DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11, 16, 117, 500, 507, and 579

[Docket No. FDA–2011–N–0922]

RIN 0910–AG10

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is adding regulations for the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals. These regulations will, for the first time, establish requirements for the current good manufacturing practice (CGMP) for food for animals. In addition, we are adding requirements for certain domestic and foreign animal food facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. We are taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to humans and animals and to implement new statutory provisions in the FDA Food Safety Modernization Act (FSMA). The rule is intended to build an animal food safety system for the future that makes modern science- and risk-based preventive controls the norm across all sectors of the animal food system.

DATES: This rule is effective November 16, 2015, except for paragraph (2) of the definition of ''qualified auditor'' in § 507.3, and §§ 507.12(a)(1)(ii), 507.105(a)(2), 507.105(c), 507.110(d)(2)(ii), 507.130(d), 507.135(d), 507.175(c)(2), and 507.175(c)(13). FDA will publish a document in the **Federal Register** announcing the effective dates of paragraph (2) of the definition of ''qualified auditor'' in § 507.3, §§ 507.12(a)(1)(ii), 507.105(a)(2), 507.105(c), 507.110(d)(2)(ii), 507.130(d), 507.135(d), 507.175(c)(2), and 507.175(c)(13). Certain provisions have later compliance dates as discussed in section LIII ''Effective and Compliance Dates.''

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Executive Summary

Purpose and Coverage of the Rule

This rule is part of FDA's implementation of FSMA, which intends to better protect public (human and animal) health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This rule establishes new requirements for the production of animal food by registered food facilities in two ways.

First, this rule creates new CGMP regulations that specifically address the manufacturing, processing, packing, and holding of food for animals. These requirements apply to establishments that are required to register with FDA as a food ''facility.'' Second, this rule creates new requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. As with the CGMPs, these requirements apply to establishments that are required to register with FDA as a food facility. This portion of the rule requires registered animal food facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards, unless an exemption applies. Facilities must also monitor their controls, conduct verification activities to ensure the controls are effective, take appropriate corrective actions, and maintain records documenting these actions.

This final rule is the result of significant stakeholder engagement, beginning before the proposed rule. In response to extensive stakeholder input on the proposed rule, we revised key provisions in a supplemental notice of proposed rulemaking. After the supplemental notice of proposed rulemaking, we conducted even more outreach to the stakeholder community to ensure that the risk-based, preventive requirements in this final rule are practical and protective of public (human and animal) health.

Summary of the Major Provisions of the Rule

The final rule establishes CGMP provisions to ensure the safety and suitability of animal food. Specifically, the rule establishes requirements in the following areas:

- Personnel;
- Plant and grounds;
- Sanitation;
- Water supply and plumbing;
- Equipment and utensils;
- Plant operations;
- Holding and distribution; and
- Holding and distribution of human food by-products for use as animal food.

We have added flexibility and clarity to the CGMPs in response to comments. These CGMPs establish baseline standards for producing safe animal food that take into consideration the unique aspects of the animal food industry and provide flexibility for the wide diversity in types of animal food facilities. In addition, the CGMPs in this final regulation allow human food facilities subject to and in compliance with CGMPs for human food and in compliance with all applicable FDA human food safety requirements to only follow the specific CGMPs for the holding and distribution of human food by-products for use as animal food, as long as they do not further process the by-product. Under this final rule, all other requirements of part 507, including the hazard analysis, preventive controls and supply-chain program provisions, would not apply to these by-products of human food production.

The final rule implements the requirements of FSMA for covered facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the rule establishes requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls;
- Monitoring;
- Corrective actions and corrections;
- Verification;
- Supply-chain program;
- Recall plan; and
- Associated records.

We have added flexibility and clarity to these provisions in response to comments. Although there are similarities between these requirements of FSMA and the requirements of food safety systems known as Hazard Analysis and Critical Control Point (HACCP) systems, not every provision in FSMA is identical to the provisions of HACCP systems, and we have revised much of our terminology to distinguish FSMA's requirements for hazard analysis and risk-based preventive controls from HACCP requirements. A facility subject to the rule must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring preventive controls. The first step of a hazard analysis is hazard identification, which must consider known or reasonably foreseeable hazards, including biological, chemical, and physical hazards. The hazard analysis must consider hazards that may be present in the animal food because they occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain. We continue to believe that hazards that may be intentionally introduced for economic gain will need preventive controls in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past. Economically motivated adulteration that affects product integrity or quality, for example, but not animal food safety, is out of the scope of this rule.

A facility subject to the rule must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by the facility will not be adulterated. The rule establishes preventive control management components (monitoring, corrective actions and corrections, and verification) as appropriate to ensure the

effectiveness of the preventive controls. One way we have clarified the risk-based flexibility of these requirements is by clearly stating in the final rule that a facility must take into account the nature of the preventive control and the facility's food safety system when considering which activities are appropriate for that facility.

We have also added flexibility and made risk-based modifications for specific preventive control management components. For example, the final rule allows flexibility for the specific records required to document monitoring of refrigeration controls during storage of an animal food that requires time/temperature control for safety. These records can be either affirmative records demonstrating temperature is controlled or ''exception records'' demonstrating loss of temperature control. As another example, the rule includes tailored, less burdensome requirements for corrections. A correction is defined in this rule as an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected animal food from entering commerce). The final rule clarifies that corrections must be taken in a timely manner and must be recorded when appropriate, but they do not, for example, need to be included in a written plan or accompanied by a reanalysis of the written food safety plan.

As a third example, the final rule provides flexibility for which verification activities must occur. In general, a facility is required to conduct verification activities, as appropriate to the nature of the preventive control and its role in the facility's food safety system, including validation, verification of monitoring, verification of corrective actions, verification of implementation and effectiveness, and reanalysis. Validation is not required for all controls. For example, the rule specifies that validation is not required for certain types of preventive controls (*i.e.,* sanitation controls, supply-chain controls, and the recall plan) and provides flexibility for the facility to not validate other preventive controls with a written justification based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system. Product testing and environmental monitoring are listed as possible verification activities, but, like other preventive control management components in general, they are only required as appropriate to the animal food, facility, the nature of the preventive control, and the preventive control's role in the facility's food safety system. In many cases, neither product testing nor environmental monitoring will be appropriate. For example, there would be little or no benefit to product testing or environmental monitoring in facilities that pack or hold raw agricultural commodities that are rarely consumed unprocessed, such as soybeans.

A facility must reanalyze the food safety plan as a whole at least once every 3 years. The final rule provides the flexibility for a facility to only reanalyze the applicable portion of the food safety plan under certain other circumstances, such as when a facility becomes aware of new information about potential hazards associated with an animal food.

The final rule also adds flexibility to the preventive controls requirements and recognizes the reality of modern distribution chains by not requiring a manufacturing/processing facility to implement a preventive control in certain circumstances when the hazard requiring a preventive control will be controlled by another entity in the distribution chain. For example, if a facility's customer (or another entity in the distribution chain) will control the hazard, then that facility can rely on its customer to provide written assurance that the identified hazard will be controlled by an entity in the distribution chain, with flexibility for how the customer provides that written assurance depending on whether the customer, or an entity subsequent to the customer, will control the hazard. We have identified four specific circumstances in which a manufacturing/processing facility can rely on another entity in the distribution chain to control a hazard, with practical solutions explained further in section XXVII. We also have provided flexibility for a facility to establish, document, and implement an alternative system that ensures adequate control, at a later distribution step, of the hazards in the food product distributed by a manufacturing/processing facility such that the facility would not need to implement a preventive control.

We revised the proposed provisions for a supplier program to add flexibility, recognizing that the receiving facility and the supplier may be separated by several entities in a supply chain. We are allowing entities such as distributors, brokers, and aggregators to determine, conduct, and document appropriate supplier verification activities as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. However, because the approval of suppliers is ultimately the responsibility of the receiving facility, the rule specifies that only a receiving facility can approve suppliers. To improve clarity and readability we redesignated the proposed provisions into eight distinct sections of regulatory text in a newly established subpart E (Supply-Chain Program).

Each facility subject to the rule must have a recall plan for an animal food with a hazard requiring a preventive control.

Many activities required by the final rule must be conducted (or overseen) by a preventive controls qualified individual, a new term we are coining here. A preventive controls qualified individual is a qualified individual who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system.

The rule establishes several exemptions (including modified requirements in some cases) from the requirements for hazard analysis and risk-based preventive controls. All of these exemptions are expressly authorized by FSMA. A facility that manufactures, processes, packs, or holds food and that is required to register with FDA would be required to comply with the requirements for hazard analysis and risk-based preventive controls unless it is covered by an exemption, as shown in the following table.

PROPOSED EXEMPTIONS FROM THE NEW REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Who or what is exempt from the requirements for hazard analysis and risk-based preventive controls	Notes
"Qualified Facility" as defined by FSMA: Business with average annual sales of <$500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or • Very small business, which the rule defines as a business (including any subsidiaries or 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)	Modified requirements apply—*i.e.*, a qualified facility is required to: • Notify FDA about its status and either: ○ Notify FDA that it is addressing hazards through preventive controls and monitoring; or ○ Notify FDA that it complies with applicable non-Federal food safety regulations, and notify consumers of the name and complete business address of the facility where the animal food was manufactured or processed. • The notification is in the form of an attestation, and must be submitted every 2 years, during the same timeframe as the facility is required to update its facility registration.
• Low-risk, on-farm activities performed by small business (<500 full-time equivalent employees). -or- • Low-risk, on-farm activities performed by a very small business (dollar threshold of $2,500,000, as described previously).	Small and very small on-farm businesses conducting only the specified low-risk activities are exempt from the requirements for hazard analysis and risk-based preventive controls. We define the low-risk, on-farm activities that qualify for the exemption, including the specific animal foods to which they relate (such as repacking roughage products, or cracking grains). • The exemption applies only with respect to microbiological hazards regulated under part 113. • The facility must be in compliance with part 113.
Activities that are subject to the "low-acid canned food" requirements of part 113 (21 CFR part 113).	These activities will be established in FDA's forthcoming rule for produce safety.
Activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety) (21 U.S.C. 350h).	
Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.	A facility that stores raw agricultural commodities that are fruits and vegetables is not exempt.
A facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.	Modified requirements apply for the storage of unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

The rule includes procedures for withdrawing a qualified facility exemption, in the event of an active investigation of a foodborne illness outbreak that is directly linked to the facility, or if FDA determines that it is necessary to protect the public (human and animal) health and prevent or mitigate a foodborne illness outbreak based on relevant conditions or conduct associated with the qualified facility. The final rule provides procedures for a facility to appeal an order to withdraw a qualified facility exemption, for a facility to request an informal hearing, for the conduct of an informal hearing, for an appeal, for revoking an order to withdraw a qualified facility exemption, and for reinstating an exemption that was withdrawn.

The rule finalizes recordkeeping provisions associated with the new provisions for hazard analysis and risk-based preventive controls. These records allow facilities to show, and FDA to determine, compliance with the new requirements. To meet these requirements, a facility may use existing records as appropriate.

Costs and Benefits

This final regulation requires domestic and foreign facilities to adopt a food safety plan, perform a hazard analysis, and to institute preventive controls for the mitigation of those hazards identified as requiring a preventive control. It also includes requirements for facilities to institute risk-based environmental monitoring, product testing, and a supply-chain program as appropriate to the animal food, the facility and the nature of the preventive controls, as well as a requirement to institute controls to help prevent hazards associated with economically motivated adulteration. The total annualized costs are estimated at $139.0 to $170.7 million per year (over 10 years at a 7 percent discount rate), and $135.6 to $166.7 million per year (over 10 years at a 3 percent discount rate). The total annualized benefits to pets are estimated at $10.1–$138.0 million.

ESTIMATED TOTAL COSTS AND BENEFITS

[Millions]

	One-time	Annual	Total annualized cost at 7% [1]	Total annualized cost at 3% [1]
Total Costs	$135.6 to $160.1	$119.7 to $147.9	$139.0 to $170.7	$135.6 to $166.7
Total Benefits to Pets	[2] N/A	$10.1 to $138.0	$10.1 to $138.0	$10.1 to $138.0

[1] Total annualized cost equal to annualized one-time cost plus annual cost.
[2] N/A = Not applicable

TABLE OF ABBREVIATIONS AND ACRONYMS

Abbreviation/Acronym	What it means
AAFCO	Association of American Feed Control Officials.
AFSS	Animal Feed Safety System.
BAM	Bacteriological Analytical Method.
Bioterrorism Act	Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188).
CCP	Critical Control Point.
CFR	Code of Federal Regulations.
CGMP	Current Good Manufacturing Practice.
Codex	Codex Alimentarius Commission.
CPG	Compliance Policy Guide.
CVM	Center for Veterinary Medicine.
EPA	U.S. Environmental Protection Agency.
EU	European Union.
FDA	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FOIA	Freedom of Information Act.
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture.
FSIS Validation Guidelines	FSIS' Compliance Guidelines on HACCP Systems Validation.
FSMA	FDA Food Safety Modernization Act.
FSPCA	Food Safety Preventive Controls Alliance.
FSVP	Foreign Supplier Verification Programs.
GAP	Good Agricultural Practices.
GFSI	Global Food Safety Initiative.
GRAS	Generally Recognized as Safe.
HACCP	Hazard Analysis and Critical Control Point.
HHS	U.S. Department of Health and Human Services.
ISO	International Organization for Standardization.
LACF	Thermally processed low-acid foods packaged in hermetically sealed contain (commonly called "low-acid canned foods").
N/A	Not Applicable.
NACMCF	The National Advisory Committee on Microbiological Criteria for Foods (advisory committee chartered under the USDA).
NIFA	National Institute of Food and Agriculture of the U.S. Department of Agriculture.
OMB	Office of Management and Budget.
PAS	British Standards Institute ''Publically Available Specification 222:2011''.
PFP	Partnership for Food Protection.
PHS	Public Health Service Act.
PRA	Paperwork Reduction Act.
PSA	Protein Surveillance Assignment.
RA	Risk Assessment.
RAC	Raw Agricultural Commodity.
RFR	Reportable Food Registry.
Section 103(c)(1)(C) draft RA	Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.
Section 103(c)(1)(C) RA	Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm (Final).
TCS	Time/Temperature Control for Safe Animal Food.
USDA	U.S. Department of Agriculture.

I. Background

A. FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public (human and animal) health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported animal food. To that end, we proposed the seven foundational rules listed in table 1 and requested comments on all aspects of these proposed rules.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed rule for preventive controls for animal food.	78 FR 64736, October 29, 2013.

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

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed rule for preventive controls for human food.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety rule	78 FR 3504, January 16, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP rule	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification rule.	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration rule (human food only).	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food	2014 proposed sanitary transportation rule.	79 FR 7006, February 5, 2014.

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

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

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

As FDA finalizes these seven foundational rulemakings, we are putting in place a framework for food safety that is modern and brings to bear the most recent science on provisions to enhance food safety, that is risk-based and focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a great deal of outreach to the stakeholder community to find the right balance in these regulations of flexibility and accountability.

Since FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, Webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Refs. 1 and 2). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in food safety. FDA believes these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will protect consumers into the future.

B. Stages in the Rulemaking for the Animal Food Preventive Controls Rule

With regard to this rulemaking, we published proposed provisions in the 2013 proposed animal food preventive controls rule and we published new and re-proposed provisions in the 2014 supplemental notice. In the 2014 supplemental notice, we reopened the comment period only with respect to specific proposed provisions. In addition, we emphasized that the re-proposed provisions we included in the regulatory text were based on a preliminary review of the comments.

In this document, we use the broad term ''proposed animal food preventive controls rule'' to refer to the complete proposed regulatory text, including both the proposed provisions we published in the 2013 proposed animal food preventive controls rule and the new and re-proposed provisions we published in the 2014 supplemental notice. We use the narrow terms ''2013 proposed preventive controls rule for animal food'' and ''2014 supplemental notice'' to refer to specific text published in the **Federal Register** of October 29, 2013 (78 FR 64736) and September 29, 2014 (79 FR 58476), respectively. We use the terms ''final preventive controls rule for animal food'' and ''this rule'' to refer to the regulations we are establishing as a result of this rulemaking.

C. Summary of the Major Provisions of Proposed Rule for Preventive Controls for Food for Animals

As part of our implementation of new statutory provisions in FSMA, we proposed to add, in newly established part 507, regulations for CGMPs. In addition, we proposed to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. As directed by FSMA (see section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g)), these new provisions would apply to domestic and foreign facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) and our regulation for Registration of Food Facilities (21 CFR part 1, subpart H; the section 415 registration regulations). As directed by FSMA (see section 418(l) and (m) of the FD&C Act), we proposed to establish

modified requirements for certain facilities. We requested comment on all aspects of the proposed requirements, including an opportunity for public comment on potential requirements for product testing, environmental monitoring, a supplier program, and hazards that may be intentionally introduced for purposes of economic gain.

We proposed to establish the requirements for CGMPs, for hazard analysis and risk-based preventive controls, and related requirements in new 21 CFR 507 as shown in table 3:

TABLE 3—PROPOSED SUBPARTS IN NEW PART 507

Subpart	Title
A	General Provisions.
B	Current Good Manufacturing Practice.
C	Hazard Analysis and Risk-Based Preventive Controls.
D	Withdrawal of an Exemption Applicable to a Qualified Facility.
E	Reserved.
F	Requirements Applying to Records That Must be Established and Maintained.

D. Draft Risk Assessment

We issued for public comment a ''Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the section 103(c)(1)(C) draft risk assessment (RA)) (78 FR 64428, October 29, 2013). The purpose of the section 103(c)(1)(C) draft RA was to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk when conducted in a facility co-located on a farm. We used the tentative conclusions of the section 103(c)(1)(C) draft RA to propose to exempt food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities from the requirements for hazard analysis and risk-based preventive controls. We are including the final risk assessment (the section 103(c)(1)(C) RA) in the docket established for this document (Ref. 3).

E. Public Comments

We received more than 2400 public submissions on the 2013 proposed preventive controls rule for animal food, and more than 140 public submissions on the 2014 preventive controls supplement notice, each containing one or more comments. We received submissions from diverse members of the public, including animal food facilities (including facilities co-located on a farm); farms; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; pet owners, consumer groups; Congress, Federal, State, local, and foreign Government Agencies; and other organizations. Some submissions included signatures and statements from multiple individuals. Comments address virtually every provision of the proposed animal preventive controls rule. In the remainder of this document, we describe these comments, respond to them, and explain any revisions we made to the proposed preventive controls rule for animal food.

Some comments address issues that are outside the scope of this rule. For example, some comments ask for more inspections of pet food facilities. Other comments express concern about the use of bioengineered animal food ingredients, and ask that animal foods containing such ingredients not be used in pet food. Other comments have concerns with FDA's general obligations for the outcome of regulations it issues and implements, general concerns with FDA's regulation and oversight of industry, concerns about banning specific products or imports from specific countries, testing procedures at the borders, and concerns about animal food marketing. We do not discuss such comments in this document.

II. Legal Authority

The proposed rule contained an explanation of its legal basis under authorities in FSMA, the FD&C Act, and the Public Health Service Act (the PHS Act). After considering comments received in response to the 2013 proposed rule and the 2014 supplemental notice, we made changes in the final rule. The legal authorities relied on for the final rule are generally the same as in the proposed rule unless otherwise described.

A. Current Good Manufacturing Practice Regulations

The CGMP regulations finalized in this document establish current good manufacturing practice requirements for the manufacturing, processing, packing and holding of animal food. FDA's legal authority to require current good manufacturing practice derives from sections 402(a)(3) and (4) and 701(a) of the FD&C Act (21 U.S.C. 342(a)(3) and (4), and 371(a)). Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The CGMP regulations we are establishing are necessary to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

In addition to the FD&C Act, FDA's legal authority for establishing CGMP requirements derives from the PHS Act to the extent such measures are related to communicable disease. Authority under the PHS Act is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary.) The CGMP regulations are necessary to prevent the spread of communicable disease.

The CGMP regulations finalized in this document include limited labeling requirements. These requirements are partly to help prevent accidental co-mingling or mix-ups of products at the facility, which could result in contaminated animal food. Thus, FDA's legal authority for these requirements derives from its authority to require current good manufacturing practice. The labeling requirements also are intended to enable animal producers and owners, and facilities receiving the animal food for further manufacture, to use the animal food appropriately. Accordingly, the requirements are supported by section 403(a)(1) of the FD&C Act, which states that a food is misbranded if its labeling is false or misleading in any particular, and by section 403(i) of the FD&C Act, which states that a food is misbranded unless

its label bears the common or usual name of the food or its ingredients.

B. Hazard Analysis and Risk-Based Preventive Controls

Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act requires that the Secretary issue regulations ''to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. . . .'' Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms ''small business'' and ''very small business,'' taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. Further, section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit ''(t)he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 (of the FD&C Act).''

In addition to rulemaking requirements, section 418 contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to ''prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 (of the FD&C Act). . . .'' In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b) to (i) contain more specific requirements applicable to facilities. These include hazard analysis (section 418(b)), preventive controls (section 418(c)), monitoring (section 418(d)), corrective actions (section 418(e)), verification (section 418(f)), recordkeeping (section 418(g)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)).

Section 103(c)(2)(C) of FSMA requires that the Secretary adopt a final rule with respect to the requirements under sections 418 and 421 of the FD&C Act from which the Secretary may issue exemptions or modifications of the requirements for certain types of facilities. Sections 418(j) to (m) of the FD&C Act and sections 103(c)(1)(D) and (g) of FSMA provide authority for certain exemptions and modifications to the requirements of section 418 of the FD&C Act. These include provisions related to low-acid canned food (section 418(j)); activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety) (section 418(k)); qualified facilities (section 418(l)); facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment (section 418(m)); and facilities engaged only in certain low-risk on-farm activities on certain foods conducted by small or very small businesses (section 103(c)(1)(D) of FSMA). In sections X, XI, XII, and XXXVI we discuss provisions that implement these exemptions and modified requirements.

In the supplemental notice, we included potential requirements for a supplier program, environmental monitoring, and product testing. We are including provisions for such activities in the final rule. Section 418(o)(3) of the FD&C Act provides supplier verification activities and an environmental monitoring program as examples of preventive controls. Section 418(f)(4) of the FD&C Act provides for the use of environmental and product testing programs as part of required verification that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.

In certain circumstances, the final rule does not require a manufacturing/processing facility to implement a preventive control for a hazard requiring a preventive control. Instead, the facility is permitted to rely on a subsequent entity in the distribution chain to significantly minimize or prevent the hazard. In such a circumstance, a facility must disclose in documents accompanying the animal food, that the food is ''not processed to control [identified hazard].'' This requirement is supported by sections 418 and 701(a) of the FD&C Act (21 U.S.C. 350g and 371(a)). The requirement that facilities apply preventive controls to significantly minimize or prevent hazards is fundamental to the public health benefits of the rule. To accommodate the realities of modern food production, the rule allows a facility to rely on a subsequent entity in the distribution chain rather than requiring that facility to apply the control. An animal food may pass through multiple entities in the distribution chain before it reaches consumers. Further, ordinarily it is not apparent from visual examination of the animal food whether a hazard requiring a preventive control has been addressed. Consequently, without labeling, a facility might not know that a facility upstream in the supply chain has not applied a preventive control and is relying on a downstream entity to do so. Therefore, the agency concludes that information that animal food has not been processed to control an identified hazard is necessary for a facility to fulfil its obligation under section 418 when a facility is relying on a subsequent entity to control the hazard. The agency also concludes that such labeling is necessary for the efficient enforcement of the FD&C Act because the labelling is critical for FDA to hold facilities responsible for their obligations under this regulatory scheme. Further, when the hazard can cause a communicable disease, FDA concludes that the requirement is necessary to prevent the spread of communicable disease from one state into another state and relies on sections 311, 361, and 368 of the PHS Act.

FDA concludes that the provisions in subpart C and related requirements in subparts A, E and F should be applicable to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b) (21 CFR 1.225(b))). The plain language of section 418 of the FD&C Act applies to facilities that are required to register under section 415 (section 418(o)(2) of the FD&C Act) and does not exclude a facility from the requirements because food from such a facility is not in interstate commerce. Further, the prohibited act provision associated with section 418 (section 301(uu) of the FD&C Act) does not require interstate commerce for a violation.

FDA also is issuing the provisions in subpart C and related requirements in subparts A, E and F, under sections 402(a)(3) and (4), and 701(a) of the FD&C Act to the extent such requirements are necessary to prevent animal food from being held under insanitary conditions whereby it may become contaminated with filth or rendered injurious to health, or being unfit for food. FDA also is finalizing those provisions under sections 311, 361, and 368 of the PHS Act relating to communicable disease to the extent

those provisions are necessary to prevent the interstate spread of communicable disease.

III. General Comments on the Proposed Rule

(Comment 1) Several comments ask us to develop guidance to accompany the rule, particularly with respect to the new requirements for hazard analysis and risk-based preventive controls. For example, comments ask us to provide guidance on topics such as hazard analysis, environmental monitoring, and validation. Some of these comments ask that drafts of the guidance first be made available for public comment. Some of these comments request that the guidance be available as soon as possible and before the rule becomes effective. Some comments request guidance specific to small businesses. Several comments suggest FDA revisit some current compliance policy guidances in light of FSMA and the proposed rules.

Other comments emphasize the importance of education and outreach and ask us to provide support for ongoing education and outreach, including an active role in providing needed instructional examples and lessons learned from current investigations and foodborne outbreaks. Some comments ask us to convene a scientific workgroup that includes experts in food and laboratory science, public health, proficiency testing, quality control, and other areas on at least an annual basis to assess what hazards should be addressed in food safety plan. Other comments ask us to engage universities and extension in education and training efforts.

Some comments ask that funding and information on funding for training be provided. Other comments assert that we must make available adequate resources to support outreach and technical assistance delivered by State regulatory Agencies, as well as Cooperative Extension programs and non-governmental organizations that work directly with farmers and facilities.

(Response 1) We are developing several guidance documents, including general guidance on hazard analysis and preventive controls, as well as guidance for complying with the CGMP requirements of subpart B (Ref. 4). We will develop and issue this guidance in accordance with our good guidance practices regulation, which establishes criteria for when we issue a guidance document as an initial draft, invite public comment, and prepare a final version of the guidance document that incorporates suggested changes, when appropriate (§ 10.115(g)) (21 CFR 10.115(g)). The public may submit comments on any guidance document at any time (§ 10.115(g)(5)). In addition, we intend to review current guidance documents and make a determination whether they need to be withdrawn or revised based on this final rule.

We agree with comments that stress the importance of education and outreach. A central element of our strategy to gain industry compliance is to help make available to facilities subject to this rule the education and technical assistance they need to understand and implement the requirements (Ref. 5). Within the Agency we are establishing a Food Safety Technical Assistance Network and seeking funding to increase FDA staffing to provide a central source of information to support industry understanding and implementation of FSMA standards (Ref. 5). This will allow us to respond in a timely and consistent way to industry questions on preventive controls technical and compliance issues (Ref. 5).

We also are working in collaboration with the Food Safety Preventive Controls Alliance (FSPCA) to develop training materials and establish training and technical assistance programs (Refs. 5 and 6). The Alliance includes members from FDA, State food protection Agencies, the food (human and animal) industry, and academia. It is funded by a grant to the Illinois Institute of Technology's Institute for Food Safety and Health, a nationally recognized leader in food safety. In addition to developing a standardized preventive controls training curriculum, the FSPCA is developing selected sections of model food safety plans for several food types that will provide needed instructional examples. Although we have provided funding to the FSPCA to develop a standardized preventive controls training curriculum, we are unable to fund training for individual groups who might need particular training materials.

We also are partnering with the National Institute of Food and Agriculture (NIFA) of the U.S. Department of Agriculture (USDA) to administer the FSMA-mandated National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, a grant program to provide technical assistance for FSMA compliance to owners and operators of small and medium-size farms and small food processors (Ref. 7). Such efforts will help ensure widespread voluntary compliance by encouraging greater understanding and adoption of established food safety standards, guidance, and protocols.

(Comment 2) Some comments ask us to explain how we will enforce the rule, particularly with respect to coordination with State and local authorities and with other Federal Agencies. For example, some comments ask whether FDA or the States will pay for inspections, whereas other comments ask us to coordinate inspection of imports with USDA's Food Safety and Inspection Service (FSIS) or ask us to combine our inspections with those of USDA where possible. Some comments express concern about the time gap between the effective date of this rule and the time it will take to incorporate applicable provisions into State law.

(Response 2) We are working through the Partnership for Food Protection (PFP) (a group of dedicated professionals from Federal, State, local, tribal, and territorial governments with roles in protecting the food supply and public health) to develop and implement a national Integrated Food Safety System consistent with FSMA's emphasis on establishing partnerships for achieving compliance (see section 209(b) of FSMA). For an example of our current thinking on establishing partnerships for achieving compliance, see the ''best practices'' document made available by PFP (Ref. 8). This ''best practices'' document provides information to FDA field and State programs on a variety of issues, including how to coordinate compliance activities. Our document entitled ''Operational Strategy for Implementing FSMA'' also recognizes the importance of developing operational partnerships with States and other government counterparts to optimize the effectiveness, efficiency, and consistency of FSMA implementation domestically (Ref. 9).

We are implementing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance (Ref. 10). This new paradigm involves a major reorientation and retraining, for which we are seeking funding, of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities, as well as thousands of State, local, and tribal inspectors (Ref. 10).

(Comment 3) Some comments ask us to reevaluate the proposed animal food preventive controls rule, compare it with existing programs, and identify a mechanism for integrating compliance verification with existing industry and

governmental programs. These comments note that many handlers/processors use and understand voluntary food safety management systems such as HACCP and HACCP-based certification programs and ask us why we proposed to create a separate inspection framework for FSMA, without integrating that inspection framework with existing programs.

(Response 3) We decline this request. As previously discussed, we are establishing this rule as required by section 103 of FSMA (78 FR 64736 at 64743 through 64745 and 64817 through 64818). However, where compliance with this rule mirrors compliance with existing regulatory requirements, there is no need to duplicate existing records, which may be supplemented as necessary to include all of the required information. (See also Response 2 regarding implementation of a national Integrated Food Safety System.)

(Comment 4) Some comments ask us to make the various rules we are establishing to implement FSMA consistent with each other. One comment specifically asks us to harmonize the human and animal food preventive controls final rules to avoid confusion by firms that produce both human and animal food.

(Response 4) We have aligned the provisions of the various rules to the extent practicable. For example, we use the same definitions of ''farm'' and the same terms used in the definition of ''farm'' (*i.e.,* packing, holding, and manufacturing/processing) in this rule, the human food preventive controls rule, and the proposed produce safety rule. However, the statutory direction is not the same for all the rules, and this difference in statutory direction does lead to some differences between the rules. For example, section 418(l) of the FD&C Act (which relates to this rule) provides for modified requirements for facilities that are very small businesses in addition to facilities that satisfy criteria for sales to qualified end-users, but section 419(f) of the FD&C Act (which relates to the proposed produce safety rule) only provides for modified requirements for direct farm marketing.

Likewise, we have worked to align the provisions of this rule with the provisions of the Foreign Supplier Verification Program (FSVP) rule. Again, however, there are statutory differences that lead to some differences between the rules. For example, section 805 of the FD&C Act (21 U.S.C. 348a), applies to an importer, whereas section 418 of the FD&C Act applies to a facility that is required to register under section 415 of the FD&C Act. Except in the circumstance where an importer is also a manufacturer/processor, an importer must conduct a hazard analysis as part of the foreign supplier verification requirements, whereas a facility that is a manufacturer/processor must conduct a hazard analysis to determine whether the requirements of the animal food preventive controls rule apply to it. As another example, section 805 of the FD&C Act does not provide an exemption for small or very small entities, whereas section 418 of the FD&C Act provides an exemption for ''qualified facilities,'' which include very small businesses.

To the extent possible, we have attempted to harmonize the animal food preventive controls final rule with the human food preventive controls final rule. The CGMP (subpart B) requirements address the manufacturing, processing, packing, and holding practices at animal food plants, but are similar to those for human food, where appropriate. Furthermore, § 507.1(d) contains provisions for a human food facility that also manufactures, processes, packs, or holds animal food. This is intended to reduce confusion and increase flexibility for facilities that produce both human and animal food.

(Comment 5) Some comments express concern that we will enforce the rule more strictly for domestic facilities than for foreign facilities, *e.g.,* because we lack the funds and manpower to enforce the rule for foreign facilities. Other comments assert that it is unprecedented for importing countries to regulate the production processes in exporting countries and that no scientific evidence supports such regulation. These comments express concern that this regulatory requirement will greatly increase trading costs and might constitute a barrier to trade for exporting countries.

(Response 5) We intend to enforce this rule in a consistent manner to ensure that imported and domestically produced animal foods are in full compliance with the requirements of this rule. We note that the forthcoming FSVP rule will require importers to help ensure that animal food imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public (human and animal) health protection as those required under this rule. The implementation of these supplier verification programs by U.S. importers will thus provide assurances that imported animal food is in compliance with this regulation.

We disagree that we are seeking to ''regulate the production processes in exporting countries'' inappropriately. This rule provides for a flexible set of principles and a framework for hazard analysis and risk-based preventive controls to be applied to a given production process in order to ensure the production of safe animal food destined for the United States. Mandating that a finished animal food is manufactured under general methods applicable to all animal foods (*e.g.,* good manufacturing practices) is a widely accepted regulatory practice and fundamentally different than mandating that animal food be produced in a certain way. We note that other countries have adopted animal food safety regulations that mandate certain principles and conditions be applied to animal food manufacturing. Because the requirements being implemented by FDA under this regulation are flexible and not prescriptive, we do not agree that this regulation will significantly increase costs or impede trade.

We also disagree that there is no scientific evidence supporting this rule. In the 2013 proposed preventive controls rule for human and animal food, we provided an extensive background discussing the scientific evidence upon which this rule is based (78 FR 3646 at 3659 through 3667, January 16, 2013 and 78 FR 64736 at 64745, October 29, 2013). In addition, the Appendix to the 2013 proposed preventive controls rule provided additional scientific information on activities such as product testing and environmental monitoring to support their role in ensuring safe food and how these align with international standards such as those of Codex Alimentarius (78 FR 64736 at 64834 through 64836).

(Comment 6) Many comments from pet owners are generally supportive of the rule; however, some request additional regulations and oversight for pet food. Many comments state that pet food should meet the same standards as human food. Some comments request that pet food be required to be tested for safety.

(Response 6) The CGMP requirements in subpart B are intended to serve as baseline standards for producing safe animal food across all types of animal food facilities, including pet food facilities. For discussion of the relevance of the CGMP requirements to pet food, see Response 163. Many pet food facilities (as well as facilities producing other animal food) will be subject to the preventive controls requirements of subpart C. These provisions require the pet food manufacturer to identify and evaluate

potential hazards for the pet food to determine whether a preventive control is required (see § 507.33). These could be hazards to the pet consuming the pet food or the person handling the pet food (*e.g.,* Salmonella). The preventive controls provisions also include requirements for product testing for pathogens or other hazards and environmental monitoring for pathogens under certain circumstances (see § 507.49), in order to help ensure the safety of the pet (animal) food. Currently, low-acid canned animal food in a hermetically sealed container (such as canned pet food) is subject to the requirements of § 500.23 (21 CFR 500.23) and part 113 to control microbiological hazards.

(Comment 7) Some comments request communication and coordination with state regulators throughout the FSMA implementation phase. Some comments specifically request training of FDA staff and regulatory partners to inspect animal food facilities because there are differences between animal food and human food facilities. Some comments request that inspectors receive training on the broad range of animal food manufacturing. At least one comment requests we establish a national advisory committee to provide ongoing input throughout FSMA implementation and enforcement. Some comments request that we provide methods for communication with State and other regulatory partners, including possibly a call center or other direct-contact resource for regulators and industry to obtain information on FSMA.

(Response 7) As discussed in Response 1, we are working in collaboration with the FSPCA to develop training materials and programs to be used by industry and regulators. The training will be specific to human or animal food and will include information on developing a food safety plan tailored to each facility's unique hazards. We will consider these and other recommendations for the content of such training as part of that collaborative effort.

As discussed in Responses 1 and 2, we are working through two working groups (FSCPA and PFP) that involve State and local regulators in order to implement this final rule. We will continue to work through these groups, as well as use other methods of communication and coordination (*e.g.,* arranged teleconference meetings with the States (*i.e.,* 50-State calls) to collaborate with State and local regulatory officials to implement this final rule. We will consider these recommendations as we communicate with State and local regulatory partners during the implementation of this final rule.

(Comment 8) Some comments request that this final rule have a provision similar to the proposed produce safety rule that allows a state or foreign country to request a variance from the rule's requirements due to procedures, processes, and practices that ensure a product is not adulterated.

(Response 8) We are implementing these regulations according to the statutory direction of FSMA. A variance request and review process is specified for produce in section 419(c)(2) of the FD&C Act; however, there are no similar provisions in FSMA directing FDA to create a variance process for facilities subject to the preventive controls regulations and we therefore are declining to do so.

(Comment 9) Some comments ask us to take a ''BASE'' approach to implementing FSMA. These comments describe this approach as follows: B stands for borders, a critical area where FDA should be focusing its attention and resources; A stands for audits, recognizing that FDA will need to actively audit states and foreign suppliers; S stands for standard, representing the standards FDA will set by which firms will be audited; and E stands for education, ensuring that all stakeholders know their roles and responsibilities required by the rules.

(Response 9) While we do not intend to follow the BASE approach described in the comment, we expect that some of our implementation efforts will be similar to the approach described. For discussion of our implementation planning, see Responses 1 and 2. To the extent this comment is referring to animal food from foreign suppliers presented for import, this is a subject of the forthcoming FSVP rule.

(Comment 10) Some comments requested exceptions or reduced requirements that were not previously proposed. One comment requests a narrower scope of requirements for facilities involved in the production of chemicals used as food additives or in accordance with generally recognized as safe (GRAS) standards.

(Response 10) We decline these requests. The CGMPs in subpart B and preventive controls in subpart C are written to serve as baseline standards for producing safe animal food across all types of animal food facilities, including those producing food additives or other ingredients.

IV. Definitions in the Section 415 Registration Regulations (21 CFR Part 1, Subpart H)

A. Definitions That Impact a Determination of Whether an Establishment Is a ''Farm''

The 2013 proposed rule for human food preventive controls contained a description (78 FR 3646 at 3675 through 3676) of the current legal and regulatory framework that governs the determination of when an establishment is required to register as a food facility in accordance with the section 415 registration regulations. That description focused on the framework that governs whether an establishment that grows and harvests crops or raises animals satisfies the definition of ''farm,'' because the facility registration requirements of section 415 of the FD&C Act do not apply to ''farms.'' Under that framework, a key factor in whether an establishment falls within the definition of ''farm,'' even with respect to crops it grows and harvests itself, is whether the activities conducted by the establishment fall within definitions of ''harvesting,'' ''packing,'' or ''holding'' (which are within the ''farm'' definition). Another key factor is whether activities conducted by the establishment fall within the definition of manufacturing/processing (which have been outside the ''farm'' definition).

In the 2014 supplemental human preventive controls notice, comments were described regarding proposed revisions to the definitions of ''farm,'' ''harvesting,'' ''packing'' and ''holding,'' as well as comments regarding the triggers for an activity to be considered manufacturing/processing (79 FR 58524 at 58530 through 58538). Additional revisions were proposed to the definitions of ''farm,'' ''harvesting,'' ''packing'' and ''holding'' to address these comments.

Even after the revisions we proposed in the 2014 supplemental human preventive controls notice, some comments assert that the overall ''farm'' definition still presents an unrealistic and incomplete understanding of how most farms in America are structured with regard to their physical location(s) and business models. See table 4 for revised definitions that are being finalized in the human food preventive controls for the section 415 registration regulations and the section 414 recordkeeping regulations.

In section IV of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, comments on the proposed changes to the section 415

registration regulations and to the section 414 recordkeeping regulations are discussed.

TABLE 4—REVISIONS TO THE PROPOSED DEFINITIONS IN THE SECTION 415 REGISTRATION REGULATIONS AND THE SECTION 414 RECORDKEEPING REGULATIONS

Definition	Revision
Farm	• A farm is an ''operation'' rather than an ''establishment.''
	• There are two types of farms: (1) Primary production farm; and (2) secondary activities farm.
Primary production farm	• A primary production farm is ''under one management'' rather than ''under one ownership.''
	• Although a primary production farm continues to be ''in one general physical location,'' we have clarified that ''one general physical location is ''not necessarily contiguous.''
	• A primary production farm is an operation devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. Although some primary production farms both grow and harvest crops, other primary production farms grow crops but do not harvest them, and other primary production farms harvest crops but do not grow them.
	• Treatment to manipulate the ripening of raw agricultural commodities (RACs), and packaging and labeling the treated RACs, without additional manufacturing/processing, is within the ''farm'' definition.
	• We added an example of drying/dehydrating RACs to create a distinct commodity that would fall within the ''farm'' definition (i.e., drying/dehydrating grapes to produce raisins), as well as an example of additional manufacturing/processing that would cause an operation that dries/dehydrates RACs to create a distinct commodity to fall outside the ''farm'' definition (i.e., slicing).
	• We added an example of additional manufacturing/processing that can cause an operation that packages and labels RACs to fall outside the ''farm'' definition (i.e., irradiation).
Secondary activities farm	• A ''secondary activities farm'' is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.
	• A secondary activities farm may also conduct those additional activities allowed on a primary production farm.
Harvesting	• We added additional examples of harvesting activities.
Holding	• We added additional examples of holding activities.
Manufacturing/Processing	• We added additional examples of manufacturing/processing activities.

B. Proposed Revisions to the Definition of Farm

In the human food proposed preventive controls rule, we proposed to revise the ''farm'' definition to (1) Provide for on-farm packing and holding of RACs to remain within the farm definition regardless of ownership of the RACs; (2) include, within the ''farm'' definition, a description of packing activities that include packaging RACs grown or raised on a farm without additional manufacturing/processing; and (3) provide for drying/dehydrating RACs to create a distinct commodity (such as the on-farm drying of grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing, to remain within the farm definition. See section IV.B of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, for a full discussion of comments and responses on the proposed revisions to the farm definition.

In the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, we have revised the definition of farm to replace the term ''under one ownership'' with the term ''under one management.'' As discussed in section IV.B of the final rule for preventive controls for human food, although the original phrase ''under one ownership'' was not referring to a single owner, the ''farm'' definition should reflect modern business models (such as cooperatives, on-farm packinghouses under ownership by multiple growers, food aggregators, and food hubs) and use language that the modern farming community understands. The term ''under one management'' refers to the control structure of the business, that is, the management of the business entity that is the farm operation. Thus, for example, a primary production farm that hires another company as a contract harvester to perform harvesting services on the primary production farm's behalf is not ''under one management'' with the primary production farm just because the primary production farm is directing the contractor's activities performed on the primary production farm's behalf. The primary production farm and the contract harvester have separate and independent management structures because they are separate and independent businesses. (See Response 25 in the final rule for preventive controls for human food). As another example, if a poultry processing company contracts with a primary production farm to raise chickens on the poultry processor's behalf, the poultry processor and the primary production farm are not ''under one management,'' even if their contract strictly controls almost all aspects of the raising of the poultry. The poultry processor and the primary production farm have separate and independent management structures because they are separate and independent businesses.

In the final rule for preventive controls for human food, we also revised the farm definition to add a new category: A ''secondary activities farm.'' (See Response 25 in the final rule for preventive controls for human food). An important limitation on the types of operations that fit within this category is that they must be majority owned (or majority jointly owned) by the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs the secondary activities farm harvests, packs, and/or holds. Thus, both product and majority ownership must link a secondary activities farm to a primary production farm(s).

For example, a primary production farm may own a majority interest in a separate business that holds RACs and processes them into animal food (*e.g.,* a feed mill). If the majority of the RACs held by the feed mill come from the primary production farm that owns the feed mill's majority interest, the feed

mill is a secondary activities farm and may manufacture/process animal food within the farm definition, but only to the extent that the animal food manufactured is consumed at the feed mill or on another farm whose ''one management'' is the same management as the feed mill. However, if the feed mill in this example manufactures/processes animal food that is consumed on farms that are not under the same management as the feed mill, that manufacturing/processing is outside the farm definition, the feed mill is subject to registration under section 415 of the FD&C Act, and its manufacturing/processing of animal food for consumption on farms not under the same management is subject to the requirements of this rule.

To further clarify, a feed mill that is not majority owned by a primary production farm(s) cannot be a secondary activities farm. Also, a feed mill that does not receive more than half of the RACs it holds from primary production farm(s) that own a majority interest in the feed mill cannot be a secondary activities farm. For example, a feed mill owned by a poultry processing company will be required to register as a food facility, unless the feed mill otherwise meets the definition of ''farm.'' When a feed mill is owned by a company such as a poultry processor, it is not majority owned by the primary production farm(s) that supply the majority of the RACs it holds, and therefore the feed mill cannot be a secondary activities farm.

C. Proposed Revisions to Definitions of Harvesting, Holding, Manufacturing/Processing, Mixed-Type Facility, and Packing

See section VIII. for a discussion of comments and responses and revisions to the definitions in part 507 of harvesting, holding, manufacturing/processing, mixed-type facility, and packing. For a discussion of comments and responses to these definitions in the section 415 registration regulations and the section 414 recordkeeping regulations, see section IV.C through IV.G of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

D. Comments on Feed Mills Associated With Fully Vertically Integrated Farming Operations

In the 2014 supplemental notice for animal food, we requested comment on whether feed mills that are part of fully vertically integrated farming operations, including cooperatives that fit this model, that meet the farm definition should be required to register under section 415 of the FD&C Act (and thus would be subject to the rule). For comments that supported applying the final preventive controls rule to feed mills that are part of fully vertically integrated farming operations, we requested input on how the farm definition should be modified. If they were required to register, we also requested comment on whether there should be exemptions from registration under section 415 based on size, such as number of animals being fed or the amount of animal food being fed (based on tonnage, monetary value, or some other factor). Lastly, since there would be no total annual sales figure for the animal food produced by these feed mills, we requested comment on how to value the animal food being fed to animals for purposes of determining whether the feed mill would be a qualified facility (proposed § 507.7) and in particular a very small business.

(Comment 11) Some comments generally agree with our recognition that there are different types of farm models for raising animals but request additional clarification on what we mean by a fully vertically integrated farming operation and the depth of integration within an operation.

(Response 11) Feed mills that are part of fully vertically integrated farming operations, or certain cooperative farming operations that meet the definition of a farm (see § 1.227, as revised by the final rule for preventive controls for human food published elsewhere in this **Federal Register**), are not subject to this final rule because they are not required to register under section 415 of the FD&C Act (see § 507.5(a)). Because expanding on the characteristics of a fully integrated farming operation is beyond the scope of this rule, we decline to further clarify the fully vertically integrated farming operation farming model discussed in the 2014 supplemental notice.

(Comment 12) Some comments do not support modifying the farm definition to subject feed mills that are part of fully vertically integrated farming operations to the requirements of this final rule. These comments state that these feed mills are currently making safe animal food and that some are following industry best practices that would meet or exceed the requirements of our proposed CGMPs. Some comments also state that these feed mills are producing a narrower range of animal food when compared to independent feed mills because these integrated feed mills typically provide animal food to a single species and therefore utilize fewer ingredients, resulting in less chance of harmful error. Some comments note that for large farming operations, feeding of the animals is overseen by dedicated individuals, such as a nutritionist, which ensures an extra layer of oversight for the safety of animal food.

Some comments express concern that feed mills associated with contract farming operations (contract feed mills) will be treated differently because, as proposed in the 2013 proposed rule, they would need to comply with the rule unlike the feed mills that are part of fully vertically integrated farming operations. These comments recommend modifications to the farm definition to incorporate the contract feed mills into the farm definition, resulting in the contract feed mills no longer being required to register under section 415 and therefore no longer being subject to the requirements of this rule. Some comments (including ones that support and ones that oppose modifying the farm definition) generally agree there is no evidence that the safety of animal food varies depending on whether a feed mill is associated with vertically integrated or contract farming. These comments also state that the farm definition as proposed has the potential to create disparity in regulatory requirements that feed mills must follow based solely on the type of farming model with which they are associated (*i.e.,* some will be subject to CGMP and preventive controls requirements, while some will be subject to neither).

