement to Establish and Implement a Supply-Chain Program

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

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 507. 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 507.105(a)(2). We are providing separate guidance to help importers who are subject to the FSVP regulation to comply with the requirements of the FSVP regulation.³

2. Exception for animal food supplied for research or evaluation use

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

- Is not intended for retail sale and is not sold or distributed to the public (21 CFR 507.105(a)(3)(i));
- Is labeled with the statement “Animal food for research or evaluation use” (21 CFR 507.105(a)(3)(ii));
- Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the animal food is used only for this purpose, and any unused quantity is properly disposed of (21 CFR 507.105(a)(3)(iii)); and
- Is accompanied with documents, in accordance with the practice of the trade, stating that the animal food will be used for research or evaluation purposes and cannot be sold or distributed to the public (21 CFR 507.105(a)(3)(iv)).

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

³ Even if you implement a supply-chain program in accordance with subpart E 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.

Contains Nonbinding Recommendations

Draft–Not for Implementation

The quantity of the animal food should be limited to the amount anticipated to be needed to perform the research, analysis, or quality assurance procedures. The amount of animal food used in research or for evaluation can vary based on the type of animal 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, a few ounces of a color additive may be needed for research, 10 pounds of an animal food ingredient could be a small quantity for performing a laboratory analysis for pesticides, and 200 pounds of an animal food ingredient may be needed if conducting a feeding study in cattle. Any unused portion must be properly disposed of (21 CFR 507.105(a)(3)(iii)).

The exemption for research or evaluation would apply to a raw material or other ingredient used in feeding studies that involve a discrete set of test subjects for the research or evaluation purposes. For example, the exemption would apply if the animal food raw material or other ingredient is incorporated into a pet food and is to be fed to pets as part of a palatability study of a pet food. The raw material or other ingredient must be supplied in a small quantity consistent with the research purpose and meet the other requirements for the exemption described in 21 CFR 507.105(a)(3).

D. 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 507.105(c).

An example of where this requirement could apply 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). 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).

Contains Nonbinding Recommendations

Draft–Not for Implementation

In the final rule establishing part 507, we noted that 21 CFR 507.105(c) may have limited applicability to raw material and other ingredients used in animal food (80 FR 56170 at 56298). The previous example is not representative of animal food production and is used to illustrate how the requirement in 21 CFR 507.105(c) may be implemented.

We do not expect the receiving facility to follow all of the requirements of subpart E applicable to approving suppliers and conducting supplier verification when verifying control by a non-supplier in the supply chain (e.g., a harvesting or packing operation). Instead, the receiving facility must verify the supply-chain-applied control or obtain documentation of an appropriate verification activity from another entity, review and assess the documentation, and document that review and assessment (see 21 CFR 507.105(c)).

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

The supply-chain program in subpart E is a preventive control (see 21 CFR 507.34(c)(3)), and preventive controls must be written (21 CFR 507.34(b)). The preventive controls are part of your food safety plan (21 CFR 507.31(c)(2)), and your food safety plan must be prepared, or its preparation overseen by, a PCQI (21 CFR 507.31(b) and 507.53(a)(1)).

VI. General Requirements Applicable to a Supply-Chain Program (21 CFR 507.110)

A. What the Supply-Chain Program Must Include

Subpart E 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 507.110(a), the general requirements are:

- Using approved suppliers as required by § 507.120 (21 CFR 507.110(a)(1));
- Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 507.125 (21 CFR 507.110(a)(2));
- Conducting supplier verification activities as required by §§ 507.130 and 507.135 (21 CFR 507.110(a)(3));
- Documenting supplier verification activities as required by § 507.175 (21 CFR 507.110(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 § 507.175, 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 § 507.175 (21 CFR 507.110(a)(5)).

Contains Nonbinding Recommendations

Draft–Not for Implementation

B. Appropriate Supplier Verification Activities

Section 21 CFR 507.110(b) of subpart E specifies four appropriate supplier verification activities for raw materials and other ingredients. We discuss these in sections VI.B.1 through VI.B.4.

1. Onsite audits (21 CFR 507.110(b)(1))

See 21 CFR 507.130(b), 21 CFR 507.135, 21 CFR 507.175(c)(7) for details about the requirements for onsite audits, and sections X.B, XI, and XII for our recommendations for how to comply with those requirements.

2. Sampling and testing of the raw material or other ingredient (21 CFR 507.110(b)(2))

Subpart E provides that sampling and testing of a raw material or other ingredient is an appropriate supplier verification activity (see 21 CFR 507.110(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 animal food 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 animal 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 animal food matrix you will be testing, and use a method that has a sensitivity appropriate to detect that hazard.

See 21 CFR 507.175(c)(8) and section XII for a list of required documentation when you conduct sampling and testing as a supplier verification activity. See section VII.B.2 for a discussion of the flexibility the regulation provides for your supplier to conduct and document sampling and testing of raw materials and other ingredients, for the hazard it controls, and to provide such documentation (such as in a Certificate of Analysis (COA)) to you in lieu of your conducting such sampling and testing yourself.