Some comments support modifying the farm definition to subject feed mills that are part of fully vertically integrated farming operations to the requirements of this final rule, and some of those comments also support providing an exclusion if it is limited to small on-farm animal food mixers. Other comments contend that some of the feed mills that are part of fully vertically integrated farming operations produce large volumes of animal food that feed a substantial portion of the U.S. food-producing animal population and that these feed mills should be subject to the final rule to ensure continual production of safe animal food. Some comments state concern that the feed mills that are part of fully vertically integrated farming operations could introduce food safety hazards into the human food supply because they are not being adequately controlled due to the feed mills' exemption from this rule.

Comments that support modifying the farm definition to subject feed mills that are part of fully vertically integrated farming operations to the requirements of this final rule recommend that any exemption from this final rule

applicable to farms be limited based on the volume of the animal feed produced or animal equivalency units.

(Response 12) The farm definition in 21 CFR part 1 has been modified based on other comments received to both the 2014 supplemental notice for human food preventive controls and to the 2014 supplemental notice for animal food preventive controls (see section IV.B of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**). However, feed mills that are part of fully vertically integrated farming operations still meet the definition of farm. As a result, they are not required to register as a food facility under section 415 and are not subject to the requirements of this rule including CGMPs (subpart B) and Hazard Analysis and Risk-Based Preventive Controls (subpart C), and supply-chain program (subpart E). We remain concerned that this leaves a gap in the protection of public (human and animal) health because these feed mill operations manufacture significant amounts of animal food. While some of these feed mills may be voluntarily implementing some type of animal food safety measures, not all feed mills that are part of vertically integrated farming operations do. In addition, the voluntary measures adopted by some feed mills may not meet the standards of the food safety requirements in this rule. Moreover, we do not and cannot enforce compliance with purely voluntary practices. Finally, we recognize that other feed mills not part of a ''farm'' as defined in part 1 will have to comply with the requirements of this rule (unless they qualify for an exemption). As we have previously stated, we do not have evidence that the safety of animal food varies depending on whether a feed mill is part of vertically integrated or contract farming. Therefore, we intend to publish a proposed rule that would require some feed mill operations that currently are part of a farm to comply with the CGMPs (subpart B) of this rule.

The animal food CGMP requirements help ensure that animal food is protected from contamination during manufacturing, processing, packing, and holding (see sections XIV to XXII for further discussion of the animal food CGMP). By implementing these CGMPs, we believe that feed mills not currently covered by this rule would be able to provide a baseline level of animal food safety, thus further protecting the public (human and animal) health. We will continue to review the comments received from the 2014 supplemental proposed rule and other available data in considering a proposed rule for feed mills that are part of fully vertically integrated farming operations that are not required to register under section 415, but produce a large volume of animal food. One reason we are not finalizing new food safety requirements for feed mills that are part of fully integrated farming operations in this rulemaking is that we need more information to help guide the scope of the requirements. As part of the future rulemaking process we will seek input on the best way to subject vertically integrated feed mills that produce large volumes of animal food to food safety requirements while avoiding overburdening on-farm feed mixers that produce a small amount of food for a small number of animals. The proposed rulemaking would not change the applicability of subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' for feed mills that are part of a farm. Because farms meeting the definition of § 1.227 are not required to register under section 415 of the FD&C Act, § 507.5(a) exempts them from compliance with subpart C, as required by FSMA.

V. Comments on the Organizing Principles for How the Status of a Food as a Raw Agricultural Commodity or as a Processed Food Affects the Requirements Applicable to a Farm Under Sections 415 and 418 of the FD&C Act

In the 2014 supplemental notice (79 FR 58476 at 58482), we referred to the 2014 supplemental human preventive controls notice that discussed comments on the organizing principles that formed the basis for proposed revisions to section 415 registration regulations and the section 414 recordkeeping regulations (79 FR 58524 at 58538). We also explained how its proposed revisions to the ''farm'' definition would require FDA to reconsider those organizing principles (79 FR 58524 at 58538).

For discussion of comments, see section V of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

VI. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities

A. Section 103(c)(1)(C) of FSMA

We previously described provisions of FSMA that direct us to conduct a science-based risk analysis to cover specific types of on-farm packing, holding, and manufacturing/processing activities that would be outside the ''farm'' definition and, thus, subject to the requirements for hazard analysis and risk-based preventive controls (see section 103(c)(1)(C)) of FSMA and 78 FR 64736 at 64751 and 64752 through 64754). Consistent with this statutory direction, we developed the section 103(c)(1)(C) draft RA and made it available for public comment (Ref. 11 and 78 FR 64428). We are including the final risk assessment (the section 103(c)(1)(C) RA) in the docket established for this document (Ref. 3).

We previously described provisions of FSMA that direct us to consider the results of the science-based risk analysis and exempt facilities that are small or very small businesses from the requirements for hazard analysis and risk-based preventive controls (or modify these requirements, as we determine appropriate), if such facilities are engaged only in specific types of on-farm activities that we determine to be low risk involving specific animal foods that we determine to be low risk (see section 103(c)(1)(D) of FSMA and 78 FR 64736 at 64751, 64753 through 64754, and 64763 through 64764). In section X.F, we discuss the provisions we are establishing in § 507.5(e) and (f), based on the results of the section 103(c)(1)(C) RA, to exempt farm mixed-type facilities that are small or very small businesses from requirements for hazard analysis and risk-based preventive controls if the only activities that the business conducts that are subject to those requirements are low-risk activity/animal food combinations.

We also previously described provisions of FSMA that direct us to: (1) Identify high risk-facilities and allocate resources to inspect facilities according to the known safety risks of the facilities (as determined by several factors) and immediately increase the frequency of inspection of all facilities (see the discussion of section 421 of the FD&C Act at 78 FR 64736 at 64754) and (2) consider a possible exemption from or modification of requirements of section 421 of the FD&C Act as we deem appropriate (see the discussion of section 103(c)(1)(D) of FSMA at 78 FR 64736 at 64744). We tentatively concluded that we should not exempt or modify the frequency requirements under section 421 based solely upon whether a facility only engages in low-risk activity/animal food combinations and is a small or very small business and requested comment on this tentative conclusion.

B. Comments on Qualitative Risk Assessment of On-Farm Activities Outside of the Farm Definition

(Comment 13) Some comments address the qualitative nature of the section 103(c)(1)(C) draft RA and assert

that it is based on professional judgment rather than data. These comments ask us to update the section 103(c)(1)(C) draft RA when more data become available. Some comments assert that we should not rely on data from the Food Processing Sector Study (Ref. 12), but instead collect data from large-scale surveys of actual farm mixed-type facilities and their activities. Other comments ask us to collect, analyze, and interpret data about the levels of hazards from animal food samples taken from small and very small mixed-type facilities and use consumption to estimate the likelihood of exposure to hazards in animal food from such facilities. Some comments ask us to consult with subject matter experts to ensure that the final risk assessment reflects sufficient geographic diversity.

(Response 13) We have acknowledged the limitations of the section 103(c)(1)(C) draft RA (Ref. 11 and 78 FR 64428; see section I.F in that document). Rather than limit public input to subject matter experts, we requested comment from all interested persons, and received a number of comments about activity/animal food combinations conducted on farms and farm mixed-type facilities, including comments from diverse geographic areas comprising both areas where farms and farm mixed-type facilities tend to be small and where they tend to be large. We disagree that we need to conduct large scale surveys, or enter into agreements with agencies/organizations, to collect additional information in light of the previous opportunity for broad public input regarding the activity/animal food combinations conducted on farms and farm mixed-type facilities.

(Comment 14) Some comments assert that we should revise the section 103(c)(1)(C) draft RA and then make it available for additional public comment before finalizing the rule.

(Response 14) We subjected the section 103(c)(1)(C) draft RA to peer review in accordance with the requirements of the Final Information Quality Bulletin for Peer Review (issued by the Office of Management and Budget to implement the Information Quality Act (Pub. L. 106–554)) before we made it available for broader public comment during a time period that exceeded 10 months. The additional iterative process recommended by these comments is not necessary and would go beyond the processes we routinely apply for public input on a risk assessment.

C. Comments Regarding an Exemption for Small and Very Small Farm Mixed-Type Facilities Under Section 421 of the FD&C Act

1. Request for Comment on Data Submission Requirements

We requested comment on whether we should establish data submission requirements that would allow us to identify types of facilities in order to exempt them from the inspection frequencies, or modify the inspection frequencies that apply to them, under section 421 of the FD&C Act. We provided examples of such data elements, including identification of a facility as a farm mixed-type facility, annual monetary value of sales, number of employees, and animal food category/activity type. We also requested comment on any other criteria that may be appropriate for the purposes of allocating inspection resources to these facilities.

Comments did not support these data submission requirements. We are not establishing any data submission requirements that would allow us to identify types of facilities in order to exempt them from the inspection frequencies, or modify the inspection frequencies that apply to them, under section 421 of the FD&C Act.

2. Request for Comment on an Exemption From the Requirements of Section 421 of the FD&C Act

We received no comments that disagreed with our tentative conclusion that we should not exempt or modify the frequency requirements under section 421 based solely upon whether a facility only engages in low-risk activity/animal food combinations and is a small or very small business. We are not establishing any exemption from, or modification to, the frequency requirements under section 421 for facilities that only engage in low-risk activity/animal food combinations and are a small or very small business.

VII. Subpart A: Comments on Proposed § 507.1—Applicability and Status

We proposed in § 507.1 to establish the significance of this part in determinations of whether animal food is adulterated. We also proposed a provision relevant to FSMA's statutory provisions for a prohibited act under section 301(uu) of the FD&C Act. We proposed that animal food covered by specific CGMPs would also be subject to those requirements. For facilities required to comply with CGMPs and preventive controls for both the proposed preventive controls rule for animal food and the proposed preventive controls rule for human food, we proposed that the facility must comply with either rule for the animal food, as long as the food safety plan addresses hazards unique to animal food. Some comments support the proposed provisions without change. Some comments that support the proposed provisions ask us to clarify how we will interpret the provisions.

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements, disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements along with editorial and conforming changes as shown in table 31.

A. Comments on Proposed § 507.1(a)—Applicability

We proposed that the criteria and definitions in part 507 apply in determining whether a food is adulterated: (1) Within the meaning of section 402(a)(3) of the FD&C Act in that the food has been manufactured under such conditions that it is unfit for food; or (2) Within the meaning of section 402(a)(4) of the FD&C Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. We also proposed that the criteria and definitions in part 507 also apply in determining whether an animal food is in violation of section 361 of the PHS Act.

(Comment 15) Some comments note that FSMA granted FDA mandatory recall authority for adulterated food. These comments express concern that theoretically we could use a violation of the requirements for hazard analysis and risk-based preventive controls to determine that food is adulterated, thereby providing the basis for a mandatory recall of that food. These comments raise three issues relevant to how we will apply § 507.1(a), with consequences for a potential mandatory recall of food.

First, these comments note that the regulatory text stating that the ''criteria and definitions'' apply in making a determination of adulteration appears to encompass the entirety of the rule. As a result, farms or facilities that violate any of the requirements in the proposed rules, including components not directly related to the safety of the food (such as recordkeeping requirements), could face a risk that we would deem their food adulterated.

Second, these comments assert that the regulatory text suggests that we

would not automatically consider a food adulterated as a result of a violation of the proposed rule, because it states that the criteria and definitions ''apply in determining'' whether a food will be considered adulterated, rather than that the food ''is'' adulterated.

Third, these comments state that it is not clear how the exemption applicable to qualified facilities is included in the ''criteria and definitions'' used in making a determination of adulteration. These comments ask us to clarify that we will not just automatically assume that qualified facilities are selling adulterated food because they are by definition exempt from the requirements for hazard analysis and risk-based preventive controls.

(Response 15) The comments are correct that the criteria and definitions ''apply in determining'' whether an animal food will be considered adulterated, rather than that the animal food ''is'' adulterated. In determining whether an animal food that is manufactured, processed, packed, or held in violation of part 507 (including a violation of the recordkeeping requirement) is adulterated, we would consider the totality of the available data and information about the violation and the animal food before reaching a conclusion that the animal food is adulterated.

Although this rule does not address the mandatory recall provisions of FSMA, the statutory provisions establish two basic criteria. (See section 423(a) of the FD&C Act (21 U.S.C. 3501).) First, we must determine that there is a ''reasonable probability'' that the animal food is adulterated under section 402 of the FD&C Act. A violation of part 507 would be relevant to determining whether an animal food is adulterated under section 402 of the FD&C Act. Second, we must determine that there is a reasonable possibility that the use of, or exposure to, that animal food will cause serious adverse health consequences or death to humans or animals. Not all animal food that is adulterated has a reasonable probability of causing serious adverse health consequences or death to humans or animals. For examples of animal food contamination with a reasonable probability of causing serious adverse health consequences or death to humans or animals, see the annual reports of the Reportable Food Registry (RFR) (Refs. 13, 14, 15, and 16).

A facility that is exempt from any requirement of part 507, including the requirements for hazard analysis and risk-based preventive controls, would not be in violation of part 507 if it did not comply with provisions that it is not subject to.

B. Comments on Proposed § 507.1(b)—Prohibited Act

We proposed that the operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States is a prohibited act under section 301(uu) of the FD&C Act if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or subparts C, D, or F of part 507 and § 507.7 (proposed § 507.1(b)).

(Comment 16) Some comments from State regulatory Agencies note that this new provision is not covered under the applicable state statute and that making any changes to the state statute can be a lengthy process that takes up to 3 years to complete.

(Response 16) See Response 2 for a discussion of our approach to working with our food safety partners in the States.

C. Comments on Proposed § 507.1(c)—Specific CGMP Requirements

We proposed § 507.1(c) would establish that animal food covered by specific current good manufacturing practice regulations also be subject to the requirement of those regulations. We received no comments that disagreed with our proposal, and are finalizing the proposed provision without change.

D. Comments on Proposed § 507.1(d)—Human Food Facilities That Manufacture Animal Food

We proposed in § 507.1(d) that a facility that would be required to comply with subpart B of part 507 and would be required to comply with subpart B of proposed part 117 for human food, may choose to comply with part 117 for the animal food. We also proposed that a facility that would be required to comply with subpart C of part 507 and would be required to comply with subpart C of proposed part 117 for human food, may choose to comply with part 117 for the animal food as long as the food safety plan also addressed hazards that are reasonably likely to occur in the animal food. We also proposed that when applying the requirements of part 117 to animal food, the term ''food'' in part 117 would include animal food.

Based on comments received in the 2014 supplemental notice, we proposed in § 507.12 that human food by-products held by the human food processor for distribution for use as animal food without additional manufacturing/processing by the human food processor would only need to comply with proposed § 507.28 in part 507 and proposed § 117.95 in part 117 (79 58476 at 58487 to 58489). (See section XIII for a discussion of comments received on proposed § 507.12.) We are finalizing the proposed provisions in 507.1(d) with the exceptions in § 507.12.

For further discussion of comments on applicability and status, see section VIII in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

VIII. Subpart A: Comments on Proposed § 507.3—Definitions

We proposed definitions in the preventive controls rule for animal food to be consistent with the proposed preventive controls rule for human food with some minor differences and clarifications applicable to animal food (*e.g.,* adding ''animal'' before ''food''). Some comments support one or more of these proposed definitions without change. For example, some comments state that they support the proposed definitions for ''microorganism'' and ''subsidiary'' with no suggested revisions. Some comments support our proposal in the 2014 supplemental notice to use the phrase ''chemical (including radiological)'' in the definition of ''hazard,'' noting that doing so is consistent with FSMA, current industry practice, and Codex and global HACCP standards. Some comments that support a proposed definition suggest alternative or additional regulatory text, such as adding examples to make the definition clearer. Some comments that support a proposed definition ask us to clarify how we will interpret the definition. Comments generally ask that we maintain consistency of terms among the FSMA rules to avoid confusion and ensure regulatory compliance.

We did not receive comment on the following terms and therefore, are finalizing them as proposed: ''calendar day,'' ''FDA,'' ''pest,'' ''water activity,'' and ''you.''

We removed some proposed definitions because the final rule does not use them. The proposed definitions that are removed in this final rule are ''batter,'' ''blanching,'' ''packaging,'' ''quality control operation,'' ''safe moisture level,'' ''should,'' and ''significant hazard.''

In the following sections, we discuss comments that ask us to clarify proposed definitions or that disagree with, or suggest one or more changes to, a proposed definition. After considering these comments, we have revised the proposed requirements with editorial

and conforming changes as shown in table 31.

We also discuss definitions for additional terms (*i.e.,* ''audit,'' ''correction,'' ''full-time equivalent employee,'' ''hazard requiring a preventive control,'' ''qualified facility exemption,'' ''raw agricultural commodity,'' ''supply-chain-applied control,'' ''unexposed packaged animal food,'' and ''written procedures for receiving raw materials and other ingredients'') that we are establishing in the final rule to simplify the regulatory text throughout the regulations and improve clarity. We also discuss a new name (*i.e.,* ''preventive controls qualified individual'') for the definition of a term that we had proposed to name ''qualified individual,'' and are establishing a new definition for the term ''qualified individual.'' Finally, we also discuss definitions that comments ask us to add, but that we did not add, to the final rule.

A. Definitions We Proposed To Establish in Part 507

1. Adequate

We proposed to define the term ''adequate'' to mean that which is needed to accomplish the intended purpose in keeping with good public health practice.

(Comment 17) Some comments express concern that there is no standard or definition for ''good public health practice'' and, for animal food establishments, the term ''good public health practice'' creates more uncertainty than it removes. The comments request that we remove from the definition the term ''good public health practice.'' Other comments ask us to develop guidance on thresholds and processes that qualify as ''adequate.'' Other comments assert that the word ''adequate'' must be used in combination with the word ''reasonable'' to properly describe the intended measures and precautions.

(Response 17) We disagree that there is no standard for ''good public health practice.'' However, we have revised the definition to add after public ''(human and animal)'' to clarify it includes both. Our intent in using the term ''adequate'' is to provide flexibility for an animal food establishment to comply with the requirement in a way that is most suitable for its establishment. We decline the request to develop guidance to explicitly address ''thresholds'' or to describe processes that qualify as adequate. The CGMPs and preventive controls requirements established in this rule are broadly applicable procedures and practices rather than very specific procedures and practices where additional interpretation from FDA might be appropriate.

2. Affiliate and Subsidiary

We proposed to define the term ''affiliate'' to mean any facility that controls, is controlled by, or is under common control with another facility. We proposed to define the term ''subsidiary'' to mean any company which is owned or controlled directly or indirectly by another company. These proposed definitions would incorporate the definition in section 418(l)(4)(A) and (D) of the FD&C Act and would make the meanings of these terms clear when used in the proposed definition of ''qualified facility.''

(Comment 18) Some comments ask us to clarify that a facility that has no material connection with another food processing operation would not be considered as an ''affiliate'' of that operation.

(Response 18) It is not clear what the comments mean by ''no material connection with another food processing operation.'' To the extent that a facility does not control, is not controlled by, or is not under common control with another facility, we agree that the facility would not be considered an affiliate of that food processing operation.

(Comment 19) Some comments assert that the definitions of ''affiliate'' and ''subsidiary'' fail to account for the legal differences between a piece of property (*i.e.,* a facility) and a business entity or person. These comments ask us to consider amending the proposed definition of ''qualified facility'' to clarify what sales to include in determining whether a facility so qualifies.

(Response 19) See Response 57.

3. Animal Food

We proposed to define the term ''animal food'' to mean food for animals other than man that includes pet food, animal feed, and raw materials and ingredients.

(Comment 20) Several comments voice concerns about including within the definition of animal food the term ''raw materials.'' The main concern is whether firms producing raw materials for animal food must register and create animal food safety plans. The comments fear firms would dispose of the raw material products due to the high cost of developing and maintaining safety plans, and disposal of those raw material products would have a significant economic impact due to a considerable increase in the cost of animal food in the United States.

(Response 20) We decline to change the definition. We do not expect that the inclusion of the term ''raw materials'' in the definition for animal food will change current practices, noting that a facility producing raw materials for animal food is already required to register. The definition of ''animal food'' is intended to clarify that the rule refers to ''food for animals'' and not ''food derived from animals.''

4. Critical Control Point

We proposed to define the term ''critical control point'' (CCP) to mean a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

(Comment 21) Some comments oppose the use of ''critical control point'' in the rule because the term is confusing and not understood by the relevant industry in the context of FSMA and the required preventive controls. The comments suggest critical control point is a HACCP term and not appropriate for use in this rule where the scope is defined differently by the statute.

(Response 21) We decline to modify or remove the definition as these comments request because we believe the term is helpful to industry. The proposed definition matches the statutory definition in section 418(o)(1) of the FD&C Act and is consistent with definitions in the Federal HACCP regulations for seafood, juice, and meat and poultry (parts 123 and 120 (21 CFR part 123 and 120) and 9 CFR part 417 respectively). By specifying that a point, step, or procedure in an animal food safety process would reduce a hazard to an ''acceptable level,'' the definition provides flexibility for a facility to determine an appropriate level in a particular circumstance.

(Comment 22) Some comments request that we define the term ''control point.'' The comments suggest defining this term as a point, step, or procedure in the production of an animal food at which a control may be applied.

(Response 22) We decline this request. We define ''critical control point'' as a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level. Also, ''control point'' is not a term used in the regulatory text of the rule and therefore does not need to be defined.

5. Environmental Pathogen

We proposed to define the term ''environmental pathogen'' to mean 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. We also proposed to specify that environmental pathogen does not include the spores of pathogenic sporeformers. By ''pathogenic sporeformers,'' we mean ''pathogenic sporeforming bacteria,'' and we are substituting the term ''pathogenic sporeforming bacteria'' for ''pathogenic sporeformers'' in the definition of ''environmental pathogen'' to make that clearer.

(Comment 23) Some comments ask us to include *Salmonella* spp. and *Listeria monocytogenes* in the regulatory text as examples of environmental pathogens. Other comments believe the definition is too broad because it would include any pathogen that is capable of surviving or persisting in the environment, and the definition should be limited to the pathogenic bacteria that are more appropriate for protecting animal food safety.

(Response 23) We agree that *Salmonella* spp. and *L. monocytogenes* are useful examples of environmental pathogens and have added these two examples to the proposed definition, which had not included examples. Adding these two examples to the definition does not mean that these two pathogens are the only environmental pathogens that a facility must consider in its hazard analysis. New environmental pathogens can emerge at any time, and other pathogens can also be environmental pathogens. *Salmonella* spp in pet food have been involved in foodborne illness outbreaks in humans (78 FR 64736 at 64747). In addition, there have been recalls of pet food found to contain L. monocytogenes, though no human or animal illnesses were associated with these recalls to date (Refs. 17 and 18).

(Comment 24) Some comments ask us to clarify the meaning of the term ''persisting'' as used in the definition, such as whether it means that a sanitation process will not remove the microorganism.

(Response 24) We use the term ''persisting'' to mean that a pathogen can get established if cleaning is not adequate. Once a pathogen gets established, appropriate sanitation measures can remove the pathogen. However, sanitation procedures necessary to eliminate an environmental pathogen that has become established generally are more aggressive than routine sanitation procedures.

6. Facility

We proposed to define the term ''facility'' to mean a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act in accordance with the requirements of part 1, subpart H. Comments directed to the meaning of the term ''facility'' address its meaning as established in the section 415 registration regulations, rather than this definition established in part 507.

For a discussion of comments on definitions in part 1, see section IV of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

7. Farm

We proposed to define the term ''farm'' by reference to the definition of that term in § 1.227(b) rather than by repeating the full text of the ''farm'' definition in part 507. For a discussion of comments to the farm definition and of the ''farm'' definition that we are establishing in § 1.227, see section IV of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

8. Food

We proposed to define the term ''food'' to mean food as defined in section 201(f) of the FD&C Act and to include raw materials and ingredients. Under section 201(f), the term ''food'' means: (1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(Comment 25) Some comments ask us to include examples in the definition. These comments also ask us to clarify whether the definition applies to food for human consumption, animal consumption, or both.

(Response 25) We decline the request to include examples in the definition. There are many examples of food and adding a limited list of examples could be confusing rather than helpful. Although the definition of food includes food for both human consumption and animal consumption, the provisions of the rule are clearly directed to food for animal consumption.

(Comment 26) Some comments ask us to consider fundamental and important differences between food additives and GRAS substances and finished food. These comments explain that food additives and GRAS substances may be synthesized using various chemical and biochemical processes, or may be extracted, hydrolyzed or otherwise modified from their natural sources, and result in food safety hazards that are quite different from finished food preparations. These comments also explain that food additives and GRAS substances are often produced using processes that minimize microbial contamination hazards and are almost always used in food products that undergo further downstream processing. These comments assert that food additives and GRAS substances generally present a significantly lower public health hazard compared to finished food and should be regulated accordingly.

(Response 26) Substances such as food additives and GRAS substances are food and are subject to the requirements of this rule. Both the CGMP requirements in subpart B and the requirements for hazard analysis and risk-based preventive controls in subparts C and E provide flexibility to address all types of food. (As discussed in section XL, the final rule establishes the requirements for a supply-chain program in subpart E, rather than within subpart C as proposed. As a result, this document refers to subparts C and E when broadly referring to the requirements for preventive controls.) A manufacturer of a food additive or GRAS substance has flexibility to comply with the requirements of the rule based on the nature of the production processes and the outcome of the hazard analysis for that animal food substance.

9. Food-Contact Surfaces

We proposed to define ''food-contact surfaces'' to mean those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' include food-contact surfaces of utensils and equipment.

(Comment 27) Several comments state that the terms ''drainage'' and ''utensils'' are not widely used or understood within animal feed and pet food industry and that the definition for ''food-contact surfaces'' should be revised by deleting ''drainage, or other,'' and by replacing ''utensils'' with ''tools.''

(Response 27) We decline these requests. See our discussion of the term ''utensils'' in Response 169. We believe the term ''drainage'' is commonly understood.

10. Harvesting

We proposed to define the term ''harvesting'' to apply to farms and farm

mixed-type facilities and to mean activities that are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. We proposed that harvesting be limited to activities performed on RACs on a farm, and that harvesting does not include activities that transform a RAC into a processed food. The proposed definition included examples of activities that would be harvesting.

In this final rule, we added or modified several examples of harvesting (see Response 28). As noted in table 31, we have reorganized the listed examples of harvesting to present them in alphabetical order.

We are defining the term ''harvesting'' to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed on farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as animal food. The definition includes examples of activities that are harvesting, as described in this section. Harvesting is also limited to activities performed on RACs, or on processed foods created by drying/dehydrating a RAC without additional manufacturing/processing, on a farm.

(Comment 28) Some comments ask us to provide more examples of harvesting activities, in the regulatory text and in guidance. Examples of the requested activities include braiding; bunching; cutting the edible portion of the crop from the plant; hydro-cooling; maintaining hydration of product; refrigerating; removing foliage; removing free water from (*e.g.* spinning); removing or trimming roots; trimming the tops of bunches of allium crops such as leeks, chives, or garlic and root crops such as carrots, beets, turnips, parsnips, etc. to prepare them for sale; and trimming the lower stems of harvested herb crops such as parsley, basil, or cilantro, or the lower stems of leafy greens. Other comments ask us to specify that harvesting also encompasses seed conditioning (*i.e.,* cleaning the seed, including removal of leaves, stems, and husks to prepare for marketing), ripening (artificial or natural) of fruit, and waxing or coating of RACs.

(Response 28) We have added or modified several examples of harvesting in the regulatory text (*i.e.,* cutting (or otherwise separating) the edible portion of the RAC from the crop plant, removing or trimming part of the RAC (*e.g.,* foliage, husks, roots or stems) and field coring and hulling). In table 1 in the Appendix to the 2014 supplemental notice (79 FR 58476 at 58520 through 58521), we provided a more extensive list of examples of harvesting activities, including examples that are not in the regulatory text. We have classified some of these activities in more than one way (see 79 FR 58476 at 58520 through 58521). For example, trimming of outer leaves from RACs can be a harvesting activity, as well as a manufacturing/processing activity. Artificial ripening of fruit is manufacturing/processing (not harvesting), but is now within the ''farm'' definition.

(Comment 29) Some comments ask us to periodically review the list of harvesting activities to ensure that it reflects current practices.

(Response 29) If particular activities present questions in the future about whether the activity is a harvesting activity within the ''farm'' definition, or a manufacturing/processing activity that is outside the ''farm'' definition, we will consider issuing guidance or updating any existing guidance to clarify our recommended classification of the activity.

(Comment 30) Some comments note that the proposed definition for ''harvesting'' seems to be much more inclusive than FDA's original proposed regulation, but is significantly more restrictive than the current regulation in part 1 because it excludes future technological developments. The comment further notes as technology and harvesting techniques advance, the risk of tying the definition to traditional activities will have a negative effect on agriculture's ability to adapt. Furthermore, harvesting is merely the first step in transforming a RAC into processed food.

(Response 30) The comment did not make a specific request or provide any suggestions as to how future technological developments should be handled; therefore, we are finalizing the definition with the changes previously described.

11. Hazard

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

(Comment 31) Some comments express concern that the rule would refer to four levels of ''hazard,'' *i.e.,* ''hazard,'' ''known or reasonably foreseeable hazard,'' ''significant hazard,'' and ''serious adverse health consequences or death to humans or animals'' hazard. These comments ask us to provide sufficient clarity to be able to distinguish between these types of hazards and to provide examples in guidance as to how these terms will be applied in determining compliance with the rule. Other comments express concern that the definitions do not establish a meaningful distinction between ''hazard'' and ''significant hazards'' and do not sufficiently distinguish between the hazards identified in the first and second steps of the hazard analysis (first narrowing hazards to ''known or reasonably foreseeable hazards'' and then narrowing the ''known or reasonably foreseeable hazards'' to ''significant hazards'').

(Response 31) The rule uses three of these terms (*i.e.,* ''hazard,'' ''known or reasonably foreseeable hazard,'' and the proposed term ''significant hazard'') to establish a tiered approach to the requirements for hazard analysis and risk-based preventive controls. The term ''hazard'' is the broadest of these three terms—any biological, chemical (including radiological), or physical agent has the potential to cause illness or injury. To conduct its hazard analysis, a facility starts by first narrowing down the universe of all potential hazards to those that are ''known or reasonably foreseeable'' for each type of food for animals manufactured, processed, packed, or held at its facility. The outcome of the facility's hazard analysis is a determination of ''significant hazards,'' *i.e.,* the subset of those known or reasonably foreseeable hazards that require a preventive control.

To make this clearer, we have: (1) Revised the proposed definitions of ''hazard'' and (2) changed the term ''significant hazard'' to ''hazard requiring a preventive control'' (formerly ''significant hazard''). See Responses 32 and 62.

The rule does not define the term ''serious adverse health consequences or death to humans or animals'' hazard. However, the requirements for a supply-chain program refer to 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 (see § 507.130(b)). For additional information on how we interpret ''serious adverse health consequences or death to humans or animals,'' see our guidance regarding the RFR (Refs. 19 and 20), which addresses statutory requirements regarding ''reportable foods.'' As explained in that guidance, a ''reportable food'' is an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or

death to humans or animals. The guidance includes examples of circumstances under which food might be reportable.

(Comment 32) Some comments assert that the distinction between the definitions of ''hazard'' and ''significant hazard'' is not discernable because the proposed definition of ''hazard'' currently takes into account whether or not a ''hazard'' is or is not controlled. These comments ask us to delete the phrase ''in the absence of its control'' from the definition of ''hazard'' to clarify that hazards are simply the agents that are reasonably likely to cause illness or injury. Likewise, other comments assert that any hazard that is ''reasonably likely to cause illness or injury in the absence of its control'' will, if known or reasonably foreseeable, likely be controlled by any knowledgeable person.

(Response 32) We have deleted the phrase ''in the absence of its control'' from the definition of ''hazard.'' We agree that deleting this phrase from the definition of ''hazard'' will more clearly distinguish between the terms ''hazard'' and ''hazard requiring a preventive control'' that we are establishing in this rule.

We also replaced the phrase ''that is reasonably likely to cause illness or injury'' with ''that has the potential to cause illness or injury'' to more clearly distinguish ''hazard'' from ''known or reasonably foreseeable hazard.'' This increases the alignment of the definition of ''hazard'' in this rule with the Codex definition of ''hazard.''

(Comment 33) Some comments ask us to include ''in the intended species'' in the definition of ''hazard.''

(Response 33) We decline this request. During the hazard analysis the facility must 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 the facility to determine whether there are hazards requiring a preventive control (§ 507.33(a)). During the hazard evaluation, the facility must consider the effect of the intended or reasonably foreseeable use on the safety of the finished animal food for the intended animal (§ 507.33(d)(8)).

12. Holding

We proposed to define ''holding'' to mean storage of food, including activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets)), but not including activities that transform a RAC into a processed food. We proposed that holding facilities could include warehouses, cold-storage facilities, storage silos, grain elevators, and liquid-storage tanks.

(Comment 34) Some comments ask us to provide more examples of holding activities, in the regulatory text and in guidance. Examples of the requested activities include fumigating RACs; application of chemicals (including fungicides, sanitizers, and anti-oxidants); and ''coating'' grain RACs with diatomaceous earth to control insects. According to these comments, these activities are incidental to storage and do not transform RACs into processed food. Other comments wanted examples of holding of human-food by-products destined for animal food (for example wet pasta that dries naturally while being held).

(Response 34) We have added or modified several examples of holding in the regulatory text (*i.e.,* fumigating animal food during storage, and drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). In table 1 in the Appendix to the 2014 supplemental notice (79 FR 58476 at 58520 through 58521), we provided a more extensive list of examples of holding activities, including examples that are not in the regulatory text. We have previously classified some of these activities in more than one way (see 79 FR 58476 at 58520 through 58521) depending on when the activity occurs. For example, sorting, culling, and grading RACs can be either a holding activity or a packing activity. Drying/dehydrating RACs is holding when the drying/dehydrating does not create a distinct commodity, but is manufacturing/processing when the drying/dehydrating creates a distinct commodity (see section IV). Holding of certain human food by-products for use as animal food is discussed in sections XIII and XXII.

(Comment 35) Some comments ask us to clarify that mixing or blending intact RACs is considered ''holding'' regardless of whether the RACs are the same or different.

(Response 35) We use the term ''blending'' when referring to RACs such as grain and when the RACs are the same. For example, we consider the activity of ''blending'' different lots of the same grain to meet a customer's quality specifications to be a practical necessity for product distribution and, thus, to be within the definition of ''holding'' (see 79 FR 58476 at 58483). However, we use the term ''mixing'' when the RACs are different. For example, we consider the activity of ''mixing'' corn and oats in the production of animal food to be manufacturing/processing, because mixing two different foods is ''making food from one or more ingredients'' (which is our definition of ''manufacturing/processing'') and the animal food produced by mixing corn and oats is a processed food.

We classify ''mixing'' intact RACs that does not create a processed animal food as incidental to, and therefore part of, ''packing'' or ''holding'' as applicable. For example, mixing heads or bunches of lettuce does not create a processed food, because the mixing has not created a distinct commodity, but only a set of mixed RACs. On the other hand, mixing that creates a processed animal food is not ''packing'' or ''holding.'' The definitions of both ''packing'' and ''holding'' are limited so that they do not include activities that transform a RAC into processed animal food. Some kinds of mixing of RACs does create a distinct commodity (for example, mixing corn and oats to make animal food). In such cases, the mixing is manufacturing/processing and is not within the farm definition.

(Comment 36) Some comments ask us to clarify whether the expanded definition of holding that we proposed in the 2014 supplemental human preventive controls notice would mean that a warehouse that both stores and fumigates a RAC to prevent pest infestation would be exempt from the requirements for hazard analysis and risk-based preventive controls for a facility solely engaged in the storage of RACs (other than fruits and vegetables) for further distribution or processing (§ 507.5).

(Response 36) Fumigating RACs to prevent pest infestation would be within the definition of ''holding'' and therefore would not prevent a facility that stores RACs (other than fruits and vegetables) from being eligible for the exemption in § 507.5(g), provided that the facility does not conduct other activities not classified as ''holding.'' However, a threshold question for any facility solely engaged in the storage of RACs is whether the stored RACs are fruits or vegetables.

(Comment 37) Some comments ask us to clarify whether there is a timeframe associated with holding and to better distinguish between ''holding'' and ''storage.''

(Response 37) There is no timeframe (maximum or minimum) associated with holding. The definition of holding

states ''Holding means storage of food'' and, thus, there is no distinction between ''holding'' and ''storing.''

(Comment 38) Some comments ask us to clarify how the definition of holding relates to practices, such as fumigation, on almond hull stockpiles held on a farm, a farm mixed-type facility or off-farm.

(Response 38) Practices that are incidental to storage of food, such as fumigation of almond hull stockpiles, are holding, regardless of whether they are conducted on-farm, on a farm mixed-type facility, or off-farm.

(Comment 39) Some comments ask us to clarify that value added activities (such as repacking and blast freezing) conducted in facilities such as warehouses would be considered holding when product is not exposed to the environment.

(Response 39) We consider the activities described in these comments to be activities performed as a practical necessity for the distribution of the food and, thus, to be within the definition of holding.

(Comment 40) Several comments do not support the proposed definition of ''holding'' stating that the definition would exempt grain receiving and storage facilities that are the primary suppliers of the main ingredient in many animal foods including distiller's products. Some comments ask us to clarify what is a practical necessity.

(Response 40) Section 418(m) of the FD&C Act provides us with the authority to exempt certain facilities from the requirements of section 418, or to modify those requirements. We proposed to use this authority to exempt facilities that solely engage in the storage (holding) of RACs (other than fruits and vegetables) intended for further distribution or processing. We tentatively concluded that there would not be significant public (human and animal) health benefit to be gained by having these facilities subject to the requirements of subpart C. Outbreaks of illness associated with feeding RACs to animals have not been traced back to storage facilities solely engaged in the storage of RACs, therefore we think it is appropriate to exempt them from the requirements of subparts C and E of the final rule. Such facilities remain subject to the requirements of section 402 of the FD&C Act that the animal food being held is not adulterated.

The revised definition of ''holding'' encompasses activities performed as a practical necessity for the distribution of RACs, such as blending of the same RAC and breaking down pallets. Sampling for grading or quality control purposes, repacking, and drying grains and oilseeds would also be considered performed as a practical necessity for the distribution of animal food within the definition of ''holding.''

13. Known or Reasonably Foreseeable Hazard

We proposed to define the term ''known or reasonably foreseeable hazard'' to mean a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

(Comment 41) Some comments support the definition as proposed, noting that it implies that the implementation of a preventive control be based both on the severity and likelihood of the hazard, can help to distinguish between the requirements of this rule and HACCP requirements, and provides for the proper consideration of both the food and the facility when determining whether a hazard is ''known or reasonably foreseeable.'' Other comments ask us to modify the definition to specify that the term means a hazard ''that is known to be, or has the potential to be, associated with the facility or the food'' to better align with the term as FDA proposed to define it in the proposed FSVP rule. (See 79 FR 58574 at 58595.)

(Response 41) We have revised the definition as requested by the comments to better align with the proposed FSVP rule.

(Comment 42) Some comments ask us to revise the definition so that it addresses a hazard that is known to be, or has the potential to be, associated with a food, the facility in which it is manufactured/processed, or the location or type of farm on which it is grown or raised. These comments assert that the type of farm may affect those hazards that are known or reasonably foreseeable.

(Response 42) We decline this request, which appears related to another difference between the definition proposed in this rule and the definition of this term in the proposed FSVP rule. The proposed FSVP rule would define ''known or reasonably foreseeable hazard'' as a hazard that is known to be, or has the potential to be, associated with a food or the facility ''in which it is manufactured/processed.'' (See 79 FR 58574 at 58595.) In this rule, we do not need to specify that the applicable facility is the one ''in which the food is manufactured/processed'' because this rule applies to the owner, operator, or agent in charge of the facility in which the food is manufactured, processed, packed, or held, and that applicability does not need to be repeated in each provision. To the extent that this comment is expressing concern about raw materials or other ingredients that a facility would receive from a farm, those concerns would be considered in the facility's hazard analysis, which would include a hazard evaluation that considers factors such as those related to the source of raw materials and other ingredients (see § 507.33(d)(3)).

14. Lot

We proposed to define ''lot'' to mean the food produced during a period of time indicated by a specific code.

(Comment 43) Some comments state that many animal food processors operate on a batch-production basis rather than a continuous-production basis and request that we take this into account with respect to the definition of ''lot.'' Other comments suggest replacing ''lot'' with ''lot identifier'' where ''lot identifier'' means a unique identifier for each lot, batch or production run that enables the manufacturer to trace accurately the complete manufacturing and distribution history of the product. Other comments ask us to modify the proposed definition so that it is not limited by a period of time and suggest using an approach that would allow for a lot to be defined by either time or by a specific identifier. Other comments express the view that the individual operators should be able to define their lot designations and make these definitions available to FDA upon request.

(Response 43) Although the term ''lot'' is associated with a period of time, an establishment has flexibility to determine the code, with or without any indication of time in the code. For example, a code could be based on a date, time of day, production characteristic (such as origin, variety, and type of packing), combination of date/time/production characteristic, or any other method that works best for the establishment. To clarify that the rule does not require that time be ''indicated'' by the code, and emphasize the establishment's flexibility to determine the code, we have revised ''period of time indicated by a specific code'' to ''period of time and identified by an establishment's specific code.''

15. Manufacturing/Processing

We proposed to define ''manufacturing/processing'' to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. We proposed that examples of manufacturing/processing activities would be cutting, peeling, trimming,

washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding. In this rule, we add more examples to include, ''artificial ripening,'' ''boiling,'' ''canning,'' ''drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins),'' ''evaporating,'' ''extruding,'' and ''pelleting.'' We also alphabetize the list of examples.

(Comment 44) Some comments express concern that some activities included in the definition of ''manufacturing/processing'' overlap with activities (such as trimming, washing, and cooling) included in the definition of ''harvesting.''

(Response 44) We acknowledge that there is some overlap in the activities that the regulatory text lists as examples of both ''manufacturing/processing'' and ''harvesting,'' because some activities can occur during more than one operation (see table 1 in the Appendix to the 2014 supplemental notice (79 FR 58476 at 58520 through 58521)). For example, ''cutting'' lettuce from the crop plant occurs on-farm in the field where the lettuce is harvested, and ''cutting'' the core of the lettuce from the rest of the harvested lettuce occurs in a fresh-cut processing facility. An important consequence of the multiple revisions we have made to the ''farm'' definition in this rulemaking is that there are fewer situations in which classification of a particular activity is the only trigger for an operation to be subject to the section 415 registration requirements. For example, the revised ''farm'' definition no longer classifies the packing and holding of others' RACs to be a manufacturing/processing activity that triggers the registration requirement. As another example, the revised ''farm'' definition specifies three manufacturing/processing activities that are within the ''farm'' definition. We conclude that the overlap in the examples of activities listed in the definitions of ''harvesting'' and ''manufacturing/processing'' does not create problems with determining the status of an operation as a ''farm'' or a ''facility'' and we are retaining examples in both definitions because doing so reflects current practices on farms and in manufacturing/processing facilities.

16. Microorganisms

We proposed to define the term ''microorganisms'' to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites, including species having animal or human health significance. We also proposed that the term ''undesirable microorganisms'' includes those microorganisms that are of animal or human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. We have revised the definition to replace ''includes species having animal or human health significance'' with ''and includes species that are pathogens,'' and replacing '''undesirable microorganisms''' includes those microorganisms that are of animal or human health significance'' with '''undesirable microorganisms''' includes those microorganisms that are pathogens.''

(Comment 45) Some comments express concern that the term ''undesirable microorganisms'' includes microorganisms that subject food to decomposition. These comments assert that the definition would expand regulation beyond food safety and ask us to clarify that decomposition means a degradation of product that is only relevant when it affects the safety of the product, rather than simple spoilage.

(Response 45) We have not modified the regulatory text of this longstanding definition of the term ''undesirable microorganisms'' regarding microorganisms that subject food to decomposition. The regulations established by this rule are designed to prevent the growth of undesirable microorganisms. The scope of the definition of ''undesirable microorganisms'' is not limited to microorganisms of public health significance because these regulations are also concerned with sanitation, decomposition, and filth (51 FR 22458 at 22460, June 19, 1986).

17. Mixed-Type Facility

We proposed to define ''mixed-type facility'' to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. We proposed that an example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. As a conforming change associated with the revisions to the ''farm'' definition, we have revised the example of a ''farm mixed-type facility'' to specify that it is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. (See section IV of the final rule for preventive controls for human food published elsewhere in this addition of the **Federal Register**.)

(Comment 46) Some comments ask us to revise the definition to exclude those establishments that only conduct low-risk activities specified in the exemptions for on-farm, low-risk activity/animal food combinations (§ 507.5(e) and (f)).

(Response 46) We decline this request. Whether a particular establishment that falls within the definition of ''mixed-type facility'' is subject to the requirements for hazard analysis and risk based preventive controls is governed by the exemptions established in this rule.

18. Monitor

We proposed to define the term ''monitor'' to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(Comment 47) Some comments assert that our proposed definition of monitor is directed to the narrow circumstance of monitoring that would be applied to a CCP under the National Advisory Committee on Microbiological Criteria for Foods (advisory committee chartered under the USDA) (NACMCF) HACCP guidelines and the Codex HACCP Annex. These comments also assert that, using such definitions, monitoring would not apply to control measures for which parameters cannot be established and that are not amenable to documentation. These comments suggest that we use a definition of monitoring consistent with that provided in ISO 22000:2005 (conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended) to clarify that monitoring may be conducted where appropriate for preventive controls that are not CCPs. (ISO is an abbreviation for ''International Organization for Standardization.'' ISO develops and publishes International Standards.) According to these comments, an advantage of this definition is that it also would clarify the difference between monitoring activities (observations conducted during the

operation of a control measure to ensure that it is under control) and verification activities (to evaluate performance of a control measure).

(Response 47) We have revised the definition of monitor to mean to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended. We agree that the revised definition, which reflects an international standard, more effectively communicates that monitoring also applies to controls that are not at CCPs and may apply to control measures for which parameters cannot be established. However, we disagree that this definition signals that it is not possible to obtain documentation when monitoring preventive controls that are not at CCPs, such as for controls that are not process controls and do not involve parameters and maximum or minimum values, or combinations of values, to which a parameter must be controlled to significantly minimize or prevent a hazard requiring a preventive control. For example, it is possible to monitor that a specific sanitation control activity has taken place, such as the cleaning of a piece of equipment to prevent cross-contact.

The requirement for documenting monitoring in records is established by the requirements for monitoring, not by the definition of monitor. As discussed in section XXX.C, we have made several revisions to the regulatory text, with associated editorial changes, to clarify that monitoring records may not always be necessary.

19. Packaging (When Used as a Verb)

We proposed to define ''packaging (when used as a verb)'' as placing food into a container that directly contacts the food and that the consumer receives.

Based on comments received to the proposed rule for preventive controls for human food, we have decided not to establish the definition ''packaging (when used as a verb)'' in part 507. For a discussion of those comments received to the human food preventive controls rule, see section IX.C.20 in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

20. Packing

We proposed to define ''packing'' as placing food into a container other than packaging the food, including activities performed incidental to packing a food (*e.g.,* activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but not including activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg). We have revised the definition to clarify that packing includes ''re-packing.''

For comments on the definition of ''packing,'' see section IV.G of the final rule for preventive controls for human food, published elsewhere in this addition of the **Federal Register**.

We are finalizing the definition as proposed, with the addition of another example of an activity performed for the safe or effective packing of the food, *i.e.,* weighing or conveying incidental to packing or repacking, and the addition of ''animal'' in front of food.

21. Pathogen

We proposed to define the term ''pathogen'' to mean a microorganism of public (human or animal) health significance.

(Comment 48) Some comments ask us to revise the definition to mean a ''microorganism of such severity and exposure that it would be deemed of public health significance'' because the significance of pathogens to public health depends on the organism's severity and the nature of exposure.

(Response 48) We decline this request. Our purpose in defining the term pathogen was to simplify the regulations, including our longstanding CGMP regulations for human food, by substituting a single term (*i.e.,* ''pathogen'') for a more complex term (*i.e.,* ''microorganism of public health (human and animal) significance'') throughout the regulations. These comments fail to explain how we have interpreted the current term ''microorganism of public health significance'' in a way that does not take into account factors such as the severity of illness and the route of exposure.

22. Plant

We proposed to define the term ''plant'' to mean the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

(Comment 49) Some comments state that it would not be helpful to use ''plant'' interchangeably with ''establishment'' when referring to a business that is not required to register. These comments ask us to consistently use one of these terms and to define a term that would mean ''a business that is not required to register'' to help distinguish such businesses from ''facilities.''

(Response 49) We agree that it is appropriate to consistently use one term when referring to a business entity. However, we disagree that it is necessary to establish a definition for a business entity that is not required to register. A business that meets the definition of ''facility'' is required to register; a business that is not required to register is simply a business that does not meet the definition of ''facility.''

To address these comments, we have revised provisions of the rule in three ways. First, we have revised the definition of ''plant'' to focus it on the building, structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food, rather than on the ''building or establishment.'' Second, we have revised applicable provisions of part 507 to use ''establishment'' rather than ''plant'' when focusing on a business entity rather than on buildings or other structures. Third, we have revised provisions that use the terms ''plant,'' ''establishment,'' or both to conform to the definition of ''plant'' and the described usage of ''establishment.'' For example, § 507.14 establishes requirements for ''the management of the establishment'' rather than ''plant management,'' because ''establishment'' is the term focusing on the business entity. As another example, § 507.17(a)(1) establishes requirements for properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the ''plant'' rather than within the immediate vicinity of the ''plant buildings or structures,'' because the defined term ''plant'' focuses on the buildings and structures, and it is not necessary to repeat ''buildings and structures'' when the term ''plant'' is used.

23. Preventive Controls

We proposed to define the term ''preventive controls'' to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of 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.

(Comment 50) Some comments ask us to clarify the meaning of ''current scientific understanding'' because scientific understanding can vary depending on the risk profile of a commodity.

(Response 50) By ''current scientific understanding,'' we mean to emphasize

that scientific information changes over time and a facility needs to keep current regarding safe handling and production practices such that the facility has the information necessary to apply appropriate handling and production practices.

24. Preventive Controls Qualified Individual

We proposed to define the term ''qualified individual'' to mean a person 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. We have changed the proposed term ''qualified individual'' to ''preventive controls qualified individual'' because we are establishing a new definition for ''qualified individual,'' with a meaning distinct from ''preventive controls qualified individual.'' To minimize the potential for confusion, for when the term ''qualified individual'' refers to the proposed meaning of the term and when the term ''qualified individual'' refers to the meaning of that term as finalized in this rule, in the remainder of this document we use the new term ''preventive controls qualified individual'' whenever we mean ''a person 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,'' even though the proposed rule used the term ''qualified individual.'' Likewise, we use the new term ''preventive controls qualified individual'' for the proposed term ''qualified individual'' when describing the comments to the proposed rule, even though those comments use the term ''qualified individual.''

In the following paragraphs, we discuss comments on this proposed definition. (See also our discussion in section XXXVII.B of the requirements applicable to the preventive controls qualified individual (§ 507.53(c)).)

(Comment 51) Some comments assert that the proposed definition of preventive controls qualified individual is ambiguous.

(Response 51) The comments provide no basis for asserting that this definition is ambiguous. The proposed definition includes a performance standard (qualified to develop and apply a food safety system), two criteria for how a person can become qualified (specialized training or job experience), and a description of the type of applicable training (development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum). The proposed definition provides flexibility for how an individual can become qualified, but this flexibility does not make the definition ambiguous.

(Comment 52) Some comments ask us to expand the definition so that it includes a team of preventive controls qualified individuals, not just a single person.

(Response 52) We decline this request. The definition applies to each preventive controls qualified individual that a facility relies on to satisfy the requirements of the rule without limiting the number of such preventive controls qualified individuals. The requirements of the rule make clear that a facility may rely on more than one preventive controls qualified individual (see, *e.g.,* § 507.53(a)).

(Comment 53) Several comments state that there is a lack of specificity about what constitutes appropriate training and experience to qualify as a ''preventive controls qualified individual.'' Another comment asks us to clarify how the qualification of the ''preventive controls qualified individual'' will be assessed. One comment asks how the resume and experience of preventive controls qualified individuals in other countries will be evaluated by FDA to determine that they meet the required qualifications.

(Response 53) As discussed further in Response 395, we do not expect to directly assess the qualifications (whether obtained by training or by job experience) of persons who function as preventive controls qualified individuals. Instead, we intend to focus our inspections of both domestic and foreign facilities on the adequacy of the food safety plan prepared by the preventive controls qualified individual (or under their oversight). As necessary and appropriate, we will consider whether deficiencies we identify in the food safety plan suggest that the preventive controls qualified individual may not have adequate training or experience to carry out the required functions. If the food safety plan suggests the preventive controls qualified individual does not have adequate training or experience, we will perform a more in-depth review of the preventive controls qualified individual's training or experience, including any associated documentation.

See also our discussion in section XXXVII.B about the requirements applicable to the preventive controls qualified individual (§ 507.53(c)).

25. Qualified Auditor

We proposed to define the term ''qualified auditor'' to mean a person who is a preventive controls qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 507.53(c)(2). As discussed in Response 399, we have revised the definition to specify that ''qualified auditor'' means a person who is a ''qualified individual'' as that term is defined in this final rule, rather than a ''preventive controls qualified individual,'' because some auditors may be auditing businesses (such as produce farms) that are not subject to the requirements for hazard analysis and risk-based preventive controls, and it would not be necessary for such an auditor to be a ''preventive controls qualified individual.'' We also have clarified that the technical expertise is obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function to align the description of applicable education, training, and experience with the description of applicable education, training, and experience in the definition of ''qualified individual'' (see § 507.3).

(Comment 54) Some comments ask us to revise the definition of qualified auditor to include persons who have technical expertise obtained by a combination of training, experience, or education appropriate to perform audits. Some comments ask us to recognize that training and/or experience can make a person a qualified auditor; the comments state that people with experience performing audits likely have applicable training but might not have completed a specific regimen of courses. Some comments maintain that we should recognize the role of the education of a potential qualified auditor, as well as training and experience to meet the criteria.

(Response 54) We agree that a qualified auditor might obtain the necessary auditing expertise in part through education, as well as through training and experience, and we have revised the definition of qualified auditor accordingly. The revised definition states that a qualified auditor has technical expertise obtained through education, training, or experience (or the combination thereof).

(Comment 55) Some comments that support the proposed definition ask us to revise the definition to specify certain individuals who would be considered qualified auditors, such as FDA inspectors, properly trained Federal auditors, and State and private auditors operating under a contract with the Federal Government.

(Response 55) We have revised the regulatory text to specify that 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 (*i.e.,* regulations in our forthcoming third-party certification rule implementing section 808 of the FD&C Act (21 U.S.C. 348d)). Although we agree that it is useful to include examples of individuals who would have the appropriate qualifications, the example of an audit agent of a certification body that has been accredited in accordance with our regulations in our forthcoming third-party certification rule adds context about the standard for such individuals. Because paragraph (2) of the new provision refers to provisions in a future third-party certification rule, we will publish a document in the **Federal Register** announcing the effective date of paragraph (2) when we finalize the third-party certification rule.

26. Qualified End-User

We proposed to define the term ''qualified end-user'' to mean, with respect to an animal food, the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227(b)) that: (1) Is located (a) in the same State as the qualified facility that sold the food to such restaurant or establishment; or (b) is not more than 275 miles from such facility; and (2) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment. We have revised the definition of ''qualified end-user'' to add ''or the same Indian reservation'' to clarify for purposes of this rule that ''in the same State'' under section 418(l)(4)(B)(ii)(I) of the FD&C Act includes both within a State and within the reservation of a Federally-Recognized Tribe.

(Comment 56) One comment requests the term ''restaurant'' be removed from the proposed definition of ''qualified end-user'' and replaced with the appropriate definitional terms for ''restaurant'' provided in § 1.227: Pet shelters, kennels, and veterinary facilities in which animal food is provided to animals. The comment also suggests we modify the definition of ''qualified end-user'' to be reflective of the customer who is the purchaser of the animal food.

(Response 56) We decline these requests. The definition of ''qualified end-user'' is consistent with the definition in section 418(l)(4)(B) of the FD&C Act. As discussed in Response 81, we decline to define consumer.

27. Qualified Facility

We proposed to define ''qualified facility'' by incorporating the description of ''qualified facility'' in section 418(l)(1) of the FD&C Act with editorial changes to improve clarity. That definition includes two types of facilities: (1) A facility that is a very small business as defined in this rule and (2) a facility to which certain statutory criteria apply regarding the average monetary value of animal food sold by the facility and the entities to which the animal food was sold.

For the second type of facility, to represent accurately the language of section 418(l) of the FD&C Act, we have changed ''animal food'' to ''food.''

Some comments discuss issues related to the definition of very small business. See section VIII.A.36 for the discussion of the definition of very small business.

(Comment 57) Some comments assert that the definitions of ''affiliate'' and ''subsidiary'' in the definition of ''qualified facility'' fail to account for the legal differences between a piece of property (*i.e.,* a facility) and a business entity or person. These comments ask us to consider revising the proposed definition of ''qualified facility'' to clarify what sales to include in determining whether a facility so qualifies.

(Response 57) We have not revised the proposed definition of ''qualified facility'' as requested by these comments. The sales to be included when a facility determines whether it meets the definition of a qualified facility are the sales of animal food by a business entity meeting the ''very small business'' definition or food by a business entity meeting the other qualified facility definition, each of which includes the parent company and all its subsidiaries and affiliates. The total sales are applicable to each entity, whether it is the parent, the subsidiary or the affiliate. We intend to address issues such as these in guidance as directed by section 418(l)(2)(B)(ii) of the FD&C Act.

(Comment 58) Some comments ask us to clarify who will determine whether a particular facility is a qualified facility.

(Response 58) Any facility that determines that it satisfies the criteria for a ''qualified facility'' must notify FDA of that determination (see § 507.7) and, thus, the first determination will be made by the facility itself. During inspection, the investigator could ask to see the records that support the facility's determination to verify the facility's determination.

In this rule, we remove the term ''quality control operation'' because the term is very broad within the animal food industry and may not be specific to animal food safety.

28. Receiving Facility

We proposed to define the term ''receiving facility'' to mean a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

(Comment 59) Some comments ask us to modify the definition to specify that the receiving facility could receive the raw material or ingredient directly from a supplier or by means of an intermediary entity. These comments assert that without this added regulatory text the proposed definition implies that the material or ingredient must be received directly from the supplier.

(Response 59) We decline this request. As discussed in section XLII.B and C, the two parties that are critical to the supplier verification program are the receiving facility and the supplier, even if there are entities in the supply chain between the two. The definition of receiving facility does not preclude the participation of intermediary entities in the supply chain, and the rule does provide for such participation (see § 507.115). However, the definition of receiving facility does highlight the fact that a receiving facility must have a link to a supplier.

29. Rework

We proposed to define ''rework'' to mean clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. In this rule, we add ''animal'' before food for clarity.

(Comment 60) Several comments request that we replace ''insanitary'' with ''unclean'' as the former term is not utilized in the animal food industry. Other comments state that the proposed definition for ''rework'' is too narrow and does not represent its use in animal food production.

(Response 60) We decline this request. The word ''insanitary'' is used in the FD&C Act and human food

regulations, including the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (currently 21 CFR part 110 and updated and included in the final rule for preventive controls for human food (21 CFR part 117) published elsewhere in this **Federal Register**). Because of the use of the term in the FD&C Act and various FDA regulations, we think industry is familiar with the word ''insanitary'' and it is an appropriate word to use in this final rule.

We disagree that the definition of the term ''rework'' is too narrow. The definition allows the flexibility for an establishment to consider clean, unadulterated animal food that was never adulterated or was successfully reconditioned to be rework.

30. Sanitize

We proposed to define ''sanitize'' to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of animal or human health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

(Comment 61) Several comments request that we replace the term ''sanitize'' with ''clean,'' as the former term is not utilized in the animal food industry. Other comments ask us to modify the definition because the destruction of all microorganisms of animal or human health concern is not always practical, and because the terminology ''adversely affecting the product or its safety for animal or humans'' is ambiguous. Others ask us to revise the definition to state that ''adequate'' or ''adequately'' means to reduce the presence of organisms of concern sufficient to help prevent illness through cleaning and sanitizing using EPA registered/FDA regulated food use antimicrobials and other means such as heat, ozone, etc. Some comments ask us to clarify that the ''cleaning'' should be appropriate to the specific food system and method used for sanitizing, and that cleaning should only be required when the sanitizing process alone would not be effective without a prior cleaning step.

Some comments express concern about whether the proposed definition of ''sanitize'' would preclude the continued, routine use of dry cleaning methods with no sanitizing step. These comments note that adding routine aqueous-based cleaning and sanitizing procedures could create a public health risk in certain operations such as low moisture food production. These comments also note that dry cleaning procedures can result in equipment that, while sanitary, is neither visibly clean nor suitable for aqueous chemical sanitizers.

(Response 61) When the destruction of microorganisms is required, we use the terms ''sanitize'' or ''sanitizing,'' to differentiate from ''cleaning'' or ''sanitation,'' which is consistent with how these terms are used throughout our current regulations for human food. Therefore, we believe that ''sanitize'' is a word that is commonly understood by industry and is used in this final rule in a way that is consistent with how it is used in our other regulations relating to food.

We consider that systems such as steam systems clean the surfaces, as well as sanitize them and, thus, satisfy the definition of ''sanitize.'' The definition of ''sanitize'' does not preclude the continued use of dry cleaning methods with no sanitizing step because the definition describes the meaning of the term ''sanitize'' without establishing any requirement for when equipment must be sanitized.

We have revised the definition so that it means adequately treating ''surfaces'' rather than ''food-contact surfaces.'' As a technical matter, adequately treating any surface—regardless of whether it is a food-contact surface—by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans, is ''sanitizing'' the surface. Clarifying this technical meaning of the term ''sanitize'' imposes no requirements to sanitize surfaces other than animal food-contact surfaces; the requirements for sanitizing surfaces are established by provisions such as § 507.19(b)(2), not by the definition of the term ''sanitize.''

31. Significant Hazard (Hazard Requiring a Preventive Control)

We proposed to define the term ''significant hazard'' to mean 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, establish controls to significantly minimize or prevent the hazard in an animal food. The rule would use the term ''significant hazard'' rather than ''hazard reasonably likely to occur'' to reduce the potential for a misinterpretation that all necessary preventive controls must be established at CCPs (79 FR 58476 at 58477 through 58478).

(Comment 62) Comments support using a term other than ''hazard reasonably likely to occur'' and agree that using a term other than ''hazard reasonably likely to occur'' throughout the rule will reduce the potential for a misinterpretation that all necessary preventive controls must be established at CCPs.

Some comments support the regulatory text of the proposed definition of the term ''significant hazard.'' These comments state that the proposed regulatory text more closely aligns with the principles in FSMA (''reasonably foreseeable'' and ''significantly minimize or prevent'') and provides operators the flexibility to implement a range of preventive controls that are commensurate with the risk and probability posed by a specific hazard. Some comments agree that the proposed regulatory text can clarify the difference between HACCP rules and the animal preventive controls rule. Some comments state that the proposed regulatory text plainly reflects the concept that significant hazards are those hazards to be addressed through the very broad category of preventive controls, and the rule is explicit that preventive controls may be controls other than CCPs. Some comments state that the definition reflects the risk-based nature (*i.e.,* both the severity of a potential hazard and the probability that the hazard will occur) of the requirements and provides additional flexibility so that facilities can take into account the nature of the preventive control in determining when and how to establish and implement appropriate preventive control management components. Some comments support including the phrase ''based on the outcome of a hazard analysis'' in the definition because it ensures that identification of significant hazards will be risk based. Some comments ask us to be clear about FDA's expectations concerning a hazard analysis conducted by those involved in animal food production. Some comments ask us to preserve in the final definition two key aspects that grant the animal food industry the flexibility that it needs: (1) The logical conclusion that not all hazards will have the same impact or will even constitute ''significant hazards'' at all, depending on the facility's products and position in the supply chain and (2) the fact that a ''person knowledgeable about the safe manufacturing, processing, packing, or holding of food'' must be knowledgeable about the specific food produced at that

facility and in that specific sector of the food industry.

Some of the comments that support the regulatory text of the proposed definition nonetheless express concern about the term ''significant hazard.'' Some of these comments express concern that a facility may not recognize hazards that need to be controlled because they do not rise to the commonly understood meaning of ''significant.'' Other comments express concern that the adjective ''significant'' is subject to many interpretations and suggest that the term ''hazard requiring control'' would be more straightforward, accurate, and suitable.

Other comments express concern that the term ''significant hazard'' could cause confusion because it has implications in HACCP systems. For example, ''significant hazard'' is often used in the context of CCPs and preventive controls are not necessarily established at CCPs. Some of these comments suggest that we eliminate the term and instead use the full regulatory text of the proposed definition in place of ''significant hazard'' throughout the regulations. Other comments suggest using a term such as ''food safety hazard'' or ''actionable hazard'' instead of ''significant hazard to avoid a term that has HACCP implications. Other comments state that the term ''significant hazard'' has implications for facilities that follow the Codex HACCP Annex and express concern that foreign facilities would be especially likely to be confused by the term ''significant hazard.''

Some comments ask us to ensure that the term ''significant hazard'' is used consistently and express the view that some regulatory text refers to a ''hazard'' or ''known and reasonably foreseeable hazard'' where ''significant hazard'' should instead be used. As discussed in Comment 31, some comments express concern that the rule would refer to multiple levels of hazard and ask us to provide sufficient clarity to be able to distinguish between these types of hazards.

(Response 62) We have changed the term ''significant hazard'' to ''hazard requiring a preventive control.'' The new term uses the explicit language of FSMA (*i.e.,* ''preventive control''), is consistent with the specific suggestion of one comment (*i.e.,* hazard requiring a control''), and is not commonly associated with HACCP systems. We decline the request to use the term ''food safety hazard'' because that term already is established in Federal HACCP regulations for seafood and meat/poultry, and the comments are particularly concerned about using a term that has implications for HACCP systems. We also decline the request to use the term ''actionable hazard,'' because the term ''actionable'' is associated with violations at a food processing plant.

We reviewed the full regulatory text of proposed subpart C and replaced ''significant hazard'' with ''hazard requiring a preventive control'' in most cases. See table 31.

We also reviewed the full regulatory text of proposed subpart C to evaluate whether there were any circumstances where the regulatory text should more appropriately refer to ''hazard requiring a preventive control'' rather than ''hazard'' or ''known or reasonably foreseeable hazard.'' The term ''known or reasonably foreseeable hazard'' appears only once, in the requirement for a facility to conduct a hazard analysis (§ 507.33(a)). We are retaining ''known or reasonably foreseeable hazard'' in that requirement because it is necessary to implement the tiered approach to the requirements for hazard analysis and risk-based preventive controls (see Response 31). To reinforce this tiered approach, and emphasize that the facility only conducts a hazard analysis for known or reasonably foreseeable hazards, we revised ''hazard'' to ''known or reasonably foreseeable hazard'' in two additional provisions in the requirements for hazard identification (see the introductory regulatory text for § 507.33(b)(1) and (2)).

In our review of the full regulatory text of proposed subpart C, we did not identify any circumstances where we believe it is appropriate and necessary to specify ''hazard requiring a preventive control'' in place of ''hazard.'' It is not necessary for the regulatory text of requirements for preventive controls, the supply-chain program, the recall plan, corrective actions, and verification to specify ''hazard requiring a preventive control'' every time that the requirements use the term ''hazard'' because the context of the requirement establishes the applicability to ''hazards requiring a preventive control.'' Although we acknowledge that using ''hazard requiring a preventive control'' in place of ''hazard'' throughout applicable provisions of proposed subpart C would emphasize the tiered approach to the requirements for hazard analysis and risk-based preventive controls, doing so would make the regulatory text unnecessarily bulky and awkward and would be inconsistent with comments that ask us to make the regulatory text understandable (see Comment 13 in section III of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**).

(Comment 63) Some comments ask us to allow facilities to continue to implement existing controls outside the framework of this rule (*i.e.,* outside the framework that requires preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the food safety system) when a hazard addressed by the existing controls does not rise to the level of ''significant hazard.''

Other comments express concern that the term ''significant hazard'' may create a disincentive for facilities to voluntarily implement preventive controls for hazards that only pose a remote risk or are very rarely encountered, because implementing preventive controls for hazards of very low probability and severity may be misinterpreted as requiring preventive controls applicable to a ''significant hazard'' even if the hazard does not meet the definition of ''significant hazard'' established in the rule. Some comments ask us to revise the definition to provide facilities with the flexibility and discretion to establish appropriate preventive controls for hazards that do not rise to the criteria of a ''significant hazard,'' as well as ensuring that preventive controls that address remote or very unlikely hazards not be subject to the preventive control management requirements for a ''significant hazard.''

(Response 63) We have revised the definition to specify that the term ''hazard requiring a preventive control'' applies when a knowledgeable person would, based on the outcome of a hazard analysis, ''establish one or more preventive controls'' rather than ''establish controls.'' By narrowing ''controls'' to ''one or more preventive controls,'' we mean to signify that the proposed term ''significant hazard'' (which we now refer to as ''hazard requiring a preventive control'') only applies to those controls that the facility establishes to comply with the requirements of subparts C and E for hazard analysis and risk-based preventive controls. A facility that establishes other controls (such as those that the comments describe as ''prerequisite programs,'' or controls directed to hazards of very low probability and severity) for hazards that are not, based on the outcome of the facility's hazard analysis, ''hazards requiring a preventive control'' would not need to establish preventive control management components for such controls. However, some controls

previously established in ''prerequisite programs'' would be considered ''preventive controls.'' We provide some flexibility for facilities with respect to how they manage preventive controls, and the preventive control management components may be different for hazards that have been managed as ''prerequisite programs'' compared to those managed with CCPs. A facility that is concerned about the potential for an investigator to disagree during inspection that certain controls are not directed to ''hazards requiring a preventive control'' could, for example, include information relevant to its classification of those other controls in its hazard analysis, whether by merely listing the ''other controls'' or by providing a brief explanation why such controls are not ''preventive controls'' as that term is defined in this rule.

(Comment 64) Some comments assert that the proposed definition of ''significant hazard'' is tautological because it essentially establishes a ''significant hazard'' to be a known or reasonably foreseeable hazard (*i.e.,* the type of hazards identified in the first step of the analysis) for which preventive controls should be implemented. These comments assert that the proposed definition of ''significant hazard'' would collapse the second step of hazard analysis into the first, which in turn would lead to the unintended consequence of facilities identifying the same hazards in the second step as in the first. Some comments ask us to revise the definition to include evaluation of severity and probability, because these concepts are integral for making a proper determination of whether a hazard is significant. Other comments ask us to revise the definition to better reflect the risk-based approach that preventive controls be implemented to control hazards that have a higher probability of resulting in public health consequence in the absence of control.

(Response 64) We have revised the definition of ''significant hazard'' (which we now refer to as ''hazard requiring a preventive control'') to specify that the hazard analysis includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. By specifying that the determination of a ''significant hazard'' is based on the outcome of a hazard analysis, the proposed definition did, as requested by the comments, include the risk-based nature of the determination. However, explicitly adding that the hazard analysis is based on probability and severity (*i.e.,* risk) makes the risk-based nature of the determination clearer.

We disagree that the proposed definition was tautological and would collapse the second step of hazard analysis into the first. A facility begins its hazard analysis by narrowing down the universe of all potential hazards to those that are ''known or reasonably foreseeable'' for each type of animal food manufactured, processed, packed, or held at its facility. The outcome of the facility's hazard analysis is a determination of a subset of those known or reasonably foreseeable hazards, *i.e.,* those hazards requiring a preventive control. To the extent that these comments are asserting that the tautology was created by the phrase ''in the absence of its control'' in the proposed definition of ''hazard,'' we have deleted that phrase from the final definition of ''hazard.''

We decline the request to repeat in the definition of ''hazard requiring a preventive control'' the requirement for the types of information that a facility would consider in conducting its hazard analysis. The requirements for hazard analysis clearly specify that a facility must conduct its hazard analysis based on experience, illness data, scientific reports, and other information (see § 507.33(a)).

(Comment 65) Some comments that broadly address the overall framework for the new requirements for hazard analysis and risk-based preventive controls ask us to consistently refer to ''the nature of the preventive control'' (rather than simply to ''the preventive control'') when communicating the flexibility that a facility has in identifying preventive controls and associated preventive control management components. Other comments that broadly address the overall framework for the new requirements for hazard analysis and risk-based preventive controls ask us to emphasize that the requirements for preventive control management components convey not only that the application of a particular element is appropriate (*i.e.,* capable of being applied), but also necessary for food safety. Some comments recommend that we do so by specifying that preventive control management components take into account the role of the preventive control in the food safety system.

(Response 65) We agree with these comments and have revised the definition of ''hazard requiring a preventive control'' to specify that preventive control management components are established as appropriate to ''the nature of the preventive control and its role in the facility's food safety system.''

(Comment 66) Some comments assert that the problem is how to separate the hazards addressed by ''HACCP'' from those addressed by CGMPs. These comments suggest that control measures that are implemented for hazards from ingredients and food-contact packaging material, and from production and process, be called CCPs and that control measures that are implemented for hazards from personnel, equipment, and the plant be called preventive controls.

(Response 66) The facility must control hazards through the application of CGMPs and preventive controls as appropriate to the hazard. Although some preventive controls will be established at CCPs, and ''CCP'' is a term commonly used in HACCP systems, this rule establishes requirements for hazard analysis and risk-based preventive controls, not ''HACCP,'' and this rule provides that preventive controls include controls at CCPs, if there are any CCPs, as well as controls, other than those at CCPs, that are also appropriate for animal food safety (see § 507.34(a)(2)).

Under the rule, some hazards may be addressed by CGMPs and others by preventive controls. For example, a facility could control a physical hazard such as metal by using screens and magnets under CGMPs and then use a metal detector as a preventive control.

(Comment 67) Some comments express concern that the term ''significant hazard'' may lead to misunderstanding by medium and smaller processors and ask how businesses with limited food safety experience will understand the difference between a food safety hazard that is ''reasonably likely to occur'' (and, thus, must be controlled by a full HACCP Plan) and a ''significant hazard'' that can be controlled by a preventive control plan.

(Response 67) It will not be necessary for an animal food processor to understand the difference between a hazard that is ''reasonably likely to occur'' in the concept of HACCP requirements and a ''hazard requiring a preventive control'' in the context of this rule. FDA does not have any HACCP regulations that apply to animal food.

(Comment 68) Some comments ask us to concur that ''temporal hazards'' in some food products (specifically, aflatoxin, pesticides, and radiological contamination) do not represent ''significant hazards'' that require monitoring and verification activities on an ongoing basis. These comments also ask us to acknowledge that in many

cases the testing done by FDA and others is sufficient for protecting public health and that it is not necessary to require ongoing monitoring by individual facilities in order to comply with the rule.

(Response 68) We decline these requests because such a determination should be facility specific. However, we have revised the considerations for the hazard evaluation to clarify that in making the determination as to what hazards require preventive controls, the facility can consider factors such as the temporal nature of the hazard (see § 507.33 and section XXV). In determining the appropriate preventive control management components, the facility can take into account the nature of the preventive control and its role in the facility's food safety system (see § 507.39(a)).

32. Significantly Minimize

We proposed to define the term ''significantly minimize'' to mean to reduce to an acceptable level, including to eliminate. We did not receive comment and are finalizing it as proposed.

33. Small Business

We proposed to define the term ''small business'' to mean, for the purposes of part 507, a business employing fewer than 500 persons. We conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 12) and used the results of the study in defining the term ''small business.'' (78 FR 64736 at 64758 through 64759.) We made the results of the Food Processing Sector Study available in Docket No. FDA–2011–N–0922 and requested public comment on that study.

(Comment 69) Some comments express concern that the Food Processing Sector Study is not comprehensive. Some comments assert that FDA did not sufficiently collaborate with USDA, and that FDA significantly underestimated the number of mixed-use facilities, particularly by neglecting to count farms that perform the processing steps on RACs to become a processed food. Other comments assert that the Food Processing Sector Study is woefully inadequate and must be undertaken again to comply with the law.

(Response 692) We previously acknowledged the limitations of the Food Processing Sector Study (78 FR 64736 at 64758 through 64759). We have revised and extended the results of our earlier study by expanding our data sources and by including representatives from USDA's Economic Research Service, USDA's Agricultural Marketing Service and the American Farm Bureau to help oversee the revised study. The revised Food Processing Sector Study is available in the docket of this rule (Ref. 21).

Our original analysis was based on the merger of Dun & Bradstreet data and FDA's Food Facility Registration data to help us estimate the number of manufacturing facilities that are also classified as farms. We have updated that data source and added data sources. To better account for farms that perform processing activities, we included Census of Agriculture (Ag Census) data both to provide a count of total U.S. farms and to estimate the number of farms conducting food processing activities, to the extent that the data identifies processing activities. We also included the Agricultural Resource Management Survey (ARMS) data because it included questions about some processing activities for select commodities.

Both the Ag Census and ARMS are silent about many processing activities. Therefore, we also obtained estimates from commodity specialists at trade associations, USDA, and universities with in-depth knowledge of the processing activities for specific agricultural commodities.

(Comment 70) Some comments ask us to explain how to calculate the number of full-time equivalent employees, *e.g.,* with respect to temporary workers, seasonal workers, and part-time workers. Other comments say it is unclear whether fewer than 500 full-time equivalent employees means those involved in the entire business or those involved only in the animal food-related portions of the business, noting that the term ''business'' is unclear (*i.e.,* whether business means a corporation and all its subsidiaries or only the portion of the business related to animal food be it animal feed, pet food and/or ingredients).

(Response 70) As previously discussed, we proposed to establish the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR part 121 for most food manufacturers, and the limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility (78 FR 64736 at 64759). We will base the calculation on ''full-time equivalent employees'' and use the same approach to calculating full-time equivalent employees for the purpose of this rule as we used to calculate full-time equivalent employees in the section 414 recordkeeping regulations (see § 1.328). This approach is similar to the approach the Agency used to calculate the small business exemption for nutrition labeling of food (§ 101.9(j)(18)(iv)(D)). Under this approach, the number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity claiming the exemption and of all of its subsidiaries and affiliates by the number of hours of work in 1 year, 2,080 hours (*i.e.,* 40 hours × 52 weeks).

The calculation for the number of employees affects exemptions (*i.e.,* the exemptions for on-farm, low-risk activity/animal food combinations in § 507.5(e) and (f), which apply only to small and very small businesses), not just compliance dates. Therefore, we are establishing the definition of ''full-time equivalent employee'' in the definitions for this rule (§ 507.3) and modifying the definition of ''small business'' to use the term ''500 full-time equivalent employees'' rather than ''500 persons.''

(Comment 71) Some comments assert that there should be no exemption from compliance with this rule based on total annual sales or number of employees, noting that all companies regardless of size should have food safety programs in place.

(Response 71) The definition of ''small business'' is relevant to the exemptions for on-farm, low-risk activity/animal food combinations for manufacturing/processing, packing, and holding animal food by mixed-type facilities. This exemption is a risk-based exemption, because it only applies to activity/animal food combinations that are low-risk and, thus, should not affect animal food safety.

34. Supplier

We proposed to define the term ''supplier'' to mean the establishment that manufactures/processes the food, raises the animal, or harvests 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.

As discussed in section IV.B of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, we have revised the ''farm'' definition to explicitly include business models in which one operation grows crops but does not harvest them, and another operation, not under the same management, harvests crops but does not grow them. This revision represents a change from the existing and proposed

''farm'' definitions, which describe a ''farm'' as an entity ''devoted to the growing *and* harvesting of crops'' (emphasis added). We proposed the ''supplier'' definition in the context of a single business entity ''devoted to the growing *and* harvesting of crops'' (emphasis added). We used the term ''harvesting,'' rather than ''growing,'' to reflect the last stage of production on a farm, except for packing.

Because the proposed ''supplier'' definition contemplated that the same business entity that grows crops also harvests them, we have revised the ''supplier'' definition so that the grower remains the supplier when the harvester is under separate management. Specifically, ''supplier'' is now defined to include an establishment that ''grows'' food rather than an establishment that ''harvests'' food. Doing so focuses the requirements for the supply-chain program (see subpart E) on the entity that produces the food, rather than on the entity that removes the food from the growing area, when the grower and the harvester are not under the same management. Doing so also simplifies the determination of who the supplier is in complex business models, such as when a ''handler'' arranges for harvest by another business entity.

(Comment 72) Some comments assert that the definition of supplier is not workable because the status of warehouses and brokers is unclear in the definition. Other comments ask us to modify the definition to specify, in addition to the proposed definition, that the supplier could be an intermediary entity that takes responsibility on behalf of the receiving facility to ensure that the food meets the requirements of this part.

(Response 72) As discussed in section XL, we agree that the role of intermediaries in the supply chain is critical and we have added options for entities other than the receiving facility to perform certain supplier verification activities, provided that the receiving facility reviews and assesses the documentation produced by the other entity and documents that review and assessment. However, this does not mean that these entities take on the role of the supplier. As discussed in Response 59 and in section XL, we believe it is important to supplier verification to retain the identities of two parties involved—the receiving facility and the supplier. Therefore, we are retaining our definition of supplier, with the minor change previously discussed.

(Comment 73) Some comments regarding RACs ask us to modify the definition of supplier in the case of comingled RACs, such that the supplier would be the person immediately back from the receiving facility in the supply chain provided that this entity (presumably a warehouse or aggregator) voluntarily complies with the requirements of subpart C of this part. One comment asks us to clarify in our definition that the supplier must be the establishment that controls the hazard in question.

(Response 73) We decline this request. As discussed in section XL, we recognize that doing supplier verification with comingled products will be a challenge. However, we believe it is important that there be a link between the receiving facility (which is manufacturing/processing the animal food) and the supplier (who controlled the hazard(s) in the animal food). We are allowing an entity such as an aggregator or distributor to perform some verification activities, so the outcome requested by these comments will be achieved while maintaining the identities of the two primary parties in the supplier verification relationship (see Response 492).

(Comment 74) One comment asks us to clarify that the proposed definition of supplier does not include sources of processing aids or chemicals required for post-harvest treatments and packing processes (including waxes, fungicides, detergents and sanitizers).

(Response 74) As defined, the supplier is the establishment growing the food, not those establishments providing inputs (such as waxes, fungicides, detergents and sanitizers) to that entity.

35. Validation and Verification

We proposed to define the term ''validation'' to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards. We proposed to define the term ''verification'' to mean those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

(Comment 75) Some comments ask us to revise the definitions of ''validation'' and ''verification'' to be consistent with the Codex definitions. Codex defines ''validation'' to mean obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. Codex defines ''verification'' to mean the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended (Ref. 22).

Some comments ask us to more clearly distinguish between ''validation'' and ''verification.'' Some comments assert that validation is not an element of verification as stated in our proposed definition and suggest that we clearly separate requirements for validation from requirements for verification, *e.g.,* by moving the proposed requirements for verification to a distinct section in the regulatory text.

(Response 75) We have explained how our proposed definitions for ''validation'' and ''verification'' align with a variety of widely recognized definitions, including definitions established by Codex, the NACMCF HACCP guidelines, and Federal HACCP (78 FR 64736 at 64758). We disagree that validation is not an element of verification, but acknowledge it is not necessary to say so within the definition of ''validation.'' Although we have moved the details of the requirements for validation from its proposed location within the requirements for verification (*i.e.,* proposed § 507.45(a)) to a separate section (§ 507.47), we did so as an editorial change to improve clarity and readability rather than as a substantive change to signal that validation is not an element of verification (see table 8, 79 FR 58476 at 58504).

We agree that validation can apply to a specific control measure as specified in the Codex definition. We also agree that validation can apply to a combination of control measures as specified in the Codex definition. The food safety plan is one example of a combination of control measures.

Although we likewise agree that verification can apply to a specific control measure as specified in the Codex definition, we disagree that to be consistent with the Codex definition we should adopt a definition that excludes the application of verification to the food safety plan. It is well established that some verification measures, such as testing for a pathogen, verify that multiple control measures operated as intended.

To more clearly distinguish between ''validation'' and ''verification,'' the definition of ''validation'' we are establishing in this rule specifies that validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, *when properly implemented,* is capable of effectively controlling the identified

hazards (emphasis added). We also made conforming changes associated with the revised definition of ''validation'' in the requirements for validation (see § 507.47(b)(2)). The definition of ''verification'' we are establishing in this rule specifies that 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 as a whole (emphasis added). Consistent with the request of the comments, the definition of ''verification'' uses the Codex description of verification as the application of methods, procedures, tests and other evaluations, in addition to monitoring.

36. Very Small Business

We proposed to define the term ''very small business'' to mean, for the purposes of proposed part 507, a business that has less than $2,500,000 in total annual sales of food for animals, adjusted for inflation. As discussed in the proposed rule, we conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 12) and used the results of the study in defining the term ''very small business'' (78 FR 64736 at 64758 through 64760). We made the results of the Food Processing Sector Study available in Docket No. FDA–2011–N–0922. Some comments support defining ''very small business'' as a business that has less than $2,500,000 in total annual sales of animal food, adjusted for inflation. Other comments disagree or offer alternative recommendations.

(Comment 76) Some comments ask us to clarify how to classify the size of a business that does not take ownership or directly sell food (*e.g.,* warehouses and contract manufacturers) to determine status as a qualified facility. Some comments recommend modifications to the proposed very small business definition based on a discussion of certain farming models in the 2014 supplemental notice for animal food (79 FR 58476 at 58482). These comments express concern that the proposed definition of very small business would not account for animal food that is not ''sold,'' but is manufactured and then distributed to another entity without a sale, such as in the contract farming model discussed in the 2014 supplemental notice.

Other comments recommend modifications to the definition to use the value or volume of animal food manufactured and distributed in establishing whether a facility is a very small business. The comments state that this would account for the animal food manufactured by feed mills servicing contract farms. Some of these comments state that the value of food produced by feed mills operating under this contract model often exceeds the $2,500,000 threshold of the proposed very small business definition. They state that because this proposed definition only includes sales, it would allow large facilities to be considered very small businesses (as they would have no or a very small amount of actual sales).

Other comments request that we modify the proposed definition to specify that animal food produced for contract farms is not included in ''sales'' in the definition for very small business; thereby allowing these feed mills to be very small businesses, which would result in qualified facility status.

Some comments ask us to specify that the monetary threshold for the definition be based on average sales during a 3-year period on a rolling basis because otherwise firms may be subject to significant changes in status from year to year. These comments also ask us to clarify that the sales are to be evaluated retrospectively, not prospectively.

(Response 76) We have revised the definition of very small business to specify that it is based on an average during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal human food manufactured, processed, packed, or held without sale (*e.g.,* held for a fee or supplied to a farm without sale). The applicable calendar year is the year after the 3 calendar years used to determine whether a facility is a very small business. The most recent applicable calendar year is the current year. For example, on June 3, 2024, 2024 is the most recent applicable calendar year and is the applicable calendar year when the 3 calendar years used to determine whether a facility is a very small business are 2021 to 2023. The exception is when 3 calendar years of records are not available, such as when a facility begins business after the compliance date for very small businesses. In such situations the applicable calendar year refers to the year during which the calculation is made but is not preceded by 3 calendar years used to determine whether a facility is a very small business.

As a companion change, we are explicitly requiring that a facility determine and document its status as a qualified facility on an annual basis by no later than July 1 of each calendar year (see § 507.7(c)(1)). Although this requirement was implicit in the proposed requirement that a facility must resubmit a notification to FDA if its status changes as a qualified facility (proposed § 507.7(c)(2), which we are finalizing as § 507.7(c)(3)), we are making this requirement explicit to clarify the responsibility of the facility to affirmatively determine its status when the calendar years that apply to the 3-year average change. The July 1 deadline for a facility to determine its status provides facilities with 6 months to make the determination after the end of the previous 3 calendar years.

We also are establishing an earlier compliance date for the financial records that a facility maintains to support its status as a very small business. Specifically, the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. Even with this earlier compliance date for these records, we realize that although the calculation for ''very small business'' in the regulatory text is based on 3 calendar years, a facility will only be required to have 2 calendar years of records as of the general compliance date for very small businesses. Specifically, by December 16, 2019 a facility that begins retaining applicable financial records on January 1, 2017, would only have such records for 2 previous calendar years. Therefore, it would be reasonable for a facility to make the calculation based on the 2 previous calendar years. If a facility has records for 3 previous calendar years, the facility could make the calculation based on the longer time period. During inspection in 2019, when a facility has records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years, we will accept records for the preceding 2 calendar years as adequate to support status as a qualified facility based on calculating an average for those two years. We note that in some situations, a shorter time period is sufficient to determine that a facility is not a very small business. For example, a facility with sales exceeding $7,500,000 for the preceding calendar year cannot qualify as a very small business because no amount of sales from other years will reduce average sales below the threshold of $2,500,000.

The available financial records for a facility that begins operations between January 1, 2018 and September 17, 2019 would not cover even 2 complete calendar years by September 17, 2019. During the first 3 calendar years of such a facility's operation, it would be reasonable for a facility to make the calculation based on records it has (*i.e.,* for 1 or 2 preceding calendar years), and

we will accept records for the preceding 1 or 2 years as adequate to support status as a qualified facility in these circumstances.

When a facility does not begin operations until after January 1, 2019, it would be reasonable for the facility to rely on a projected estimate of revenue (or market value) when it begins operations. We would evaluate the credibility of the projection considering factors such as the facility's number of full-time equivalent employees. After the facility has records for 1 or 2 preceding calendar years, it would be reasonable for the facility to make the calculation based on records it has (*i.e.,* for 1 or 2 preceding calendar years) and we will accept records for the preceding 1 or 2 years as adequate to support status as a qualified facility in these circumstances.

We agree with the comments that state the animal food distributed, but not ''sold,'' by feed mills operating under contract farming agreements (and required to register as a food facility under section 415 of the FD&C Act) should be included in determining whether a facility is a very small business. In addition to annual sales of animal food, the market value of the animal food supplied to a farm(s) without sale must be included when determining if a business is a very small business for purposes of this rule.

The qualified facility exemption of § 507.7 applicable to very small businesses is intended to enable these businesses to comply with modified requirements because they have fewer resources to direct to full compliance with subpart Cs and E of the rule and they provide a small volume of animal food for consumption. Many of the businesses that have feed mills that provide animal food under contract farming agreements are extensive and sophisticated businesses, such as some large-scale meat and poultry operations. Such businesses are not the intended beneficiaries of the qualified facility exemption because they should have adequate resources, such as personnel, equipment, and expertise, to implement the requirements of subparts C and E at their feed mills. In addition, many of these feed mills manufacture and distribute a large volume of animal food yearly. These were some of the factors we considered when we revised the proposed definition of a very small business to include the market value of the animal food that is manufactured, processed, packed, or held without sales or supplied to a farm without sales.

(Comment 77) Some comments support the proposed dollar threshold of $2,500,000, noting that it would provide sufficient flexibility to companies that receive the exemption to allow them to continue to operate. Some comments say there should be no exemption from compliance with this rule based on total annual sales or number of employees and that all companies regardless of size should have food safety programs in place. Several comments request different dollar amounts for determining the threshold.

Some comments propose that the threshold should be $1,000,000, a figure that would provide greater coverage than the $2,500,000 proposed threshold and also would simplify compliance with all FSMA rules for animal food facilities. Other comments suggest the definition for a very small business should mean, for purposes of part 507, a business that has less than $1,000,000 in total annual sales of animal food, adjusted for inflation, and distributes less than 5,000 tons of animal food annually. Several comments urge us to consider applying a $500,000 threshold to the value of animal feed produced by a facility, not just the value of animal food that is sold. The comments state that the vertically integrated structure of some livestock and poultry operations means that some animal feed produced at large operations may never be sold because the company supplies feed to contract operations raising animals owned by the company.

Other comments suggest ensuring sufficient flexibility for a diverse array of animal food businesses and that we should establish an outright exemption from the rule for businesses with, at the very most, $100,000 or less in annual average monetary value of animal food sold over the previous 3-year period, adjusted for inflation. Another comment suggests a threshold of $250,000. Other comments recommend defining a very small business as one with less than $10,000 in annual sales believing that a rule encompassing virtually all ingredient and feed manufacturing and distribution facilities will encourage large firms to continue to do business with very small firms. One comment suggested excluding the value of donated by-product in the calculation of total annual sales of animal food.

(Response 77) We are establishing a $2,500,000 threshold for the definition of ''very small business.'' Under section 418(l)(1)(A) and (B) of the FD&C Act, a very small business is a qualified facility; under the exemption authorized in section 418(l)(2) of the FD&C Act, a qualified facility is subject to modified requirements rather than the requirements for hazard analysis and risk-based preventive controls. We have acknowledged that a $2,500,000 threshold exempts a greater portion of the animal food supply than thresholds of either $500,000 or $1,000,000 (79 FR 58476 at 58502), but reaffirm that under the $2,500,000 threshold the businesses that would be exempt from the requirements for hazard analysis and risk-based preventive controls would represent a small portion of the potential risk of foodborne illness; businesses that fall within this definition of ''very small business,'' collectively, produce less than 0.6 percent of the animal food supply (Ref. 3). In addition, most of these facilities will be subject to the CGMP requirements in subpart B; the only exemptions from those CGMP requirements are the exemptions in § 507.5(a) (which applies to farms and activities of ''farm mixed-type facilities'' that fall within the definition of ''farm''), and in § 507.5(h) (which applies to: (1) The holding or transportation of one or more RACs; (2) hulling, shelling, and drying nuts and hulls (without manufacturing/processing); and (3) the ginning of cotton (without manufacturing/processing)). Facilities subject to and in compliance with human food CGMPs and applicable FDA human food safety requirements that process human food and ''donate'' or sell the human food by-products without further processing for use as animal food are only subject to certain provisions in subpart B for those by-products. This applies whether they are a qualified facility or not. They are not subject to the requirements of subparts C and E for the human food by-products used for animal food.

(Comment 78) Some comments ask us to only include the total annual sales of food in the United States, adjusted for inflation, for foreign facilities that export food to the United States.

(Response 78) We decline this request. The purpose of the definition of ''very small business'' is principally to enable such businesses to comply with modified requirements, because they have fewer resources to direct to full compliance with the rule. A foreign business that sells more than the threshold dollar amount of animal food has more resources than the businesses being excluded, even if less than that threshold dollar amount reflects sales to the United States. Likewise, a domestic business that sells more than the threshold dollar amount of food has more resources than the businesses being excluded, even if that domestic business exports some of its food and, as a result, less than that threshold dollar amount reflects sales within the United States.

(Comment 79) Some comments ask us to base the threshold on the total ''volume of product'' or ''amount of product'' handled or sold. These comments assert that an approach using product volume or amount would be more risk based because it would correlate more closely to consumer exposures than dollar amounts, which can be skewed by product values.

(Response 79) We acknowledge that dollar amounts can be skewed by product values but nonetheless disagree that we should base the threshold on the total ''volume of product'' or ''amount of product'' handled or sold. We see no practical way to identify a threshold based on volume or amount of product that could be applied across all product sectors, and the comments provide no suggestions for how their recommendation could be carried out.

(Comment 80) Some comments express concern that establishing a threshold based on U.S. dollars would place domestic firms at a disadvantage relative to foreign firms whose sales are often denominated in currencies valued lower than the dollar and often reflect much lower costs for factors such as land, labor, and environmental compliance. These comments ask us to base the threshold on an alternate measure, such as number of employees, or to calculate the sales of foreign very small businesses using an appropriate measure of purchasing power parity, if there is a straightforward way to do so.