3. Review of the supplier's relevant food safety records (21 CFR 507.110(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

Contains Nonbinding Recommendations

Draft–Not for Implementation

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 extruded cat food using meat meal and rely on your supplier (the renderer making the meat meal) to control metal in the meat meal that you will use to produce the extruded cat food, you could obtain copies of the monitoring records for the preventive control that the renderer uses to control metal in meat meal.

Relevant food safety records also include records demonstrating that your supplier has verified control of a hazard by its own supplier, when applicable. Such records could include records of your supplier's audit of its supplier's food safety activities. For example, if you produce a complete sheep food and obtain a mineral premix from your supplier, you could obtain a copy of your supplier's records documenting the audits of the facilities supplying the individual minerals.

See 21 CFR 507.175(c)(9) and section XII for a list of required documentation when you conduct a review of the supplier's relevant food safety records as a supplier verification activity.

4. Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient (21 CFR 507.110(b)(4))

Subpart E 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 this supplier on a biennial rather than annual basis as provided by 21 CFR 507.130(b)(2), you could review the records demonstrating the results of the supplier's environmental monitoring program (if applicable) during the year that you do not conduct an audit.

See 21 CFR 507.175(c)(10) and section XII 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.

C. Assurance that a Hazard Has Been Significantly Minimized or Prevented

The supply-chain program in subpart E is a type of preventive control and, thus, must comply with the requirements applicable to preventive controls in 21 CFR 507.34. Under 21 CFR 507.34(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 507.110(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

Contains Nonbinding Recommendations

Draft–Not for Implementation

to the PCAF requirements in part 507 are required to develop and implement a food safety plan that will significantly minimize or prevent hazards associated with the animal food manufactured, processed, packed or held by the facility (see 21 CFR 507.31) and to document they are following their plan (see 21 CFR 507.55).

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

As noted in section VI.A, subpart E specifies that you must approve suppliers and determine appropriate supplier verification activities (including determining the frequency of conducting the activity). See 21 CFR 507.110(a)(1) and 21 CFR 507.110(a)(2). Section 21 CFR 507.110(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 VI.D.1 through VI.D.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 an animal food received from that supplier. See a discussion of the exception in 21 CFR 507.110(d)(2) and in section VI.D.5.

As noted in sections VII.A and VII.B, only you can approve suppliers, but subpart E 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.

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 animal food, conducted in accordance with 21 CFR 507.33. See 21 CFR 507.110(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 507.110(d)(1)(i). In the following paragraph, we explain the requirements of part 507 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 507 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 animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. See 21 CFR 507.33(a). If you determine that there are any hazards that require a preventive control, with few exceptions part 507 further requires that you must identify and implement a preventive control. See 21 CFR 507.34(a). When the preventive control will be applied to a raw material or other ingredient before receipt, part 507 requires that you establish and implement a risk-based supply-chain program for that raw material or other ingredient. See 21 CFR 507.105.

Contains Nonbinding Recommendations

Draft–Not for Implementation

As part of your hazard analysis, you would evaluate the hazard to assess the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. See 21 CFR 507.33(c)(1). 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 to humans or animals (SAHCODHA), 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 507.130(b) and the discussion in section X.B. 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 an animal 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 507.33(c)(2). If, for example, you are purchasing a flavor enhancer that will be applied to a pet food post heat treatment, and you expect that a sanitation control will be applied to address the environmental pathogen *Salmonella*, you could ask to review the flavor enhancer producer's written procedures for the environmental monitoring it does to verify the sanitation controls. See 21 CFR 507.49(b)(3). You also could periodically verify your supplier's controls by sampling and testing the flavor enhancer for *Salmonella*. Because *Salmonella* is a hazard for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death to humans or animals, you also would conduct an annual onsite audit to verify that your supplier controls *Salmonella* when it manufactures the flavor enhancer by using a kill step such as heat treatment of liver digest used to make the flavor enhancer and sanitation controls to significantly minimize contamination from *Salmonella* in the environment, with environmental monitoring to verify controls for *Salmonella*.

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 507.110(d)(1)(iii) (see the discussion in section VI.D.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.

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 507.110(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 verification activities to your supplier's supplier, but there is flexibility in how you could do this. For example, 21 CFR 507.110(a)(5) allows you to verify a control applied by your supplier's supplier, or, to obtain

Contains Nonbinding Recommendations

Draft–Not for Implementation

documentation from another entity (such as your direct supplier) that shows that your supplier's supplier is applying the control.

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.

3. Supplier performance

The third 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 supplier performance. See 21 CFR 507.110(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 507.110(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 animal food and other FDA compliance actions related to animal food safety (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, and information relevant to the supplier's compliance with those laws and regulations) (21 CFR 507.110(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 animal food, and responsiveness of the supplier in correcting problems (21 CFR 507.110(d)(1)(iii)(C)).

As noted in section VI.D.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.

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 the supplier's food safety programs (e.g., a sanitation control program, or a mycotoxin control program);

Contains Nonbinding Recommendations

Draft–Not for Implementation

- Asking the supplier to provide documents such as an animal food safety plan and third-party food safety and good manufacturing practice audit results;
- Conducting a pre-approval site visit to assess programs and process capabilities; and
- A system with defined metrics to evaluate supplier performance, examples may include 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 an animal food safety issue).