(Response 80) We decline these requests. As previously discussed, we use dollar estimates to evaluate the percent of all food produced in the United States that would not be covered by the rule (79 FR 58476 at 58502). We acknowledge that the definition of ''small business'' is based on number of employees, and that two exemptions (*i.e.,* the exemptions in § 507.5(e) and (f) for on-farm, low-risk activity animal food combinations) apply to small businesses. However, the exemptions for on-farm, low-risk activity animal food combinations are limited to a narrow sector of the animal food industry, whereas the exemption applicable to a very small business will apply to all sectors of the animal food industry.

We do not know of a straightforward way to calculate the sales of foreign very small businesses using an appropriate measure of purchasing power parity and, thus, are basing the threshold only on U.S. dollars.

B. Comments Asking FDA To Establish Additional Definitions or Otherwise Clarify Terms Not Defined in the Rule

Some comments ask us to define certain terms such as ''associated,'' ''contaminate,'' ''directly linked,'' ''integrated operator,'' ''material to the safety of food,'' ''written,'' and ''necessary.'' We believe that it is not necessary to define these and certain other new terms proposed by the comments. We discuss in this section of this document comments that ask us to establish other new terms or clarify terms in the rule not defined.

1. Consumer/Final Consumer/Customer

(Comment 81) A few comments request that we define consumer as the animal consuming the food. Some comments ask us to define ''customer'' as the purchaser of the animal food. Other comments ask us to define ''final consumer'' to mean a person that feeds animals under the control or ownership of that person. The comments suggest ''final consumer'' could be used in the animal food rule to help clarify the meaning of qualified end user.

(Response 81) We decline these requests. We stated that for purposes of the proposed rule, the term consumer refers to the person purchasing the animal food to feed to an animal(s), as well as the animal(s) consuming the food (78 FR 64736 at 64756 through 64757). To limit the definition of consumer to the animal consuming the food would be inconsistent with how that term is used throughout FSMA and would create confusion. Therefore, ''consumer'' also includes the person purchasing the animal food.

2. Corrections

(Comment 82) Some comments assert that clearly distinguishing between the terms ''corrective actions'' and ''corrections'' will be imperative for industry to comply with the rule and for regulators to enforce the rule. Some comments ask us to use the ISO definitions of ''corrective actions'' and ''corrections.'' (According to ISO 22000:2005 definition 3.13, a ''correction'' is action to eliminate a detected non conformity; according to ISO 22000:2005 definition 3.14, corrective action is action to eliminate the cause of a detected non conformity or other undesirable situation.) Other comments ask us to eliminate the term ''correction'' and instead revise the rule to clarify the type of situation in which ''corrective actions'' are neither necessary nor appropriate. As an example, these comments suggest that the proposed provisions for corrections could refer to ''prompt actions taken in response to minor and isolated deviations that do not directly impact product safety.''

Other comments agree with the concept of simple ''corrections'' but assert that the term ''corrections'' is unnecessary and could be confusing because different facilities may use the term differently. These comments explain that sometimes ''correction'' is used to refer to the action taken to fix a deviation, and may or may not be part of an overall corrective action taken to identify the root cause of the deviation and to prevent a similar occurrence. These comments suggest that the provisions explain that prompt actions taken to address minor and isolated deviations are not subject to the same requirements as corrective actions to address potentially systemic concerns, without defining the term ''corrections.''

(Response 82) We are defining the term ''correction'' to mean an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce). We agree that clearly distinguishing between the terms ''corrective actions'' and ''corrections'' will be important for both industry and regulators. We acknowledge that one way to distinguish between ''corrective actions'' and actions that we would consider ''corrections'' could be to avoid the term ''corrections'' and instead say what we mean each time the rule uses the term ''corrections.'' However, after reviewing the full regulatory text of proposed subpart C, we concluded that it was not practical to do so, because the term ''corrections'' was used more often in a title or a cross-reference than in a provision where the full text of what we mean by the term ''corrections'' is necessary to communicate a requirement. Our definition of ''corrections'' focuses on the first step in a ''corrective action procedure'' (*i.e.,* identify and correct the problem) and also specifies those aspects of a corrective action procedure that do not apply to a correction (*i.e.,* actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce). (A note to the ISO 22000:2005 definition of corrective action indicates that it includes cause analysis and is taken to prevent recurrence.) We believe that this definition will be adequate to

distinguish ''corrective actions'' from ''corrections.''

As an example, if a facility applies sanitation controls for an environmental pathogen such as *Salmonella* spp. and animal food residue is observed on ''clean'' equipment prior to production, corrections would involve re-cleaning and sanitizing the equipment before it is used. Because the observation of animal food residue was made prior to production of animal food, no animal food is affected, and no actions are needed with respect to animal food. Although there are actions that can be taken to prevent reoccurrence, such as retraining sanitation personnel, these types of situations may reoccur from time to time.

3. Crop

(Comment 83) Some comments request we define a new term ''crop'' to mean the edible or inedible cultivated or harvested plants.

(Response 83) We decline this request. The term ''crop'' has a common meaning, and it is not necessary to establish a meaning for this term in this rule.

4. Establishment

(Comment 84) Several comments request we establish a definition for establishment as it is used in the supplier definition. Also, the comments suggest that we replace in the definition of farm the term ''establishment'' with ''operation.''

(Response 84) Comments concerning the meaning of the term ''establishment'' as it relates to the ''supplier'' definition are addressed in section XL pertaining to subpart E, the supply-chain program. Comments directed to the meaning of the term ''establishment'' as it relates to the farm definition are addressed in section IV.A and B of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register.**

5. Parameter and Value as Used in the Requirements for Process Controls

(Comment 85) Some comments ask us to define the terms ''parameter'' and ''value'' used in the requirements for preventive controls (§ 507.34). These comments ask us to define ''parameter'' as a measurable attribute and ''value'' as a specific measurement.

(Response 85) We decline this request. Both of these terms are used in the context of process controls and both have common meanings when associated with process controls. Therefore, it is not necessary for the rule to define them.

6. Prerequisite Program

(Comment 86) Some comments ask that we adapt the definition of prerequisite program from the ISO's food safety standard, ISO 22000:2005, noting that the ISO definition is: Basic practices and procedures in animal food production that are necessary for the manufacture, handling and provision of safe end products and safe food for animal consumption.

(Response 86) We do not use the term ''prerequisite program'' in the regulations established by this rulemaking and do not find it necessary to define it. We understand that some facilities may refer to practices and procedures such as CGMPs, training, or certain controls for hazards as a ''prerequisite program.''

7. Qualified Facility Exemption

(Comment 873) Some comments note that some of the terminology associated with the exemption for qualified facilities in the preventive controls rule is different from terminology associated with an exemption in the proposed produce safety rule. These comments point out that the exemption in the proposed produce safety rule refers to ''qualified exemptions'' (§ 112.5), whereas the exemption in the proposed animal preventive controls rule refers to ''exemptions'' and ''qualified facilities'' (§ 507.5(d)).

(Response 873) We have added a definition for the term ''qualified facility exemption,'' to mean an exemption applicable to a qualified facility under § 507.5(d) (see the regulatory text in § 507.3). We also have made conforming changes throughout the rule to use the term ''qualified facility exemption'' when it applies. (See table 31).

8. Qualified Investigator

(Comment 88) Once comment proposes a new term ''qualified investigator'' where the term ''qualified investigator'' means an FDA or state commissioned investigator that has successfully completed a formal training course on inspections; CGMPs; hazard analysis and preventive controls for animal food facilities, both animal feed and pet food, and has demonstrated an understanding of the differences between pet food and animal feed manufacturing facilities.

(Response 88) We decline this request. Our inspectors will be trained on the requirements of this part.

9. Reanalysis

(Comment 89) Some comments request we define the term reanalysis to mean a reassessment of the validity of a preventive control or food safety plan to control a hazard.

(Response 89) We decline this request. Section 418(i) of the FD&C Act sets the requirement for conducting a reanalysis, which is in the regulatory text in § 507.50, including how often and under what circumstances a reanalysis of the food safety plan must be performed, and how to handle the results. Therefore, we have determined that a definition of ''reanalysis'' is not necessary. For a discussion of the reanalysis requirement, see section XXXV.

10. Risk Assessment

(Comment 90) Some comments request that we add a new term ''risk assessment'' and define this term as a scientifically based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization.

(Response 90) We do not use the term ''risk assessment'' in the regulations established by this rulemaking and do not find it necessary to define it. As directed by section 103(c) of FSMA, we issued for public comment a draft risk assessment, as described in section I.D and are including the final risk assessment in the docket established for this rule.

The definition proposed by the comment is similar to the requirements for the hazard analysis of § 507.33. The term ''hazard analysis'' comes from section 418 of the FD&C Act. For discussion of hazard analysis, see section XXV.

11. Undesirable Microorganisms

(Comment 91) Some comments request we define a new term ''undesirable microorganisms'' as those microorganisms that are of animal or human health significance, thereby rendering the animal food unfit for consumption or distribution.

(Response 91) We decline this request. See Response 45.

12. Unexposed Packaged Animal Food

As discussed in section XXXVI, some comments ask us to clarify that modified requirements for packaged animal food that is not exposed to the environment only apply to such animal food that requires time/temperature controls for safety (TCS animal food). To do so, we are defining the term ''unexposed packaged animal food'' to mean packaged animal food that is not exposed to the environment and using this term throughout the rule. Doing so simplifies the regulatory text and makes it clearer.

C. Additional Definitions To Clarify Terms Not Defined in the Proposed Rule

1. Audit

As already noted, some comments ask us to make the various rules we are establishing to implement FSMA consistent with each other, and we have worked to align the provisions of this rule with the provisions of the FSVP rule to the extent practicable. (See Comment 4 and Response 4.) To align these provisions, we are establishing in this final rule a definition of ''audit'' analogous to the definition of ''audit'' we proposed for the FSVP rule. For the purposes of this rule, ''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 a supplier's food safety processes and procedures.

2. Full-Time Equivalent Employee

As discussed in Response 70, we have established a definition for ''full-time equivalent employee'' as a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its subsidiaries and affiliates by the number of hours of work in 1 year, 2,080 hours (*i.e.,* 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

3. Qualified Individual

As discussed in section IX.A, we are clarifying in new § 507.4(b)(1) that each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. To better align with the FSVP rule, we use the term ''qualified individual'' in new § 507.4 and are defining the term ''qualified individual'' to mean 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 individuals assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

4. Raw Agricultural Commodity

We have added a definition of the term ''raw agricultural commodity'' to have the meaning given in section 201(r) of the FD&C Act. We decided to define this term in the rule to simplify the provisions in part 507 that refer to raw agricultural commodities.

5. Supply-Chain-Applied Control

We have added a definition of the term ''supply-chain-applied control'' to mean 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. We decided to define this term in the rule to simplify the provisions in part 507, and in this document, that refer to preventive controls applied by a supplier before receipt by a receiving facility.

6. Written Procedures for Receiving Raw Materials and Other Ingredients

We have added a definition of 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 decided to define this term in the rule to simplify the provisions in part 507, and in this document, that refer to these procedures.

IX. Subpart A: Comments on Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Animal Food

In the 2013 proposed preventive controls rule for animal food we proposed that personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices. We asked if the recommendations should be requirements for employee education and training (78 FR 64736 at 64778). In addition, we requested comment on how best to implement section 418(o)(3) of the FD&C Act and the recommendations of the CGMP Working Group for human food with respect to training (78 FR 64736 at 64778). We requested comment on whether the rule should specify that each person engaged in animal food manufacturing, processing, packing, or holding (including temporary and seasonal personnel and supervisors) must receive training as appropriate to the person's duties; specifying the frequency of training (*e.g.,* upon hiring and periodically thereafter); specify that training include the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as applied at the facility; and specify that records document required training of personnel and, if so, specify minimum requirements for the documentation (*e.g.,* the date of the training, the type of training, and the person(s) trained). We also requested comment on whether to establish some or all of the potential requirements for education and training in subpart B, subpart C, or both.

In the following paragraphs, we discuss comments that respond to our requests for comment on potential requirements for education and training and whether to establish any requirements in subpart B, subpart C, or both. After considering these comments, we are establishing requirements for the qualifications of individuals engaged in manufacturing, processing, packing, or holding animal food, as well as the associated recordkeeping requirements in new § 507.4 in subpart A. The regulatory text makes clear that these requirements, established in subpart A, apply to individuals engaged in manufacturing, processing, packing, or holding animal food regardless of whether the individuals conduct these activities under the framework of the CGMPs established in subpart B or the framework for hazard analysis and risk-based preventive controls established in subparts C, D, and E. The regulatory text also makes clear that the qualification requirements apply to the recordkeeping requirements of subpart F. See table 5 for a description of these provisions.

TABLE 5—PROVISIONS FOR QUALIFICATIONS OF INDIVIDUALS WHO MANUFACTURE, PROCESS, PACK OR HOLD ANIMAL FOOD

Final section designation	Proposed section designation	Description
507.4(a)(1)	N/A	Applicability to individuals who manufacture, process, pack, or hold animal food subject to subparts B and F.
507.4(a)(2)	N/A	Applicability to individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F.
507.4(b)(1)	507.14(b)	Each individual engaged in manufacturing, processing, packing, or holding animal food must have the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties.
507.4(b)(2)	507.14(b)	Required training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene.
507.4(c)	507.14(c)	Additional qualifications of supervisory personnel.
507.4(d)	507.4(d)	Records of required training. The required records are subject to the recordkeeping requirements of subpart F.

A. Applicability and Qualifications of All Individuals Engaged in Manufacturing, Processing, Packing, or Holding Animal Food (Final § 507.4(a), (b), and (d))

(Comment 92) Some comments prefer that we continue to only provide recommendations for education and training and allow the animal food industry to determine the appropriate level of specific employee training that may be needed. Some comments say that we should allow facilities to conduct employee training in a flexible manner, with the facility determining the training content and frequency that is appropriate for the duties of a given employee as they relate to ensuring the safe production and distribution of animal food.

Some comments recommend that employees be trained ''initially'' and ''periodically thereafter'' but ask that we recognize the seasonal nature of a facility's workforce. Some comments ask that the training include the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene as applied at the facility.

Some comments ask that training requirements be established in subpart B so that the requirements would also apply to establishments that manufacture, process, pack, or hold animal food, including establishments that are not subject to FSMA's requirements for hazard analysis and risk-based preventive controls. Some comments that recommend establishing the training requirement in subpart B assert that training is more appropriately considered a prerequisite program than a preventive control that would belong in subpart C.

Other comments ask that the training and related recordkeeping requirements for the facility's preventive controls qualified individuals be established under subpart C because this is directly related to the facility's food safety plan. Other comments ask that training requirements be established in both subpart B and subpart C. Other comments say that including requirements for education and training in both subparts B and C would be confusing.

(Response 92) We are establishing a series of requirements for the qualifications of individuals engaged in manufacturing, processing, packing, or holding animal food in new § 507.4. First, to clarify how these qualification requirements apply to establishments subject to subparts B and F, we are requiring that the management of an establishment ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F are qualified to perform their assigned duties (§ 507.4(a)(1)). To clarify how these qualification requirements apply to facilities, we are requiring that the owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F are qualified to perform their assigned duties (§ 507.4(a)(2)).

We are not requiring training specific to the person's assigned duties. Each establishment engaged in the manufacturing, processing, packing and holding of food for animal consumption would already have procedures in place to ensure that all individuals who manufacture, process, pack, or hold animal food know how to do their jobs. However, to emphasize that we expect all individuals who conduct such activities to know how to do their jobs, we are specifying that each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties (§ 507.4(b)(1)). To better align with the forthcoming FSVP rule, we are using the term ''qualified individual'' in new § 507.4(b)(1) and are defining the term ''qualified individual'' to mean a person who has the education, training, or experience (or 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. See the discussion of the term ''preventive controls qualified individual'' in section VIII.A.10, including a discussion of how we have changed the proposed term ''qualified individual'' to ''preventive controls qualified individual'' because we are establishing a new definition for ''qualified individual,'' with a meaning distinct from ''preventive controls qualified individual.''

We also are requiring that each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof, receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the person's assigned duties (see § 507.4(b)(2)). Records that document this required training must be established and maintained and are subject to the recordkeeping requirements of subpart F (§ 507.4(d)). The rule does not specify the frequency

of the required training. We expect that production employees will receive training before working in production operations. We expect that most facilities will also provide some form of refresher training.

We disagree that we should continue to only provide recommendations for education and training. Although the comments express concern about overly prescriptive requirements that may not consider variables that would affect an establishment's training program (such as training course content, training provider, effectiveness of the course and instructor and frequency of training per topic, an employee's type and length of experience, nature of formal education, and the animal food product type and point in the animal food supply chain at which the employee works with the animal food product), the training requirement we are establishing in the rule provides flexibility for each establishment to provide training, and determine the scope and frequency of the training, in a way that works best for the establishment.

We agree that it is appropriate to establish training requirements so that the requirements apply to all establishments that manufacture, process, pack, or hold animal food, including establishments that are not subject to FSMA's requirements for hazard analysis and risk-based preventive controls, and we are establishing the qualification and training requirements in subpart A to clarify the applicability of these requirements to all establishments and facilities subject to part 507. Although we agree that employees in facilities that are subject to the requirements for hazard analysis and risk-based preventive controls need to understand their responsibilities under the facility's food safety plan, we are setting forth a training requirement focused on the principles of animal food hygiene and animal food safety. We consider training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, to be fundamental to the concept of CGMPs. We agree that establishing a training requirement in both subpart B and subpart C could be confusing.

(Comment 93) Some comments agree that training should be documented and assert that those records should show the date of training, a description of the training, and the name of the person trained. However, comments ask that we allow flexibility in the way these records are kept. Other comments assert that requiring that records document required training of personnel is burdensome, arbitrary, and capricious.

(Response 93) The rule requires that records that document training required by § 507.4(b)(2) be established and maintained without prescribing any content of those records. Although one approach to documenting training would be to provide the date of training, a description of the training, and the name of the person trained, the rule provides flexibility for each establishment to document its training in a way that works best for that establishment. We disagree that requiring records to document required training is burdensome, arbitrary, and capricious in light of the flexibility provided by the rule for the content of training records.

(Comment 94) Some comments agree that any requirements should include training appropriate to the person's duties but emphasize that the decision as to what is appropriate to the person's assigned duties should be determined by the establishment.

(Response 94) The requirement for employees to receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the person's assigned duties, provides flexibility for the establishment to provide training that is appropriate for its employees in light of each person's assigned duties. However, the rule does not require training specific to the person's assigned duties.

(Comment 95) Some comments assert that the training requirement would be an unreasonable burden for small businesses and that companies may incur substantial cost for the time that workers would be in training rather than in production. Some comments ask us to provide non-specific training recommendations for smaller processors that need flexibility to control the cost of training. Some comments assert that the training and education requirements must be accessible and flexible enough to allow employers to bring in temporary help when demand is high without causing a delay in hiring.

(Response 95) All employees will need enough training to do their job and understand the importance of hygiene for animal food safety. The training offered does not need to be expensive (*e.g.,* offsite training or off-the-shelf purchased training) and we expect that much of the training will be provided in-house by knowledgeable employees. As discussed in Response 1, the FSPCA is developing a preventive controls training curriculum. These training materials will be available online, and we expect these training materials to be useful to small businesses to use for in-house training.

B. Additional Requirements Applicable to Supervisory Personnel (Final § 507.4(c))

We proposed that responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel in § 507.14(c). We are finalizing this provision in § 507.4(c). We are correcting ''all requirements of this subpart'' to ''all requirements of this part.'' As a conforming change for consistency with the provisions of § 507.4(b), we are replacing the phrase ''competent supervisory personnel'' with the phrase ''supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production safe animal food.''

X. Subpart A: Comments on Proposed § 507.5—Exemptions

We proposed to establish a series of exemptions from the requirements for hazard analysis and preventive controls that would be established in subpart C, with modified requirements in some cases.

Some comments support one or more of the proposed exemptions without change. For example, some comments note that the exemptions are specified in FSMA and, thus, reflect the intent of Congress. Some comments state that some exemptions (*i.e.,* those for products already subject to our regulations for the control of microbiological hazards for low-acid canned foods (LACF)) make sense because they are risk-based. Other comments that support one or more of the proposed exemptions ask us to clarify particulars associated with these exemptions or expand the scope of some of these exemptions. Other comments ask us to include additional exemptions in the rule.

In the remainder of this section, we discuss comments that ask us to clarify the proposed exemptions or that disagree with, or suggest one or more changes to, the proposed exemptions. We also discuss comments that ask us to include additional exemptions in the rule. After considering these comments, we have revised the proposed exemptions as shown in table 6 with editorial and conforming changes as shown in table 31. A key conforming change that affects all proposed exemptions from the requirements of subpart C is that the final exemptions are from the requirements of subpart E,

as well as subpart C. As discussed in section XL, the final rule establishes the requirements for a supply-chain program in subpart E, rather than within subpart C as proposed.

TABLE 6—REVISIONS TO THE PROPOSED EXEMPTIONS

Section	Exemption	Modification
507.5(e)	From the requirements of subpart C for on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the specified low-risk packing or holding activity/animal food combinations.	• Changes consequential to the revised ''farm'' definition—*i.e.*, no longer identifying any packing or holding activities for any RACs. • Clarification that the modified requirements do not apply to on-farm packing or holding of food by a very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the listed low-risk packing or holding activity/animal food combinations. • Updated animal food categories consistent with the animal food categories included in table 1 in the section 103(c)(1)(C) RA. • Additions of low-risk packing or holding activity/animal food combinations as a result of an updated risk assessment.
507.5(f)	From the requirements of subpart C for on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are the specified low-risk manufacturing/processing activity/animal food combinations.	• Changes consequential to the revised ''farm'' definition—*i.e.*: • No longer distinguishing between manufacturing/processing activities conducted on a farm mixed-type facility's own RACs and manufacturing/processing activities conducted on food other than the farm mixed-type facility's own RACs; and • Eliminating activities, conducted on others' RACs, that would no longer be classified as manufacturing/processing and instead would be classified as harvesting, packing, or holding. • Clarification that the modified requirements do not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are the listed low-risk manufacturing/processing activity/animal food combinations. • Updated animal food categories consistent with the animal food categories included in table 1 in the section 103(c)(1)(C) RA. • Additions of low-risk manufacturing/processing activity/animal food combinations as a result of an updated risk assessment.
507.5(h)	From the requirements of subpart B for the holding and transportation of RACs.	Change from an exemption for specific activities (*i.e.*, holding and transportation of RACs) to facilities solely engaged in those activities.

A. General Comments on the Proposed Exemptions

(Comment 96) Some comments ask us to provide the same flexibility for foreign small businesses as for domestic small businesses.

(Response 96) The exemptions apply to both foreign small businesses and domestic small businesses.

(Comment 97) Some comments ask us to clarify whether an establishment that is exempt from the requirements for hazard analysis and risk-based preventive controls in subpart C remains subject to the CGMP requirments in subpart B.

(Response 97) An establishment that is exempt from the requirements for hazard analysis and risk-based preventive controls in subparts C and E remains subject to the CGMP requirements in subpart B, unless that establishment is specifically exempt from subpart B under § 507.5(a) (which applies to farms and activities of ''farm mixed-type facilities'' that fall within the definition of ''farm''); or § 507.5(h) (which applies to: (1) Establishments solely engaged in the holding or transportation of one or more RACs; (2) hulling, shelling, and drying nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and (3) ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed)).

(Comment 98) Some comments request that we clearly articulate what activities are not covered and why; as well as what activities we are specifically exempting and why. This comment requests clarification about the differences between the categories of ''not covered'' and ''exempt.''

(Response 98) We use the terms ''not covered'' and ''exempt'' interchangeably to describe what animal food operations or activities within an operation are not required to comply with all or parts of this rule. Farms, for example, are ''not covered'' by this rule, as established in § 507.5, which lists certain exemptions. As another example, a business meeting the very small business criteria is a qualified facility subject to the requirements of § 507.7, but ''exempt'' from the requirements of subparts C and E (see § 507.5(d)). Whether a particular exemption applies to an animal food operation depends on the type of operation and the activities it is conducting. We believe the exemptions as codified provide enough specificity for a facility to determine whether it must comply with or is exempt from this final regulation, or certain provisions of the final regulation.

(Comment 99) One comment expressed the opinion that exemptions should be driven by risk of activities rather than by whether they are conducted on or off a farm.

(Response 99) Consistent with the statutory direction in section 103(c) of FSMA, including conducting a qualitative risk assessment, we have finalized exemptions for on-farm activity/animal food combinations conducted by farm-mixed-type facilities that are small or very small businesses as discussed further in sections VI and X.

B. Proposed § 507.5(a)—Exemption for Facilities Not Required To Register Under Section 415 Regulations

We proposed that this part does not apply to establishments, including ''farms'' (as defined in § 1.227 of this

chapter), that are not required to register under section 415 of the FD&C Act. However, we proposed that subpart B would apply to the packaging, packing, and holding of dried commodities if a ''farm'' or ''farm mixed-type facility'' dries/dehydrates raw agricultural commodities that are produce to create a distinct commodity.

After reviewing all of the comments concerning raw agricultural commodities as discussed elsewhere in this final rule, we have removed the requirement that subpart B would apply to the packaging, packing, and holding of dried commodities from a ''farm'' or ''farm mixed-type facility'' that dries/dehydrates RACs that are produce to create a distinct commodity. We have made this change because produce RACs are not typically dried or dehydrated to create distinct animal food commodities, as they are to create human food commodities (*e.g.,* drying/dehydrating grapes to make raisins).

(Comment 100) One comment requests that we provide clarity and examples for animal food facilities that are exempt from facility registration and therefore exempt from compliance with part 507 because they are considered restaurants or retail food establishments.

(Response 100) Our food facility registration requirements are found in 21 CFR part 1, subpart H. Specifically, ''restaurant'' and ''retail food establishment'' are defined in 1.227(b). Additional information may be found in our ''Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition)'' (Ref. 23). As discussed in section I.E. of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register,** we are addressing the requirements of section 102(c) of FSMA in a separate rulemaking and issued a separate proposed rule to amend the definition of ''retail food establishment'' in the section 415 registration regulations and the section 414 recordkeeping regulations (80 FR 19160, April 9, 2015).

C. Proposed § 507.5(b)—Exemption Applicable to Food Subject to 21 CFR Part 113—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

We proposed that activities in animal food facilities that are regulated under and are in compliance with § 500.23 and part 113 would be exempt from subpart C only with respect to microbiological hazards regulated under part 113. We further proposed that the facilities must comply with subparts C and F with regard to all other potential hazards and must comply with subparts A and B. We requested comment on the criteria that should be used to determine whether a facility is in compliance with § 500.23 and part 113 (78 FR 64736 at 64762).

(Comment 101) Some comments express concern that the partial exemption for products subject to part 113 could generate confusion for both regulators and regulated facilities. These comments also assert that the partial exemption for products subject to part 113 would generate duplicative recordkeeping requirements under the two rules.

(Response 101) We acknowledge the potential for confusion and expect any confusion to decrease over time as both regulators and facilities gain experience with the new requirements. We also expect that in most instances a facility that is subject to § 500.23 and part 113, and that evaluates potential microbiological hazards as part of its hazard analysis, would conclude that the potential hazards are controlled by the targeted requirements of part 113 and conclude there are no significant microbiological hazards that require preventive controls to significantly minimize or prevent the hazards.

We disagree that the partial exemption for products subject to part 113 would generate duplicative recordkeeping requirements. The requirements of part 113 to control biological hazards are different from the requirements of subparts C and E to conduct a hazard evaluation for chemical and physical hazards, and implement preventive controls and associated preventive control management components to address significant chemical and physical hazards. Likewise, the records associated with the control of biological hazards under part 113 are not the same as the records associated with a hazard analysis, preventive controls, and associated preventive control management components for control of chemical and physical hazards. However, to the extent that a facility determines that existing records required by part 113 can be used to comply with the requirements of subparts C and E, a facility may rely on those records (see § 507.212).

(Comment 102) Some comments ask us to provide guidance to industry and the regulatory community regarding the criteria that will be used to determine when a facility is ''in compliance with'' part 113.

(Response 102) As an example, an LACF manufacturing facility that has ongoing problems controlling biological hazards may be better able to address biological hazards by preparing and implementing a written food safety plan. As with facilities subject to our HACCP regulations, we expect that situations in which enforcement actions to ensure compliance with part 113 are insufficient to correct problems, and lead to a facility losing its exemption from the requirements of subparts C and E, will be rare and will depend on very specific circumstances. Therefore, at this time we do not anticipate issuing guidance on when violations of part 113 could lead to this outcome.

D. Proposed § 507.5(c)—Exemption Applicable to Activities Subject to Standards for Produce Safety in Section 419 of the FD&C Act

We proposed that subpart C would not apply to activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety) of the FD&C Act (21 U.S.C. 350h).

(Comment 103) Some comments request that we broaden the exemption to operations that handle culls of raw, intact, fresh produce. One comment requested that fresh citrus be considered a low risk product or excluded from the rule entirely. This comment requested that culls should not be considered a by-product of fresh citrus production.

(Response 103) We decline these requests. We have included a provision under § 507.12 that exempts by-products of off-farm packing and holding of RACs for animal food use from most of part 507 if ''the human food facility is subject to and in compliance with § 117.8 of part 117, and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations.'' The human food facility also must not further manufacture or process the by-products intended for use as animal food. The resulting animal food must be held and distributed in accordance with the CGMPs for the holding and distribution of human food by-products for use as animal food in § 507.28 and § 117.95. Thus, facilities subject to and in compliance with § 117.8 and applicable safety requirements of the FD&C Act and its implementing regulations, that pack or hold produce culls off-farm for use as animal food (without manufacturing or processing the culls) would be exempt from part 507, except for the limited holding and distribution CGMPs in § 507.28. Facilities that manufacture or process culls of raw, intact, fresh produce for use as animal food would be subject to part 507. Activities, such as packing fresh citrus, of a facility that is subject to section 419 of the FD&C Act are exempt from subparts C.

E. Proposed § 507.5(d)—Exemption Applicable to a Qualified Facility

We proposed that subpart C would not apply to a qualified facility, except as provided by subpart D (Withdrawal of an Exemption Applicable to a Qualified Facility), and that qualified facilities would be subject to the requirements in § 507.7.

(Comment 104) Some comments support the proposed exemption for a qualified facility. Other comments oppose this proposed exemption, asserting that it is not risk based and expressing concern that qualified facilities would cause significant food safety problems. Some comments ask us to strictly construct and narrowly apply the exemptions to as few businesses as possible.

Some comments do not agree that qualified facilities should be subject to modified requirements because even the modified requirements are burdensome. Some comments assert that qualified facilities having an average annual value of animal food sold during the previous 3-year period of $10,000 or less should be exempt from all requirements related to hazard analysis and risk-based preventive controls, including modified requirements. One comment does not specify an amount of annual sales of animal food, but states that whether a facility is a qualified facility should be based on whether the facility has caused any reported injury or illness to humans or animals.

(Response 104) The exemption for qualified facilities, including the criteria for being a qualified facility and the applicability of modified requirements, is expressly directed by section 418(l) of the FD&C Act. In defining ''very small business'' to mean a business (including any subsidiaries or 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), we constructed this exemption to apply to businesses that, collectively, produce less than 2 percent of the dollar value of animal food produced in the United States. This is comparable to the percentage of the human food supply that is exempt under the definition of very small business for human food (see section XI.B of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**). As previously discussed in section VIII.A.36, the businesses that will be exempt from the requirements for hazard analysis and risk-based preventive controls, and will instead be subject to other requirements, will produce a small portion of the animal food at potential risk of causing foodborne illness (see the discussion at 79 FR 58476 at 58502).

(Comment 105) Some comments assert that a qualified facility should be exempt from the CGMP requirements of subpart B, as well as the requirements for hazard analysis and risk-based preventive controls in subpart C.

(Response 105) The exemption for qualified facilities is expressly directed by section 418(l) of the FD&C Act and is limited to an exemption from the requirements for hazard analysis and risk-based preventive controls in subparts C and E. The comments provide no basis for why new statutory requirements for hazard analysis and risk-based preventive controls should in any way impact CGMP requirements that apply to the manufacturing, processing, packing, and holding of animal food. CGMPs provide the basic requirements for ensuring production of safe animal food. Following the CGMPs is essential to properly address public (human and animal) health risks from very small facilities that are provided an exemption from subparts C and E in order to minimize the burden on such facilities.

(Comment 106) Some comments ask us to provide that a qualified facility may voluntarily choose to comply with the requirements for hazard analysis and preventive controls.

(Response 106) A qualified facility may voluntarily choose to comply with the requirements for hazard analysis and risk-based preventive controls without a specific provision authorizing it to do so. One way that a qualified facility could comply voluntarily would be to simply not submit the attestation that it is a qualified facility (see § 507.7(b) for the requirement for a qualified facility to submit an attestation regarding its status as a qualified facility). When we inspect the facility, we would inspect the facility for compliance with the requirements for hazard analysis and risk-based preventive controls. Another way for a facility to voluntarily comply would be to submit the attestation, and specify that it will satisfy the statutory documentation requirement through documentation of its food safety practices rather than documentation that it is in compliance with non-Federal food safety law.

(Comment 107) Some comments ask us to specify in guidance that a qualified facility is not required to prepare and implement a food safety plan.

(Response 107) We intend to recommend in guidance how a qualified facility could comply with the requirements in § 507.7 without satisfying all of the requirements in subparts C and E.

F. Proposed § 507.5(e) and (f)—Exemptions Applicable to On-Farm Low-Risk Activity/Animal Food Combinations Conducted by a Small or Very Small Business

As discussed in section VI.A, consistent with the statutory direction in section 103(c) of FSMA, including conducting a qualitative risk assessment, we proposed three exemptions for on-farm activity/food combinations conducted by farm-mixed-type facilities that are small or very small businesses (proposed §§ 507.5(e), (f)(1), and (f)(2)).

1. General Comments on the Proposed Exemptions Applicable to On-Farm Low-Risk Activity/Animal Food Combinations Conducted by a Small or Very Small Business

(Comment 108) Some comments assert that conducting a low-risk activity/food combination should be sufficient to qualify any facility for exemption from subpart C, regardless of whether the activity is conducted on-farm or off-farm, or meets the economic threshold for a small or very small business.

(Response 108) The statute provides specific direction for those facilities that can qualify for this exemption. (See sections 418(l) and 418(o)(2) of the FD&C Act.) See also Response 104 in this final rule, and Responses 220 and 222 in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

(Comment 109) Some comments state that the exemptions for farming activities are confusing.

(Response 109) The activity/animal food combinations listed in § 507.5(e) are directed to an exemption for packing and holding activities, whereas the activity/animal food combinations listed in § 507.5(f) are directed to an exemption for manufacturing/processing activities. Although these exemptions are more complex than other exemptions (*e.g.,* because they are directed to specific activities conducted on specific animal foods), the final ''farm'' definition has simplified them to the extent practicable. For example, under the ''farm'' definition in the 2013 proposed human preventive controls rule, whether an activity was packing or manufacturing/processing depended, in part, on whether the RACs being packed

were the farm's own RACs or others' RACs. In contrast, under the ''farm'' definition established in the final rule for preventive controls for human food published elsewhere in this **Federal Register**, packing RACs is a ''packing'' activity, regardless of ownership of the RACs being packed.

(Comment 110) Some comments note a distinction between the exemptions for on-farm low-risk activity/animal food combinations conducted by small and very small businesses and the exemption for qualified facilities. Specifically, the comments state that a farm mixed-type facility that only conducts low-risk activity/animal food combinations (such as grinding grains) would be exempt from the requirements of subpart C, whereas an off-farm qualified facility grinding grains, while exempt from the requirements of subpart C, would nonetheless be subject to the requirements for a qualified facility in § 507.7. These comments ask whether it would be better for a farm or farm mixed-type facility that satisfies criteria for a small or very small business, and also satisfies criteria for a qualified facility, to classify itself as a small or very small business or to classify itself as a qualified facility.

(Response 110) In light of the final ''farm'' definition, these comments no longer apply with respect to activities within the farm definition.

For activities conducted by a farm mixed-type facility, we acknowledge that the exemptions provided by § 507.5(e) and (f) for on-farm low-risk activity/animal food combinations are different from the exemption provided by § 507.5(a) for a qualified facility. A farm mixed-type facility that only conducts low-risk activity/animal food combinations listed in § 507.5(e) and (f) is fully exempt from the requirements of subparts C and E, and is not subject to the requirements for a qualified facility in § 507.7, even if that farm mixed-type facility is also a very small business (and, thus, also is a qualified facility). To make this clear, we have revised proposed § 507.5(e) to specify that § 507.7 does not apply to on-farm packing or holding of animal food by a very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the listed low-risk packing or holding activity/animal food combinations. Likewise, we have revised proposed § 507.5(f) to specify that § 507.7 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are the listed low-risk manufacturing/processing activity/animal food combinations.

With these changes, a farm mixed-type facility that is a very small business and that only conducts the low-risk activity/animal food combinations listed in § 507.5(e) and/or (f) may find it advantageous to classify itself as a very small business eligible for the exemption in § 507.5(e) and/or (f) rather than as a qualified facility, which would be subject to the requirements in § 507.7.

(Comment 111) Some comments ask for a process to keep the list of low-risk activity/food combinations up to date, such as through guidance.

(Response 111) We decline this request. The exemptions established in this rule are binding, whereas any list of additional activity/animal food combinations established in a guidance document would not be binding. We established the list of activity/animal food combinations included in these exemptions through an extensive public process, including a request for comments on the section 103(c)(1)(C) draft RA. From this time forward, the process available to a person who wishes us to consider an additional activity/animal food combination is to submit a citizen petition in accordance with 21 CFR 10.30.

2. Proposed § 507.5(e)—Exemption Applicable to On-Farm Low-Risk Packing or Holding Activity/Animal Food Combinations Conducted by a Small or Very Small Business

We proposed that subpart C would not apply to on-farm packing or holding of animal food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are low-risk packing or holding activity/animal food combinations on animal food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership.

(Comment 112) Many comments state that it is common practice among farms to hold RACs from farms under different ownership and that classifying establishments as being within the ''farm'' definition, or outside the ''farm'' definition, based on who owns the RACs being packed is not a risk-based classification.

(Response 112) We proposed a revised definition of ''farm'' in the 2014 preventive controls supplemental notice for human food to include packing and holding of RACs grown on another farm not under the same ownership (79 FR 58524 at 58531 through 58532). As a consequential change in light of the final ''farm'' definition established in the final rule for preventive controls for human food published elsewhere in this **Federal Register**, the exemption no longer identifies any packing or holding activities for any RACs (whether the farm's own RACs or others' RACs), because an on-farm establishment would no longer be subject to the requirements for hazard analysis and risk-based preventive controls (subpart C) when it packs or holds RACs, regardless of whether it is packing and holding its own RACs or others' RACs. In light of the change in the ''farm'' definition, we have revised the section 103(c)(1)(C) RA, starting with the list of on-farm activity/animal food combinations outside the farm definition in table 1, to exclude packing and holding of RACs.

3. Proposed § 507.5(f)—Exemption Applicable to On-Farm Low-Risk Manufacturing/Processing Activity/Animal Food Combinations Conducted by a Small or Very Small Business

We proposed that subpart C would not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are those listed in the proposed exemption. The proposed exemption specified those activity/animal food combinations that would be exempt when conducted on a farm mixed-type facility's own RACs and those activity/animal food combinations that would be exempt when conducted on animal food other than the farm mixed-type facility's own RACs for distribution into commerce.

As a consequential change in light of the final ''farm'' definition, the final exemption no longer distinguishes between manufacturing/processing activities conducted on a farm mixed-type facility's own RACs and manufacturing/processing activities conducted on animal food other than the farm mixed-type facility's own RACs. As another consequential change, the exemption has been revised to eliminate activities, conducted on others' RACs, which no longer are classified as manufacturing/processing and instead are classified as harvesting, packing, or holding. In addition, we have revised the final exemption to list animal food categories consistent with the animal food categories included in table 1 in the section 103(c)(1)(C) RA (Ref. 3), modified in response to revisions of the ''farm'' definition. (See Response 112.) In constructing

categories of animal food based upon the new ''farm'' definition, we grouped together processed grain products (*e.g.,* flour, grits, etc.) and grain by-products (*e.g.,* brewers' grain, distillers' grain, and corn gluten meal). The category does not include culled products from processing grain for human food such as misshapen pasta. Pasta used in animal food falls under a new category (any other animal food that does not require time/temperature control for safety) that was added to include the wide range of possibilities for animal food that was originally processed to be human food, as well as other types of animal food not listed separately.

(Comment 113) Some comments ask us to include in the exemption a single list of low-risk manufacturing/processing activity/food combinations applicable to farm mixed-type facilities conducting activities on their own RACs and farm mixed-type facilities conducting activities on other's RACs.

(Response 113) These comments no longer apply. As a consequence of the ''farm'' definition established by the final rule for preventive controls for human food published elsewhere in this **Federal Register,** the exemption no longer distinguishes between manufacturing/processing activities conducted on a farm mixed-type facility's own RACs and manufacturing/processing activities conducted on animal food other than the farm mixed-type facility's own RACs.

(Comment 114) Some comments ask us to include manufacturing of animal food from low risk ingredients as additional activity/animal food combinations in the exemption. Other comments support our conclusion that manufacturing animal food ready for consumption is not a low risk activity.

(Response 114) We evaluated manufacturing of animal food as one of the activity/animal food combinations within the qualitative risk assessment (Ref. 3). The 103(c)(1)(C) RA explains why we determined that manufacturing animal food ready for consumption is not a low-risk activity/animal food combination.

G. Proposed § 507.5(g)—Exemption Applicable to Facilities Solely Engaged in Storage of Raw Agricultural Commodities Other Than Fruits and Vegetables Intended for Further Distribution or Processing

We proposed that subpart C would not apply to facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. In the following paragraphs, we discuss comments that ask us to clarify how the proposed exemption would apply to specific circumstances.

(Comment 115) Some comments ask whether this proposed exemption (proposed § 507.5(g)) would apply to facilities such as peanut buying points or bean elevators and assert that such commodities are analogous to grains and the activities conducted at such facilities are analogous to those performed by grain elevators.

(Response 115) We classify peanuts and beans (such as kidney beans, lima beans, and pinto beans) within the category of ''fruits and vegetables''; we classify soybeans as grain (see the discussion of grains at 78 FR 64736 at 64764 and 79 FR 58476 at 5848, and fruits and vegetables at 78 FR 3646 at 3690 and proposed §§ 112.1 and 112.2 in the proposed produce safety rule). The exemption for facilities solely engaged in storage of RACs intended for further distribution or processing does not apply to facilities that store fruit and vegetable RACs and, thus, does not apply to facilities such as peanut buying points and bean elevators. As discussed in section IV.B, we have revised the ''farm'' definition to provide that an operation devoted only to the harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the ''farm'' definition, provided that the farms that grow or raise the majority of the RACs harvested, packed, and/or held by the operation own, or jointly own, a majority interest in the operation. With this revision, some operations dedicated to holding RACs, including fruit and vegetable RACs, will be within the ''farm'' definition.

Peanut buying points and bean elevators that do not meet the revised farm definition are storing RACs that are ''fruits and vegetables'' and do not meet the criteria for exemption under § 507.5(g). However, we would not expect such facilities to need an extensive food safety plan. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

(Comment 116) One comment states that genetically modified food should be added to the list of hazards that are seen as potential risks for animals.

(Response 116) We decline this request. We have not seen evidence that foods derived from genetically engineered plants differ from other foods in any meaningful or uniform way, or that, as a class, such foods present different or greater safety concerns than their non-genetically engineered counterparts. We have a voluntary consultation process for foods derived from genetically engineered plants through which we engage with the developers of genetically engineered plants to help ensure the safety of the derived foods. Foods that have undergone this consultation process are as safe as foods from conventionally bred plants. Foods derived from genetically engineered plants, irrespective of the method of development, are subject to the same food safety and other regulatory requirements as foods derived from conventionally-bred plants. Therefore genetically engineered foods do not need to be singled out as a hazard.

(Comment 117) Some comments assert that the exemption for storage of raw agricultural commodities (other than fruits and vegetables) should extend to those distinct and physically separate portions of oilseed processing facilities that are devoted solely to RAC storage. According to these comments, in the overwhelming majority of cases the inclusion of a separate RAC storage area in the same building as the oilseed processing area will not introduce additional risk either to the processing area or to the operations that take place there and that storage areas, whether standing alone as a separate facility or incorporated into a larger processing facility, store RACs safely. These comments ask us to recognize that storage activities may include grain drying to standardize moisture levels and preserve product quality.

(Response 117) The activities included within the definition of holding include activities that are performed as a practical necessity for the distribution of RACs. In the 2014 supplemental notice, we explained that facilities that conduct operations similar to those conducted at grain elevators and silos, such as some facilities that hold oilseeds, may satisfy the criteria for exemption if activities other than storage are performed as a practical necessity for the distribution of RACs (see 79 FR 58476 at 58483 and the definition of ''holding'' in § 507.3). Examples of holding activities include drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (see § 507.3). Thus, the specific example of drying grains to standardize moisture levels and preserve product quality would fall within the definition of holding as a practical necessity for the distribution of RACs. A facility that stores oilseeds, and dries them as a practical necessity for the distribution of RACs, would be covered by the exemption in § 507.5(g).

However, we decline the request to modify the exemption in § 507.5(g) to also apply to distinct and physically separate storage areas that are used solely for storage of RACs (other than fruits and vegetables) intended for further distribution or processing. To the extent that the comments are asking us to do so to provide for facilities that conduct activities as a practical necessity for the distribution of RACs to be eligible for the exemption, doing so is not necessary in light of the definition of holding. To the extent that the comments are asking us to do so to provide for facilities that conduct manufacturing/processing activities in addition to holding activities, we disagree that doing so would be consistent with the statutory direction in FSMA. As previously discussed, section 418(m) of the FD&C Act provides in relevant part that we may by regulation exempt or modify the requirements for compliance under section 418 of the FD&C Act with respect to facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (78 FR 64736 at 64764). The plain meaning of ''solely'' is only, completely, entirely; without another or others; singly; alone (Ref. 24). Facilities that conduct manufacturing/processing activities in addition to holding activities are not ''solely'' engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution and processing.

(Comment 118) Some comments request that the language of § 507.5(g) explicitly state that the exemption from subpart C would apply to facilities that are solely engaged in the packing and holding of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. These comments indicate that packing is frequently involved when a facility distributes raw agricultural commodities that they have been holding. They cite the § 110.19(a) exemption from the human food CGMP regulation for establishments ''engaged solely in the harvesting, storage, or distribution of one or more 'raw agricultural commodities' '' and remark that in application of the regulation, the activity of packing has been encompassed within the term ''distribution.'' In addition, some comments ask that the exemption proposed in § 507.5(g) be extended to an exemption from subpart B, as well as from subpart C.

(Response 118) We decline the request to add the term ''packing'' to § 507.5(g). As discussed in Response 117, the activities included within the definition of holding include activities that are performed as a practical necessity for the distribution of RACs. Under § 507.5(h), subpart B does not apply to the holding or transportation of one or more RACs. (See section X.H.)

H. Proposed § 507.5(h)—Exemption Applicable to the Holding or Transportation of One or More Raw Agricultural Commodities

We proposed to provide that subpart B would not apply to the holding or transportation of one or more RACs as defined in section 201(r) of the FD&C Act.

(Comment 119) Some comments ask us to include the term ''packing'' in § 507.5(h) to say ''Subpart B of this part does not apply to the packing and holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.''

(Response 119) We decline the request to add the term ''packing'' to § 507.5(h). As discussed in Response 117, the activities included within the definition of holding include activities that are performed as a practical necessity for the distribution of RACs.

(Comment 120) Some comments ask us to clarify that CGMP requirements (such as using protective coverings where necessary and appropriate (§ 507.17(c)) do not apply to the bulk outdoor storage of RACs for further processing.

(Response 120) We are returning to the longstanding approach that the exemption applies to establishments ''solely engaged'' in specific activities. Under the exemption we are establishing in § 507.5(h)(1), those activities are holding and transportation of RACs. We explain why in the following paragraphs.

These comments appear to interpret the proposed exemption in a way that goes beyond the longstanding ''RAC exemption'' in the human food CGMPs in § 110.19 and is inconsistent with the intent in updating § 110.19 to adjust and clarify what activities fall within this exemption based on experience and changes in related areas of the law since issuance of this exemption from the CGMPs (78 FR 64736 at 64764 and 78 FR 3646 at 3710). The suggestion of these comments, *i.e.,* that CGMPs should not apply to the holding of RACS in a facility that manufactures, processes, or packs RACs—would not make sense in some circumstances and would create complex situations for establishments (in determining how to comply with the CGMP requirements) and for regulators (in determining how to enforce the CGMP requirements). For example, it does not make sense for the part of a facility that holds RACs prior to processing to be exempt and the parts of the facility that are processing the RACs and storing them after processing to be covered. Likewise, it does not make sense for part of a transportation vehicle to be covered and part to be exempt.

By revising the proposed ''RAC exemption'' so that it applies only to establishments ''solely engaged'' in the storage or transportation of RACs, we are providing for a predictable framework for interpreting exemptions for facilities ''solely engaged'' in other activities. For example, as discussed in Comment 117, comments ask us to expand the exemption (in § 507.5(g)) from the requirements for hazard analysis and risk-based preventive controls for facilities that are ''solely engaged'' in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing to also apply to distinct and physically separate storage areas that are used solely for storage of such RACs. In our response, we noted that facilities that conduct manufacturing/processing activities in addition to holding activities are not ''solely engaged'' in the storage of such RACs (see Response 117). In addition, as discussed in Comment 146, comments ask us to apply the exemption (in § 507.10) from the requirements for hazard analysis and risk-based preventive controls for facilities that are ''solely engaged'' in the storage of unexposed packaged food to storage areas of facilities that also engage in food processing activities, *e.g.,* for distributors that are engaged in limited food processing, such as blending seeds to make bird food. In our response, we noted that such distributors are not ''solely'' engaged in the storage of unexposed packaged animal food (see Response 146).

The exemption we are establishing in this rule for establishments solely engaged in the storage or transportation of RACs remains consistent with our announced intent to adjust and clarify what activities fall within this exemption based, in part, on changes in related areas of the law since this exemption from the CGMP requirements was first issued. As discussed in section IV of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, we have made a number of changes to the ''farm'' definition, including changes that provide for an operation devoted to harvesting, packing, and/or holding of RACs to be a ''farm'' (*i.e.,* a ''secondary activities

farm'') (and, thus, be exempt from the CGMP requirements under § 507.5(a)) even though the operation does not grow RACs (see § 507.3). With this revised ''farm'' definition, some establishments solely engaged in the ''storage'' of RACs will be exempt from the CGMP requirements because they are a ''farm.'' For further discussion on this provision, see section XI.J in the final rule for preventive controls for human food.

I. Comments Requesting Additional Exemptions

(Comment 121) Some comments request additional exemptions from the requirements for hazard analysis and risk-based preventive controls in subpart C, the CGMP requirements of subpart B, or both.

(Response 121) We believe that our CGMP regulations, coupled with implementation of FSMA's directives to focus more on preventing food safety problems than on reacting to problems after they occur, will play an important role in increasing animal food safety. We did not propose any exemptions or exceptions from the requirements of subpart C other than those authorized by section 103 of FSMA (78 FR 64736 at 64743 through 64744). We drew on our experience with the CGMP regulation for human food and changes in related areas of the FD&C Act since issuance of the CGMP regulation (78 FR 3646 at 3709 through 3711) to adjust and clarify what activities fall within a longstanding exclusion related to raw agricultural commodities (see § 110.19) and to modify the CGMPs for human food by-products for use as food for animals.

(Comment 122) Some comments state that facilities that hull, shell, and dry tree nuts without further processing could be characterized as establishments engaged solely engaged in the harvesting, storage, or distribution of one or more raw agricultural commodities. These comments express an expectation that since hulled or shelled dried nuts retain their raw agricultural commodity status, that facilities hulling, shelling and drying tree nuts without further processing would qualify for exemption under both proposed §§ 507.5(g) and 507.5(h).

(Response 122) Hulling and shelling of tree nuts (such as walnuts, almonds, and pistachios) are harvesting activities that are within the ''farm'' definition when conducted on a farm or farm mixed-type facility. Drying/dehydrating RACs without creating a distinct commodity (such as drying walnuts and hulls) is a holding activity that also is within the ''farm'' definition when conducted on a farm or farm mixed-type facility. As discussed in section IV.B of the final rule for preventive controls for human food (published elsewhere in this issue of the **Federal Register**) we have revised the ''farm'' definition to provide that an operation, not conducted on a Primary Production Farm, devoted to the harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the ''farm'' definition (as a ''secondary activities farm''), provided that the primary production farm(s) that grow or raise the majority of the RACs harvested, packed, and/or held by the secondary activities farm own, or jointly own, a majority interest in the operation. Non-farm facilities dedicated to the hulling, shelling, and drying of nuts and hulls perform the same activities as those performed by farms. When done on a primary production farm or by a secondary activities farm, those activities would not be subject to CGMPs. Furthermore, these activities do not transform the RAC into a processed food. Therefore, we have added regulatory text in § 507.5(h) to provide an exemption from subpart B for hulling, shelling, and drying nuts and hulls (without further manufacturing/processing) by a non-farm hulling/shelling/drying facility because of the similarity in the activities of a farm-owned operation and a non-farm owned facility. However, non-farm facilities are not exempt from subparts C and E under § 507.5(g) as they are not solely engaged in the storage of raw agricultural commodities. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

(Comment 123) Some comments state that ginning cotton to separate cotton fiber from cotton seed is a low-risk harvesting activity. Comments further note that since cotton seed used as animal food is a by-product from the production of cotton lint, the cotton seed coming from a ginning facility would not qualify as a human food by-product. The comments request that facilities whose entire operation consists of receiving and ginning cotton without further processing the cotton seeds be exempt from both subpart C under § 507.5(g) and subpart B under § 507.5(h).

(Response 123) Ginning cotton is a harvesting activity that is within the ''farm'' definition when conducted on a farm or farm mixed-type facility. Drying/dehydrating the cottonseed without further processing is a holding activity that also is within the ''farm'' definition when conducted on a farm or farm mixed-type facility. (See Response 122 for a discussion on modification to the farm definition). When done on a primary production farm or by a secondary activities farm, these activities (ginning, drying, dehydrating) would not be subject to CGMPs, and these activities do not transform the RAC into a processed food. Therefore, we have added regulatory text in § 507.5(h)(2) to provide an exemption from subpart B for the ginning of cotton (without further manufacturing/processing) by a non-farm cotton ginning facility because of the similarity between a farm-owned operation and a non-farm owned facility (See Response 122). However, non-farm facilities are not exempt from subparts C and E under § 507.5(g) as they are not solely engaged in the storage of raw agricultural commodities. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

XI. Subpart A: Comments on Proposed § 507.7—Requirements That Apply to a Qualified Facility

As previously discussed (78 FR 64736 at 64765), sections 418(l)(2)(A) and (B) of the FD&C Act provide that a qualified facility must submit two types of documentation to us. The first type of required documentation relates to food safety practices at the facility, with two options for satisfying this documentation requirement. Under the first option, the qualified facility may choose to submit documentation that demonstrates that it has identified potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective. Alternatively, under the second option, the qualified facility may choose to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law. The second type of required

documentation relates to whether the facility satisfies the definition of a qualified facility.

If a qualified facility does not prepare documentation demonstrating that it has identified potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective, it must provide notification to consumers of certain facility information by one of two procedures, depending on whether an animal food packaging label is required on the animal food.

Consistent with the statutory direction of section 418(l) of the FD&C Act, we proposed the following requirements for qualified facilities: (1) Submission of certain documentation (proposed § 507.7(a)); (2) procedures for submission of the documentation (proposed § 507.7(b)); (3) the frequency of the submissions (proposed § 507.7(c)); (4) notification to consumers in certain circumstances (proposed § 507.7(d)); and (5) applicable records that a qualified facility must maintain (proposed § 507.7(e)).

In the 2013 proposed preventive controls rule for animal food, we tentatively concluded that a certified statement would be acceptable for the purposes of satisfying the submission requirements of proposed § 507.7(a). We also requested comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility.

Some comments support one or more of the proposed requirements without change. For example, some comments state that our proposed interpretation of the statutory term ''business address'' is consistent with our use of the term ''business address'' in our regulations regarding information that must be included in a prior notice for imported food (§ 1.281). Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In this section, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. We also address comments discussing our tentative conclusion regarding the submission of certified statements to FDA, including submitting certified statements using the existing mechanism for registration of food facilities. After considering these comments, we have revised the proposed requirements as shown in table 7 with editorial and conforming changes as shown in table 31.

As discussed in Response 76, we have revised the definition of very small business to specify that it is based on an average (of sales plus market value of animal food held without sale) during the 3-year period preceding the applicable calendar year and, as a companion change, we are explicitly requiring that a facility determine and document its status as a qualified facility on an annual basis (see § 507.7(c)(1)).

TABLE 7—REVISIONS TO THE PROPOSED REQUIREMENTS FOR QUALIFIED FACILITIES

Section	Description	Revision
507.7(a)	Documentation to be submitted.	• Specify that the submitted documentation is an ''attestation.'' • Add ''tribal'' as an example of applicable non-Federal food safety law.
507.7(b)	Procedure for submission.	Update details regarding the electronic and paper submission of a form specific to the attestation requirement.
507.7(c)	Frequency of determination and submission.	• New requirement to determine and document status as a qualified facility on an annual basis no later than July 1 of each calendar year. • Specify that a facility that begins manufacturing, processing, packing, or holding animal food after September 17, 2019 must submit the attestation before beginning such operations. • Specify that a facility must notify FDA of a change in status from ''not a qualified facility'' to ''qualified facility'' by July 31 of the applicable calendar year. • Specify that when the status of a facility changes from ''qualified facility'' to ''not a qualified facility'' based on the annual determination, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year. • Specify that the required biennial submissions of the attestations must be made during a timeframe that will coincide with the required biennial updates to facility registration.
507.7(d)	Timeframe for compliance with the requirements of subparts C and E.	When the status of a facility changes from ''qualified facility'' to ''not a qualified facility,'' the facility must comply with subparts C and E no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.
507.7(e)	Notification to consumers.	Conforming changes associated with the term ''attestation.''
507.7(f)	Records	Conforming changes associated with the term ''attestation.''

A. Comments on Submission of a Certification Statement

(Comment 124) Some comments ask us to clarify the distinction between the documentation that would be submitted to FDA and the records that a qualified facility relies on to support the submitted documentation.

Some comments agree with our tentative conclusion to use certified statements to satisfy the proposed submission requirements, noting that it would save time and money and reduce the paperwork burden on qualified facilities. Some comments ask us to revise the proposed requirements to make this use of certified statements explicit in the regulatory text.

Other comments disagree with our tentative conclusion to use certified statements to satisfy the submission requirements. These comments focus on the importance of actual copies of documents in determining compliance with the documentation requirements and assert that proof of qualification requires more than a checked box in an online registration database. Some comments ask us to require that a qualified facility affirm that it has the original documents on file and available for FDA inspection. Other comments assert that requiring qualified facilities to submit copies of the actual documentation would enable us to

easily review food safety plans or inspection reports and to target our compliance and enforcement activities to those qualified facilities that pose a greater risk because of inadequate prevention measures or deficient inspections.

(Response 124) We are affirming our tentative decision that we will not require a qualified facility to submit to FDA as part of its attestation the underlying documentation that establishes its compliance. We agree that the underlying records are needed to determine compliance with the documentation requirements and that a qualified facility must retain the documents it is relying on to support its attestation and make them available to us during inspection. We also agree that the regulatory text needs to be explicit regarding the required documentation and that we need to clearly distinguish between the documentation that would be submitted to FDA and the records that a qualified facility relies on to support the submitted documentation. Therefore, we have made the following three revisions to the proposed regulatory text.

First, we have revised proposed § 507.7(a) to specify that the submitted documentation is an ''attestation.'' Second, we have revised proposed § 507.7(b) to update details regarding the electronic and paper submission of a form specific to this attestation requirement. Third, we have revised proposed § 507.7(e) (final § 507.7(f)) to specify that you must maintain those records relied upon to support the ''attestations'' that are required by § 507.7(a).

We acknowledge that requiring submission of the actual documentation would enable us to easily review food safety plans or inspection reports and to target our compliance activities based on information that we see in those food safety plans or inspection reports. However, as discussed in Response 245, we are not requiring that other facilities submit a ''facility profile'' that would allow us to more broadly review food safety plans and target our compliance activities based on information that we see in those food safety plans and will instead explore other mechanisms to achieve the goals we described in the 2013 proposed preventive controls rule for animal food for a facility profile.

B. General Comments on Requirements That Apply to a Qualified Facility

(Comment 125) Some comments assert that the proposed requirements would create a costly burden for qualified facilities (*e.g.,* registering and making submissions to FDA) that would not be imposed on other types of exempted facilities. Some of these comments question whether the exemption for qualified facilities is meaningful in light of the significant burden imposed by the proposed requirements. Some comments contrast the proposed requirement for qualified facilities to submit documentation to FDA with proposed requirements for all other facilities to simply establish and maintain applicable records.

(Response 125) The submission requirements that we are establishing in this rule for qualified facilities reflect the statutory framework for qualified facilities (section 418(l)(2)(B) of the FD&C Act). Although the submission requirements only apply to qualified facilities, the reporting burden associated with submission of an attestation is much lower than the recordkeeping burden for facilities that are subject to the requirements for hazard analysis and risk-based preventive controls (see section LVIII).

(Comment 126) Some comments ask us to minimize setting different standards even though the requirements reflect express statutory provisions.

(Response 126) These comments appear to be referring to the statutory provisions of section 418(n)(3)(C) of the FD&C Act, which specify that the regulations we establish to implement section 418 of the FD&C Act acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods. We disagree that the statutory provisions of section 418(n)(3)(C) are directly relevant to the submission requirements of this rule for qualified facilities. The requirements for qualified facilities, but not other facilities, to submit documentation to FDA reflect different regulatory requirements. The different regulatory requirements are directed at different facilities, and do not set separate standards for particular animal foods. Regardless, even if the statutory provisions of section 418(n)(3)(C) were relevant to the submission requirements of qualified facilities, provisions of this rule that reflect express statutory provisions would not conflict with the statutory direction in section 418(n)(3)(C).

(Comment 127) Some comments emphasize that the requirements need to ensure adequate protection of public health and state that we should maintain and exercise oversight of qualified facilities. Some comments ask that we provide enough specificity so that qualified facilities know and understand their food safety responsibilities towards consumers.

(Response 127) A facility that satisfies criteria to be a qualified facility continues to be responsible to produce animal food that will not be adulterated under section 402 of the FD&C Act. Such a facility is also subject to the requirements of section 421 of the FD&C Act regarding frequency of inspection of all facilities and to the new administrative tools provided by FSMA, such as for suspension of registration (section 415 of the FD&C Act) and for mandatory recall (section 423 of the FD&C Act). As discussed in Response 77, we expect that most qualified facilities will be subject to the CGMP requirements of subpart B. When they are inspected, we will be ensuring they are in compliance with the CGMP requirements once the applicable compliance date is reached.

(Comment 128) Some comments ask which exemption a farm mixed-type facility should follow if it satisfies criteria for a qualified facility (§ 507.5(d)), as well as criteria for a very small business that only conducts on-farm low-risk activity/animal food combinations (specified in § 507.5(e) and (f)) and one comment suggests that FDA should allow such a facility to choose which exemption to follow.

(Response 128) We describe these comments in more detail in Comment 110. A farm mixed-type facility that is a very small business and that only conducts the low-risk activity/animal food combinations listed in § 507.5(e) and (f) may find it advantageous to classify itself as a very small business eligible for the exemption in § 507.5(e) and (f) (which is not subject to the requirements in § 507.7) rather than as a qualified facility (which is subject to the requirements in § 507.7).

(Comment 129) Some comments express concern about State access to the records that a qualified facility maintains to support its attestations, particularly when a State would conduct an inspection for compliance with part 507 under contract to FDA. These comments express concern about the time and resources necessary to verify the status of a facility as a qualified facility and note that previous mechanisms whereby we provide information to States in advance of inspection have been slow. These comments also express concern that if the state must verify the ''qualified facility'' status of all firms, including those that are not FDA contracts, this could delay their ability to conduct timely inspections and increase inspection time, reducing the number of inspections conducted.

(Response 129) We are sensitive to the time required for various inspection

activities and intend to communicate with States regarding our expectations for how to verify whether a facility is a qualified facility.

(Comment 130) Some comments point out that the proposed procedures for submission are silent on the process and timeframe for our review and approval of the submitted documentation and ask us to clarify this process and timeframe. Other comments ask us to clarify the consequences to a facility if its submission is found to be insufficient.

(Response 130) We will not be approving the submitted attestations. Instead, we intend to use the information to determine whether the facility should be inspected for compliance with the requirements for hazard analysis and risk-based preventive controls, or for compliance with the requirements for a qualified facility. During the inspection, we would ask to see the records that the facility maintains to support any submitted attestations.

(Comment 131) Some comments ask us to clarify whether a foreign facility would need to submit documentation of its status as qualified facility. These comments note that a foreign facility also would be required to provide information to an importer and assert that submitting information to both FDA and an importer would be a duplication of effort. These comments ask us to allow a foreign facility that is a qualified facility to submit information to either FDA or the importer, rather than to both FDA and the importer.

(Response 131) We decline this request. Documentation submitted to an importer would not reach FDA and, thus, could not satisfy the requirements of this rule. We are requiring submission of an attestation, on a form that can be submitted either electronically or on paper, rather than submission of the underlying information.

C. Proposed § 507.7(a)—Documentation To Be Submitted

1. Section 507.7(b)(1)—Documentation That the Facility Is a Qualified Facility

We proposed that a qualified facility must submit documentation that the facility is a qualified facility. We also proposed that for the purpose of determining whether a facility satisfies the definition of a qualified facility, the baseline year for calculating the adjustment for inflation is 2011. As discussed in Response 124, we have revised the provision to specify that the documentation that must be submitted is an attestation.

(Comment 132) Some comments ask us to clarify the documentation required to certify that an operation is a qualified facility. Some comments ask us to explicitly state that the documentation must include financial and sales records of the business and its subsidiaries or affiliates. Some comments ask us to clarify the types of records that would be required to be submitted by foreign establishments to support the classification of a foreign establishment as a ''qualified facility.''

(Response 132) The submission to FDA will be an attestation rather than the records that the qualified facility relies on to support the attestation; however, you must maintain those records relied upon to support the ''attestations'' (see § 507.7(f)). As previously discussed, consistent with section 418(l)(2)(B)(ii) of the FD&C Act, we intend to issue guidance on the records that a facility could retain to demonstrate that it is a qualified facility (78 FR 64736 at 64767). As discussed in Response 124, we have revised the regulatory text to provide for qualified facilities to submit an attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law. We intend to focus on records demonstrating that a facility is a very small business (*i.e.,* financial records demonstrating that a business averages 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)) rather than records demonstrating that the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users during a 3-year period exceeded the average annual monetary value of the food sold by the facility to all other purchasers. We expect that financial records demonstrating that a business is a very small business will be less burdensome for a qualified facility to maintain and require fewer resources for FDA to review.

During an inspection, we expect the facility to be able to show us how the facility is complying with the applicable food safety regulation (including relevant licenses, inspection reports, certificates, permits, credentials, or certifications), and producing safe animal food.

(Comment 133) Some comments ask how the adjustment for inflation will be calculated and how regulators such as the states will get this information.

(Response 133) We intend to use the Federal calculation for the Gross Domestic Product price deflator, as provided by the Bureau of Economic Analysis, to adjust for inflation. We will make the inflation-adjusted dollar value to the baseline very small business cutoffs (*e.g.* $2,500,000 in 2011) available on our Internet site. We will update the values for the very small business exemptions and qualifications annually using this calculation.

2. Proposed § 507.7(a)(2)(i)—First Option for Documentation: Food Safety Practices.

We proposed two options for satisfying the statutory documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act. Under the first option (the food safety practices option), a qualified facility could submit documentation demonstrating that it has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective. As discussed in Response 124, we have revised the provision to specify that the submission is an attestation.

(Comment 134) Some comments assert that the rule is vague about what the applicable documentation should include and how exhaustive it should be. Some comments ask whether documentation (such as a food safety plan) must address all operations at the establishment or only those that trigger the registration of the establishment as a facility. Some comments ask us to clarify the difference between having documentation to support food safety practices and attesting that the facility has such documentation. Other comments ask whether a qualified facility would need to have records documenting a risk analysis and monitoring.

(Response 134) If a qualified facility submits an attestation regarding its food safety practices, the documentation that the facility maintains for review during inspection must specify that the facility has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective (see § 507.7(a)(2)(i)). For example, a qualified facility that produces raw dog food might have documentation specifying that it has determined that *Salmonella* is a hazard requiring a preventive control, describing the process that will

control *Salmonella,* describing sanitation controls to prevent contamination of raw dog food with *Salmonella,* and describing an environmental monitoring program to verify that its sanitation controls are effective. Likewise, a qualified facility that makes a custom cattle food might have documentation specifying that it has determined that metal objects are a hazard requiring a preventive control and supporting the use of a magnet to remove metal objects from the cattle food, with procedures for monitoring the magnet's use if applicable.

As discussed in Response 124, a qualified facility that chooses the food safety practices option for complying with the submission requirements of this rule will attest to that by checking a statement on a form. In contrast, a food safety plan (or other documentation) that the qualified facility relies on to support the attestation will be a record subject to the recordkeeping requirements of subpart F.

3. Proposed § 507.7(a)(2)(ii)—Second Option for Documentation: Compliance With Other Applicable Non-Federal Food Safety Law

Under the second option for satisfying the statutory documentation requirement, a qualified facility could submit documentation that it is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. As discussed in Response 124, we have revised the provision to specify that the submission is an attestation. We also have revised the provision to add ''tribal'' as an example of applicable non-Federal food safety law to clarify for purposes of this rule that a qualified facility could submit an attestation that it is in compliance with tribal food safety law.

(Comment 135) Some comments object to the proposed provision. These comments point out that State and local requirements are inconsistent and assert that such requirements are not sufficiently rigorous to substitute for the FSMA requirement to conduct a hazard analysis and establish and execute a documented food safety plan. One comment asserts that the state laws may not provide the same level of protection to consumers.

(Response 135) The provision reflects the express statutory direction of section 418(l)(2)(B)(i)(II) of the FD&C Act. Most of these qualified facilities are subject to the CGMP requirements of subpart B and a facility that satisfies criteria to be a qualified facility continues to be responsible to produce animal food that will not be adulterated under section 402 of the FD&C Act.

(Comment 136) Some comments ask us to specify that a qualified facility must document compliance with all applicable non-Federal food safety laws. One comment asks what evaluation FDA will conduct of any non-Federal food safety law before determining that compliance with such law constitutes compliance under FSMA for a qualified facility.

(Response 136) We decline this request. Section 418(l)(2)(B)(i)(II) of the FD&C Act refers to apply to compliance with ''State, local, county, *or* other applicable non-Federal food safety law'' (emphasis added). As discussed in Response 132, we have revised the regulatory text to provide for qualified facilities to submit an attestation that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law During an inspection, we expect the facility to be able to show us how the facility is complying with the applicable food safety regulation (including relevant licenses, inspection reports, certificates, permits, credentials, or certifications), and producing safe animal food.

(Comment 137) Some comments ask us to provide resources to the States to implement the proposed provision. These comments also ask us to develop and implement a strategic plan to provide resources (*e.g.* training, guidance) to State and local inspection agencies in advance of the anticipated increased burden on State and local inspection programs that will be created by the provision.

(Response 137) We do not believe that specific training for State or other government counterparts is necessary for the purposes of inspecting a qualified facility that attested to having documentation from a non-Federal regulatory authority. The State or other government counterpart would merely examine applicable documentation (such as a license, inspection report, certificate, permit, credentials, or certification by an appropriate agency (such as a State department of agriculture)), which is specified in the provision. After inspecting such documentation, the State or other government counterpart would focus on inspection for compliance with CGMPs.

D. Proposed § 507.7(b)—Procedure for Submission

We proposed that the documentation must be submitted to FDA either electronically or by mail. As discussed in Response 124, we have revised the regulatory text to update details regarding the electronic and paper submission of a specific form. We are developing paper and electronic versions of Form FDA 3942b, which is an information collection provision that is subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 to 3520). We intend to make the paper Form FDA 3942b available in the near future and invite comments consistent with procedures for approval of the form by OMB.

(Comment 138) Some comments recommend that any interface for electronic submission of certification statements post adequate notice of requirements the facility must meet and warnings detailing potential penalties (*e.g.,* for fraudulent submission).

(Response 138) We intend that the electronic submission system will operate in a manner similar to the existing electronic submission system for registration of food facilities, including a certification statement advising the person signing the form that, under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. We intend to include a similar certification statement on paper forms that will be available for qualified facilities that choose to submit by paper rather than through the electronic system. The electronic and paper submission forms will focus on the attestation statements rather than on other requirements to which the facility is subject. The Small Entity Compliance Guide that we will issue in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121) will be better suited to helping qualified facilities understand the requirements of the rule than information presented on a submission form.

E. Proposed § 507.7(c)—Frequency of Determination and Submission

We proposed that the documentation must be: (1) Submitted to FDA initially within 90 days of the applicable compliance date and (2) resubmitted at least every 2 years, or whenever there is a material change to the information applicable to determining the status of a facility.

(Comment 139) Some comments assert that the proposed timeframe of 90 days to submit the required documentation would not provide sufficient time to gather and submit the required documentation and ask us to extend the timeframe, *e.g.,* to 120 or 180 days.

(Response 139) We are retaining the proposed timeframe for the initial

submission (within 90 days of the applicable compliance date). The only documentation that the qualified facility will need to submit is an attestation, which does not need to be gathered. Importantly, however, documentation supporting the attestation must be available for inspection by September 17, 2019. As discussed in Response 76, the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. As a companion change, we are explicitly requiring that a facility determine and document its status as a qualified facility on an annual basis by no later than July 1of each calendar year (see § 507.7(c)(1)).

In addition, we have revised proposed § 507.7(c)(1) (which we are finalizing as § 507.7(c)(2)(i)(A), (B), and (C)) to specify the timeframe for the initial submission for three distinct circumstances: (A) By December 16, 2019 for a facility that begins manufacturing, processing, packing, or holding animal food before September 17, 2019; (B) Before beginning operations, for a facility that begins manufacturing, processing, packing or holding animal food after September 17, 2019; or (C) By July 31 of the applicable calendar year, when the status of a facility changes from ''not a qualified facility'' to ''qualified facility'' based on the annual determination required by paragraph (c)(1) of this section. See the discussion in Response 76 regarding the approach we intend to take in a number of circumstances that could lead to a facility having records to support its status as a qualified facility for fewer than 3 preceding calendar years.

We have revised the provision to specify that the required biennial submissions of the attestations must be made during a timeframe that will coincide with the required biennial updates to facility registration (see section 102 of FSMA), *i.e.,* during the period beginning on October 1 and ending on December 31, beginning in 2020. In determining that 2020 would be the first year for the required biennial submissions of the attestations, we first considered that the first submission of an attestation would be approximately December 2019 for qualified facilities that are operating as of the date of this final rule (*i.e.,* approximately 90 days after the date of publication of this rule). For qualified facilities that do not begin operations until after December 2019, the first biennial submission will be required in a timeframe less than 2 years, but once the qualified facility has made its first submission the subsequent biennial submissions will all be at 2-year intervals. Coordinating the biennial submissions of the required attestations with the biennial registration will reduce the cumulative economic impact on the animal food industry of complying with two separate requirements because qualified facilities that choose to submit electronically will be able to submit electronically while accessing the same electronic portal used for facility registration.

(Comment 140) Some comments ask us to include an option within the system to notify us when a facility's status as a ''qualified facility'' changes, *e.g.,* because its business expands or changes.

(Response 140) Notifying us when there is a material change in the facility's status from ''qualified facility'' to ''not a qualified facility'' is a requirement rather than an option. We included this requirement in the proposed rule, and are establishing it in this final rule. We made editorial changes to the provision to make this clearer.

We also established a series of dates associated with the facility's change in status from ''qualified facility'' to ''not a qualified facility.'' First, we are specifying that when the status of a facility changes from ''qualified facility'' to ''not a qualified facility'' based on the required annual determination, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year (see § 507.7(c)(3)). We have provided the facility with flexibility to wait until July 1 of a given calendar year to determine whether its status changes (see § 507.7(c)(1)); 30 days is an adequate timeframe to submit the form notifying us of the change in status.

Second, we are specifying that when the status of a facility changes from ''qualified facility'' to ''not a qualified facility,'' the facility must comply with subparts C and E no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility (see § 507.7(d)). In essence, this provision can provide a facility with up to a full year to comply with the full requirements for hazard analysis and risk-based preventive controls when the facility determines its change in status early in the calendar year. A facility that does not determine that change in status until the required date of July 1 would still have 6 months to comply with the full requirements for hazard analysis and risk-based preventive controls. As we have done in the case of a qualified exemption being withdrawn (see § 507.65(d)(1)), we are providing flexibility for a facility to comply in an alternative timeframe if agreed to by FDA and the facility.

(Comment 141) One comment asks us to specify that the required attestations be submitted every 5 years rather than every 2 years. This comment asserts that doing so would be consistent with the statutory direction of section 201 of FSMA (Targeting of Inspection Resources) for non-high risk food facilities. This comment also asserts that we did not provide specific reasons for the proposed 2-year timeframe and that resubmitting the attestations every 2 years will increase cost in time and labor.

(Response 141) We decline the request. The rule requires resubmission whenever there is a material change to the information that changes the status of a facility as a qualified facility. Therefore, if the facility's sales change its status, so that it is no longer a qualified facility, the rule requires that facility to notify us when its status changes. (Note that the definition of very small business established in this rule bases the threshold dollar amount for a very small business on an average (of sales plus the market value of animal food held without sale) during the 3-year period preceding the applicable calendar year, rather than on annual sales plus market value. A biennial submission is adequate to otherwise require a qualified facility to affirmatively attest that it continues to satisfy the criteria for being a qualified facility. A biennial submission is not overly burdensome, because a facility can coordinate its biennial submission with its biennial update to its facility registration. The suggested 5-year submission based on the targeted inspection frequency for non-high risk animal food facilities implies that all qualified facilities produce such animal foods, which is not the case.

F. Proposed § 507.7(d)—Notification to Consumers (Final § 507.7(e))

We proposed that a qualified facility that does not submit documentation of its food safety practices must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address, or P.O. Box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities).

(Comment 142) One comment recommends that information giving the location of the manufacturing site, and not just the corporation contact information, be provided on the animal food labels. Other comments state that specifically for pet food and pet treats, the manufacturer should be required to include the co-packer information on

the product labels to include the co-packer's name, private label contact information, address, and co-packer's contact information (phone and/or email).

(Response 142) Section 418(l)(7) of the FD&C Act specifically mandates for a qualified facility that ''the name and business address of the facility where the food was manufactured or processed,'' not the corporate contact information, be included on a label for a food for which a food packaging label is required. It does not require co-packer information. The statute makes no requirements for non-qualified facilities.

G. Proposed § 507.7(e)—Records (Final § 507.7(f))

We proposed that a qualified facility must maintain those records relied upon to support the required documentation. We also proposed that the records that a qualified facility must maintain would be subject to the requirements that would be established in subpart F of this rule. As discussed in Response 124, after considering comments we have revised the rule to specify that a qualified facility must maintain those records relied upon to support the required attestations (rather than the required documentation).

(Comment 143) Some comments ask us to explicitly specify that we have access to documents that establish a facility as a qualified facility. Some comments assert that a facility may reasonably assume that records such as financial records would not be available to us because such records are excluded from the records that we have access to under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and as provided by § 1.362.

(Response 143) The rule explicitly specifies that we have access to records that are required by the rule (see § 507.200). If a facility relies on financial records to demonstrate its status as a qualified facility, we will have access to those financial records. The exemption referred to by the comments for financial records (§ 1.362) is narrowly targeted to records required by the section 414 recordkeeping regulations and does not apply to records required by this preventive controls rule for animal food.

XII. Subpart A: Comments on Proposed § 507.10—Applicability of Part 507 to a Facility Solely Engaged in the Storage of Unexposed Packaged Animal Food

We proposed that subpart C would not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and does not require time/temperature control to ensure the safety of the animal food (proposed § 507.10(a)). We also proposed that a facility solely engaged in the storage of packaged animal food that is not exposed to the environment but requires time/temperature control for safety would be subject to the modified requirements that would be established in proposed § 507.48 of subpart C (proposed § 507.10(b)).

Some comments support these proposed provisions without change. For example, one comment expresses the view that a facility solely engaged in the storage of packaged animal food that does not require time/temperature control for safety does not need to conduct its own hazard analysis, nor establish and implement preventive controls because there would be no hazards to trigger such activities. Other comments that support the proposed provisions ask us to clarify some aspects of the provisions or to clarify how the provisions will apply in particular circumstances. Other comments that support the proposed provisions ask us to broaden them.

In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, the proposed provisions. After considering these comments, we have revised the proposed requirements as shown in table 8 with editorial and conforming changes as shown in table 31. A key conforming change that affects § 507.10 is that it includes an exemption from the requirements of subpart E, as well as subpart C. As discussed in section XL, the final rule establishes the requirements for a supply-chain program in subpart E, rather than within subpart C as proposed.

TABLE 8—REVISIONS TO THE PROPOSED APPLICABILITY OF SUBPART C TO A FACILITY SOLELY ENGAGED IN THE STORAGE OF UNEXPOSED PACKAGED ANIMAL FOOD

Section	Description	Revision
507.10(b)	Applicability of modified requirements in § 507.51 of subpart C.	Clarification that § 507.51 of subpart C only applies to those unexposed packaged animal foods that require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(Comment 144) Some comments ask us to clarify that temperature controls should be implemented when determined to be necessary by the facility or preventive controls qualified individual. Some comments ask us to clarify that if a facility stores both TCS food and non-TCS food (*i.e.,* unexposed packaged animal food that does not require time/temperature control for safety), then the modified requirements only apply for the portion of the facility that holds the TCS foods.

(Response 144) We have revised § 507.10(b) to clarify that a facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 of subpart C of this part for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(Comment 145) Some comments ask us to revise the regulatory text to be explicit that frozen unexposed packaged food is not a TCS food subject to modified requirements.

(Response 145) We decline this request. In the 2013 proposed animal food preventive controls rule, we tentatively concluded that it would be rare for a frozen animal food to be a TCS food (78 FR 64736 at 64802), and we affirm that conclusion in this document. However, specifying in the regulatory text that a frozen animal food is not a TCS food would require us to conclude that a frozen animal food would ''never'' (rather than ''rarely'') be a TCS food, and we lack information to support ''never.''

(Comment 146) Some comments ask us to apply the exemption to storage areas of facilities that also engage in food processing activities, *e.g.,* for distributors that are engaged in limited food processing, such as blending seeds to make bird food. These comments

assert that the intent of the term ''solely'' is to make clear that a facility that conducts an activity subject to the exemption does not escape responsibility for complying with the requirements for hazard analysis and risk-based preventive controls when conducting activities that are not exempt.

(Response 146) We disagree with the comment's interpretation of the term ''solely.'' The plain meaning of ''solely'' is only, completely, entirely; without another or others; singly; alone (Ref. 24). The facility described in the comment is not ''solely'' engaged in the storage of unexposed packaged animal food.

Such a facility must conduct a hazard analysis that addresses all activities conducted by the facility. The preventive controls that the facility would establish and implement would depend on the facility, the animal food, and the outcome of the facility's hazard analysis and any preventive control management components associated with a facility's preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system. A facility that stores unexposed packaged animal food that is not a TCS animal food could, for example, determine that no preventive controls and associated management components would be necessary. A facility that stores unexposed refrigerated packaged TCS animal food could, for example, determine that preventive controls and management components patterned after the modified requirements in § 507.51 are adequate to address significant hazards associated with that animal food.

(Comment 147) Some comments ask us to allow a facility to designate a storage area as a separate facility for purposes of compliance with the requirements for hazard analysis and risk-based preventive controls. In the comments' view, an area solely engaged in the storage of unexposed packaged food could fall within the exemption in § 507.10 even though other areas would be subject to the requirements for hazard analysis and risk-based preventive controls.

(Response 147) We disagree that a designated storage area in an establishment that conducts manufacturing, processing, or packing in addition to storage can fall within the exemption for facilities ''solely engaged in . . . storage.'' The statute provides authority for us to exempt or modify the requirements for compliance with respect to ''facilities'' that are solely engaged in the storage of packaged foods that are not exposed to the environment (section 418(m) of the FD&C Act). The statute defines ''facility'' as a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act (section 418(o)(2) of the FD&C Act). The section 415 registration regulations define facility as ''any establishment, structure, or structures under one ownership at one general physical location . . .'' The comment's interpretation that we could view ''areas'' of registered facilities to be ''facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment'' is inconsistent with the statutory and regulatory framework under sections 415 and 418 of the FD&C Act.

(Comment 148) Some comments ask us to consider an alternative to the exemption for unexposed packaged foods when a facility conducts manufacturing, processing, packing, or holding activities in addition to storing unexposed packaged food. Specifically, these comments ask us to recognize that the minimal risks of storing unexposed packaged foods can be addressed through a combination of compliance with the modified requirements for TCS foods (if applicable) and the CGMPs in subpart B and state that doing so would be consistent with our discussion in the 2013 proposed animal food preventive controls rule.

(Response 148) These comments appear to suggest the outcome of a facility's hazard analysis and food safety plan for storing unexposed packaged animal food, *i.e.,* that the only significant hazards are the potential for growth of pathogens in refrigerated unexposed packaged animal foods and that the preventive controls and preventive control management components specified in the modified requirements for TCS animal food are adequate to address such hazards. It is the responsibility of the facility's preventive controls qualified individual to identify the significant hazards associated with the facility and the animal food it stores, as well as the appropriate preventive controls and preventive control management components. However, we agree that in some cases the approach suggested in these comments would be appropriate.

(Comment 149) Some comments assert that it is difficult to identify TCS foods. These comments ask us to work with industry and professional organizations to develop guidance on when the modified requirements apply.

(Response 149) This document does not include guidance on whether specific animal foods are TCS foods. We will consider including guidance on animal foods that are TCS foods in the implementing guidances we are developing (see Response 1). A facility solely engaged in storage of unexposed packaged animal food can work with the manufacturer of the food to identify TCS food. Alternatively, such a facility could simply treat any refrigerated food as a TCS food.

XIII. Subpart A: Comments on Proposed § 507.12—Applicability of Part 507 to the Holding and Distribution of Human Food By-Products for Use as Animal Food.

We proposed to add provisions for human food by-products for use as animal food. We proposed that the requirements of this part would not apply to by-products of human food production that are packed or held by that human food facility for distribution as animal food if: the facility is subject to and in compliance with subpart B of part 117 (the CGMPs in the proposed preventive controls rule for human food) and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations; and the facility does not further manufacture or process the by-products intended for use as animal food. Proposed § 507.12(b) would require that once the animal food was separated from the human food, the facility would need to comply with proposed §§ 507.28 and 117.95 of part 117 for the holding and distribution of that animal food. We also proposed § 117.95 be added to the proposed preventive controls rule for human food and asked for comment on whether the requirements should be placed in both § 117.95 and § 507.28.

Section 507.12 does not apply to human food by-products when contamination or other adulteration has occurred that is materially related to food safety. We handle requests for diversion of these products for animal food use on a case-by-case basis. Additional information on diversion of contaminated or adulterated food for animal food use is available in compliance policy guidances (CPG) CPG Sec. 675.100 ''Diversion of Contaminated Food for Animal Use'' and CPG Sec. 675.200 ''Diversion of Adulterated Food to Acceptable Animal Feed Use'' (Refs. 25 and 26). We asked for comment on whether we should include regulations for these types of requests.

Many comments generally support the concept that certain human food by-products intended for use as animal food which do not undergo further processing by the human food

manufacturer only need to comply with proposed § 507.28 for holding and distribution of human food by-products for use as animal food. Some of these comments note that human food by-products are an important source of animal food. Other comments agree but request changes and/or additional exemptions.

We have modified § 507.12 to clarify that the requirements of part 507 do not apply to off-farm packing and holding of RACs packed or held by a human food facility for distribution as animal food provided certain conditions are met. For off-farm packing and holding of produce (as defined in part 112 of this chapter), if the human food facility is subject to and in compliance with § 117.8 of part 117 of this chapter and in compliance with all applicable human food safety requirements of the FD&C Act and implementing regulations, and the human food facility does not further manufacture or process the by-products intended for use as animal food, then the requirements of part 507 do not apply to the by-products.

(Comment 150) Some comments request that the proposed provisions be included in both this rule and the final rule for preventive controls for human food so that it would be easier for human food processors to understand the requirements for human food by-products intended for use as animal food. One comment does not support placing these provisions in both of the final rules, preferring that all animal food provisions be in part 507, and that part 117 should pertain only to human food.

(Response 150) Section 117.95—''Holding and distribution of human food by-products for use as animal food'' is established in this rule. Section 117.95 will appear in 21 CFR part 117, preventive controls for human food. The by-products holding and distribution provisions also will appear in § 507.28, the animal food CGMPs. The requirements of § 117.95 and § 507.28 are identical and appear in both places for the convenience of the facilities to which the provisions would apply.

(Comment 151) Two comments state it must be clear in the rule that not only by-products but also products which are already authorized for food like gelatin or collagen must be authorized for food for animals, without further requirements and additional CGMP implementation.

(Response 151) We understand this comment to be stating that a human food product that also may be used as an animal food should not be required to comply with part 507 if it is in compliance with human food requirements. We agree with this comment. A facility that manufactures and sells a food just for human consumption is not subject to part 507, even if the purchaser of that food may use it for animal food.

If a facility manufactures, processes, packs, or holds human food and animal food, and is subject to subpart C of part 117, it can comply with subpart C of part 117 for the animal food, but needs to address any hazards unique to the animal food that require a preventive control, if applicable. Except as provided by § 507.12 for human food by-products, if a facility is required to comply with subpart B of part 507 and also subpart B of part 117 because the facility manufactures, processes, packs, or holds human food and animal food, then the facility may comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility (see the regulatory text for § 507.1(d)).

(Comment 152) Some comments request that facilities regulated by the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) not be required to comply with part 507 for animal-derived human food by-products intended for use as animal food. Some comments state the requirements are duplicative and are unnecessary because FSIS food safety requirements are already in place, and that oftentimes the FSIS establishment is unaware of what purpose or animal species the purchaser will use the by-product for as animal food.

(Response 152) Only animal food facilities that are required to register as a food facility under section 415 of the FD&C Act are required to comply with this rule. Establishments regulated exclusively throughout by FSIS under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act, *i.e.,* establishments handling only meat, poultry, or certain egg products, are exempt from registration under section 415 of the FD&C Act (see § 1.226(g) (21 CFR 1.226(g))). Therefore, these establishments are not subject to this rule.

(Comment 153) Some comments state we did not provide support for the tentative conclusion that animal-derived by-products carry different risks than other by-products, and therefore did not provide a basis for why animal-derived by-products should be subject to all of part 507 while other human food by-products are subject to only § 507.28.

(Response 153) As explained in Response 152, animal-derived by-products from establishments that are not required to register as food facilities would not be subject to part 507.

Facilities may be jointly regulated by FDA and FSIS if they produce some products that are under FDA jurisdiction and some that are under FSIS jurisdiction. Such facilities may be required to register as a food facility under section 415 of the FD&C Act. Examples of facilities jointly regulated by FDA and FSIS include FSIS establishments that also process animal food (such as certain pet food), and facilities that process meat and nonmeat products (such as frozen entrees, some of which contain meat and are regulated by FSIS, and some of which do not contain meat but which contain seafood or vegetables that are regulated by FDA).

FSIS establishments that are required to register with FDA because they also process FDA-regulated human food, must follow §§ 507.28 and 117.95 for the holding and distribution of their FDA-regulated human food by-products for use as animal food, if the establishments meet the requirements of § 507.12(a). FSIS establishments that are required to register with FDA because they also process FDA-regulated animal food must comply with the provisions in the preventive controls rule for animal food (part 507).

(Comment 154) Some comments assert that requiring FSIS-regulated establishments to comply with part 507 would result in more by-products being diverted to other disposal methods which might have an economic or environmental impact.

(Response 154) We do not agree that compliance with part 507 will likely result in substantially less use of human food by-products as animal food because it applies only to those establishments that are required to register under section 415 of the FD&C Act. Furthermore, other disposal methods for these products may be more cost prohibitive than compliance with these regulations.

(Comment 155) One comment requests the wording in proposed § 507.12 be revised to explicitly exclude animal-derived human food by-products for use as animal food because of pathogen risk.

(Response 155) Animal-derived human food by-products have a long history of use in the animal food industry. These human food by-products typically are sold from the human food facility to an animal food manufacturer/processor, such as a pet food manufacturer, that uses the by-products as an ingredient in a finished animal food. These manufacturers/processors are required to comply with

part 507 and must address any potential pathogens. Furthermore, 21 CFR 589.2000 prohibits the use of mammalian protein in the manufacture of animal food given to ruminant animals, such as cows, sheep, and goats, and regulations issued under the Swine Health Protection Act (7 U.S.C. 3801 *et seq.*) are intended to ensure that food waste containing meat does not contain active disease organisms that pose a risk to swine who eat it (see 9 CFR part 166).

(Comment 156) A few comments state that USDA, not FDA, should issue any regulations concerning the food safety of animal-derived by-products intended for use as animal food.

(Response 156) The FD&C Act gives FDA certain authority to regulate food, which includes food for animals. As explained in section XV of the 2013 proposed preventive controls rule for animal food, the FD&C Act authorizes FDA to issue CGMP and preventive controls regulations to enhance the safety of animal food, including human food by-products that are intended for use as animal food. We decline to address what USDA's role in animal food safety should be as is it out of the scope of this rulemaking.

(Comment 157) One comment suggests an alternative approach to animal-derived human food by-products. The comment suggests that we consider a provision that would allow the purchaser to take legal responsibility for evaluating and mitigating risk associated with by-products intended for use as animal food if both parties agree.

(Response 157) For facilities subject to subpart C, the supply-chain program in subpart E is required when the receiving facility's hazard analysis identifies a hazard requiring a supply-chain-applied control and the receiving facility's manufacturing/processing will not control the hazard. However, when a manufacturer/processor identifies a hazard requiring a preventive control, but can demonstrate and document that the hazard will be controlled by an entity in its distribution chain (*e.g.,* its customer), then the manufacturer/processor is not required to implement a preventive control (see §§ 507.36 and 507.37). For a discussion of these provisions, see section XXVII. For facilities exempt from the requirements of subpart C, we are aware that parties may enter into purchase contracts that include specifications or information for the animal food purchased.

(Comment 158) The comments support seafood, dietary supplements, and infant formula by-products intended for use as animal food without further processing be subject only to the holding and distribution provisions in proposed § 507.28.

(Response 158) We agree with these comments. We did not receive comments indicating by-products from these human foods have specific problems if used as animal food. Facilities that process seafood, dietary supplements, and infant formula that meet the requirements of § 507.12(a) must follow the requirements of § 507.28 and § 117.95 for human food by-products for use as animal food.

(Comment 159) Some comments state that all human food by-products, including those further processed, should only have to comply with the holding and distribution requirements in proposed § 507.28. Other comments support the requirement that human food by-products which are further processed should be required to comply with all of proposed part 507. Some comments request clarification about what constitutes further processing.

(Response 159) We decline the request to exempt human food by-products that are further processed from the requirements of part 507 because following CGMPs for the processing will help ensure the animal food's safety and because processing can introduce hazards requiring preventive controls. Further processing includes any manufacturing/processing as defined in § 507.3 and includes activities such as cooking, freezing, pelleting, and milling. Some passive activities such as dewatering by holding a by-product in a container with a screened bottom which allows water to escape, or holding in a perforated container which allows natural drying to occur are not considered further processing. Holding by-products at particular temperature to facilitate easier transportation of the by-products is not considered further processing; however, cooking or freezing a by-product to prevent deterioration or adulteration is considered further processing. Facilities holding human food by-products for use as animal food must follow the requirements of § 507.28.