Applicable food safety regulations

You should determine what FDA food safety regulations a potential supplier is subject to, such as the CGMP and PCAF requirements in 21 CFR part 507, the produce safety regulation (21 CFR part 112), the requirements applicable to low-acid canned foods (21 CFR 500.23, 500.24, and parts 108 and 113), CGMPs for medicated feeds (21 CFR part 225), 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 website "Supplier Evaluation Resources" for resources that are available to help you evaluate the supplier's compliance with relevant FDA regulations (Ref. 3).

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 regulatory requirements. Mechanisms to do so include:

- Asking the supplier to provide documentation of any recent regulatory inspections on file;
- 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 website "Supplier Evaluation Resources" (Ref. 3); and
- Searching for actions that we publicize, such as animal food recalls, updates on foodborne illness outbreaks, and suspension of a facility's registration. We generally make these available from our animal and veterinary homepage (Ref. 4).

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 compliance 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.

Contains Nonbinding Recommendations

Draft—Not for Implementation

Part 507 includes several provisions that reflect that some suppliers operate in a foreign country. See, e.g., the definition of “qualified auditor” in 21 CFR 507.3 and the provisions of 21 CFR 507.105(a)(2), 507.130(c), 507.135(c)(1)(ii), 507.135(c)(2), and 507.175(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, when applicable, consider relevant laws and regulations of that country, and information relevant to the supplier’s compliance with those laws and regulations. See 21 CFR 507.110(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, 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 draft guidance, we have not developed a systems recognition process for animal food. Therefore, there are no signed systems recognition arrangements with any foreign food safety authority related to animal food. The currently existing systems recognition arrangements relate solely to human food and do not apply to animal food.

Supplier’s food safety history

Before you became subject to the requirements of subpart E, 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 E, you would consider this same type of information for suppliers that you approve in compliance with subpart E.

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 actions. For example, you obtain a meat meal for use in pet food from a supplier that is controlling biological hazards (e.g., *Salmonella*) and become aware that meat meal from this supplier has been associated with a physical hazard (e.g., large bone fragments). You should consider whether you should implement verification activities related to the control of physical hazards to prevent bone fragments in the meat meal you receive for a period of time adequate to demonstrate that problems that could lead to the presence of bone fragments have been resolved.

Contains Nonbinding Recommendations

Draft–Not for Implementation

4. Other factors

Section 507.110(d)(1)(iv) specifies that you must consider any other factors as appropriate and necessary, such as storage and transportation practices, in (1) approving suppliers, (2) determining appropriate supplier verification activities, and (3) determining the frequency of conducting those activities. For 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 ingredients from a facility that is owned by your corporate parent, you may consider your knowledge of corporate-wide animal 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 V.B of a circumstance where an individual at the corporate level is the PCQI for the purposes of the supply-chain program.

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

Section 507.110(d)(2) provides that considering supplier performance can be limited to the supplier's compliance history (as required by 21 CFR 507.110(d)(1)(iii)(B)), if the supplier is: (i) A qualified facility as defined by 21 CFR 507.3; (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.

E. Supplier Nonconformance

Section 507.110(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 507.42 ("Corrective actions and corrections") to ensure that raw materials or other ingredients from the supplier do not cause animal food that you manufacture or process to be adulterated under section 402 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:

- Discontinuing use of the supplier until the cause or causes of nonconformance or adulteration are adequately addressed;
- Notifying the supplier of the problem and requesting documentation of corrective actions taken by the supplier;

Contains Nonbinding Recommendations

Draft–Not for Implementation

- 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 animal food.

VII. Responsibilities of the Receiving Facility (21 CFR 507.115)

Section 507.115 describes your responsibilities as a receiving facility. As noted in section III.B, subpart E 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 507.115 both specifies this flexibility provided by subpart E and places some bounds on that flexibility. We discuss this flexibility and its bounds in sections VII.A through VII.D.

A. Your Responsibility to Approve Suppliers

Section 507.115(a)(1) specifies that the receiving facility must approve suppliers. Although 21 CFR 507.115(a)(2) through (a)(4) provide some flexibility for other entities to determine and conduct appropriate supplier verification activities (see section VII.B), ultimately the receiving facility is responsible for its supply-chain program (see the discussion in the final rule establishing part 507, Response 430 in 80 FR 56170 at 56294). See section VI.D for considerations in approving suppliers. See section VIII for the requirement to approve suppliers before receiving raw materials and other ingredients from those suppliers and the requirement to establish written procedures for receiving raw materials and other ingredients.

As noted in section III.B, the definition of “supplier” in part 507 means that a broker or distributor is not a supplier; the supplier is the establishment that manufactures/processes the animal 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 animal food, raises the animal, or grows the food as a supplier of the animal food that you purchase from that broker or distributor.

B. Your Responsibility to Determine and Conduct Appropriate Supplier Verification Activities

Section 507.115(a)(2) requires that the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of subpart E. However, sections 507.115(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 VI.D for considerations in determining appropriate supplier verification activities and the frequency of conducting them.

Contains Nonbinding Recommendations

Draft–Not for Implementation

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

Under 21 CFR 507.115(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 507.115(a)(3)(i));
- Document that written procedures for receiving raw materials and other ingredients are being followed by the entity (21 CFR 507.115(a)(3)(ii)); and
- Determine, conduct, or both determine and conduct the appropriate supplier verification activities (21 CFR 507.115(a)(3)(iii)), with appropriate documentation.

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

2. Supplier verification activities that the supplier can conduct and document

Under 21 CFR 507.115(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 507.115(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 animal foods, or lots, contained in a specific shipment have been met. Sampling and 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.

C. What You May Not Accept from a Supplier as a Supplier Verification Activity

Section 507.115(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 507.115(b)(1));
- An audit conducted by its supplier of that supplier (21 CFR 507.115(b)(2));

Contains Nonbinding Recommendations

Draft–Not for Implementation

- A review by its supplier of that supplier’s own relevant food safety records (21 CFR 507.115(b)(3)); or
- The conduct by its supplier of other appropriate supplier verification activities for that supplier (see 21 CFR 507.115(b)(4)).

The only supplier verification activities in which the supplier can play a role are sampling and testing (see section VII.B.2) and providing an audit of the supplier conducted by a third party (see section VII.D).

D. Audit Provided by the Supplier

Under 21 CFR 507.115(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 E applicable to audits (i.e., 21 CFR 507.130(f) and 507.135). We discuss these requirements applicable to audits in sections X.F and XI, respectively.

VIII. Using Approved Suppliers (21 CFR 507.120)

As noted in sections VI.A and VII.A, subpart E requires that a receiving facility approve suppliers. See 21 CFR 507.110(a)(1) and 507.115(a)(1).

A. Approving Suppliers

Section 507.120(a) specifies that the receiving facility must approve suppliers in accordance with the requirements of 21 CFR 507.110(d), and document that approval, before receiving raw materials and other ingredients from those suppliers. As discussed in section VI.D, 21 CFR 507.110(d) 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.

B. Written Procedures for Receiving Raw Materials and Other Ingredients

Section 507.120(b) specifies that:

- Written procedures for receiving raw materials and other ingredients⁴ must be established and followed (21 CFR 507.120(b)(1));

⁴ As noted in the glossary of terms in Appendix A, 21 CFR 507.3 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.

Contains Nonbinding Recommendations

Draft–Not for Implementation

- 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 507.120(b)(2)); and
- Use of the written procedures for receiving raw materials and other ingredients must be documented (21 CFR 507.120(b)(3)).

You have flexibility to design appropriate written procedures for receiving raw materials and other ingredients that are tailored to your facility and operations. 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, and criteria to approve temporary suppliers). Written procedures to ensure that raw materials or 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 E 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 507.115(a)(3)). A written procedure is appropriate to help ensure you are receiving raw materials and other ingredients only from an approved supplier. 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 VII.A and VIII.A), 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 the checklist from the broker/distributor at the time of receipt. In the following paragraphs, 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 ingredients

Contains Nonbinding Recommendations

Draft–Not for Implementation

(Ref. 5). 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 and refer to a list of approved suppliers to verify that the raw material or ingredient is received from an approved supplier (e.g., put a check mark on the receiving document if the supplier is an approved supplier) (Refs. 6 and 7).

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 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, material received, and the quantity of 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 E 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 507.120(b)(2) and (Ref. 7). 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 crisis (e.g., a tornado or severe drought or flooding in the area where the supplier is located);
- A major equipment breakdown at the facility of a sole supplier of an animal 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 website 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

Contains Nonbinding Recommendations

Draft–Not for Implementation

adequate verification activities before acceptance for use. See 21 CFR 507.120(b)(2). For example, if you are receiving a raw material or ingredient such as poultry by-product meal and your temporary supplier controls *Salmonella*, you could sample and test each shipment of food from the temporary 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 poultry by-product meal.

You should use unapproved suppliers only on a temporary basis until you are able to fully evaluate and approve a different 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, 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 raw material or other ingredient 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 raw material or other ingredient 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 experiences an emergency.

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 E 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 507.120(b)(2). You should document the verification activities that you conducted before accepting raw materials or other ingredients from a temporary supplier.

Contains Nonbinding Recommendations

Draft–Not for Implementation

IX. Determining Appropriate Supplier Verification Activities (Including Determining the Frequency of Conducting the Activity) (21 CFR 507.125)

Section 21 CFR 507.125 requires that appropriate supplier verification activities (including the frequency of conducting the activity) be determined in accordance with the requirements of 21 CFR 507.110(d). Section 21 CFR 507.110(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 507.110(d) and our recommendations for complying with those requirements, see section VI.D.

X. Conducting Supplier Verification Activities for Raw Materials and Other Ingredients (21 CFR 507.130)

Section 21 CFR 507.130 specifies requirements to conduct one or more of the supplier verification activities specified in 21 CFR 507.110(b), provides for alternative supplier verification activities in certain circumstances, and prohibits certain financial conflicts of interest. We discuss these provisions in sections X.A through X.F.