(Comment 160) Some comments state we should not include diversion requests for contaminated or adulterated human food to animal food in the regulations; that the information contained in the guidance documents should remain in guidance and be handled on a case-by-case basis. However, some comments request that the existing compliance policy guidances be reviewed and updated and provide suggested changes.

(Response 160) We have not included regulations for diversion of contaminated or adulterated human food for animal food use in this final rule. We will continue to handle diversion requests on an individual basis. We will consider reviewing and revising the current compliance policy guidances, CPG Sec. 675.100, ''Diversion of Contaminated Food for Animal Use'' and CPG Sec. 675.200, ''Diversion of Adulterated Food to Acceptable Animal Feed Use'' (Refs. 25 and 26).

(Comment 161) One comment requests clarification on whether these provisions would apply to retail outlets such as grocery stores or bakeries. One comment asserts that when a pig farmer gets outdated milk from a dairy processing bottling plant after the plant takes it back from grocery stores that the dairy processor (the human food manufacturer) would be exempt from the animal food preventive controls final rule.

(Response 161) Retail food establishments such as grocery stores and bakeries are not required to register as food facilities (see §§ 1.226(c) and 1.227(b)(11)) and as a result are not required to comply with part 507. However, the products they distribute for animal food must not be adulterated.

If milk has been returned to a processing plant because it is contaminated or adulterated, the facility must follow our compliance policy guidances for requests to divert human food for use as animal food (Refs. 25 and 26). If the returned milk is not contaminated or adulterated, but is returned for a quality reason, the facility must follow the holding and distribution requirements of § 507.28 and § 117.95, but would be exempt from the other provisions in subpart B and subpart C of part 507.

(Comment 162) One comment requests clarification on whether a facility that is producing human food by-products intended for animal food that fall under proposed § 507.12 has to state in its food safety plan that § 507.12 applies.

(Response 162) If the human food processor meets the requirements in § 507.12(a), the facility only needs to comply with § 507.28 and § 117.95, for the holding and distribution of the human food by-products for use as animal food. The facility does not need to include this information in its food safety plan for the human food, but may choose to include it so that employees and other individuals viewing the food safety plan understand what regulatory requirements the human food processor is applying to those human food by-products intended for animal food.

XIV. Subpart B: General Comments on Proposed Subpart B—Current Good Manufacturing Practice

In the 2014 supplemental proposed rule we revised the proposed CGMPs to be more appropriate for the animal food industry. Following are comments on the proposed CGMP requirements.

(Comment 163) Some comments state that the risks for pet food, especially with respect to pathogens, are different than the risks for livestock feed, and therefore FDA should issue two sets of CGMPs. Some comments say that CGMPs for pet food should be modeled after the human food CGMPs because of the high level of care people provide and demand for their pets, pets may eat or sleep with humans, and pet owners often store pet food close to human food.

(Response 163) We believe the single set of CGMPs can serve as baseline standards for producing safe animal food across all types of animal food facilities and animal food. We considered the diverse needs of industry and the ultimate goal of animal food safety as we finalized the CGMP regulations. We believe the final requirements are flexible enough to be applied appropriately in various animal food production settings. For example, § 507.19(b) contains requirements for the cleaning of animal food-contact surfaces of equipment and utensils to protect against contamination of animal food. We do not specify exactly how this is to be done (except some requirements for cleaning with wet processing of animal food), knowing that what constitutes adequate cleaning will depend on the plant and the animal food. (See Response 182).

As discussed in the 2013 proposed rule for preventive controls for animal food, in 2003 we introduced the concept of the Animal Feed Safety System (AFSS) which was intended to address the safety of all animal food at all stages of production and use. After obtaining input from the general public, State regulatory officials, industry, veterinarians, and consumers, the AFSS working group began developing a proposed rule for process controls for animal food, prior to FSMA, that was intended to apply to all animal food (including pet food, livestock feed, and raw materials and other ingredients) (78 FR 64736 at 64740).

When we revised the proposed CGMPs in the 2014 supplemental notice, we not only consulted the human food CGMPs and their development history, but also reviewed the draft AFSS process controls proposed rule. We also reviewed CGMPs developed by organizations such as the British Standards Institute's Publicly Available Specification (PAS) 222 and the Association of American Feed Control Officials (AAFCO) model GMPs for feed and feed ingredients (which are adopted by many states for regulation of animal food) (Refs. 27 and 28). Both PAS 222 and AAFCO GMPs apply to pet food and other animal food such as feed for livestock. Many of the raw materials and other ingredients used in making finished animal food are used by multiple types of animal food manufacturers producing a variety of animal food products. It would not be feasible to enforce different sets of standards for pet food and livestock feed in a plant supplying the same ingredients to a pet food manufacturer and a livestock feed manufacturer. We expect our CGMP requirements to be applied appropriately in all facilities manufacturing and processing animal food.

(Comment 164) Some comments say that CGMP requirements for animal food in general are not appropriate for some products used in animal food. Comments provide examples such as rendered products, which are thermally processed before being used as ingredients in animal food; humic products because raw mined materials are low risk; and oilseed products because they have not been associated with any significant food safety risks and are intermediate ingredients that will undergo a subsequent kill step.

(Response 164) We understand that some ingredients utilized in the production of animal food may pose a low risk. Nevertheless, facilities that are required to register under section 415 of the FD&C Act and are suppliers of ingredients used in animal food will be required to meet the CGMP requirements being finalized in this rule. We believe these CGMPs provide a great deal of flexibility in establishing baseline standards for safely manufacturing, processing, packing, or holding the wide diversity of ingredients used in animal food.

(Comment 165) One comment suggests that a new section be added at the end of subpart B that would eliminate the need to comply with the CGMPs if a facility showed that the hazard analysis and risk-based preventive controls required by subpart C had been properly conducted, implemented and validated.

(Response 165) We decline this request. The requested change is counter to the intent of this regulation, that the CGMPs in subpart B provide baseline safety and sanitation standards, while hazards specific to a facility and the animal food it produces are identified and controlled under subpart C. We consider CGMPs to be a prerequisite program important for effective preventive controls, and believe that the CGMPs being finalized in this rule provide enough flexibility for a facility to use CGMPs to address certain hazards so they do not become hazards that would require a preventive control.

(Comment 166) One comment from a foreign government says that minimum requirements for recordkeeping and traceability, which are recommended in the CODEX Code of Practice on Good Animal Feeding, might be appropriate in subpart B so that they would apply to establishments exempt from subpart C.

(Response 166) We agree that traceability and associated recordkeeping are important tools for a facility to use for tracing animal food in the event of a recall or foodborne illness outbreak. Recordkeeping requirements currently exist in the Bioterrorism Act, and implementing regulations in part 1 subpart J for persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. In addition, the responsible party at any food facility required to register under section 415 of the FD&C Act (domestic and foreign) is subject to the RFR requirements under section 417 of the FD&C Act. Section 417 requires under certain circumstances that the responsible party notify the previous source and subsequent recipient of the article of reportable food, providing traceability.

(Comment 167) Some comments request that we use the term ''adulteration'' instead of ''contamination'' in subpart B of the final rule because ''adulteration'' of food is the regulatory standard for action, whereas contamination is currently undefined. These comments state that the term contamination should carry a different meaning than in part 117 because what is considered a contaminant in human food may differ from what is considered a contaminant in animal food.

(Response 167) We decline this request. Section 402(a)(3) and (4) of the FD&C Act were added to expand our bases for initiating enforcement proceedings against adulterated food, particularly to allow us to act where a food has been prepared, packed, or held under insanitary conditions, whereby it may have become contaminated. In other words, a food need not be shown to contain contaminants to be adulterated; a showing that the food was prepared, packed, or held under

conditions whereby it may become contaminated is sufficient to prove adulteration. Thus, the word ''contamination'' serves a necessary purpose in the context of adulteration. The CGMPs in this final rule are intended to help protect against the contamination of animal food, so that it will not become adulterated.

The word ''contamination'' is used widely in FDA regulations, including our Current Good Manufacturing Practice for Medicated Feeds (21 CFR part 225), Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR part 113), and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (21 CFR part 110, and updated and included in the final rule for preventive controls for human food, 21 CFR part 117, published elsewhere in this **Federal Register**). In addition, ''contamination'' is used in Codex Good Practices for the Feed Industry and PAS 222 (Ref. 27). Because of the wide use of the term throughout current FDA regulations and in international standards, we conclude that industry is familiar with the word ''contamination'' and it is an appropriate word to use in this final rule.

We recognize that it may not always be possible to prevent contamination of animal food. Therefore, we have changed the regulatory text throughout subpart B to stress that the goal of the regulations is to ''protect against'' or ''minimize'' the contamination of animal food. We recognize that what is considered contamination of human food may not be considered contamination in animal food.

(Comment 168) Some comments object to the use of the terms ''sanitize'' and ''sanitation'' in the CGMPs, saying that the destruction of microorganisms is not always necessary in animal food facilities and therefore ''cleaning'' or ''housekeeping'' should be used instead of ''sanitizing.'' Some of these comments also ask that we change the title of proposed § 507.19 from ''Sanitation'' to ''Cleaning and Housekeeping.''

(Response 168) We decline this request. We use the term ''sanitation'' in a general way that we believe is well understood by the animal food industry and does not mean the destruction of microorganisms. For example, the term ''sanitation'' is defined in PAS–222 (Ref. 27). When the destruction of vegetative cells of pathogens and substantial reduction of numbers of other undesirable microorganisms is required, we use the terms ''sanitize'' or ''sanitizing,'' not ''sanitation,'' which is consistent with how these terms are used throughout our current regulations for human and animal food. The only requirement for sanitizing in subpart B is in regards to wet processing (see regulatory text for § 507.19(b)(2)). Therefore, we believe that ''sanitation'' is a word that is commonly understood by industry and is used in this final rule in a way that is consistent with how it is used in our other regulations relating to human and animal food.

(Comment 169) Some comments request that we use ''tools'' instead of ''utensils'' in the CGMPs to better fit the terminology used in the animal food industry.

(Response 169) We decline this request. We recognize that ''utensil'' is not commonly used in the animal food industry; however, we believe it is well understood. The term ''utensil'' is used in PAS–222 and Codex Good Practices for the Feed Industry, as well as in the CGMPs for human food in part 110 and in the revised CGMPs in the final rule for preventive controls for human food, part 117 (Refs. 27 and 29). Further, because ''tools'' is broadly used to refer to such things as construction equipment, software, educational material, and even laws and regulations, we believe it is not a good substitute for ''utensils.''

(Comment 170) A number of comments request that wherever we require measures to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, that we delete animal food-contact surfaces and animal food-packaging materials because the focus should be solely on the animal food.

(Response 170) We decline this request. While the ultimate goal of the CGMP requirements is to protect against contamination of animal food, we believe that protecting animal food-contact surfaces and animal food-packaging material from contamination is a necessary step to achieve this goal because the surfaces and packaging can be a source of contamination.

XV. Subpart B: Comments on Proposed § 507.14—Personnel

We proposed that plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food. We are finalizing this provision with the discussed changes in § 507.14(a). We have changed ''plant'' to ''establishment'' for clarity. We are finalizing the proposed list of methods for maintaining cleanliness that were proposed in § 507.14(a)(1) through (5) in new § 507.14(b)(1) through (5). We have added paragraph (b) to read: ''the methods for conforming to hygienic practices and maintaining cleanliness include.''

(Comment 171) Some comments ask us to remove ''all'' because it is too extreme and prescriptive.

(Response 171) We have revised the regulatory text to delete ''all''. We disagree that the term ''all'' is too extreme and prescriptive, but conclude that the term ''all'' is not necessary to communicate the intent of the requirement.

A. Proposed § 507.14(a)(1)—Personal Cleanliness (Final § 507.14(b)(1))

We proposed that the methods for maintaining cleanliness include maintaining adequate personal cleanliness. We did not receive comments specific to this provision and are finalizing it as proposed.

B. Proposed § 507.14(a)(2)—Hand Washing (Final § 507.14(b)(2))

We proposed that the methods for maintaining cleanliness include washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to prevent contamination.

(Comment 172) One comment disagrees with FDA's decision to revise the language from the 2013 proposed rule by removing the parenthetic statement about sanitizing hands if necessary to protect against contamination with undesirable organisms. The comment recommends that FDA add a qualifying statement that if hand washing facilities are not readily available, the use of hand sanitizers is permitted.

(Response 172) We decline this request. We deleted the parenthetic statement because we did not intend to require hand sanitizing after hand washing. We are providing flexibility for plant management to determine if hand sanitizing after washing is necessary to protect against contamination of animal food with undesirable microorganisms. We recognize that there may be some situations where hand washing facilities are not readily available. The use of waterless hand cleaners (including hand sanitizers) may be adequate under these circumstances.

C. Proposed § 507.14(a)(3)—Unsecured Jewelry and Other Objects (Final § 507.14(b)(3))

We proposed that personnel be required to remove or secure jewelry and other objects that might fall into animal food, equipment, or containers.

(Comment 173) One comment says this requirement is unnecessary since the proposed CGMPs contain numerous other provisions that require facilities to protect against the adulteration of products. The focus placed on jewelry and other items that may potentially fall into products is unwarranted due to the limited risk of such occurrences.

(Response 173) We believe that a specific provision to protect against jewelry and other personal items falling into animal food is appropriate, and is not redundant to other requirements in the CGMPs that are intended to protect against adulteration of animal food.

D. Proposed § 507.14(a)(4)—Storing Clothing and Personal Belongings (Final § 507.14(b)(4))

We proposed requiring personnel to store clothing and other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned.

(Comment 174) One comment says that the requirement is not practical or necessary to ensure the safety of animal food. The comment states that the temperature in a facility can be highly variable, so it would be unreasonable to require an employee to store clothing outside of areas where animal food is exposed.

(Response 174) We understand that personnel may need layers of clothing in certain plants that are exposed to varying temperatures. However, when clothing is removed, it needs to be stored away from exposed animal food so it does not become a source of contamination. We believe storing clothing and other personal belongings in areas other than where animal food is exposed is a reasonable protection.

E. Proposed § 507.14(a)(5)—Taking Other Necessary Precautions (Final § 507.14(b)(5))

We proposed that personnel must take any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(Comment 175) One comment requests that we provide examples in a guidance document for the requirement to take ''any other necessary precautions to protect against contamination of animal food, animal food contact surfaces, or animal food packaging materials.''

(Response 175) We believe this provision indicates that the listed requirements are not meant to be exhaustive and provides needed flexibility for the diverse animal food industry to implement precautions specific to their operations to protect against the contamination of animal food. We will consider providing examples in any future guidance.

XVI. Subpart B: Comments on Proposed § 507.17—Plant and Grounds

A. Proposed § 507.17(a)—Grounds Surrounding an Animal Food Plant

We proposed that the grounds surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food, including provisions to keep areas from being a harborage for pests, maintaining areas so they are not a source of contamination, adequately draining areas, and treating and disposing of waste so it is not a source of contamination.

(Comment 176) One comment says that the term ''surrounding'' the plant is too ambiguous, and that we should specify the distance from a plant that must be controlled to prevent animal food contamination.

(Response 176) We decline to specify a distance from the plant because the area that could impact plant operations is highly variable from plant to plant. We have replaced the word ''surrounding'' with the word ''around,'' meaning the grounds of the plant under control of the plant management that could impact plant operations.

(Comment 177) Some comments say that the requirements are highly prescriptive and should be more flexible. Other comments state that the general language that requires the grounds to be kept in a condition that will protect against the contamination of animal food is sufficient and that the specific requirements should be recommendations.

(Response 177) The specific requirements provide the baseline expectations we have for plants to maintain their grounds in a way that does not result in the contamination of animal food. The specific requirements are common to most plants and provide necessary information to the plant management about what it must do to comply with this final rule. However, the requirements do not preclude a plant from addressing unique circumstances that could lead to the contamination of animal food.

B. Proposed § 507.17(b)(1)—Adequate Space Between Equipment, Walls, and Stored Materials

We proposed that the buildings, structures, fixtures, and other physical facilities of the plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contract surfaces, and animal food-packaging materials. We also proposed that the plant must provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment.

(Comment 178) Two comments disagree with this requirement. One comment says that the focus is on equipment design and not protecting against animal food contamination. The other comment suggests simplifying the requirement to provide access between equipment and walls.

(Response 178) We believe protecting animal food from contamination requires proper plant design. We decline the request to change the requirement by deleting the reference to stored materials because we do not agree that stored materials should be allowed to prevent employees from performing their duties or inhibit the cleaning and maintenance of equipment. We did modify the language in paragraph (b) to replace ''buildings, structures, fixtures, and other physical facilities of the plant'' with ''the plant'' because the plant would include its buildings, structures, fixtures, and physical facilities.

C. Proposed § 507.17(b)(2)—Dripping and Condensation

We proposed that the plant must be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination.

(Comment 179) One comment asks that we allow for facilities to be ''constructed or maintained,'' rather than ''constructed'' only, to ensure that drip or condensate does not serve as a source of animal food contamination. Another comment asks that the requirement be deleted, since it is generally not relevant and is redundant to the opening statement in proposed paragraph (b). Other comments say that requirements pertaining to the construction of buildings and structures are too prescriptive and should specify only that the plant be constructed in such a manner as to protect against adulteration of animal food.

(Response 179) We decline the requests to revise or delete this requirement. The requirements in (b)(1) to (5) are some of the specific requirements that we believe are needed to meet the general requirement in paragraph (b) that the plant be designed and constructed to reduce the potential for contamination. We believe it is important to specify that fixtures, ducts, and pipes be constructed so that they do not serve as a source of contamination because condensate and drip may serve as a source of contamination. As specified in § 507.20(b)(3), plumbing must be maintained to avoid being a source of contamination to animal food. In addition, as specified in 507.19(a), the fixtures and physical facilities of the plant must be kept in good repair to prevent animal food from becoming adulterated. This would include fixtures, ducts, and pipes. Thus, we agree that one way to manage dripping and condensation is through maintenance or repair to the plumbing or structure, and do not intend that existing plants must be redesigned or reconstructed.

D. Proposed § 507.17(b)(3)—Ventilation

We proposed that the plant must provide adequate ventilation or control equipment to minimize vapors (for example, steam) and fumes in areas where they may contaminate animal food, and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food.

(Comment 180) One comment says that while steam is a key manufacturing component, it is unlikely to be a source of potentially hazardous contaminants. Several comments state that steam is not commonly used in animal food processing, and should not be specified in the rule, or language stating ''where appropriate and necessary'' should be included in the regulatory text. Other comments suggest additional alternative language.

(Response 180) We agree that not all plants use steam and the phrase ''where appropriate and necessary'' provides that distinction and have added it to the regulatory text. We also recognize that animal food facilities commonly rely on natural ventilation. As a result, we have added the parenthetical (mechanical or natural) to the regulatory text to read: ''Provide adequate ventilation (mechanical or natural) . . .''

E. Proposed § 507.17(b)(4)—Lighting

We proposed that the plant must provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned. We received no comments on this provision and are finalizing it as proposed.

F. Proposed § 507.17(b)(5)—Glass

We proposed that the plant must provide safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage. We did not receive specific comments on this paragraph. However, for clarity, we have replaced the term ''safety-type'' with ''shatter-resistant.''

G. Proposed § 507.17(b)(6)—Outdoor Storage

We proposed that animal food stored outdoors in bulk be protected by any effective means, including using protective coverings, controlling areas over and around the bulk animal food to eliminate harborages for pests, and checking on a regular basis for pests and pest infestation.

(Comment 181) Several comments say that protecting animal food stored outdoors is better addressed in proposed § 507.19 (Sanitation). One comment says that at livestock facilities and farms animal food such as hay, silage, grain, human food by-products, and other commodities are commonly stored outside with no cover. Another comment requests that the regulation be revised to recommend rather than require the provisions.

(Response 181) While we disagree with the recommendation to move this requirement to § 507.19 (Sanitation), we moved it from proposed paragraph (b) to new paragraph (c) in § 507.17 because paragraph (b) pertains to buildings and structures and this requirement is about animal food stored outside of the building or structure. We have revised the regulatory text in paragraph (c)(1) to read ''Using protective coverings where necessary and appropriate'' to account for the situations that may not require protective coverings. In addition, we have added checking for product condition related to the safety of the animal food in paragraph (c)(3) to ensure that if the animal food is not covered, animal food safety is maintained. We decline to specify under what circumstance protective coverage is required (such as, to protect against adverse weather conditions) since there could be several reasons for needing protective coverage to help protect against contamination of the animal food.

XVII. Subpart B: Comments on Proposed § 507.19—Sanitation

A. Proposed § 507.19(a)—Buildings

We proposed that buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming contaminated. We received no comments on this provision, however we are replacing ''contaminated'' with the broader standard ''adulterated'' as proposed in the 2013 proposed preventive controls rule for animal food.

B. Proposed § 507.19(b)—Cleaning

We proposed that animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary and appropriate to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials, and that when necessary, equipment be disassembled for thorough cleaning.

(Comment 182) Two comments state that the proposed provision is too prescriptive because of the requirement to disassemble equipment for cleaning when necessary.

(Response 182) We believe the language provides flexibility for plants to prevent contamination of animal food contact and non-contact surfaces of utensils and equipment. The language ''when necessary'' provides the plant the option whether to disassemble the equipment for cleaning based on the manufacturer's knowledge and experience of when this cleaning procedure is necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

C. Proposed § 507.19(b)(1)—Wet Cleaning

We proposed that when it is necessary to wet-clean animal food-contact surfaces used for manufacturing, processing, packing, or holding low-moisture animal food, the surfaces must be thoroughly dried before subsequent use.

(Comment 183) One comment states that ''low-moisture animal food'' is not defined, so for clarity we should either define it or replace it with ''safe moisture level animal food'' because ''safe moisture level'' is already defined in the proposed rule.

(Response 183) We agree that the term ''low-moisture'' is not well known when applied to the animal food industry as a whole and we have removed the term. We believe that in most cases, animal

food contact surfaces must be thoroughly dried after wet cleaning because the moisture could provide an environment for growth of undesirable microorganisms. However, we also understand that in some situations, for example in wet processing areas, it would not be necessary to dry surfaces thoroughly before subsequent use in order to protect against contamination. Therefore, we have inserted ''when necessary,'' so that the requirement is appropriate for all types of animal food facilities.

(Comment 184) Two comments note that the proposed rule includes explicit requirements for wet cleaning, but none for dry cleaning. One comment suggests adding language to paragraph (b) for dry cleaning, including vacuuming or sweeping. The second comment suggests adding language for dry cleaning when used solely for low-moisture feed ingredients.

(Response 184) We decline these requests. The regulatory text in paragraph (b) requires that utensils and equipment be cleaned and maintained, but it does not specify the exact procedures. Adequate cleanout of so-called dry feeds has been an important CGMP requirement applicable to medicated feed for more than 40 years and, as such, some of the animal food industry is well aware of this practice. The dry cleaning procedures suggested in the comments would be allowable methods of cleaning and maintaining where appropriate to protect against the contamination of animal food. We do not believe additional language is necessary in the regulatory text for dry cleaning. The provisions in paragraph (b)(1) for wet cleaning are in addition to the more general requirements in paragraph (b) to help ensure that water from the wet-cleaning process does not result in subsequent contamination of animal food.

D. Proposed § 507.19(b)(2)—Wet Processing

We proposed that in wet processing, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

(Comment 185) One comment says the proposed requirements for cleaning in wet processing areas should be more flexible and suggests the additional wording ''as necessary to protect against adulteration of animal food.''

(Response 185) We believe this requirement is sufficiently flexible because it applies only when necessary to protect against the introduction of undesirable microorganisms into animal food.

E. Proposed § 507.19(c)—Cleaning Compounds and Sanitizing Agents

We proposed that cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use. We received no comments on this provision and are finalizing it as proposed.

F. Proposed § 507.19(d)(1)—Toxic Materials

We proposed that only certain toxic materials may be used or stored in a plant where animal food is manufactured, processed, or exposed, *i.e.,* those that are required to maintain clean and sanitary conditions, those necessary for use in laboratory testing procedures, those necessary for plant and equipment maintenance and operation, and those necessary for use in the plant's operations.

(Comment 186) Some comments say that the proposed regulation would require an absolute prohibition of any potentially toxic materials that are stored but not used by an animal food plant. The comments note that animal food plants that hold and distribute materials such as fertilizers and pesticides would either need to discontinue this practice or construct new storage buildings, which may be expensive. Several comments suggest alternative language to allow toxic materials to be held and distributed in a way that would not require significant physical improvements to the plant.

(Response 186) We agree that it might be common for an animal food plant to have toxic materials not identified in paragraph (d)(1), such as fertilizers or other non-plant chemicals, as part of its business inventory. However, we disagree with the comments that state the provisions in the rule would require new investments in storage buildings. The intent of the provision is to keep toxic chemical categories not listed in paragraph (d)(1) out of the plant area so animal food is not exposed. We revised the regulatory text to add paragraph (d)(3), which reads ''Other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.'' We expect that this will result in toxic materials not identified in paragraph (d)(1) being separated from animal food either by sufficient space or a sufficient physical barrier such that they are not able to contaminate the animal food. With this clarification, we do not believe that establishments will need to make significant investments to their buildings and structures to comply with these requirements.

G. Proposed § 507.19(d)(2)—Identification, Use, and Storage of Toxic Materials

We proposed that toxic materials described in paragraph (d)(1) of this section (for example, cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(Comment 187) A number of comments object to the use of ''toxic'' in proposed paragraph (d)(2). Several comments suggest that ''cleaning materials'' rather than ''toxic cleaning compounds'' be used in paragraph (d)(2) because any substance may be considered ''toxic'' if handled or used inappropriately. One comment asks that the term ''toxic materials'' be deleted and requirements established instead for the control of substances that are not approved for use in animal food.

(Response 187) We decline the request. The term ''toxic'' is important to specify that this paragraph applies to toxic cleaning compounds. The term ''cleaning compounds'' would be too general and might include materials that would not need to be handled as specified in these requirements to protect against the contamination of animal food. For example, water could be considered a cleaning compound, but it is not considered toxic at regular use levels and we would not expect a plant to treat its use of cleaning water in a manner consistent with this requirement. We decline the request to substitute ''substances that are not approved for use in animal food'' for ''toxic materials.'' Not all animal food ingredients have been or must be preapproved by the Agency before being used to produce animal food. Additionally, ingredients that have not been approved by the Agency would not necessarily be toxic.

H. Proposed § 507.19(e)—Pest Control

We proposed that effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of insecticides and rodenticides in the plant is permitted only under precautions and restrictions that will

protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. We received no comments on this provision. We have replaced the words ''insecticides and rodenticides'' with ''pesticides'' for simplicity and because we have defined pest as ''any objectionable animals or insects including birds, rodents, flies, and larvae.'' Thus, pests are not limited to insects and rodents.

I. Proposed § 507.19(f)—Trash and Garbage

We proposed that trash and garbage must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash and garbage to become an attractant and harborage or breeding place for pests. We received no comments on this provision; however we are removing the term ''garbage.'' (See Response 227).

XVIII. Subpart B: Comments on Proposed § 507.20—Water Supply and Plumbing

A. Proposed § 507.20(a)—Water Supply (Final § 507.20(a)(1)–(4))

We proposed that the water supply must be adequate for the operations and must be derived from a suitable source. Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing or processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities. Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use. Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(Comment 188) One comment suggests that we develop an enforcement plan for water quality that takes into account the intended use of the animal food being manufactured. Another comment says that many of the details contained in this paragraph of the proposed regulation should be handled as guidance rather than regulation.

(Response 188) We believe that the details contained in this paragraph should remain requirements because they are important to helping ensure the safety of animal food and to provide the regulated facility with information about what is expected of the water supply for the plant and the animal food being manufactured, processed, packed or held. We will consider including water supply in any future guidance.

(Comment 189) Two comments say that that the requirements pertaining to the water supply are overly prescriptive and we should require only that the water supply be adequate for the operations. Two comments suggest that the requirement about the reuse of water be reworded to provide more clarification on the recycling of water within the plant.

(Response 189) We believe the source of the water is relevant to ensuring that animal food is protected from contamination. We also believe specifying that water be safe for its intended use, and that it be provided at a suitable temperature and pressure where it is needed for manufacturing, processing, cleaning, and hand washing helps protect against animal food contamination. With respect to reuse of water, we believe our statement that water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food allows flexibility for recycling water within the plant. Additional clarification could have the unintended effect of reducing flexibility.

B. Proposed § 507.20(b)—Plumbing

We proposed that plumbing be designed, installed, and maintained to carry adequate quantities of water to required locations throughout the plant; properly convey sewage and liquid disposable waste from the plant; avoid being a source of contamination to animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies, equipment, or utensils, or creating an unsanitary condition; provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and ensure there is no backflow or cross-connections between piping for water for processing and for waste water.

(Comment 190) One comment says we are proposing to establish specific requirements for plumbing design, installation, and maintenance that are not necessary to prevent the adulteration of animal food, and suggests deleting the plumbing design section entirely. Two comments say that floor drains are not the only way to remove water or other fluids from floors, and suggest we allow other options such as vacuuming, mopping, or fans.

(Response 190) We decline these requests. We believe these are basic and necessary requirements for helping ensure production of safe animal food. The regulatory text requires adequate floor drainage for areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor. Plants that do not perform these activities as part of their normal operations would not be expected to have floor drainage and vacuuming or mopping may be adequate.

C. Proposed § 507.20(c)—Sewage

We proposed that sewage must be disposed of through an adequate sewerage system or through other adequate means.

(Comment 191) Some comments say that the requirement to provide an adequate sewer system is covered by the requirement in proposed § 507.20(b)(2) for plumbing and that one of the requirements should be deleted to eliminate this redundancy.

(Response 191) The requirement in paragraph (b)(2) is intended to make sure the plumbing in the plant is sufficient to remove sewage and liquid disposable waste from the points at which it is generated within the plant, while the requirement in paragraph (c) is intended to make sure that the sewage and liquid disposable waste created by the plant is delivered to a wastewater system, such as a sewer or septic system, which has a capacity adequate to ensure that this wastewater does not contaminate the animal food.

D. Proposed § 507.20(d)—Toilet Facilities

We proposed that each plant must provide employees with adequate, readily accessible toilet facilities, and that the toilet facilities be kept clean and not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(Comment 192) Some comments suggest adding ''as appropriate'' to the requirement to provide adequate toilet facilities for plant employees.

(Response 192) We decline this request. We understand that there may be an exception where toilet facilities are not inside a plant, but we believe it is important that toilet facilities are available near the plant for employee use, and the requirement as proposed provides this flexibility.

E. Proposed § 507.20(e)—Hand-Washing Facilities

We proposed that each plant must provide hand-washing facilities

designed to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(Comment 193) Some comments suggest adding the words ''as appropriate'' to the requirement to provide flexibility for those plants that may not need hand-washing facilities. Another comment asks that we add an option that allows for the use of hand sanitizing in plants that may not need hand-washing facilities.

(Response 193) We understand that there may not be running water in every plant, but we believe it is important that hand-washing facilities be available to employees. We understand that in some cases hand-washing facilities might consist of waterless hand cleaners (including hand sanitizers).

XIX. Subpart B: Comments on Proposed § 507.22—Equipment and Utensils

A. Proposed § 507.22(a)(1)—Plant Equipment and Utensils

We proposed that all plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained.

(Comment 194) Some comments suggest that this be a recommendation rather than a requirement because it is too prescriptive and applies to all equipment in a plant, rather than only to equipment used in the production of animal food.

(Response 194) We decline this request. We believe that all plant equipment with the potential to contaminate animal food must be cleanable and maintained. To clarify this requirement, we have added language stating that this requirement applies to equipment and utensils used in manufacturing, processing, packing, and holding animal food, as well as equipment and utensils that do not come in contact with animal food but could still serve as a source of contamination of animal food.

B. Proposed § 507.22(a)(2)—Design of Equipment and Utensils

We proposed that the design, construction, and use of equipment and utensils must preclude the contamination of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(Comment 195) Some comments say that this requirement is too prescriptive because equipment and utensils are designed and constructed by entities independent of the animal food manufacturers/processers. Some comments also say that we should clarify that we are not requiring the use of food-grade lubricants.

(Response 195) We understand that plants do not normally design and construct the equipment they use. However, we believe it is the plant's responsibility to select equipment and utensils that when used will not adulterate animal food. We have revised the text to clarify that the presence of non-food grade lubricants, fuel, metal fragments, contaminated water, or other contaminants in animal food may render it adulterated. We also have revised the wording for easier reading. We are not requiring that only food grade lubricants be used in the plant, but food grade lubricants must be used on equipment that comes in contact with animal food. When a non-food grade lubricant is used on non-food contact equipment, it must not adulterate the animal food. We have added the term ''non-food grade'' for lubricants to clarify this.

C. Proposed § 507.22(a)(3)—Equipment Installation

We proposed that equipment should be installed and maintained in such a way as to facilitate the cleaning of the equipment and adjacent spaces. This provision has been revised to be a requirement, not a recommendation as it is a requirement, not guidance.

(Comment 196) One comment suggests that we combine proposed §§ 507.22(a)(1) and 507.22(a)(3).

(Response 196) We decline this request. The first provision requires that equipment be properly designed and constructed, and the second requires that it be installed in a way that facilitates cleaning and maintenance. We have revised the wording in (a)(3) for clarity.

D. Proposed § 507.22(a)(4)—Animal Food Contact Surfaces

We proposed that animal food-contact surfaces must be made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, and sanitizing agents; be made of nontoxic materials; and maintained to protect animal food from being contaminated.

(Comment 197) Some comments ask us to specify that food-contact surfaces must be designed to withstand cleaning procedures.

(Response 197) We have revised the regulatory text to include cleaning procedures. For example animal food-contact surfaces must be designed to withstand the actions of scrubbing utensils that could damage the equipment.

E. Proposed § 507.22(a)(5)—Non-Animal Food Contact Equipment (Final § 507.22(a)(1))

We proposed that equipment in the animal food in manufacturing/processing area, that does not come into contact with animal food must be constructed in such a way that it can be kept in a clean condition.

(Comment 198) One comment says that this requirement should be deleted because it is highly prescriptive, redundant to proposed paragraph (a)(1), and not performance based or necessary. Further, the comment states FDA's focus should be on whether the area is adequately cleaned, not on whether equipment that does not come in contact with animal food is properly designed.

(Response 198) We disagree that the requirement is too prescriptive. However, we agree that there is some redundancy between proposed paragraphs (a)(1) and (a)(5). We have removed proposed paragraph (a)(5) and have modified the regulatory text in paragraph (a)(1) as discussed in section XIX.A.

F. Proposed § 507.22(b)—System Design and Construction

We proposed that holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way that does not contaminate animal food.

(Comment 199) Several comments suggest that this requirement be revised or deleted to allow plants the flexibility to maintain their equipment in a manner that is appropriate for their facility, and because it is redundant to proposed § 507.22(a)(1) through (4).

(Response 199) We decline to revise or eliminate this provision. The requirements in § 507.22(a) are specific to individual pieces of equipment. The requirement in § 507.22(b) is meant to address entire systems that may contain multiple pieces of equipment. While an individual piece of equipment may be designed, constructed and maintained so that it protects against the contamination of animal food, when that piece of equipment becomes part of a system, its use in the system must be in a manner that protects against the contamination of animal food. (See Response 167.)

G. Proposed § 507.22(c)—Monitoring Cold Storage Temperatures

We proposed that each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-monitoring device.

(Comment 200) Some comments state requiring monitoring devices for each compartment goes too far. Facilities should have flexibility in controlling temperatures in freezers and cold storage compartments. One comment says this requirement should not require the use of continuous temperature-monitoring devices.

(Response 200) We believe that a temperature-measuring device for each compartment is necessary because the temperature may be different in each compartment. We have replaced the term ''temperature -monitoring device'' with ''temperature-measuring device'' as we do not intend the establishment to use a continuous monitoring device or temperature recording device.

H. Proposed § 507.22(d)—Instruments

We proposed that instruments and controls used for measuring, regulating, or recording temperatures, pH, a_w, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses. We received no comments on this provision and are finalizing it as proposed.

I. Proposed § 507.22(e)—Compressed Air

We proposed that compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way so animal food is not contaminated. We received no comments on this provision and are finalizing it as proposed with the revision ''to protect against the contamination of animal food.'' (See Response 167.)

XX. Subpart B: Comments on Proposed § 507.25—Plant Operations

A. Proposed § 507.25(a)(1)—CGMPs

We proposed that plant management must ensure that all operations in the manufacturing, processing, packing, and holding of animal food are conducted in accordance with the CGMP requirements of this subpart. We received no comments on this provision. We are revising paragraph (a) to read ''Management of the establishment must ensure that:'' based on the definition of ''plant'' (see section VIII.A.23).

B. Proposed § 507.25(a)(2)—Identifying Contents of Containers

We proposed that plant management must ensure that containers holding animal food, including raw materials, other ingredients, or rework, accurately identify the contents.

(Comment 201) Some comments suggest that we revise the proposed requirements by clarifying that the contents of containers, not the containers themselves, are accurately identified, and that we clarify that bulk silos and bins are not required to be placarded, because this is impractical and not industry practice.

(Response 201) We agree that the animal food in the containers is what must be identified and have clarified the language in the regulatory text to require management to ensure animal food, including raw materials, other ingredients, or rework is accurately identified. We recognize that a variety of systems are used by establishments to identify animal food within the plant including labeling, computer systems, paper records, chalkboards, and other methods. It is necessary that plant personnel be able to accurately identify animal food, including raw materials, other ingredients, or rework within the plant so that animal food is not commingled, substituted, or incorrectly formulated in a manner that results in adulterated animal food.

C. Proposed § 507.25(a)(3)—Labeling of Finished Product (Final § 507.27(b))

We proposed that plant management must ensure that the labeling for finished animal food product contains information and instructions for safely using the product for the intended animal species.

(Comment 202) Many comments suggest that instead of specifying that labeling for the finished animal food product contains information and instructions for safely using the product for the intended animal species we specify only that labeling for finished animal food products conforms to requirements in existing FDA regulations. One comment asks that we clarify that finished product means the product that the animal receives.

(Response 202) We decline the request. We do not intend ''finished animal food product'' to mean only product that the animal receives. A finished animal food product could be ready-to-eat animal food or it could be an ingredient or mixture of ingredients that will be further processed, mixed, or blended before it is suitable for feeding to animals.

Labeling containing information and instructions for safe use is important for both the person feeding the animal(s) and the downstream facilities that may use an ingredient or mixture of ingredients to further process, mix, or blend into an animal food product. Some animal food products may pose a food safety concern for some species for which the food is not intended, or may pose a food safety concern for an intended species if not used properly. For example, the manufacturer of a copper product might include the use levels for food for different species or a labeling statement specifying the maximum safe level of copper in an animal food intended for sheep.

We have moved this requirement to paragraph (b) in § 507.27 ''Holding and Distribution.'' We believe that this move helps to clarify that the labeling is intended for finished animal food leaving the plant. We have renumbered the other requirements in this section accordingly.

D. Proposed § 507.25(a)(4)—Animal Food Packaging Material (Final § 507.25(a)(3))

We proposed that plant management must ensure that animal food-packaging materials are safe and suitable.

(Comment 203) One comment suggests that instead of requiring that animal food-packaging materials are safe and suitable, we require that they are safe and suitable for the intended use.

(Response 203) We disagree that this clarification is needed because the intended use is inherent in the current wording of this regulation.

E. Proposed § 507.25(a)(5)—Responsibility for Overall Plant Cleanliness (Final § 507.25(a)(4))

We proposed that plant management must ensure that overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function.

(Comment 204) One comment suggests that we require that the competent individuals responsible for overall cleanliness of the plant be ''qualified competent individuals.''

(Response 204) As discussed in Response 92, we expect all individuals who perform activities required under part 507 to know how to do their jobs; thus, we are establishing new § 507.4(b), which specifies that all individuals who perform activities required under part 507 must be ''qualified individuals'' as that term is defined in § 507.3 (*i.e.,* a person who has the necessary education, training, and experience to perform an activity required under part 507). A qualified individual may be, but is not required to be, an employee of the establishment.

F. Proposed § 507.25(a)(6)—Contamination Precautions (Final § 507.25(a)(5))

We proposed that plant management must ensure that reasonable precautions are taken so that plant operations do not contribute to the contamination of animal food, animal food-contact surfaces, and animal food packaging materials. We received no comments on this provision. We did replace the term ''reasonable'' with the term ''adequate'' to be more consistent with the rest of the regulatory text in subpart B.

G. Proposed § 507.25(a)(7)—Testing Procedures (Final § 507.25(a)(6))

We proposed that plant management must ensure that chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination.

(Comment 205) Some comments say that the need for chemical, microbial, or extraneous-material testing should be determined by a facility when identifying hazards and controls under subpart C, and therefore it should not be required under CGMPs. One comment says that it should be deleted because it is already addressed under the testing provisions in subpart C.

(Response 205) The CGMP regulations in subpart B are intended to establish baseline requirements that apply to all plants that manufacture, process, pack, or hold animal food (and thus are required to register as food facilities in accordance with § 415 of the FD&C Act). Using testing procedures, where necessary, to identify sanitation failures or to identify contaminated animal food may be an important component of manufacturing, processing, packing, or holding animal food. This type of testing may be independent of the requirements of subpart C, hazard analysis and risk based preventive controls, and therefore we have included it in the CGMP regulations. The provision provides flexibility for management to determine when testing is required by providing that testing be used ''where necessary.''

H. Proposed § 507.25(a)(8)—Contaminated Product (Final § 507.25(a)(7))

We proposed that plant management must ensure that animal food that has become contaminated to the extent that it is adulterated is rejected, disposed of, or if permissible, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food. Whatever methods are used to dispose of adulterated animal food, the methods should comply with state and local requirements.

(Comment 206) One comment requests that if we require reconditioning of an animal found to be adulterated, that we clarify that such a requirement does not apply to grains subject to the review inspection provisions provided for by 7 CFR 800.125 and 800.135.

(Response 206) In most cases, grains subject to the review inspection provisions provided for by 7 CFR 800.125 and 800.135 are RACs that are being held or transported and subpart B (including § 507.25(a)(7)) would not apply to the grains (see § 507.5(h)). In addition this provision only applies to animal food that has actually been found to be adulterated. The provisions provided for by 7 CFR 800.125 and 800.135 are administered by USDA's Federal Grain Inspection Service and relate to their mission of facilitating the marketing of grains and related commodities.

I. Proposed § 507.25(a)(9)—Protecting Against Contamination (Final § 507.25(a)(8))

We proposed that plant management must ensure that all animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms or for the contamination of animal food.

(Comment 207) Some comments suggest that we remove the requirement to minimize the potential for the growth of undesirable microorganisms, so that the requirement would be to minimize contamination of animal food or protecting against adulteration of animal food.

(Response 207) We decline this request. In addition to other contaminants, we conclude that it is important for an establishment to address undesirable microorganisms because they are a common source of contamination (78 FR 64736 at 64747).

J. Proposed § 507.25(b)(1)—Raw Materials and Ingredients

We proposed that raw materials and ingredients must be inspected to ensure that they are suitable for manufacturing/processing into animal food and handled under conditions that protect against contamination and minimize deterioration. We are revising the phrase ''raw materials and ingredients'' to read ''raw materials and other ingredients'' to make it clear that raw materials are ingredients.

(Comment 208) Some comments ask that we insert ''as appropriate and necessary'' into the requirement to inspect raw materials and ingredients to ensure that they are suitable for manufacturing/processing into animal food. Another comment says that ''minimize deterioration'' and ''deterioration'' are highly subjective and should be deleted.

(Response 208) We decline the requests. However, we have revised the regulatory text by replacing ''inspected'' with ''examined.'' We believe that the use of the word ''examined'' provides more clarity for the animal food industry because the term ''inspected'' often implies a regulatory activity. We believe such an examination is necessary to protect against contamination of animal food. An examination of raw materials and other ingredients may include basic activities such as a simple visual examination of the product (*e.g.,* looking for broken bags), or performing a chemical or microbial analysis. Deterioration of animal food includes the loss of palatability or nutritive value typically associated with the animal food and we believe this could be a safety concern because animals are often fed the same food containing the same ingredients for prolonged periods of time. As a result, food refusal or consumption of animal food containing fewer nutrients than the animal food is expected to provide may result in poor animal productivity or health issues. Furthermore, deterioration can indicate that the animal food has been held under conditions that would also support the growth of undesirable microorganisms.

K. Proposed § 507.25(b)(1)(i)—Shipping Containers

We proposed that shipping containers (for example, totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be inspected upon receipt to determine whether contamination or deterioration of animal food has occurred.

(Comment 209) Some comments say that inspection of shipping containers should be as appropriate and necessary, or at a frequency appropriate and necessary.

(Response 209) We decline this request. We have revised the regulatory text by replacing ''inspected'' with ''examined.'' We believe this change better conveys our intent that incoming containers consistently be checked to make sure there is no gross visible contamination or deterioration of animal food.

L. Proposed § 507.25(b)(1)(ii)—Raw Materials

We proposed that raw materials must be cleaned as necessary to minimize soil or other contamination.

(Comment 210) Many comments say that it is not always necessary to minimize soil contamination of raw materials because livestock routinely ingest soil when consuming pasture plants, hay, and other feeds without adverse consequences. Recommendations are to delete reference to soil or else insert ''as appropriate.''

(Response 210) We agree. We have revised the regulatory text to remove the words ''soil or other'' from the requirement.

M. Proposed § 507.25(b)(1)(iii)—Raw Materials

We proposed that raw materials and ingredients must be stored under conditions that will protect against contamination and deterioration.

(Comment 211) One comment suggests that the requirement that raw materials be stored under conditions that will protect against contamination and deterioration be qualified to say ''unreasonable contamination'' and ''excessive deterioration'' to be more appropriate for raw materials that will be rendered. One comment asks that we delete ''and deterioration.'' Another comment suggests that a new section be added to require that air flow be controlled so that contamination does not spread from the raw material areas into the finished product areas of the plant.

(Response 211) We believe the rule as proposed is clear, and that the qualifiers suggested do not help reduce subjectivity and may create confusion about what is considered unreasonable or excessive. We decline to add a requirement that specifically addresses air flow, because ventilation is addressed in § 507.17(b)(3). Also, the broad language requires that raw materials and other ingredients must be stored under conditions that will protect against contamination, which would include protection from airborne contaminants. We have determined, however, that it is logical from a food safety standpoint to include rework in this provision. Therefore, we have incorporated proposed § 507.25(b)(3) into this requirement.

N. Proposed § 507.25(b)(2)—Raw Materials Susceptible to Mycotoxins

We proposed that raw materials and ingredients susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans.

(Comment 212) Several comments suggest that we eliminate this requirement because this activity belongs in subpart C, not subpart B. Other comments say that the requirement could be interpreted to mean that every load of incoming cereal grains must be evaluated for mycotoxins, which would not always be necessary. Other suggestions are to remove ''evaluated'' from the requirement, leaving only the requirement that raw materials and ingredients susceptible to mycotoxin contamination be used in a manner that does not result in harm to humans or animals.

(Response 212) We are locating requirements that are common to most establishments and plants and serve as a baseline for animal food safety in subpart B, current good manufacturing practice. Also, we do not intend that every load of grain received must be tested before it can be used. We intend for ''evaluation'' to be broad and flexible enough to consider any information that allows the plant to use the raw materials and other ingredients in a manner that does not result in harm to humans or animals. For example, an evaluation could be based on a general review of the weather conditions during the growing season and whether it could result in mycotoxins.