A. Requirement to Conduct Supplier Verification Activities

With some exceptions, 21 CFR 507.130(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)⁵ 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 507.130(c), (d), and (e). See the discussion of the exceptions to this requirement in sections X.C through X.E.

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 (Refs. 5, 8, and 9). Periodic verification provides routine feedback on the supplier's performance, rather than only when a problem arises (Ref. 5).

Subpart E includes specific requirements for conducting onsite audits (21 CFR 507.135) and for documenting the conduct of supplier verification activities (21 CFR 507.175). See sections X.B and XI for discussions of conducting an onsite audit as a supplier verification activity. See section XII for a discussion of documenting of supplier verification activities.

⁵ The list of appropriate supplier verification activities is specified in 21 CFR 507.110(b). The receiving facility determines which activity to conduct in accordance with 21 CFR 507.110(d). See the discussion of the appropriate supplier verification activities in section VI.B. See the discussion of determining appropriate supplier verification activities in section VI.D.

Contains Nonbinding Recommendations

Draft–Not for Implementation

B. Specific Requirements When the Hazard Requiring a Preventive Control is a SAHCODHA Hazard

1. Requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODHA hazard

With one exception (see section X.B), 21 CFR 507.130(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 or animals (i.e., SAHCODHA hazard):

- The appropriate supplier verification activity is an onsite audit of the supplier (21 CFR 507.130(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 507.130(b)(1)(ii)).

SAHCODHA hazards are those for which a recall of a violative product posing such a hazard is designated as “Class 1” under 21 CFR 7.3(m)(1) (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 or animals include pathogens (e.g., *Salmonella* in pet food) and nutrient deficiencies and toxicities (e.g., copper toxicity in food for sheep). Animal food containing a SAHCODHA hazard is considered reportable food, 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 Amendments Act of 2007” and the annual reports of the Reportable Food Registry for examples of animal food that we have considered to contain SAHCODHA hazards (Refs. 10, 11, and 12).

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 intend 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 onsite audit, see 21 CFR 507.135 and section XI. For a discussion of documentation associated with an onsite audit, see section XII.

Contains Nonbinding Recommendations

Draft–Not for Implementation

2. Exception to the requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODHA hazard

The exception to the requirement to conduct an annual onsite audit when the hazard requiring a preventive control is a SAHCODHA 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 507.130(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 V.E).

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 dog food, and obtain meat meal 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 meat meal 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 V.B of a circumstance where an individual at the corporate level is the PCQI for the purposes of the supply-chain program.

However, if a SAHCODHA hazard is identified for the animal 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.

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

Section 21 CFR 507.130(c) provides for an alternative supplier verification activity if a supplier is a qualified facility as defined by 21 CFR 507.3. 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 507.110(b) (i.e., onsite 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 SAHCODHA hazard, if you:

Contains Nonbinding Recommendations

Draft–Not for Implementation

- Obtain written assurance that the supplier is a qualified facility as defined by § 507.3:
 - Before first approving the supplier for an applicable calendar year (21 CFR 507.130(c)(1)(i)); and
 - On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year (21 CFR 507.130(c)(1)(ii)); 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 animal food (21 CFR 507.130(c)(2)(i)); 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 (21 CFR 507.130(c)(2)(ii)).

A facility is a qualified facility if it is a very small business as that term is defined in part 507. See the definitions for “qualified facility” and “very small business” in 21 CFR 507.3 and in the Glossary in Appendix A. A qualified facility is not subject to the PCAF requirements for hazard analysis and risk-based preventive controls, including the supply-chain program. The supplier is responsible for determining whether it is a qualified facility; you are responsible for obtaining 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.⁶ See 21 CFR 507.7(a). In its attestation, the qualified facility attests that: (1) it meets the definition of a qualified facility; and (2) either it has established and is following certain food safety practices, or it is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. See section VI.D.3 for a discussion of the applicability of

⁶ For a facility that begins manufacturing, processing, packing or holding food before September 17, 2019, the facility must make its first submission by December 16, 2019. For a facility that begins manufacturing, processing, packing or holding food after September 17, 2019, the facility must make its first submission before beginning operations. See 21 CFR 507.7(c)(2).

Contains Nonbinding Recommendations

Draft–Not for Implementation

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 3942b. A supplier that is a qualified facility could provide a copy of that form to its customers to help them comply with 21 CFR 507.130(c)(1). (A qualified facility that submits the attestation electronically could print a copy for this purpose). Subpart E 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 animal food, or a statement that the qualified facility is in compliance with an applicable non-Federal food safety law (see 21 CFR 507.130(c)(2)). For example, a qualified facility that supplies a flavor enhancer could include in its written assurance: (1) a brief written description of its preventive controls to control *Salmonella* in the flavor enhancer (e.g., heat treatment at a specified temperature for a specified time period), or (2) a statement that it complies with the food safety laws of the state in which it is located.

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

Section 21 CFR 507.130(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 507.110(b) or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODHA 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 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 average monetary value of all food sold and the relative value of food sold directly to qualified end users as

Contains Nonbinding Recommendations

Draft–Not for Implementation

compared to all other buyers,⁷ and FDA has not withdrawn the farm’s exemption. The supplier is responsible for determining whether it is not subject to the produce safety regulation; you are responsible for obtaining written assurance from the supplier that it is not subject to the produce safety regulation.

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 farm 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 VI.D.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.

E. 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 507.130(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 507.110(b), or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODHA 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. The supplier is responsible for determining whether it not subject to the requirements for the production, storage, and

⁷ 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.”

Contains Nonbinding Recommendations

Draft–Not for Implementation

transportation of shell eggs; you are responsible for obtaining 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 shell egg producer 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 VI.D.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.

F. Financial Conflict of Interest

Section 21 CFR 507.130(f) specifies that there must not be any financial conflicts of interests that influence the results of the verification activities listed in 21 CFR 507.110(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 507.130(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 507.130(f) do not prohibit employees of a supplier from performing the functions specified in 21 CFR 507.115 in accordance with 21 CFR 507.115. See the discussion of functions that a supplier can perform in accordance with 21 CFR 507.115(a)(4) in section VII.B.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 507.130(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 507.115(c) in section VII.D.

Contains Nonbinding Recommendations

Draft–Not for Implementation

XI. Onsite Audit (21 CFR 507.135)

Section 21 CFR 507.135 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 XI.A through XI.C.

A. Who Conducts an Onsite Audit?

Section 21 CFR 507.135(a) requires that an onsite audit of a supplier be performed by a qualified auditor (see also 21 CFR 507.53(b)). Section 21 CFR 507.3 defines “qualified auditor” as a person who is a qualified individual as defined in part 507 and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. 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 in 21 CFR part 1, subpart M.

Part 507 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 and safe animal 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 507.3 and in the Glossary in Appendix A. The requirements applicable to a qualified auditor are set forth in 21 CFR 507.53(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 507. 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) (Ref. 13), a qualified auditor should 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 animal 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

Contains Nonbinding Recommendations

Draft–Not for Implementation

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 507 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 XI.D), 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 (Ref. 13). 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.

See 21 CFR 1.650(a).

The Guidance on Accredited Third-Party Certification further recommends education and/or experience for entry level auditors (audit agents) and lead auditors, as well as auditor skills such as observational, reasoning, analytical, and communication skills (Ref. 13). For purposes of the third-party certification program, auditors should be trained to understand and properly apply FDA's food safety requirements under the FD&C Act and FDA regulations for purposes of auditing. Technical training may vary depending on the processes and products being audited. Training methods may include classroom training, annual food safety training, and joint audits with a qualified trainer to help the audit agent apply classroom learning (Ref. 13).

The Global Food Safety Initiative (GFSI) provisions for auditor competency in "GFSI Food Safety Auditor Competencies" are also useful in determining the knowledge, experience, and skills for a qualified auditor (Ref. 14). The GFSI's auditor competency model lists three main components for auditor competencies: (1) auditing skills and knowledge; (2) technical skills and knowledge; and (3) behavior and systems thinking. Within each main component, GFSI provides details of specific tasks and the required auditor knowledge and skills to perform the specific tasks.

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.

Contains Nonbinding Recommendations

Draft–Not for Implementation

B. Consideration of Food Safety Regulations

Section 21 CFR 507.135(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., 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 507.135(a) would vary depending on what regulations apply to the supplier.

A supplier that is subject to the PCAF requirements must have a food safety plan (see 21 CFR 507.31). If your supplier is subject to the PCAF 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 mineral premix for which you had identified copper toxicity as a hazard from a supplier subject to the PCAF requirements, you would audit the supplier (or obtain documentation of an audit performed by a third party) to determine whether the supplier’s manufacturing process adequately controlled the level of copper in the mineral premix. Because the supplier was subject to the PCAF requirements, the onsite audit should include a review of the supplier’s food safety plan. The auditor should review whether the manufacturing process had been validated to significantly minimize excess levels of copper in the mineral premix and should examine whether the supplier had implemented the manufacturing procedures in accordance with its food safety plan (e.g., through observing the establishment’s procedures and reviewing records).

An onsite 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 onsite audit of a manufacturing/processing facility subject to the PCAF requirements should address process, 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 animal food.

There are several national and international auditing schemes 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

Contains Nonbinding Recommendations

Draft–Not for Implementation

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 507.135. 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, if any, and its implementation, with respect to the hazard being controlled, are likely to satisfy the requirements for an onsite audit.

C. Substitution of an Inspection for an Audit

Section 21 CFR 507.135(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 507.135(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 507.135(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 animal 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 507.135(c)(2)).

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 was sufficiently relevant to compliance with applicable FDA food safety regulations to credibly substitute for an onsite audit. For example, inspection by a State agency to determine whether a facility satisfies the requirements of the BSE regulations (see 21 CFR part 589) could constitute an appropriate inspection that could substitute for an audit if the hazard being controlled is BSE, but an inspection by a State agency to determine whether a facility meets the BSE regulation could not substitute for an inspection if the hazard being controlled by the supplier is a nutrient deficiency or toxicity hazard.