(Comment 213) One comment disagrees with our decision in the 2014 supplemental proposed rule to remove a requirement in § 507.25(b)(2) of the 2013 proposed rule for preventive controls for animal food that raw materials and ingredients not contain microorganisms injurious to human or animal health. This comment says that we should have modified the regulatory text to require that raw materials that are expected to contain levels of microorganisms that may be injurious to animal or human health, such as materials to be rendered, be stored and handled in a way that prevents contaminating the facility and finished product, and that the materials be treated (*e.g.,* heat treated) during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(Response 213) Incoming raw materials and other ingredients may contain microorganisms injurious to human or animal health. As we stated in the 2014 supplemental notice for animal food, we proposed to remove this requirement because we did not intend that incoming raw materials and other ingredients must be tested for pathogens. Instead, we have included requirements that are meant to minimize the growth of undesirable microorganisms, and protect animal food from the contamination with undesirable microorganisms from raw materials and other ingredients, including those that may be injurious to human or animal health. We believe these requirements are sufficient to help ensure the safety of animal food.

O. Proposed § 507.25(b)(3)—Raw Materials and Rework (Final § 507.25(b)(1)(iii))

We proposed that raw materials and ingredients and all rework must be held in containers designed and constructed in a way that protects against contamination, and must be held under conditions, *e.g.,* appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and in a manner that prevents the animal food from becoming adulterated.

(Comment 214) Some comments say that requiring that rework be held under conditions that will minimize the potential for growth of undesirable microorganisms is too prescriptive, and suggest that the requirement be modified to require that all rework must be held in a manner that prevents the animal food from becoming adulterated. Some comments say that this requirement should be addressed in subpart C rather than subpart B.

(Response 214).We disagree that the requirement should be addressed in subpart C instead of subpart B because we consider this to be a baseline requirement that should apply to all establishments that manufacture, process, pack, or hold animal food. However, we have decided that proposed paragraph (b)(3) contains requirements that are similar to proposed § 507.25(b)(1)(iii). We have moved this provision and included it in paragraph (b)(1)(iii) in the final rule.

P. Proposed § 507.25(b)(4)—Frozen Raw Materials (Final § 507.25(b)(3))

We proposed that raw materials and ingredients, if frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.

(Comment 215) One comment says that the requirement to keep frozen raw materials frozen or thaw them in a manner that minimizes the potential for the growth of undesirable microorganisms is redundant to other requirements in § 507.25(b)(1) and therefore should be deleted.

(Response 215) We decline this request. The requirements in § 507.25(b)(1) and 507.25(b)(1)(iii) address raw material and other ingredient inspection, storage and handling in general. This requirement speaks specifically to the storage and handling of frozen raw materials. We believe it is important for those establishments that use frozen raw material to thaw that material safely to minimize the potential for the growth of undesirable microorganisms during the thawing process.

Q. Proposed § 507.25(c)(1)—Appropriate Conditions for Animal Food

We proposed that animal food must be maintained under conditions, *e.g.,* appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding.

(Comment 216) Some comments say that the requirement to hold and manufacture products at a temperatures and relative humidity that will minimize the potential for growth of undesirable microorganisms should be deleted because it is not relevant to most animal food facilities. With this deletion, the requirement would be that animal food be maintained under conditions that would prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding.

(Response 216) Temperature and relative humidity are examples of conditions and may not apply to all plants and animal food. This requirement is important for animal food safety in plants that produce animal food that must be handled under specific processing, packing or holding conditions to prevent the growth of undesirable microorganisms and adulteration.

R. Proposed § 507.25(c)(2)—Control of Undesirable Microorganisms

We proposed that measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (for example, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling a_w) must be adequate to prevent adulteration of animal food.

(Comment 217) Most of the comments say that measures to significantly minimize or prevent the growth of undesirable microorganisms should be addressed under subpart C, and that this requirement should be removed from the CGMPs. One comment recommends deleting only the examples of measures that might be taken. Another comment recommends deleting the term ''significantly'' as this term is not defined and is difficult to quantify.

(Response 217) We disagree that the requirement should be addressed in subpart C instead of subpart B. We consider controlling undesirable microorganisms to be a baseline requirement that should apply to all establishments that manufacture, process, pack, or hold animal food. We also decline the request to remove the examples of measures that can be used to significantly minimize or prevent the growth of undesirable microorganisms because they are examples of practical solutions already used by industry. We decline to delete the term ''significantly.'' The term ''significantly minimize'' is defined in § 507.3 and means to reduce to an acceptable level, including to eliminate.

S. Proposed § 507.25(c)(3)—Work-in-Process and Rework

We proposed that work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms.

(Comment 218) Some comments request that we delete ''and the growth of undesirable microorganisms'' and require only that work-in-process and rework be handled in such a way that it is protected against adulteration.

(Response 218) We decline this request. Because undesirable microorganisms are a common source of contamination of animal food, including work-in-process and rework, we have decided to specify that establishments must protect against the growth of undesirable microorganisms, as well as other contamination.

T. Proposed § 507.25(c)(4)—Processing Steps

We proposed that steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food.

(Comment 219) One comment suggests that we revise the requirement to say that steps be performed in a way that protects against animal food adulteration rather than protects against animal food contamination. Another comment suggests that the requirement be deleted because it is redundant to other requirements in the proposed rule.

(Response 219) As discussed in Response 167, we believe contamination is the better word to use in this context. These specific requirements provide a level of detail that we believe is important because these activities are common in the animal food industry and can contribute to the contamination of animal food. We believe that this requirement for these activities is not redundant to other requirements in this final rule.

U. Proposed § 507.25(c)(5)—Processing Operations

We proposed that filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms.

(Comment 220) One comment requests that we delete ''and the growth of undesirable microorganisms'' and require only that operations be performed in such a way that the animal food is protected against adulteration. Another comment suggests that the requirement be deleted because it is redundant, but does not identify the redundant section.

(Response 220) As discussed in Response 167, we believe contamination is the better word to use in this context. These specific requirements, including the requirement for the protection against the growth of undesirable microorganisms, provide a level of detail that we believe is important because these activities are common in the animal food industry and can contribute to the contamination of animal food. We believe that these requirements for these activities are not redundant with other requirements in this final rule.

V. Proposed § 507.25(c)(6)—Controlling Water Activity (a_w)

We proposed that animal food that relies on the control of water activity for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(Comment 221) Some comments request that we delete the requirement because controlling water activity belongs in subpart C, not in the CGMP regulations. Another comment says that controlling moisture level is not sufficient and the requirement should be revised to require that animal food that relies on the control of water activity for preventing the growth of undesirable microorganisms be processed to and maintained at a suitable water activity, not a safe moisture level. We also received comments asserting that water activity may not be the only factor responsible for preventing the growth of undesirable

microorganisms in dry products and that we should modify the regulatory text to take into account other synergistic barriers for microbial growth and toxin formation.

(Response 221) We disagree that controlling water activity belongs in subpart C. While not all animal food establishments rely on the control of water activity for preventing the growth of undesirable microorganisms in their animal food, we have determined it is important to have this requirement in CGMP regulations for those establishments that do, considering the potential public health significance of undesirable microorganisms. We agree that the term ''safe water activity level'' is more commonly understood by the animal food industry than ''safe moisture level'' and we have revised the regulatory text accordingly. We agree with the comment that water activity may not be the only factor responsible for preventing growth of undesirable microorganisms in certain animal food and have revised the regulatory text to clarify that such products rely ''principally'' on the control of water activity.

W. Proposed § 507.25(c)(7)—Controlling pH

We proposed that animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH.

(Comment 222) Some comments request that we delete this proposed requirement because controlling pH belongs in subpart C, not in subpart B. One comment also says that it is too prescriptive and duplicative of protections against adulteration in other proposed sections of subpart B.

(Response 222) We decline the request. While not all animal food establishments principally rely on the control of pH for preventing the growth of undesirable microorganisms in their animal food, we have determined it is important to have this requirement in the CGMP regulations for those establishments that do, considering the potential public health significance of undesirable microorganisms.

X. Proposed § 507.25(c)(8)—Ice

We proposed that when ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

(Comment 223) One comment suggests that this requirement be deleted because ice is rarely used in the manufacturing/processing of animal food.

(Response 223) We decline this request. We have established this requirement to help ensure that when ice is used for the manufacture of animal food, the ice is made from water that is safe so that it does not contaminate the animal food it contacts.

XXI. Subpart B: Comments on Proposed § 507.27—Holding and Distribution

A. Proposed § 507.27(a)—Holding and Distribution

We proposed that animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration.

(Comment 224) A few comments request that we remove ''minimize deterioration'' from this requirement. These comments say that although deterioration may lead to animals refusing food, an animal's refusal of food does not necessarily mean that the food has deteriorated. The comments suggest that we instead use the phrase ''ensure product integrity throughout the intended shelf life,'' or that we clarify the definition of deterioration if we do not remove it.

(Response 224) We decline this request. We believe it is important that animal food be held and distributed in manner that does not lead to deterioration. Deterioration of animal food includes the loss of palatability or nutritive value typically associated with the animal food and we believe this could be a safety concern because animals are often fed the same food containing the same ingredients for prolonged periods of time. As a result, food refusal or consumption of animal food containing fewer nutrients than the animal food is expected to provide may result in poor animal productivity or health issues. Furthermore, deterioration can indicate that the animal food has been held under conditions that would also support the growth of undesirable microorganisms.

B. Proposed § 507.27(a)(1)—Containers

We proposed that containers used for holding animal food for distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent contamination of animal food.

(Comment 225) A few comments request that the terms ''designed'' and ''constructed of appropriate material,'' which may have different interpretations, be replaced by ''fit for purpose'' a term recognized by the animal food industry.

(Response 225) We decline the request. We believe the terms ''designed'' and ''constructed of appropriate material'' are well understood by the animal food industry and ''fit for purpose'' does not improve clarity.

(Comment 226) A few comments note containers used to hold animal food may include bins, totes or other intermediate storage containers, each of which may require differing levels and frequency of cleaning. Some of these comments ask that we add the phrase ''where necessary'' when discussing cleaning to provide flexibility.

(Response 226) We agree that containers used to hold animal food will require different cleaning methods and frequency of cleaning. These differences may result from the types of containers used, the amount and type of animal food held, the frequency at which containers are reused, as well as other factors. As a result, we agree that it is appropriate to include language that indicates that different methods and frequencies of cleaning may be appropriate to protect against contamination of the animal food and we have revised the regulatory text to add ''as necessary'' after cleaned.

C. Proposed § 507.27(a)(2)—Protection From Contamination

We proposed that animal food held for distribution must be held in a way that prevents contamination from sources such as trash and garbage.

(Comment 227) A few comments request that the phrase ''from sources such as trash and garbage'' be deleted. A few comments request that the term ''garbage'' not be used because some products that may be considered garbage may actually be suitable for use as animal food. Some of these comments suggested alternative language.

(Response 227) We agree in part with this comment. The mistaken inclusion of trash or garbage into animal food could be a potential source of contamination. The terms ''trash'' and ''garbage'' are intended in their general sense and refer to items that are not suitable for animal food, or are not intended for animal food. However, under the Swine Health Protection Act, ''garbage'' as defined by the act is prohibited for use as food for swine, unless it is treated to kill disease organisms. For this reason, and because the terms can be considered synonyms, we are removing the term ''garbage'' throughout subpart B to avoid confusion.

D. Proposed § 507.27(a)(3)—Labeling of Animal Food Held for Distribution (Final § 507.27(b))

We proposed that labeling identifying the product by the common or usual name must be affixed to or accompany the animal food.

(Comment 228) Some comments support the labeling requirement because accurate identification of animal food throughout the distribution chain is an important food safety step and loss of identity can have serious animal and human health implications. One comment suggests that this requirement be revised to specify that the proposed labeling be required during holding and distribution of both packaged animal food and bulk animal food. One comment says that FDA's primary interest should be identification, not labeling, because labeling for animal food being held for distribution in bulk is impractical. The comment also notes that plants may use a central computer system or other method to identify animal food location. A few comments suggest that we should require that animal food held for distribution be labeled as required by regulations for finished products.

(Response 228) We agree that animal food may be identified in the plant through methods other than labeling. We expect that while animal food is being processed in the plant that the animal food is accurately identified as required in § 507.25(a)(2) of this final rule.

We have moved the requirement that labeling must include information and instructions for safely using the animal food product for the intended animal species from proposed § 507.25(a)(3) ''Plant operations'' in the 2014 supplemental proposed rule to § 507.27(b) of ''Holding and distribution'' to clarify that this labeling information must be included when the product is ready for distribution. We think that placing the labeling requirements for animal food products ready for distribution under ''Holding and distribution'' will help reduce confusion and make these requirements for labeling for distribution easier to find in the final rule. Labeling that meets applicable FDA labeling regulations must accompany or be affixed to the animal food and that the labeling must include, when applicable, information and instructions for safely using the product for the intended animal species. We have added the clarification that it is ''when applicable,'' understanding that not all animal food product will need information on its safe use. We have deleted the requirement that labeling that identifies the product by the common or usual name must be affixed to or accompany the animal food in this section because it is already covered by current FDA regulations.

E. Proposed § 507.27(b)—Shipping Containers (Final § 507.27(c))

We proposed that shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

(Comment 229) Some comments state that the requirement to inspect shipping containers is not practical because containers are frequently reused without intervening cleaning or because the animal food is distributed in dedicated containers or vehicles. One comment says that it is pointless to inspect the containers when the product being distributed may be decayed and may be dumped on the ground for the animals to eat. Other comments state that sometimes nobody is available to inspect the vehicle when third-party transportation is used and that third-party transportation vehicles may already contain animal food or by-products because they are used to pick up from several facilities. Some comments say that contractual provisions specify how third-party shipping container may be used, and therefore inspection prior to each load would not be necessary to manage this risk.

(Response 229) Though we disagree with the comments, we are revising the regulatory text in §§ 507.27 and 507.28 to replace the word ''inspected'' with ''examined''. We believe that the use of the word ''examined'' provides more clarity for the animal food industry because the term ''inspected'' often implies a regulatory activity. This does not mean that the shipping container must be cleaned prior to each use. The plant or facility is responsible for examining shipping containers and bulk vehicles that it uses to transport the animal food (*e.g.,* the facility transports the animal food, or arranges with a third-party to distribute the animal food to the facility's customer). We expect the plant or facility personnel involved in the process of loading the product into the shipping container or vehicle to be aware of the condition of the shipping container or vehicle, and consider whether its condition would contaminate the animal food. This examination could include viewing the shipping container or vehicle to observe whether there are any unusual residues in it that may contaminate the animal food, or it could be simply knowing what the shipping container or vehicle had previously been used for and because of that, whether the container needed to be cleaned prior to use. We do not expect a plant or facility to examine the shipping container or bulk vehicle when a customer transports the animal food or arranges for a third-party to pick up the animal food. However, a plant or facility may choose to examine a customer's shipping container or bulk vehicle as a business decision to ensure that shipping container or bulk vehicle will not lead to the contamination or adulteration of the animal food.

F. Proposed § 507.27(c)—Returned Animal Food (Final § 507.27(d))

We proposed that animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed. We received no comments on this requirement and are finalizing it as proposed.

G. Proposed § 507.27(d)—Unpackaged Bulk Animal Food (Final § 507.27(e))

We proposed that unpackaged or bulk animal food must be held in a manner that does not result in cross contamination with other animal food. We received no comment on this requirement and are finalizing it as proposed with one wording change. We have added the term ''unsafe'' to modify cross contamination to make it clear that this requirement applies to cross contamination that would result in unsafe animal food.

XXII. Subpart B: Comments on Proposed § 507.28—Holding and Distribution of Human Food By-Products for Use as Animal Food

We proposed to add provisions for human food by-products for use as animal food. We proposed that the requirements of this part (with the exception of proposed § 507.28) would not apply to by-products of human food production that are packed and held by that facility for distribution as animal food if certain requirements were met (see discussion in section XIII). The facility would only need to comply with proposed § 507.28 of this part and proposed § 117.95 of part 117 (which contains identical requirements).

A. Proposed § 507.28(a)—Contamination

We proposed that human food by-products held for distribution as animal food must be held under conditions that will protect against contamination.

(Comment 230) Multiple comments request that the term ''human food by-products,'' not ''animal food,'' be used throughout §§ 507.28 and 117.95 (of part 117). These comments note that it is important to make clear that human food by-products do not change from human food to animal food until they are transferred to someone with the intent to use it as an animal food.

(Response 230) We disagree that human food by-products are not animal food until they have been transferred to someone with the intent to use it as animal food. Furthermore, we think that the use of the term ''human food by-products'' would be more confusing here because not all human food by-products are intended for use as animal food. However, we have revised the regulatory text to use the term ''human food by-products for use as animal food'' throughout this section to differentiate it from other requirements in parts 117 and 507. The purpose of these provisions in §§ 507.28 and 117.95 is to ensure that when the processer is holding and distributing human food by-products for use as animal food, the by-products are recognized as human food by-products for use as animal food by all employees and treated as such.

B. Proposed § 507.28(a)(1)—Containers

We proposed that containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food.

(Comment 231) Some comments state that the provisions about containers are too prescriptive because by-products may be held and conveyed in ways that do not use containers (such as using storage silos, augers, pipes, chutes or conveyor belts to convey product directly to transportation vehicles). Some comments request clarification on cleaning the containers because they are frequently reused for holding by-product without intervening cleaning procedures.

(Response 231) We agree that human food by-products for use as animal food may be held and conveyed using equipment instead of containers. We have revised the regulatory text to add ''equipment'' in addition to containers, and have added the words ''convey'' and ''cleaned as necessary'' (see regulatory text for §§ 507.28(a)(1) and 117.95(a)(1)). We expect containers and equipment to be cleaned at a frequency that protects against contamination of human food by-products for use as animal food by contaminants that could be harmful to the public (human and animal) health. This may not require cleaning after each use.

C. Proposed § 507.28(a)(2)—Protection From Contamination

We proposed that animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage. As discussed in Response 227, we have revised the regulatory text to remove the term garbage. We did not receive additional comments related to this paragraph and are finalizing the proposed language with changes previously discussed. (See Responses 227 and 230.)

D. Proposed § 507.28(a)(3)—Labeling

We proposed that labeling identifying the product by the common or usual name must be affixed to or accompany animal food.

(Comment 232) Some comments state that by-products only need to be reasonably identified while they are being held by the facility and state that once they are ready for distribution, they should be labeled in conformance with applicable regulatory requirements. One comment states that what is considered the ''common and usual name'' varies between the human food industry, the animal food industry, producers and regulators. This comment suggests that FDA work with regulatory partners to provide guidance on the proper ''common and usual name'' of by-products to promote consistency.

(Response 232) We agree in part with these comments. As with animal food subject to all of part 507, we expect that while human food by-product for use as animal food is being held in the human food facility, it is accurately identified. (See Response 201.) We have revised the regulatory text to clarify that the human food by-product for use as animal food must be accurately identified while held in the human food facility (see § 507.28(a)(3) of the final rule). We retained the requirement that when the human food by-product for use as animal food is distributed, it must have labeling that identifies the common or usual name of the product affixed to or accompanying it (see § 507.28(b) of the final rule).

Our CPG Sec. 665.100 discusses common or usual names for animal food ingredients (Ref. 25). There are also industry and other regulatory resources that may assist facilities in determining the common or usual name of the animal food. For example, USDA maintains the National Nutrient Database for Standard Reference, a database that includes a list of names for human food items (Ref. 30). We will take into consideration these comments when determining whether to issue additional guidance about the common or usual name of animal food.

(Comment 233) One comment requests that FDA require human food manufacturers to document the recipient's intended use of the by-products so the by-products do not become ingredients of human food. This comment also requests that these by-products be required to be labeled with the statement ''For Use as Animal Feed Only.''

(Response 233) We decline these requests. Human food is produced under human food regulations, such as CGMPs, and HACCP regulations for juice and seafood, and facilities must meet the applicable requirements for food that is manufactured, processed, packed, or held to ensure the safety of that human food. This requirement in § 507.28 is meant only for human food by-products for use as animal food that are only held and distributed (*i.e.* not further processed). Human food by-products may be used as human food ingredients as long as they are in compliance with the applicable human food regulations. However, we would not object if a facility labels the human food by-products for use as animal food ''For Use as Animal Food Only.''

E. Proposed § 507.28(b)—Shipping Containers

We proposed that shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food. This provision is paragraph (c) of this section in the final rule.

(Comment 234) We received the same comments on § 507.28(c) as § 507.27(c). (See Comment 229.)

(Response 234) We are revising the regulatory text in §§ 507.28(c) and 117.95(c). (See Response 229.)

XXIII. Subpart C: Comments on Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

In the 2014 supplemental notice for preventive controls for animal food, we proposed a series of changes to proposed subpart C and reopened the comment period specifically with respect to these changes. The proposed changes included: (1) Eliminating the term ''hazard reasonably likely to occur'' throughout proposed subpart C (and, thus, deleting the definition we had proposed for this term); (2) adding a new defined term, ''significant hazard,'' and, in general, using this new term instead of ''hazard reasonably likely to occur'' throughout the re-

proposed regulations; (3) defining ''known or reasonably foreseeable hazard'' in place of ''reasonably foreseeable hazard'' and clarifying that the new term means a hazard ''that has the potential to be associated with the facility or the food'' rather than ''a potential . . . hazard that may be associated with the facility or the food''; and (4) providing additional flexibility to address concerns about rewriting existing plans or programs to conform with the requirement of the preventive controls rule.

We received many comments on the overall framework for hazard analysis and risk-based preventive controls. We discuss each of these comments in the discussion of the specific regulatory text applicable to each comment. We show highlights of the changes we made after considering these comments in table 9.

TABLE 9—REVISIONS TO THE OVERALL FRAMEWORK FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Section	Description	Revision
507.3	Definition of ''significant hazard''	Revise the proposed term ''significant hazard'' to ''hazard requiring a preventive control'' and revise the definition to emphasize the role of risk in determining whether a hazard requires a preventive control.
507.3	Definition of ''corrections''	Define the term ''correction'' to distinguish ''corrections'' from ''corrective actions.''
507.34(c)(1), 507.39(a), 507.40, 507.45(a), 507.47(a), 507.49(a), 507.49(b).	Flexibility in preventive controls and preventive control management components for monitoring, corrective actions and corrections, and verification.	Clarify that preventive control management components depend on the role of a preventive control in the facility's food safety system, as well as the nature of the preventive control.
507.33(b)(1)	Hazard identification	Emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).
507.33(b)(2)		
507.40(c)(2)	Monitoring records	Provide for the use of ''exception records'' for monitoring preventive controls.
507.42(a)	Corrective action procedures	Clarify that corrective action procedures depend on the nature of the hazard.
507.42(c)	Corrections	Provide for additional circumstances when corrections, rather than corrective actions, are warranted.
507.47(c)	Preventive controls that do not require validation.	Clarify that a list of preventive controls that do not require validation is not an exhaustive list.
507.49(a)(5)	Activities to verify implementation and effectiveness.	Clarify that there could be alternative verification activities of implementation and effectiveness other than those that we specify in the rule.
507.49(b)	Written procedures for verification of implementation and effectiveness.	Clarify that written procedures for verification of implementation and effectiveness are established and implemented as appropriate to the role of the preventive control in the facility's food safety system, as well as appropriate to the facility, the animal food, and the nature of the preventive control.
507.50(b)	Reanalysis	Provide for reanalysis of an applicable portion of the food safety plan (rather than the complete food safety plan) in specified circumstances.

XXIV. Subpart C: Comments on Proposed § 507.31—Food Safety Plan

We proposed requirements for a food safety plan. Some comments support the proposed requirements without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following sections, we discuss comments that ask us to clarify the proposed requirements, or disagree with, or suggest one or more changes to the proposed requirements. After considering these comments, we are finalizing the provisions as proposed, with editorial and conforming changes as shown in table 31.

We proposed that the food safety plan be under the oversight of one or more ''qualified individuals.'' As discussed in section VIII.A.24, we have changed the proposed term ''qualified individual'' to ''preventive controls qualified individual'' because we are establishing a new definition for ''qualified individual,'' with a meaning distinct from ''preventive controls qualified individual.'' To minimize the potential for confusion for when the term ''qualified individual'' refers to the proposed meaning of the term and when the term ''qualified individual'' refers to the meaning of that term as finalized in this rule, in the remainder of this document we substitute the new term ''preventive controls qualified individual'' for the proposed term ''qualified individual,'' even though the proposed rule used the term ''qualified individual.'' Likewise, we substitute the new term ''preventive controls qualified individual'' for the proposed term ''qualified individual'' when describing the comments to the proposed rule, even though those comments use the term ''qualified individual.''

We proposed that several other provisions of subpart C be under the oversight of a ''qualified individual'' (now ''preventive controls qualified individual''), and also proposed requirements that would apply to the ''qualified individual'' (now ''preventive controls qualified individual''). See, *e.g.,* §§ 507.47, 507.49, 507.50, 507.51, 507.53, and 507.55). As discussed in the preceding paragraph, in the remainder of this document, we substitute the new term ''preventive controls qualified individual'' for the proposed term ''qualified individual,'' when describing these proposed provisions and the comments to these proposed provisions.

A. Proposed § 507.31(a)—Requirement for a Food Safety Plan

We proposed that you must prepare, or have prepared, and implement a written food safety plan.

(Comment 235) Some comments ask us to develop a final preventive controls

rule with separate requirements for food safety plans for manufacturers of livestock food and for manufactures of food for other animal species.

(Response 235) We decline this request. The required elements of the food safety plan listed in § 507.31(c) apply to each type of animal food manufactured at a facility. Animal food types or production method types may be grouped together if the hazards, preventive controls, parameters, and management components (monitoring, corrective actions and corrections, and verification) necessary to ensure the effectiveness of the preventive controls are essentially identical. We have provided additional flexibility within the required elements of the food safety plan in the final rule. Therefore the same requirements for a food safety plan are applicable to a facility that makes food for livestock and one that makes food for other animal species.

(Comment 236) Some comments ask us to add regulatory text to this section stating that an existing written food safety plan, including any plan intended to satisfy the requirements of a foreign jurisdiction or that complies with existing standards developed by other organizations (such as PAS 222 (Ref. 27)), satisfies the requirements of this section if it contains the information specified by § 507.31(c).

(Response 236) To the extent that an existing food safety plan includes all required information, a facility can use such plans to meet the requirements of this rule. We expect that many existing plans will need only minor supplementation to fully comply with these requirements. Relying on existing records, with supplementation as necessary to satisfy the requirements of the preventive controls rule, is acceptable (see § 507.212).

(Comment 237) Some comments agree with our previous statements that facilities should be able to group animal food types or production method types if hazards, control measures, parameters, and required procedures, such as monitoring, are identical (78 FR 64736 at 64779). Some comments ask us to emphasize that each facility needs only one food safety plan, regardless of how many animal species it makes food for, or how many different types of food it makes. These comments further state that facilities are under the impression that any given facility will need multiple food safety plans if they make many food types or make food for multiple animal species.

(Response 237) We are requiring that a facility have a written food safety plan that covers all types of animal food it manufactures, processes, packs, or holds and all of the animal species for which the food is intended. We recognize that, to the extent that the controls are the same, there may be common controls that broadly apply to some or all of a facility's animal food products. However, any product-, process-, or animal species-specific differences must be carefully delineated and observed in practice.

In some facilities with limited types of animal food products or animal species for which the food is intended, the written food safety plan may contain a single set of procedures that addresses all of the products produced. For other facilities, there may not be a practical way to group the products and the written food safety plan may need to contain more than one set of procedures to address all of its products.

(Comment 238) Some comments ask us to emphasize that ''written'' means ''any type of recordable and reproducible format'' (*e.g.,* as paper or electronic documents). Some comments ask us to specify that the components of the food safety plan need not be in a single document or stored in one place.

(Response 238) A ''written'' food safety plan can be either a paper document or an electronic document, as provided for by § 507.202(a). The final rule specifies that required information (which would include the food safety plan) does not need to be kept in one set of records (see § 507.212(b)), and a food safety plan may be prepared as a set of documents kept in different locations within the facility (*e.g.,* based on where they will be used), provided that each set of documents is onsite. As provided in the recordkeeping provisions, electronic records are considered to be onsite if they are accessible from an onsite location.

(Comment 239) Some comments ask us to provide that the food safety plan be handled at the corporate level rather than the facility level if a corporation owns many facilities.

(Response 239) A corporation may designate an individual at the corporate level as the owner, operator, or agent in charge of a particular facility. In addition, an employee of the corporation, whether at headquarters or at another facility owned by the corporation, may provide input into a particular facility's food safety plan. As previously discussed, the food safety plan does need to be facility specific (see the discussion of the facility-based nature of the food safety plan in the 2013 proposed preventive controls rule for animal food, 78 FR 64736 at 64780). For example, even if a corporation makes similar products at two separate facilities, it is unlikely that the two facilities have exactly the same equipment and layout. Procedural instructions must be tailored to the equipment being used, and the layout of a facility may affect its approach to preventive controls.

(Comment 240) Some comments assert that a food safety plan should only be required for high-risk processing facilities because adhering to CGMPs is sufficient for low-risk facilities. Some comments assert that FSMA does not authorize us to require farms to develop food safety plans.

(Response 240) We decline the request to establish additional exemptions based on risk, other than the exemptions for on-farm low-risk activity/animal food combinations provided by section 103(c)(1)(D) of FSMA (§ 507.5(e) and (f)). The applicability of the requirements of the preventive controls rule to facilities that are required to register is required by the statute (see the definition of facility in section 418(o)(2) of the FD&C Act). Section 418(h) of the FD&C Act requires that a facility prepare and implement a food safety plan, unless an exemption applies. Neither FSMA nor this rule establishes an exemption for ''low-risk'' facilities, including ''low-risk'' facilities that are regularly inspected by State, local, or tribal government Agencies. A farm is not subject to this rule for activities within the ''farm'' definition. A farm mixed-type facility that is a small or very small business and only conducts the low-risk activity/animal food combinations specified in § 507.5(e) and (f) is exempt from the requirements of subparts C and E, including the requirement for a food safety plan.

(Comment 241) Some comments ask us to clarify that a food safety plan is not required when a facility is exempt as a qualified facility (§ 507.7(a)) or as a facility solely engaged in the storage of packaged food that is not exposed to the environment (§ 507.10)

(Response 241) A qualified facility is exempt from the requirements of subparts C and E, including the requirement to prepare and implement a food safety plan, and is instead subject to the requirements in § 507.7. Likewise, a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is exempt from the requirements of subparts C and E, including the requirement to prepare and implement a food safety plan. See Response 242 for unexposed, packaged TCS animal food.

(Comment 242) Some comments ask us to clarify that a food safety plan is not required for facilities that store unexposed, refrigerated, packaged TCS animal foods.

(Response 242) We agree that a facility ''solely engaged'' in the storage of unexposed, refrigerated, packaged TCS animal food is exempt from the requirements of subparts C and E, including the requirement to prepare and implement a food safety plan, and instead is subject to the modified requirements in § 507.51 (see § 507.10). However, if a facility engages in other activities in addition to the storage of unexposed, refrigerated, packaged TCS animal food, the exemption does not apply. In such a case, the facility must prepare and implement a food safety plan. However, the modified requirements of § 507.51 can be informative with respect to what the food safety plan could include regarding the storage of unexposed, refrigerated, packaged TCS animal food.

B. Proposed § 507.31(b)—Preparation of the Food Safety Plan by a Preventive Controls Qualified Individual

We proposed that the food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

(Comment 243) Some comments ask us to provide for a group of qualified individuals to prepare, or oversee the preparation of, a food safety plan.

(Response 243) The proposed regulatory text included in the 2014 supplemental notice provides for the food safety plan to be prepared, or its preparation overseen, by one or more preventive controls qualified individuals, and we are finalizing it as proposed.

C. Proposed § 507.31(c)—Contents of a Food Safety Plan

We proposed that the written food safety plan must include the written hazard analysis, preventive controls (including the supplier program and recall plan), procedures for monitoring the implementation of the preventive controls, corrective action procedures, and verification procedures. As discussed in more detail in section XL, we have revised the phrase ''supplier program'' to ''supply-chain program'' throughout the regulatory text. In the remainder of this document, we use the phrase ''supply-chain program'' in section headings and when referring to the provisions of the final rule. We continue to use the term ''supplier program'' when describing the proposed provisions and the comments regarding the proposed provisions.

(Comment 244) Some comments ask us to specify that sanitation controls must be in the food safety plan. Some comments ask us to require that the food safety plan include the qualifications of the preventive controls qualified individual.

(Response 244) Sanitation controls are one type of preventive control. As appropriate to the facility and the animal food (*e.g.,* to control hazards such as environmental pathogens), sanitation controls for cleanliness of animal food-contact surfaces and prevention of cross contamination are required to be in the food safety plan (§ 507.34(c)(2)).

We are requiring that you document all applicable training taken by the preventive controls qualified individual (see § 507.53(d)). This documentation must be established and maintained (see § 507.55(a)(6)).

D. Proposed § 507.31(d)—Records

We proposed that the food safety plan is a record that is subject to the recordkeeping requirements of subpart F. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

E. Comments on Potential Requirements for Submission of a Facility Profile to FDA

We requested comment on whether to require submission to FDA of a subset of the information that would be in a food safety plan (78 FR 64736 at 64809). This information, which could be referred to as a ''facility profile,'' could be submitted through an electronic form using a menu selection approach at the same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration. We described potential benefits to having a facility's food safety plan in advance of an inspection, such as aiding in the efficient oversight of preventive controls by allowing us to better target inspectional activities to facilities that produce foods that have an increased potential for contamination (particularly with biological hazards). We noted that facilities could benefit from our advance preparation through interaction with better-informed investigators and potentially reduced inspection time. We requested comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile. We also requested comment on any additional benefits that might be obtained from using such an approach and any potential concerns with this approach.

We noted that we had previously announced an opportunity for public comment on the proposed collection of additional food facility profile information on a voluntary basis from firms that complete the FDA food facility registration process (**Federal Register** of May 11, 2012, 77 FR 27779). In contrast to the voluntary submission of food facility profile information described in that document, in the 2013 proposed preventive controls rule for animal food we requested comment on whether the submission of such information should be required.

(Comment 245) Some comments state that submission of a facility profile would be useful and support requiring such a submission. However, most of the comments that addressed our request for comments on such a submission express concern. Some comments assert that requiring submission of a facility profile is outside of FDA's statutory authority under FSMA. Other comments assert that submitting a facility profile would not advance food safety goals or have a commensurate benefit to food safety. Some comments express concern about protection of confidential information. Other comments express concerns that we would misinterpret the submitted information in the absence of discussion with the facility. Some comments assert that receiving and evaluating the submitted information would be too time-consuming for FDA, whereas other comments assert that submitting the information would be too time-consuming for the facility. Some comments state that a subset of the information that would be submitted could be found in the Establishment Inspection Reports. Some comments assert that we could use information already available through the RFR to identify facilities that have needed to address a serious food safety violation and target our inspectional resources to those facilities. Some comments state that a facility profile is a not a static document and would be very difficult to keep up to date. Other comments state that such a profile would be of limited or no use to FDA because information regarding hazards and preventive controls is best assessed in the context of a full food safety plan and related documentation. These comments further state that food safety plans will constantly evolve as facilities undertake new activities and refine their processes; a profile would present only a static picture of the food safety measures in place at a given time; FDA has already implemented changes to the

registration process that require facilities to provide more information about the activities at the facility. One comment asks us to refrain from requiring written or electronic submission of facility profiles.

(Response 245) We have decided that we will not establish a requirement for submission of a facility profile. We will explore other mechanisms to achieve the goals we described in the 2013 proposed preventive controls rule for animal food.

XXV. Subpart C: Comments on Proposed § 507.33—Hazard Analysis

We proposed requirements for hazard analysis, including hazard identification and hazard evaluation. Some comments support the proposed requirements without change. For example, some comments support our proposal for the hazard analysis to address ''known or reasonably foreseeable hazards'' because this is consistent with Codex. Other comments agree that the hazard analysis should address both the severity of the potential hazard and the probability that the hazard will be present in an animal food product. Other comments state that testing for environmental pathogens may be impractical in certain situations for facilities in chemical plants that also produce food additives and that the proposed requirements for hazard evaluation make it clear that in such facilities environmental monitoring would not be required. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 10 with editorial and conforming changes as shown in table 31.

TABLE 10—REVISIONS TO THE PROPOSED REQUIREMENTS FOR HAZARD ANALYSIS

Section	Description	Revision
507.33(a)(1)	Requirement for a hazard analysis	Specify that a facility must ''conduct a hazard analysis'' to identify and evaluate known or reasonably foreseeable hazards, rather than merely specify that a facility must ''identify and evaluate'' known or reasonably foreseeable hazards.
507.33(a)(2)	Requirement for the hazard analysis to be written.	Clarify that the hazard analysis must be written, regardless of its outcome.
507.33(b)(1) and (b)(2)	Hazard identification	Emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).
507.33(b)(1)(ii)	Hazard identification	Replace ''imbalances'' with'' deficiencies or toxicities'' and provide examples of these hazards.
507.33(b)(1)(iii)	Hazard identification	Add examples of physical hazards.
507.33(c)(2)	Hazard evaluation	Provide that hazard evaluation does not need to include an evaluation of environmental pathogens whenever finished animal food is exposed to the environment prior to packaging if the packaged food includes a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.
507.33(d)(10)	Hazard evaluation	Provide an example of ''other relevant factor'' that the hazard evaluation must consider (the example is the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins)).

A. Proposed § 507.33(a)—Requirement for a Written Hazard Analysis

We proposed that you must 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 significant hazards. We also proposed that the hazard analysis must be written.

As discussed in Response 62, we have revised the term ''significant hazard'' to ''hazard requiring a preventive control.'' In addition, we have revised the regulatory text to specify that the outcome of a hazard analysis is to determine whether there are any hazards requiring a preventive control.

(Comment 246) Some comments ask us to specify that the rule requires a written hazard analysis even if the hazard analysis concludes that no hazards exist.

(Response 246) As proposed, the regulatory text would require a written hazard analysis even if the hazard analysis concludes that no hazards exist. To make this clearer, we have made two revisions to the regulatory text. First, we have revised the regulatory text to specify that a facility must ''conduct a hazard analysis'' to identify and evaluate known or reasonably foreseeable hazards, rather than merely specify that a facility must ''identify and evaluate'' known or reasonably foreseeable hazards. Second, we have revised the regulatory text to specify that the hazard analysis must be written regardless of its outcome.

(Comment 247) Some comments assert that a facility should not be able to conclude that no hazard exists in its production process and that any such conclusion reached should be a ''red flag'' to FDA investigators.

(Response 247) The purpose of a hazard analysis is to identify and evaluate known or reasonably foreseeable hazards to determine whether there are any hazards requiring a preventive control. If a facility appropriately determines, under the oversight of a preventive controls qualified individual, that no such hazards exist, then that is the outcome of its hazard analysis, and the facility must document that outcome in its written hazard analysis.

We expect that there will be many circumstances in which a facility appropriately determines that certain biological, chemical, or physical hazards are not hazards requiring a preventive control that must be addressed in the food safety plan. The provisions of the rule that allow a facility to appropriately determine that a particular hazard is not a hazard requiring a preventive control in certain animal food products are not equivalent to an exemption from the rule. For example, a facility that appropriately determines that there are no hazards requiring a preventive control associated with its animal food products

must document that determination in its written hazard analysis (§ 507.33); however, no preventive controls, including supplier verification activities, and associated management components would be required in such a situation. There are several types of animal food products for which a facility may determine that there are no hazards requiring a preventive control. Such products include, but are not limited to: alfalfa cubes, vegetable oils, and molasses.

However, we agree that our investigators should take appropriate steps to evaluate a facility's hazard analysis when the outcome is that there are no hazards requiring a preventive control. We expect that our investigators would both review the facility's written hazard analysis and discuss the outcome with the facility. During the initial stages of implementation, we also expect that our investigators will ask subject matter experts in our Center for Veterinary Medicine (CVM) to review such a hazard analysis. Over time, as our investigators gain experience with appropriate determinations that there are no hazards requiring a preventive control, we expect that there will be fewer circumstances in which our investigators would consult CVM about such an outcome.

(Comment 248) Some comments ask us to require that the hazard analysis be re-evaluated every 3 years and updated as needed.

(Response 248) The written hazard analysis is one component of the food safety plan, and the food safety plan is subject to reanalysis at least once every 3 years, and sooner under certain circumstances (see § 507.50).

(Comment 249) Some comments ask us to modify the provision to specify that the hazard analysis identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility, *including hazards in the raw materials and ingredients used in the animal food* (emphasis added).

(Response 249) We decline this request. Other provisions in the requirements for hazard analysis specify that the hazard evaluation must consider raw materials and ingredients (see § 507.33(d)(3)). It is not necessary to repeat the specific requirements associated with the hazard evaluation in the provision that directs each facility to conduct a hazard analysis.

(Comment 250) Some comments state that the standard for hazard analysis in the preventive controls rule should both align with the reproposed requirements for hazard analysis set forth in the supplemental FSVP notice and be consistent with the statutory standard for hazard analysis in section 418(b)(1) of the FD&C Act.

(Response 250) We have aligned the requirements of the animal food preventive controls rule and the proposed FSVP rule to the extent practicable, consistent with the applicable statutory requirements.

B. Proposed § 507.33(b)—Hazard Identification

We proposed that the hazard identification must consider hazards that include biological, chemical, and physical hazards. We proposed examples of biological hazards (*e.g.,* microbiological hazards such as parasites, environmental pathogens, and other pathogens) and chemical hazards (*e.g.,* radiological hazards and substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances).

In the preamble for the 2013 proposed preventive controls rule for animal food, we explained that nutrient imbalance hazards can result from excessive levels of a nutrient in animal food resulting in toxicity to the animal, or a nutrient deficiency in the animal food that can compromise the health of an animal and provided examples (78 FR 64736 at 64782). These nutrient imbalance hazards are of particular concern for animals that consume one animal food type as their sole source of nutrition. Because different species have different nutritional needs, certain quantities of a nutrient that are needed by one species of animal could pose a health risk to another species of animal.

In the preamble for the 2013 proposed preventive controls rule for animal food we also provided examples of physical hazards (*e.g.,* stones, glass, or metal fragments that could inadvertently be introduced into animal food) (78 FR 64736 at 64782) but did not include these examples in the proposed regulatory text.

We also proposed that the hazard identification must consider hazards that may be present in the animal food if they occur naturally or may be unintentionally introduced. In the 2014 preventive controls supplemental notice for animal food we proposed to add that the hazard analysis also must consider hazards that may be intentionally introduced for purposes of economic gain (proposed § 507.33(b)(2)(iii)).

(Comment 251) As discussed in Comment 62, some comments express concern that the rule would refer to multiple levels of hazards (*i.e.,* ''hazard,'' ''known or reasonably foreseeable hazard,'' and ''significant hazard'' (which we now refer to as ''hazard requiring a preventive control'') and ask us to provide sufficient clarity to be able to distinguish between these types of hazards.

(Response 251) As discussed in Response 62, we have revised the requirements for hazard identification to emphasize that the hazard identification focuses on known or reasonably foreseeable hazards (rather than on all hazards).

(Comment 252) Some comments ask us to include examples of physical hazards in the regulatory text.

(Response 252) We have added stones, glass, and metal fragments as examples of physical hazards in the regulatory text. This is consistent with the regulatory text for biological and chemical hazards, even though the hazards listed in section 418(b)(1) of the FD&C Act include examples of chemical and biological hazards but do not include examples of physical hazards.

(Comment 253) Some comments ask us to separately list some hazards (such as parasites and drug residues) rather than include them as examples of biological hazards and chemical hazards.

(Response 253) We decline this request. Although section 418(b)(1)(A) of the FD&C Act lists such items separately, we believe it is clearer to acknowledge that some of the hazards listed in the statute are in fact a subset of the broader categories of biological and chemical hazards.

(Comment 254) Some comments ask us to rephrase the requirement for hazard identification to specify ''The hazard analysis must identify hazards'' rather than ''The hazard identification must consider hazards.''

(Response 254) We decline this request. The provision is directed to the first step of a hazard analysis, *i.e.,* hazard identification, rather than to the overall hazard analysis (which is addressed in § 507.33(a)). The purpose of the hazard identification is to consider the types of hazards listed as a step in determining whether there are any hazards requiring a preventive control; the suggestion of the comments implies that such hazards will always be identified. As discussed in Response 247, the outcome of a hazard analysis for an animal food product could be that there are no hazards requiring a preventive control.

(Comment 255) Some comments ask us to revise the chemical hazard examples by replacing the term ''nutrient imbalances'' with ''nutrient deficiencies or toxicities.''

(Response 255) We agree that the suggested revision adds clarity and have modified the regulatory text to replace ''nutrient imbalances'' with ''nutrient deficiencies or toxicities,'' and provide examples, such as ''inadequate thiamine in cat food,'' ''excessive vitamin D in dog food'', and ''excessive copper in food for sheep.''

(Comment 256) Some comments assert that nutrient imbalances should not be addressed in an animal food safety plan because they pose no threat to humans.

(Response 256) We disagree with these comments. The preventive controls rule for animal food is intended to protect animal health, as well as human health. Section 418 of the FD&C Act, which authorizes the preventive controls rules, applies to facilities registered under section 415 of the FD&C Act, which includes facilities that manufacture, process, pack, and hold animal food.

(Comment 257) Some comments assert that while serious, ongoing imbalances of nutrients such as copper and selenium must be avoided with checks and balances, and perhaps product testing, there could be a multitude of other incidents that could occur without serious consequences and to address every possible scenario, by species, when the Agency is aware of a limited number of rare cases, is unreasonable. Some comments state that the notion that nutrient deficiencies or toxicities for animals are hazards likely to occur in the manufacture of animal food seems like a poor fit in this set of food safety regulations.

(Response 257) The Agency has a history of animal food incidents resulting in recall of animal food and in animal illnesses and deaths from nutrient deficiencies or toxicities.

From 2012 to 2014, FDA received multiple reports through its RFR that were attributable to animal food associated with nutrient deficiencies or toxicities. For example, during the 2010/2011 reporting period, 3.57 percent of 224 primary (industry and voluntary) RFR entries were associated with nutrient deficiencies or toxicities in animal food. During the 2012/2013 period, 2.97 percent of 202 entries were attributable to nutrient imbalances or toxicities in animal food (Refs. 14 and 16). Reports included low levels of thiamine in cat food; high levels of vitamin D in dog food; low levels of vitamin D in food for swine; high levels of vitamin D in food for guinea pigs, fish, and other animal species; high levels of calcium and phosphorus in food for broiler chickens and turkeys causing the death of several hundred young birds (Refs. 13 to 16); high levels of salt in food for broilers; high levels of protein/urea in food for cattle; and high levels of copper in food for sheep. Many of these animal foods with nutrient imbalances (deficiencies or toxicities) resulted in a recall of the affected animal food (Refs. 31 to 39).

Moreover, an analysis of thiamin levels in randomly selected commercial canned cat foods was conducted during a period from December 2012 through January 2013 (Ref. 40). The study found 13.3 percent of the cat foods tested fell below the minimum set for thiamine by AAFCO and 15.6 percent were below the recommended allowance of the National Research Council.

We also disagree with the implication that facilities must address every possible hazard. Facilities must identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring a preventive control.

(Comment 258) Some comments suggest that nutrient imbalances should be addressed through CGMPs.

(Response 258) We disagree with these comments. We consider nutrient deficiencies and toxicities to be a type of chemical hazard that are appropriately addressed through preventive controls. If a facility identifies a nutrient deficiency or toxicity as a hazard that is known or reasonably foreseeable in an animal food and is a hazard that requires a preventive control, the facility must implement preventive controls for that hazard. The facility has flexibility in determining what preventive controls it needs to implement to control the hazard. Preventive controls for identified nutrient toxicity or deficiency hazards can include CGMPs, but the specific CGMP needs to be included in the food safety plan (or for a qualified facility, the documentation supporting an attestation under § 507.7(a)(2)).

(Comment 259) Some comments ask us to consider revising the proposed rule to include food allergens in animal food much in the same way that they have been proposed in the human food rule.

(Response 259) We decline this request. We are not aware of evidence indicating that foodborne allergens pose a significant health risk to animals (78 FR 64736 at 64771). Animals with actual food allergies typically have digestive disorders or dermatologic conditions, not the anaphylactic reaction that humans have to the major food allergens (defined in section 201(qq) of the FD&C Act).