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 VI.D.3 for information on countries for which we have a Food Safety Systems Recognition Arrangement or other cooperative arrangement with a foreign country.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Some countries issue certifications or recognitions to facilities for compliance with certain requirements such as for hazard analysis and critical control points (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 PCAF 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 onsite audit on a less frequent basis than annually (see section X.B.2).

D. Audits Conducted to Meet the Requirements of Subpart E Do Not Have to Comply with the Requirements of the Accredited Third-Party Regulation

Section 21 CFR 507.135(d) specifies that if an onsite audit is solely conducted to meet the requirements of part 507 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 507.135 may be conducted by a person who had been accredited under part 1, subpart M; 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.

XII. Records Documenting the Supply-Chain Program

Section 21 CFR 507.175 specifies that the records documenting the supply-chain program are subject to the requirements of subpart F of part 507. See 21 CFR 507.175(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 507.212 in subpart F explains how you can use existing records to satisfy the recordkeeping requirements of part 507.

Section 21 CFR 507.175 requires that you must review the records of the supply-chain program in accordance with 21 CFR 507.49(a)(4). See 21 CFR 507.175(b). Under 21 CFR 507.49(a)(4)(ii), records of the supply-chain program must be reviewed by (or under the oversight of) a PCQI within a reasonable time after the records are made 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.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Table 2 lists the records required for the supply-chain program. See 21 CFR 507.175(c).

Table 2. List of Records Required for the Supply-Chain Program

Section	Description	Discussion
507.175(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 507.206.
507.175(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 E.
507.175(c)(3)	Documentation of the approval of a supplier	Your written determination of the basis for approving the supplier. You could include a paper list of approved suppliers or an electronic system that can generate a list of approved suppliers as needed.
507.175(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.
507.175(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.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Section	Description	Discussion
507.175(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 VI.D.
507.175(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 animal food 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, identify 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>

Contains Nonbinding Recommendations

Draft–Not for Implementation

Section	Description	Discussion
507.175(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.
507.175(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 by (or under the oversight of) a PCQI within a reasonable time after the records are made 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 507.49(a)(4).
507.175(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 should 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 should have a record of the information you considered.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Section	Description	Discussion
507.175(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 or animals.	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 21 CFR 507.31. See the discussion in section X.B.2 for examples of what such a written determination could address.
507.175(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 § 507.3; 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 3942b). 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 X.C of the two different types of attestation.

Contains Nonbinding Recommendations

Draft—Not for Implementation

Section	Description	Discussion
507.175(c)(13)	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; 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).	You and your suppliers have some flexibility to determine the appropriate documentation in a way that works best for your specific business relationship.
507.175(c)(14)	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; 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).	You and your suppliers have some flexibility to determine the appropriate documentation in a way that works best for your specific business relationship.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Section	Description	Discussion
507.175(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 is 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.
507.175(c)(16)	Documentation of actions taken with respect to supplier nonconformance.	Your documentation of actions taken with respect to supplier nonconformance would depend on the nature of the nonconformance. See the examples of potential supplier nonconformance in section VI.E.
507.175(c)(17)	Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier.	If you obtain the documentation of the verification activity from another entity, the documentation you receive from the other entity should be similar to the documentation you would have if you had conducted the activity yourself.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Section	Description	Discussion
507.175(c)(18)	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 §§ 507.130(f) and 507.135; 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.	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.

XIII. Compliance Dates

In the preamble of the final rule establishing part 507, we provided compliance dates for the requirements of the supply-chain program in subpart E. See Table 33 in the final rule, 80 FR 56170 at 56329. 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 the CGMP or PCAF requirements (or both) of part 507. For those suppliers subject to part 507, you are not required to conduct supplier verification activities until after your supplier's compliance date is reached.

Contains Nonbinding Recommendations

Draft–Not for Implementation

For your convenience, Table 3 provides the information from Table 33 in the preamble of the final rule establishing part 507.

Table 3. Compliance Dates for the Requirements of the Supply-Chain Program

Situation	Compliance date:
You are a small business and your supplier will be subject to the CGMPs, but not the preventive control requirements, of part 507.	6 months after your supplier of that raw material or other ingredient is required to comply with the CGMP requirements of part 507.
You are a small business and your supplier is subject to the CGMP and PCAF requirements of part 507.	The later of: September 17, 2018 or 6 months after your supplier of that raw material or other ingredient is required to comply with part 507.
You are not a small business or a very small business and your supplier will be subject to CGMPs, but not the preventive control requirements, of part 507.	6 months after your supplier of that raw material or other ingredient is required to comply with the CGMP requirements of part 507.
You are not a small business or a very small business and your supplier will be subject to the CGMP and preventive control requirements of part 507.	The later of: September 18, 2017 or 6 months after your supplier of that raw material or other ingredient is required to comply with part 507.

Contains Nonbinding Recommendations

Draft–Not for Implementation

XIV. References

1. FDA. 2018. Draft Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals. (<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm593060.htm>). Last accessed 3/9/18.
2. FDA. 2018. Draft Guidance #245 – Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. (<https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM592870.pdf>). Last accessed 3/9/18.
3. FDA. 2016. Supplier Evaluation Resources. (<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm>). Last accessed 3/9/18.
4. FDA. 2018. Animal and Veterinary Website. (<https://www.fda.gov/AnimalVeterinary/default.htm>). Last accessed 3/9/18.
5. Zaura, D., 2005. Effective Supplier Program. Food Quality Magazine, December/January, 86-88. (<http://www.foodqualityandsafety.com/article/effective-supplier-programs/2/>). Last accessed 3-23-18.
6. International Featured Standards (IFS). 2014. IFS Food: Standard for auditing quality and food safety of food products, Version 6. (https://www.ifs-certification.com/images/standards/ifs_food6/documents/standards/IFS_Food_V6_en.pdf). Last accessed 3-23-18.
7. Safe Quality Food Institute (SQFI). 2014. SQF Code 7.2. A HACCP-Based Supplier Assurance Code for the Food Industry. (http://www.sqfi.com/wp-content/uploads/SQF-Code_Ed-7.2-July.pdf). Last accessed 3-23-18.
8. Eldridge, B., 2012. Supplier Management: Six Steps to Selecting the Right Supplier. Food Safety Magazine, 18 (4): 30-31. (<https://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2012/supplier-management-six-steps-to-selecting-the-right-supplier/>.) Last accessed 3-26-18.
9. Eastern Research Group, Inc. (ERG). 2004. Good Manufacturing Practices (GMPs) for the 21st Century - Food Processing. Section Four. Common Food Safety Problems in the U.S. Food Processing Industry: A Delphi Study. (<https://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm110914.htm>.) Last accessed 3.12.18.

Contains Nonbinding Recommendations

Draft–Not for Implementation

10. FDA. 2009. “Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007.” (<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/RFR/ucm180761.htm>.) Last accessed 3-26-18.
11. FDA. 2010. “Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2).” (<https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM213214.pdf>.) Last accessed 3-26-18.
12. FDA. 2016. “The Reportable Food Registry: A Five-Year Overview of Targeting Inspection Resources and Identifying Patterns of Adulteration, September 8, 2009 – September 7, 2014.” (<https://www.fda.gov/downloads/food/complianceenforcement/rfr/ucm502117.pdf>) Last accessed 3-26-18.
13. FDA. 2016. Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff. (<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM455331.pdf>.) Last accessed 3.9.18.
14. Global Food Safety Initiative & The Consumer Goods Forum 2013. “GFSI Food Safety Auditor Competencies, Edition 1.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Appendix A – Glossary of Terms

Definitions Established in 21 CFR 507.3

Adequate means that which is needed to accomplish the intended purpose in keeping with good public (human and animal) health practice.

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

Audit means 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 an audited entity's food safety processes and procedures.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm means farm as defined in 21 CFR 1.227.

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the animal food or onto surfaces that contact the animal food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and animal food-contact surfaces of equipment.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Holding means storage of animal food and also includes activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that animal food, such as fumigating animal food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that animal food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks.

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

Lot means the animal food produced during a period of time and identified by an establishment's specific code.

Manufacturing/ processing means making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating animal 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, pelleting, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject animal food to decomposition, that indicate that animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Packing means placing animal food into a container other than packaging the animal food and also includes repacking and activities performed incidental to packing or repacking an animal food (e.g., activities performed for the safe or effective packing or repacking of that animal food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public (human or animal) health significance.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified auditor means a person who is a qualified individual as defined in part 507 and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. 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 part 1, subpart M. (Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications).

Qualified facility means 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 as defined in part 507, 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 part 507) 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.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal 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.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Raw agricultural commodity (RAC) has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act (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 means a facility that is subject to subparts C and E of part 507 and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supplier means the establishment that manufactures/processes the animal 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.

Supply-chain-applied control means 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.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Very small business means a business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).

Written procedures for receiving raw materials and other ingredients means 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).

Other Terms Used in This Guidance

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.

Customer: An entity that receives a product, raw material, or ingredient from a receiving facility.

Identified hazard: A known or reasonably foreseeable 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.

Contains Nonbinding Recommendations

Draft—Not for Implementation

SAHCODHA 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 or animals.

Third-party audit: An audit conducted by a qualified auditor that is not an employee of either the receiving facility or the supplier.

Contains Nonbinding Recommendations

Draft–Not for Implementation

Appendix B – Table of Abbreviations and Acronyms Used in This Guidance

Abbreviation or Acronym	What It Means
BSE	Bovine Spongiform Encephalopathy
CFR	Code of Federal Regulations
CGMP	current good manufacturing practice
COA	Certificate of Analysis
FDA	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
GFSI	Global Food Safety Initiative
HACCP	Hazard Analysis and Critical Control Point
<i>L. monocytogenes</i>	<i>Listeria monocytogenes</i>
PCAF	“Preventive Control for Animal Food” (requirements in 21 CFR part 507 for hazard analysis and risk-based preventive controls for animal food in accordance with 418 of the FD&C Act)
PCQI	preventive controls qualified individual
SAHCODHA	Serious Adverse Health Consequences or Death to Humans or Animals
USDA	U.S. Department of Agriculture