(Comment 260) Some comments assert that physical hazards in animal food are not likely to cause any serious injuries to humans as the contaminant is not assimilated into edible tissue.

(Response 260) We disagree with these comments. The rule defines the term hazard to include a physical agent that has the potential to cause injury or illness in animals, as well as humans. Physical hazards in animal food can cause illness or injury in animals.

(Comment 261) Some comments ask us to delete ''decomposition'' from the list of chemical hazards in this provision.

(Response 261) We decline this request. As discussed previously, decomposition of animal food consists of microbial breakdown of the normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by abnormal odors, taste, texture, color, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, resulting in illness or death (see 78 FR 64736 at 64782).

(Comment 262) Some comments assert that we should not require all food safety plans to specifically address the likelihood of radiological hazards.

(Response 262) The rule only requires that a facility consider whether radiological hazards are known or reasonably foreseeable, and we have described situations where radiological hazards could be considered to be known or reasonably foreseeable. A facility that appropriately determines that no radiological hazards are known or reasonably foreseeable would document that determination in its written hazard analysis but would not need to establish preventive controls and associated preventive control management components to address radiological hazards.

(Comment 263) Some comments assert that predictable intentional hazards should be in the food safety plan but unexpected intentional hazards should be part of a food defense plan.

(Response 263) This rule only requires a facility to consider intentionally introduced hazards when such hazards are introduced for purposes of economic gain. Hazards that may be intentionally introduced by acts of terrorism are the subject of the 2013 proposed intentional adulteration rule (78 FR 78014, December 24, 2013), which applies only to human foods.

(Comment 264) Some comments disagree that the animal food preventive controls rule should address hazards that are intentionally introduced for purposes of economic gain (economically motivated adulteration).

Some of these comments assert that economically motivated adulteration is not a good fit for the hazard analysis and preventive controls framework because it is, in all but the rarest of circumstances, an issue of product integrity and quality, whereas food safety systems are designed and built to prevent or mitigate food safety hazards. Some comments state that traditional food safety hazards are primarily both identified and addressed at the facility level, but economically motivated adulteration is typically handled by the corporate parent company, where supply-chain management programs are typically located. These comments also assert that food safety-related economically motivated adulteration is extremely rare and that predicting economically motivated adulteration to prevent it is extremely difficult. Some comments assert there will be no measurable benefit to food safety by imposing requirements to consider economically motivated adulteration as part of a food safety plan and that doing so will consume limited resources without a corresponding increase in consumer protection. Other comments assert that there is no need to require a facility to identify hazards intentionally introduced for purposes of economic gain because the misbranding and adulteration provisions of the FD&C Act already sufficiently provide safeguards against economic gain.

(Response 264) We agree with the comments that state that the requirement to consider hazards intentionally introduced for purposes of economic gain is narrow. Such hazards will be identified in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past. In addition, we define hazards to only include those agents that have the potential to cause illness or injury. Economically motivated adulteration that affects product integrity or quality, for example, but not animal food safety, is out of the scope of this rule. We continue to believe that there is benefit in taking this preventive approach to economically motivated adulteration and not relying solely on enforcing the preexisting misbranding and adulteration provisions of the FD&C Act after a violation occurs.

As discussed in sections XL through XLVII, we are finalizing supply-chain program provisions. It is consistent with the framework of this rule for a facility to address hazards requiring a preventive control that may be intentionally introduced for purposes of economic gain through the facility's supply-chain program.

(Comment 265) Some comments express concern about identifying hazards that may be intentionally introduced for purposes of economic gain because there are potentially an unlimited number of unknown or yet-to-be identified hazards that could be intentionally introduced for purposes of economic gain by an unscrupulous supplier. These comments disagree with our attempt to narrow the field of potential scenarios for economically motivated adulteration to circumstances where there has been a pattern of such adulteration in the past.

Some comments assert that our attempt to narrow the field of potential scenarios for economically motivated adulteration is both too broad and too narrow at the same time. These comments assert that our attempt is too broad, because we expect facilities to consider patterns of adulteration from the past ''even though the past occurrences may not be associated with the specific supplier or the specific food product'' and a requirement to consider every potential product and potential supplier makes the task open ended. These comments further assert that our attempt is too narrow, because a focus on patterns of adulteration in the past is unlikely to reveal potential future instances of economically motivated adulteration and because those intending to defraud purchasers for economic gain are trying to avoid detection. According to these comments, once an animal food safety related instance of economically motivated adulteration is uncovered, perpetrators quickly move to carry out their fraudulent activities in a different way. Some comments assert that there are alternative ways to control hazards that may be intentionally introduced for purposes of economic gain without specific regulatory requirements, such as by having an effective supplier approval program with appropriate qualification and verification activities; through business-to-business relations, expectations, and contracts; and through a vulnerability assessment and control plan tailored specifically to economically motivated adulteration.

(Response 265) We disagree that the requirement is too broad. A facility must conduct a hazard analysis for each type of animal food manufactured, processed, packed, or held at the facility. There is no requirement to consider every potential product or potential supplier. We also disagree that the requirement is too narrow. Some individuals intending to defraud purchasers for economic gain will develop entirely novel ways of adulterating food to suit their purposes. We agree that these circumstances may not lend themselves to the preventive approach required here. We encourage, but do not mandate, that facilities adopt other measures they deem appropriate to mitigate the risks of economically motivated adulteration that this rulemaking does not address. Still, the repeated use of melamine over the years, in animal foods and in foods for people, demonstrates that patterns of economically motivated adulteration can emerge and should be considered as part of a hazard analysis.

(Comment 266) Some comments ask us to limit the requirement to identify hazards that may be introduced for purposes of economic gain to only those hazards that pose a risk to public health for which there has been a pattern in the past. Some comments assert that in those few instances where a hazard was intentionally introduced the underlying intention was to defraud rather than to cause harm, and the food safety hazard was an unintended consequence. Some comments ask us to focus the hazard identification solely on inbound products, because it is obvious that hazards introduced by the facility itself will not be prevented through a hazard analysis. Some comments ask us to narrow the scope of the requirement by specifying that facilities focus on three situations: (1) Situations in which there has been a pattern of similar adulteration in the past; (2) animal foods or ingredients for which quality assurance methods may not sufficiently characterize the animal food or ingredient to assure its identity, and; (3) animal foods or ingredients for which there are substitutes that are likely to be harmful that would be considered obvious to one skilled in food science.

(Response 266) We decline to make the changes suggested in these comments because they are unnecessary. Because of our definition of hazard, the requirement is already limited to economically motivated adulteration that is reasonably likely to cause illness or injury. Under the final rule, a facility does not need to identify a hazard related to economically motivated adulteration when there is no risk to public health or when the economically motivated adulteration is not known or reasonably foreseeable.

We agree that the three circumstances suggested by the comments are an appropriate focus for facilities who seek guidance on how to approach the requirements, but decline the request to specify these limitations of the scope in the regulatory text. As already noted, some comments assert that our attempt to narrow the field of potential scenarios for economically motivated adulteration

is both too broad and too narrow at the same time. (See Comment 265.) Although we continue to believe that the instances in which a facility will identify a hazard intentionally introduced for economic gain will be rare, we also consider that limiting the scope of the requirement in the regulatory text would be both prejudging the future and inconsistent with the public health objectives of this rule.

(Comment 267) Some comments ask us to allow implementation of the major provisions in FSMA before establishing requirements to address economically motivated adulteration. These comments assert that economically motivated adulteration requires a completely different paradigm than unintentional adulteration. In addition, because economically motivated adulteration is typically addressed through product specifications, supplier relationships, and good business practices, implementation of these other provisions of the animal food preventive controls rule are likely to have a positive effect on preventing economically motivated adulteration.

(Response 267) We disagree that economically motivated adulteration requires a completely different paradigm than unintentional adulteration. Hazards intentionally introduced for economic gain are addressed here with the same preventive framework as every other hazard. As such, we do not see a compelling reason to delay implementation of the requirements to address economically motivated adulteration.

C. Proposed § 507.33(c) and (d)—Evaluation of Whether a Hazard Requires a Preventive Control

We proposed that the hazard analysis must include an evaluation of the identified hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls; and environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment that would significantly minimize the pathogen (proposed § 507.33(c)(2)). We also proposed that the hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended consumer: (1) The formulation of the animal food; (2) the condition, function, and design of the facility and equipment; (3) raw materials and ingredients; (4) transportation practices; (5) manufacturing/processing procedures; (6) packaging activities and labeling activities; (7) storage and distribution; (8) intended or reasonably foreseeable use; (9) sanitation, including employee hygiene; and (10) any other relevant factors (proposed § 507.33(d)(1) through (10)).

(Comment 268) Some comments ask us to revise the requirement to include an evaluation of environmental pathogens to avoid the implication that an intervention is needed when there may be other controls (such as pH or formulation) that would significantly minimize or prevent the pathogen. These comments suggest that we revise the provision to require that a hazard evaluation include an evaluation of environmental pathogens whenever a food is exposed to the environment prior to packaging and the packaged food does not receive a treatment ''or otherwise include a control measure'' that would significantly minimize the pathogen.

(Response 268) We have revised the provision on the hazard evaluation for environmental pathogens to specify that the packaged animal 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. We agree that controls such as formulation can function as a ''kill step'' and that the provision should make clear that such controls can be used in lieu of ''treatment.''

(Comment 269) Some comments ask us to clarify what we meant by ''other relevant factors'' and note that natural disasters (which we previously discussed) (78 FR 64736 at 64785) are ''usually exceptional events'' that are best managed in a facility crisis management plan. Other comments ask us to specify that the hazard evaluation must consider any relevant geographic, temporal, agricultural, or other factors that may affect the severity or probability of the hazard.

(Response 269) We included ''other relevant factors'' to emphasize that the list of factors in the provision is not an exhaustive list and that a facility is responsible for considering those factors that play a role in its determination of whether a potential hazard is a hazard requiring a preventive control, regardless of whether those factors are listed in the provision. A facility that already addresses circumstances such as natural disasters in other plans may consider the applicable part of those plans to be part of its food safety plan (see § 507.212).

We agree that geographic, temporal, and agricultural factors are examples of ''other relevant factors.'' For example, hazards such as aflatoxin are subject to a weather-dependent effect in that aflatoxin levels in some RACs are more of a problem in some years than in others. We have added the temporal nature of some hazards associated with some RACs as an example of ''other relevant factors'' to consider (see § 507.33(d)(10)).

(Comment 270) Some comments ask us to specify that the hazard evaluation be more specific about issues relevant to raw materials and ingredients, including how raw materials are selected and shipped, how suppliers are evaluated, and how shipments are inspected on receipt.

(Response 270) We decline this request. When a hazard requiring a preventive control in a raw material or other ingredient is controlled before receipt, the receiving facility would address such specifics in the supply-chain program that would be required as a preventive control (see subpart E).

(Comment 271) Some comments assert that the proposed requirements for hazard evaluation could be interpreted in many ways. For example, a facility could conclude that the presence of a hand sink or boot dip prior to entering the processing area will reduce the likelihood of environmental pathogens and that environmental pathogens are not a significant hazard, whereas a regulator could interpret this provision to mean that a facility must always consider an environmental pathogen to be a significant hazard when the criteria in the provision are met, unless the facility can provide evidence to the contrary.

(Response 271) We agree that the requirements for hazard evaluation are subject to alternative interpretations. This is often the case, particularly when a regulation is new. The provision specifies that a facility must evaluate whether an environmental pathogens is a hazard requiring a preventive control in particular circumstances, *i.e.,* whenever a finished animal food (for which an environmental pathogen is identified as a hazard) is exposed to the environment prior to packaging and the packaged animal 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. The written hazard analysis must be prepared (or its preparation overseen by) a preventive controls qualified individual (see § 507.31(b) and (c)(1)). The preventive controls qualified individual for a facility that determines that an environmental pathogen is not a hazard requiring a preventive control in

such circumstances must document that determination, and a regulator would consider the adequacy of the documented determination before reaching a conclusion as to whether the facility had failed to satisfy the requirements. However, the use of a hand sink or boot dip prior to entering the processing areas to reduce the likelihood of environmental pathogens may also be considered to be part of the sanitation controls for the environmental pathogen.

(Comment 272) Some comments ask us to focus on language that will clearly differentiate between functions, processes, and controls for facilities with food safety plans that identify microbial hazards and those that do not identify microbial hazards, and other known or reasonably foreseeable hazards. These comments assert that sanitation of objects and surfaces may be appropriate for the former, but not necessarily for the latter.

(Response 272) The facility is responsible for conducting a hazard analysis, and if hazards are identified that require a preventive control, the facility must consider the effect of sanitation on the safety of the finished animal food for the intended animal (see § 507.33(d)). Based on the outcome of its hazard evaluation, the facility may determine that sanitation is not an appropriate preventive control for the hazards it identified.

(Comment 273) Some comments assert that a food safety plan and hazard analysis should not include numerous hazards and hazard analysis steps. Some comments assert that hazard analysis should not be as detailed (stringent) for animal food as it is for human food. These comments maintain that prerequisite programs, which reduce the likelihood of a potential hazard to the point where the hazard is not reasonably likely to occur, would satisfy the requirement that the hazard be adequately controlled, making it unnecessary for a facility to include the identified hazards in its hazard analysis and preventive controls. Other comments assert that many hazards can be exclusively controlled through prerequisite programs without a need for CCPs.

(Response 273) While known and reasonably foreseeable hazards and the outcome of a hazard analysis for human food and animal food may not be identical, in each case the purpose of a hazard analysis is to identify and evaluate known or reasonably foreseeable hazards for the type of food manufactured, processed, packed, or held to determine whether there are any hazards requiring a preventive control. As previously discussed in the 2013 animal food preventive control proposed rule (78 FR 64736 at 64781), the process of identifying and evaluating the hazards that may occur for specific types of animal food handled in a facility provides an efficient means for keeping track of multiple hazards that may occur in a facility that handles several types of animal food. Such a process also provides an efficient means for ensuring that preventive controls are applied to specific animal food products when required. If a facility identifies a hazard requiring a preventive control, the facility must determine an appropriate preventive control and include that preventive control in its food safety plan. A facility that establishes other controls (such as those that the comments describe as ''prerequisite programs'') for hazards that are not, based on the outcome of the facility's hazard analysis, ''hazards requiring a preventive control'' would not need to establish preventive control management components for such controls. However, some controls previously established in ''prerequisite programs'' would be considered ''preventive controls.'' We provide some flexibility for facilities with respect to how they manage preventive controls, and the preventive control management components may be different for hazards that have been managed as ''prerequisite programs'' compared to those managed with CCPs. The same principles would apply for the hazards a facility identifies as needing a preventive control.

(Comment 274) Some comments assert that the statutory language within FSMA does not mandate that covered animal food and pet food facilities implement regulatory HACCP plans. These comments further urge us to remove reference to HACCP.

(Response 274) We agree that section 103 of FSMA does not mandate HACCP regulations; however, we have concluded that HACCP is the appropriate framework to reference in interpreting and implementing section 103 of FSMA. For discussion, see section II.C.2. of the 2013 proposed preventive controls rule for human food (78 FR 3646 at 3660).

(Comment 275) Some comments ask us to allow consideration of both severity and probability in the scientific hazard analysis as this would be consistent with international standards.

(Response 275) Section 507.33(c)(1) requires that a hazard evaluation must include an assessment of the severity of the injury or illness if a hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

For additional discussion of comments on hazard analysis, see section XXV in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

XXVI. Subpart C: Comments on Proposed § 507.36—Preventive Controls (Final § 507.34)

We proposed requirements to identify and implement preventive controls to provide assurances that significant hazards will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act. Some comments support the proposed requirements without change. For example, some comments agree that preventive controls must be written and include process controls, sanitation controls, a recall plan, and other controls as appropriate and necessary. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 11, with editorial and conforming changes as shown in table 31.

TABLE 11—REVISIONS TO THE PROPOSED REQUIREMENTS FOR PREVENTIVE CONTROLS

Section	Description	Revision
507.34(c)(1)	Process controls	Clarify that the requirements for process controls depend on the role of the process control in the food safety system.

A. Proposed § 507.36(a)—Requirement To Identify and Implement Preventive Controls (Final § 507.34(a))

We proposed that you must identify and implement preventive controls, including at critical control points, if any, to provide assurances that significant hazards will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act. We also proposed that these preventive controls include controls at CCPs, if there are any CCPs, and controls, other than those at CCPs, that are also appropriate for animal food safety.

Some comments support the flexibility provided to facilities to implement preventive controls that are appropriate to the facility and the animal food. Other comments support the clarification, in the 2014 supplemental notice, that not all preventive controls are established at CCPs and that some food safety plans will not have CCPs. We are finalizing the provision as proposed with the editorial and conforming changes in table 31.

B. Proposed § 507.36(b)—Requirement for Written Preventive Controls (Final § 507.34(b))

We proposed that preventive controls must be written.

(Comment 276) Some comments ask us to clarify whether documentation of treatment by a ''custom processor'' would be accepted as a ''written preventive control'' when the ''custom processor'' controls the hazard.

(Response 276) The question posed by these comments highlights the difference between the records required in the food safety plan and the records documenting the implementation of the food safety plan. The ''written preventive controls'' are part of the food safety plan, whereas the records documenting treatment are implementation records. Implementation records documenting treatment, whether by a facility or its ''custom processor,'' would not satisfy the requirements for written preventive controls. However, specifying that the preventive control for a specific hazard is a particular treatment by a ''custom processor,'' along with information that describes the treatment, would satisfy the requirement for written preventive controls.

C. Proposed § 507.36(c)(1)—Process Controls (Final § 507.34(c)(1))

We proposed that preventive controls include process controls as appropriate to the facility and the animal food. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal foods. Process controls must include, as appropriate to the applicable control, parameters associated with the control of the hazard, and the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.

(Comment 277) Some comments state that assigning a parameter and associated minimum and maximum values for some process controls (such as refrigeration (including freezing), or water activity) may be possible, but not be necessary for food safety. These comments ask us to require minimum and maximum values to be assessed against the applicable food safety need, or otherwise make clear that the implications of not controlling minimum and maximum values must be assessed in light of the circumstances. Other comments express concern that ''as appropriate to the applicable control'' could be interpreted as suggesting that if it is merely feasible to establish parameters for a process control, they must be established. Other comments express concern that the proposed requirement suggests that if a parameter is not ''controlled,'' a regulator could conclude that the facility is not in compliance with the rule because it necessarily has not significantly minimized or prevented a significant hazard.

Some comments recommend incorporating recognition that the degree of rigor in application of subpart C parameters should be applied on a sliding scale, commensurate with the nature of the risk and the preventive control used. The comments request that the language in this section is altered to indicate that the parameters will not always be applicable.

(Response 277) See Response 293. We have revised the regulatory text to specify that process controls must include parameters and minimum or maximum values as appropriate to both the nature of the applicable control and its role in the facility's food safety system. We decline the request to indicate that parameters of subpart C will not always be applicable, as the revised regulatory text provides adequate flexibility for a facility to determine what preventive controls, including process controls, are appropriate to the facility and its animal food, if a hazard requiring a preventive control is identified.

(Comment 278) Some comments ask us to delete the phrase ''to significantly minimize or prevent a significant hazard.''

(Response 278) We decline this request. ''Significantly minimize or prevent a significant hazard'' (which we have revised to ''significantly minimize or prevent a hazard requiring a process control'') is the standard for controlling the hazards. Although the phrase could be viewed as redundant with the standard in the requirement to identify and implement preventive controls (§ 507.34(a)(1)), repeating that standard in the requirements for parameters and the minimum or maximum values associated with control of the hazard emphasizes the standard, which is appropriate for process controls.

D. Proposed § 507.36(c)(2)—Sanitation Controls (Final § 507.34(c)(2))

We proposed that preventive controls include, as appropriate to the facility and the animal food, sanitation controls that include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. We also proposed that sanitation controls must include procedures, practices, and processes for the cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment, and procedures for the prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product.

(Comment 279) One comment states that sanitation is not always a feasible step for facilities handling animal food, especially in dry blending facilities and dry storage operations. The comment asks us to remove the reference to ''sanitary condition'' and replace it with language consistent with the GMP section such as ''to ensure the facility is adequately cleaned and properly maintained to significantly minimize or prevent hazards.''

(Response 279) We decline this request. The sanitation controls are flexible so that a facility can determine what sanitation controls are necessary for their facility and animal food if they identify a hazard requiring sanitation controls as a preventive control. Replacing the term ''sanitary condition'' with the suggested language would not improve the flexibility of the sanitation control requirements.

(Comment 280) Some comments assert that sanitation controls are not necessary to prevent any hazards in distribution facilities where animal food-contact surfaces are not present. Other comments assert that sanitation controls should be required in all cases (rather than ''as appropriate'') given their central importance.

(Response 280) Under the framework established by FSMA, and implemented in this rule, each facility determines through its hazard analysis when sanitation controls are necessary to control a hazard requiring a preventive control. The rule neither establishes circumstances (such as in distribution centers) where sanitation controls are not necessary nor prejudges whether sanitation controls are necessary in specific circumstances. Although we do not expect that facilities such as distribution centers would determine through their hazard analysis that sanitation controls are required, we do expect all animal food establishments that are subject to the CGMP requirements established in subpart B to fully comply with the applicable requirements for sanitation.

(Comment 281) One comment states that sanitation is discussed in two sections, as a CGMP and as a preventive control, and asks that all of the discussion related to sanitation is moved to one section.

(Response 281) The two sections discuss sanitation for different purposes. The requirements for general sanitation are located in the CGMP regulations, which may be considered prerequisites to the preventive controls. The requirements for sanitation as a preventive control are specific for controlling an identified hazard. Sanitation activities conducted at a facility may be different depending on whether the sanitation activity is used as general facility sanitation or specifically to control a hazard. Also, sanitation as a preventive control is subject to the management components of § 507.39.

E. Proposed § 507.36(c)(3)—Supplier Controls (Final § 507.34(c)(3))

We proposed that supplier controls include the supplier program. See the discussion of comments on the supply-chain program, now in subpart E, in sections XL through XLVII.

F. Proposed § 507.36(c)(4)—Recall Plan (Final § 507.34(c)(4))

We proposed that preventive controls include, as appropriate, a recall plan as would be required by proposed § 507.38. See the discussion of comments on the recall plan in section XXVIII.

G. Proposed § 507.36(c)(5)—Other Controls (Final § 507.34(c)(5))

We proposed that preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

(Comment 282) Some comments ask us to specify that preventive controls include controls on raw materials and other ingredients.

(Response 282) The final rule specifies that preventive controls include supply-chain controls as appropriate to the facility and the animal food. The request of these comments is addressed by the requirements for the supply-chain program (see § 507.34(c)(3) and subpart E).

(Comment 283) One comment asks us to require compliance with the good manufacturing and feeding practices that apply to GRAS substances, found in § 582.1(b), as a preventive control.

(Response 283) Facilities required to register that manufacture, process, pack, or hold GRAS substances are subject to this final rule, including applicable preventive controls requirements. Preventive controls are intended to address certain known or reasonably foreseeable hazards, not an animal food facility's compliance with the good manufacturing and feeding practices of § 582.1(b), although a facility may determine that a good manufacturing practice is a preventive control for a particular hazard.

XXVII. Subpart C: Circumstances in Which the Owner, Operator or Agent in Charge of a Manufacturing/Processing Facility Is Not Required To Implement a Preventive Control (Final §§ 507.36 and 507.37)

In the 2014 supplemental notice, we provided an opportunity for public comment on potential requirements for a supplier program as a preventive control, including comments on when a supplier program would not be required. As discussed in more detail in section XL, we have revised the phrase ''supplier program'' to ''supply-chain program'' throughout the regulatory text. As summarized in table 12 and discussed more fully in the following paragraphs, after considering comments on when a supplier program would not be required, we are establishing two new provisions. Although both sets of provisions have an effect on the required supply-chain program, they will be implemented outside the framework of a supply-chain program.

TABLE 12—SUMMARY OF APPLICABLE PROVISIONS REGARDING WHEN THE OWNER, OPERATOR, OR AGENT IN CHARGE OF A MANUFACTURING/PROCESSING FACILITY IS NOT REQUIRED TO IMPLEMENT A PREVENTIVE CONTROL

Final section designation	Proposed section designation	Description	Revision
507.36(a)(1)	N/A	A manufacturer/processor is not required to implement a preventive control if it determines and documents that the type of animal food could not be consumed without application of an appropriate control.	N/A.
507.36(a)(2)	507.37(a)(1)(ii)(C)	A manufacturer/processor is not required to implement a preventive control if it relies on its customer, who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C, to ensure that the identified hazard will be significantly minimized or prevented and both: (1) Discloses in documents accompanying the animal food that the animal food is ''not processed to control [identified hazard]'' and (2) annually obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the identified hazard.	Includes a requirement for documentation that the animal food is ''not processed to control [identified hazard].''

TABLE 12—SUMMARY OF APPLICABLE PROVISIONS REGARDING WHEN THE OWNER, OPERATOR, OR AGENT IN CHARGE OF A MANUFACTURING/PROCESSING FACILITY IS NOT REQUIRED TO IMPLEMENT A PREVENTIVE CONTROL—Continued

Final section designation	Proposed section designation	Description	Revision
507.36(a)(3)		A manufacturer/processor is not required to implement a preventive control if it relies on its customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and it: (1) Discloses in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]'' and (2) annually obtains from its customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements.	N/A.
507.36(a)(4)	507.37(a)(1)(ii)(C)	A manufacturer/processor is not required to implement a preventive control if it relies on its customer to ensure that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and both: (1) Discloses in documents accompanying the animal food that the animal food is ''not processed to control [identified hazard]'' and (2) annually obtains from its customer written assurance that the customer will both disclose the information that the animal food is ''not processed to control [identified hazard]'' and will only sell to another entity that agrees, in writing, it will either follow procedures that will significantly minimize or prevent the identified hazard (if the entity is subject to subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) or obtain a similar written assurance from the entity's customer.	• Addresses the circumstance where an entity (other than the facility's customer) in the distribution chain controls the hazard • Includes a requirement for documentation that the animal food is ''not processed to control [identified hazard].''
507.36(a)(5)	N/A	A manufacturer/processor is not required to implement a preventive control if it has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the animal food product it distributes and documents the implementation of that system.	N/A.
507.36(b)	507.37(g)(3)	Records documenting the applicable circumstances in § 507.36(a).	Includes a requirement for documentation of the additional circumstances in which a manufacturer/processor is not required to implement a preventive control.
507.36(c)	N/A	If a customer of the manufacturer/processer has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species, the customer may provide this determination (including animal species and why the identified hazard is not a hazard) in its written assurance under § 507.36(a)(2)(ii) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.	N/A.
507.36(d)	N/A	If a customer of the customer of the manufacturer/processer (i.e., another entity in the distribution chain) has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species, the entity may provide this determination (including animal species and why the identified hazard is not a hazard) in its written assurance under § 507.36(a)(4)(ii)(B instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.	N/A.

TABLE 12—SUMMARY OF APPLICABLE PROVISIONS REGARDING WHEN THE OWNER, OPERATOR, OR AGENT IN CHARGE OF A MANUFACTURING/PROCESSING FACILITY IS NOT REQUIRED TO IMPLEMENT A PREVENTIVE CONTROL—Continued

Final section designation	Proposed section designation	Description	Revision
507.37	N/A	A facility that provides a written assurance under § 507.36(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.	N/A.

The first provision allows a manufacturer/processor to not implement a preventive control if the manufacturer/processor determines and documents that the type of animal food could not be consumed without application of the appropriate control by an entity in the supply or distribution chain other than that manufacturer/processor (see § 507.36(a)(1)). We describe comments leading to this provision, and our response to those comments, in Comment 284 and Response 284 respectively. Although we are establishing these provisions outside the framework of the supply-chain program, these provisions continue to play a role in the requirements for a supply-chain program, because they also provide an exception to the requirements for a manufacturer/processor to establish and implement a supply-chain program.

The second provision relates to comments we received on a proposed exception to the requirement for a manufacturer/processor to establish and implement a supplier program (proposed § 507.37(a)(1)(ii)(C)). (See Comment 285). Under proposed § 507.37(a)(1)(ii)(C), a receiving facility would not have been required to have a supplier program if it relied on its customer to control the hazard and annually obtained from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. As discussed in Response 285, we are replacing this provision with several provisions that apply when a manufacturer/processor identifies a hazard requiring a preventive control (''identified hazard''), does not control the identified hazard, but can demonstrate and document that the identified hazard will be controlled by an entity in its distribution chain. A manufacturer/processor that satisfies the criteria in these provisions will not be required to implement a preventive control for the identified hazard. Under these provisions, the combination of three requirements will provide adequate assurance that the animal food will be processed to control the identified hazard before it reaches consumers. These requirements are: (1) Documentation provided by the manufacturer/processor to its direct customer that the animal food is ''not processed to control [identified hazard]''; (2) written assurances from customers regarding appropriate procedures to ensure that the animal food will receive further processing to control the identified hazards; and (3) provisions relating to accountability for written assurances. (In these provisions, ''customer'' means a commercial customer, not a consumer.)

(Comment 284) Some comments express concern about the ability for distributors/cooperatives identify the individual raw material or other ingredient supplier when the supplier that applied the control is more than one step back in the food chain. Some comments assert that receiving facilities should not be required to verify suppliers with which they do not have a direct commercial relationship. For example, in the case of the soybean supply chain, the U.S. processing facility likely has no direct relationship with the many farms involved in the growing and harvesting of the soybeans. Some comments ask for an exemption from supplier verification activities for animal foods such as soybeans because it is problematic to have a requirement that potentially could necessitate trace back to farms.

(Response 284) We are establishing a provision, applicable to both the supply chain and the distribution chain of a manufacturer/processor, for a circumstance when a manufacturer/processor does not need to implement a preventive control. We are providing that a manufacturer/processor does not need to implement a preventive control if it determines and documents that the type of animal food could not be consumed without application of the appropriate control (see § 507.36(a)(1)). However, depending on the facility, the raw material or other ingredient, and the type of animal food produced by the manufacturer/processor, there may be some circumstances where a manufacturer/processor could determine that a particular animal food that passes through its facility satisfies the criterion ''could not be consumed without application of the appropriate control.'' In other cases, a facility may have determined through its hazard analysis that there are no hazards requiring a preventive control, and will not consider whether one of the circumstances in new § 507.36 apply.

As a consequential addition, new § 507.36(b) specifies the records that a manufacturer/processor would need to satisfy the documentation requirements established in new § 507.36(a)(1), and we have added new § 507.36(b) to the list of implementation records (§ 507.55) that are subject to the recordkeeping requirements of subpart F.

See also Comment 429, in which we discuss comments asking us to add flexibility to the requirements for a supply-chain program such that any entity other than the receiving facility can perform supplier verification activities. As discussed in Response 429, the rule provides additional flexibility in the supply-chain program with regard to who can perform certain activities (see § 507.115).

(Comment 285) Some comments ask us to delete the criterion for control of the hazard by the receiving facility's customer, with annual written assurance that the customer had established and was following procedures (identified in the written assurance) that would significantly minimize or prevent the hazard. The stated reasons varied. For example, some comments state that a receiving facility may have so many customers that it is not possible to obtain written assurance annually from all customers. Other comments express concern that a customer may be unwilling to describe confidential trade secrets in order to identify in writing the procedures the customer has established and is following to control the hazard. Other comments express concern about ''legal issues'' when a receiving facility needs to assess the adequacy of the customers' procedures for controlling a hazard because under current business practices a vendor can provide assurance to a buyer (its customer), but buyers do not typically provide such

assurance to vendors. Some comments express concern that written assurance does not guarantee that the customer is actually doing anything to significantly minimize or prevent the hazard.

Some comments ask us to provide an alternative that would allow the receiving facility to provide documentation to its customer about a hazard that needs a preventive control at a processing facility later in the distribution chain rather than obtain written assurance that its customer will control a hazard. If written assurance must be required, these comments ask us to allow the written assurance provided by the customer to state that the customer would evaluate the hazard and if necessary establish and follow procedures to significantly minimize or prevent the hazard.

Some comments state the receiving facility may not know the identity of all its ultimate customers, particularly if the receiving facility sells its products to a distributor who then sells to other entities. Some comments ask us to provide flexibility for facilities to determine whether annual updates of written assurance are necessary. Other comments ask us to specify that a receiving facility need not establish and implement a supplier program for raw materials and ingredients intended for further processing.

Some comments assert that the presence of low levels of pathogens on a raw product that will be subject to a lethal process further downstream does not pose a risk to the consumer, and should not be considered a significant hazard (*i.e.,* a hazard requiring a preventive control). These comments also assert that if we maintain that *Salmonella* contamination is a significant hazard for each member of the supply chain, then we should allow the preventive control to be applied in a subsequent step at another facility. Other comments ask us to clarify that a facility would not need to develop preventive controls where it produces raw materials or ingredients that are subject to subsequent processing that will address known or reasonably foreseeable hazards.

(Response 285) We are establishing several provisions, specifically applicable to the distribution chain of a manufacturer/processor, for circumstances when a manufacturer/processor does not need to implement a preventive control (§§ 507.36(a)(2), (3), (4), and (5); 507.36(b)(2), (3), (4) and (5); 507.36(c); 507.36(c) and (d), 507.37; and 507.215). See Response 284 for another new provision that applies to the supply chain in addition to the distribution chain (§ 507.36(a)(1)).

Under the first of these provisions (§ 507.36(a)(2)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer (who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) to ensure that the identified hazard will be significantly minimized or prevented and: (1) Discloses in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and (2) annually obtains from its customer written assurance, subject to the requirements of § 507.37, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. The manufacturer/processor would include the specific hazard requiring a preventive control (*e.g., Salmonella*) where the statement says ''[identified hazard].'' A facility that provides the written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance (see new § 507.37). The documents could be bills of lading or other papers that accompany the animal food or labels on the containers of the animal food.

Under the second of these provisions, (§ 507.36(a)(3)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer (who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C), to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and it: (1) Discloses in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and (2) annually obtains from its customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements. By ''customer who is not required to implement preventive controls under this part'' we mean entities such as qualified facilities and retail food establishments.

Under the third of these provisions (§ 507.36(a)(4)), a manufacturer/processor is not required to implement a preventive control if it relies on its customer to provide assurance that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and: (1) Discloses in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and (2) annually obtains from its customer written assurance, subject to the requirements of § 507.37, that the customer will disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''. The manufacturer/processor also must obtain written assurance that its customer will only sell to another entity that agrees, in writing, it will either: (1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C), or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C) or (2) obtain a similar written assurance from the entity's customer.

Under the fourth of these provisions (§ 507.36(a)(5)), a manufacturer/processor is not required to implement a preventive control if it has established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the animal food product it distributes and documents the implementation of that system. Comments did not provide examples of such a system, but we do not want to preclude the development of such systems.

We have added several other requirements related to the four new provisions that we are specifically establishing as circumstances in which a manufacturer/processor need not implement a preventive control. As already noted in this response, new § 507.37 requires that a facility that provides a written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance. In addition, new § 507.36(b)(2), (3), (4), and (5) specify the records that a manufacturer/processor would need to satisfy the documentation requirements established in new § 507.36(a)(2), (3), (4) and (5), and new § 507.215 establishes requirements applicable to the written assurance between a manufacturer/processor and its customer. Taken together, the provisions of §§ 507.37 and 507.215 establish legal responsibilities for a facility that provides a written assurance under § 507.36(a)(2), (3) or

(4), even if that facility is not a manufacturer/processor.

The point of these provisions is to ensure that hazards that a manufacturer/processor has determined, through its hazard analysis, require a preventive control, but are not controlled in the supply chain before the manufacturer/processor or by the manufacturer/processor itself, are in fact controlled by a subsequent entity in the distribution chain. With the assurance from the manufacturer/processor's customer that the hazards will be controlled after the animal food product leaves the manufacturer/processor it is not necessary for the first manufacturer/processor to implement the applicable preventive control. We continue to believe that annual written assurance from a manufacturer/processor's direct customer is an appropriate mechanism to ensure that its customer is aware of the identified hazard and is taking steps to ensure that the animal food is processed to control the identified hazard. We do not believe that a manufacturers/processor will need all of the details of its customer's process to satisfy the requirement to state in writing the procedures the customer has established and is following to control the hazard. For example, the customer could merely state that its manufacturing processes include a lethality step for microbial pathogens of concern.

We agree that it is appropriate to require that the manufacturer/processor provide documentation to its customer indicating that the animal food must be processed to control an identified hazard. Such documentation will be a means of clear communication from the manufacturer/processor to its customer. When the hazard will not be controlled by the customer, the customer will still have documentation that can be passed on to the entity that is expected to process the animal food to control the identified hazard, so that it will be very clear to that entity that the identified hazard still needs to be controlled.

We understand that not all identified hazards in an animal food will be a hazard to all species of animals. For example, we consider all serotypes of *Salmonella* to be a hazard for dog and cat food. However, we would not consider *Salmonella* Heidelberg a hazard in food for cattle. Therefore, we have added provisions to allow this determination to be included in the customer's written assurance regarding an identified hazard so that the customer will not be required to assure it is controlling a hazard that it has determined does not need to be controlled for a specific animal species.

For the written assurance required by § 507.36(a)(2)(ii), new paragraph (c) of this section provides that if the customer has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species, the customer's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.

For the written assurance required by § 507.36(a)(4)(ii)(B), new paragraph (d) of this section provides that if the entity in the distribution chain subsequent to the customer is subject to subpart C and has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species, that entity's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) in its written assurance instead of providing assurance that the identified hazard will be significantly minimized or prevented.

(Comment 286) Some comments that ask us to delete the proposed requirement to maintain the written assurance as a record. Other comments ask us to revise the regulatory text of the documentation requirement to focus on documentation that (1) the receiving facility has notified its customers of the existence of actual or potential hazards in animal food provided to them by the receiving facility; or (2) the receiving facility has notified its customers of the existence of actual or potential hazards in animal food provided to them by the receiving facility and has received a written assurance that the customer will evaluate the hazard and, if necessary, will follow procedures to significantly minimize or prevent the hazard.

(Response 286) We decline this request. As already discussed in this section, it is the combination of requirements (*i.e.,* for documentation that the animal food is ''not processed to control [identified hazard]''; assurance from customers regarding appropriate procedures to ensure that the animal food will receive further processing to control the identified hazards; and provisions relating to accountability for written assurances) that will provide adequate assurance that the animal food will be processed to control the identified hazard before it reaches consumers. Records documenting the written assurances are a key component of the provisions.

XXVIII. Subpart C: Comments on Proposed § 507.38—Recall Plan

We proposed that you must establish a written recall plan for animal food with a significant hazard and that the recall plan must include certain procedures. Some comments support the proposed requirements without change. For example, some comments express the view that a written recall plan is critical in the event of a system breakdown where adulterated animal foods have been distributed. Some comments that support the proposed requirements suggest alternative or additional regulatory text or other changes.

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the requirements as proposed with the conforming revision to use the term ''hazard requiring a preventive control'' rather than ''significant hazard.'' See Response 62 and table 31. As discussed in section XXVII, we are establishing a provision applying to certain assurances in § 507.37.

A. Proposed § 507.38(a)—Requirement for a Written Recall Plan

We proposed that you must establish a written recall plan for animal food with a significant hazard.

(Comment 287) Some comments ask us to require a written recall plan for all animal food (rather than just for animal food with a significant hazard) and to establish the requirements for a written recall plan as CGMP requirements in subpart B rather than as part of the requirements for hazard analysis and risk-based preventive controls in subpart C. These comments assert that all products can be subject to a recall. These comments contrast recall plans with other preventive controls in that recall plans are often specific to a firm or facility, but rarely are specific to particular animal foods. In addition, these comments note that a recall may be administered and managed at the corporate office rather than at the specific manufacturing facility that produced the animal food.

Some comments note the requirements for a written recall plan are sufficiently different from other provisions in subpart C that we proposed to specify that the recall plan would not be subject to the preventive control management requirements for monitoring, corrective actions, and verification (see § 507.39(c)). Other

comments assert that a recall plan is not a preventive control because it deals with products after they have been produced. Some comments note that facilities that are exempt from the requirements of subpart C, but remain subject to the CGMP requirements, would not be required to have a recall plan unless we establish the requirements in subpart B. Other comments note that the requirement for a recall plan is only if there is a hazard that requires a preventive control, but assert that a recall should only be initiated if a hazard has actually been identified to be present in the product.

Some comments note that our authority to require recall plans is not limited to section 418 of the FD&C Act and that we can use other legal authority to impose a requirement for recall plans in subpart B. Some comments note that FSMA specifically amended the FD&C Act to provide us with the authority to mandate a food recall (section 423 of the FD&C Act). These comments assert that it would be reasonable for us to conclude that in order to efficiently carry out section 423 of the FD&C Act we should issue requirements governing the conduct of recalls, because section 423 of the FD&C Act requires that we provide a firm with an opportunity to voluntarily recall a product before issuing an order to the firm to cease distribution and recall a product.

(Response 287) We decline the request to establish requirements for a written recall plan as a CGMP requirement in subpart B and are establishing the requirements as a preventive control in subpart C as proposed. We acknowledge that a recall plan would be useful to all animal food establishments, and we encourage all animal food establishments to have a recall plan. However, the report issued by the human food CGMP Modernization Working Group did not identify the lack of a written recall plan as something that needed to be changed (Ref. 41). (See 78 FR 3646 at 3651, the proposed rule for preventive controls for human food, for a discussion of the CGMP Modernization Working Group and the process leading to its report.) However, going forward we intend to monitor whether the lack of a broader requirement for a recall plan leads to problems when animal food establishments that are not subject to the requirements of subpart C are faced with recall situations. As we gain experience with the impact of the new requirement for a recall plan on those facilities subject to subpart C, we can reassess at a later date whether to conduct rulemaking to broaden the requirement to apply to all animal food establishments subject to the CGMP requirements in subpart B. For now, animal food establishments that are not subject to subpart C can continue to follow our longstanding recall policy in part 7 (21 CFR part 7).

Consistent with the overall framework of FSMA, a recall plan (like other preventive controls) is only required when the facility has identified a hazard requiring a preventive control. A facility could establish a recall plan that applies to other animal foods it manufactures. We recognize that recalls may be managed by the corporate office of a firm rather than at the specific manufacturing facility that produced the animal food. Nothing in the rule precludes this approach. In such cases the corporate recall policy would be reflected in a facility's recall plan. (See also Response 239.) In addition, a facility that identifies one or more hazards requiring a preventive control in multiple animal food products could use the same recall plan for all applicable animal food products.

The rule specifies that the requirements for preventive control management components (*i.e.,* monitoring, corrective actions and corrections, and verification) apply as appropriate to ensure the effectiveness of the preventive control, taking into account the nature of the preventive control (§ 507.39(a)). As previously discussed, the preventive control management components are directed at animal food that remains at the facility, whereas the recall plan addresses animal food that has left the facility (78 FR 64736 at 64788). Our determination that the nature of the recall plan does not require these preventive control management components demonstrates the flexibility provided by FSMA and this rule, not that the recall plan must be considered a CGMP rather than a preventive control.

We have not yet made a determination of whether we should issue requirements governing the conduct of recalls, rather than rely on the guidelines in part 7, in order to fully implement section 423 of the FD&C Act. However, we have issued a draft guidance entitled ''Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls'' which, when finalized, would address topics such as the criteria for a mandatory recall and the process that FDA must follow for a mandatory recall (Ref. 42).

(Comment 288) Some comments ask us to cross-reference the provisions of part 7 (21 CFR part 7) rather than establish requirements that these comments assert would be duplicative with the provisions of part 7. These comments ask us to address any more substantive requirements than are already in part 7 as part of a review of part 7. These comments assert that part 507 should require a written recall plan, but not require a written recall plan for the animal food, to be consistent with the approach of part 7.

(Response 288) We decline these requests. Part 7 addresses enforcement policy and the provisions for recalls in subpart C of part 7 are ''Guidance on Policy, Procedures, and Industry Responsibilities.'' These recall provisions do not establish requirements and are not binding on industry. They also are broadly directed to recalls for all FDA-regulated products, not just food. As already discussed in Response 284, nothing in this rule would prevent a facility that establishes a recall plan for a particular animal food from using that recall plan for any animal food product that the facility decides to recall.

(Comment 289) Some comments request that we have separate recall program requirements for human food by-products so that by-products produced during the manufacture of food and sold, or otherwise provided, for use in animal food would not be recalled if the product for people is recalled. Other comments assert we will need to define the criteria for an animal food recall in guidance.

(Response 289) We decline the request to have separate recall program requirements for human food by-products for use as animal food. Whether or not the by-product of a human food that is recalled should itself be recalled may depend on assessment of several factors such as what the hazard is, whether the hazard for which the human food is recalled is also a hazard for the animal(s) that consume the by-product, and where the hazard occurred in the manufacturing process. We have previously addressed the request for guidance. (See Response 1.)

B. Proposed § 507.38(b)—Procedures That Describe the Steps To Be Taken, and Assign Responsibility for Taking Those Steps

We proposed that the recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility: (1) Directly notify the direct consignees of the animal food being recalled, including how to return or dispose of the affected animal food; (2) notify the public about any hazard presented by the animal

food when appropriate to protect human or animal health; (3) conduct effectiveness checks to verify that the recall is carried out; and (4) appropriately dispose of recalled animal food (*e.g.,* through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying). We requested comment on whether: (1) The proposed procedures are appropriate for all types of facilities; (2) we should require a recall plan to include procedures and assignment of responsibility for notifying FDA of recalls subject to the plan; and (3) we should include a requirement for a mock recall as a verification activity.

(Comment 290) Some comments ask us to delete the proposed requirement that the recall plan include procedures for a facility to notify the public about any hazard presented by the animal food when appropriate to protect public health. These comments assert that such a requirement would be highly subjective and create a nebulous regulatory burden that could subject facilities to unnecessary regulatory oversight and enforcement actions. Other comments indicate that the requirement for notifying the public should specifically prevent silent recalls when manufacturers pull products from store shelves without consumer notification.

(Response 290) We decline this request. Our guidance for a recall strategy has long recommended issuing a public warning to alert the public that a product being recalled presents a serious hazard to health in urgent situations where other means for preventing use of the recalled product appear inadequate (§ 7.42(b)(2)). Operationally, such notification to the public is so common that our current home page on our Internet site (Ref. 43) gives prominence to recall information and we have established a free email subscription service for updates on recalls (Ref. 44). Consistent with the longstanding recall policy in part 7, subpart C, the proposed requirement qualifies that the notification to the public is ''when appropriate to protect public health.'' A market withdrawal of a product (see § 7.3(j)) is not a recall that would be subject to public notification.

(Comment 291) Some comments ask us to specify that the procedures require facilities to notify us about a recall to ensure that all suppliers, retailers, and consumers will have adequate notification of the recall action. Other comments agree that it is important for facilities to involve us in a recall situation as soon as possible, but assert that the best way to address such a notification is through the existing RFR system. These comments assert that additional procedures or means to notify us would involve unnecessary additional steps and be duplicative, with no improvement to the public health. Some comments assert that if the recall is issued by a foreign facility, the responsibility should be with the importer of the product for notifying FDA. Some comments ask us to specify that the appropriate State regulatory Agency with inspection jurisdiction be notified in the event of a recall.

(Response 291) We agree with comments that it is important to notify us about a recall and that doing so can help to ensure that suppliers, retailers, and consumers will have adequate notification of the recall action. We also agree that the existing procedures to notify us through the RFR system can accomplish this goal when an animal food presents a risk of serious adverse health consequences or death and that it therefore is not necessary to duplicate the notification procedures already established in the RFR system in part 507. However, we encourage facilities to include in their recall plan any procedures they have to comply with the RFR or to include a cross-reference to those procedures. Doing so may save time, which is critical during a recall. When the recalled animal food does not present a risk of serious adverse health consequences or death (and, thus, there is not a report to the RFR), our guidance entitled ''Guidance for Industry: Product Recalls, Including Removals and Corrections'' recommends that recalling firms notify the local FDA District Recall Coordinator as soon as a decision is made that a recall is appropriate and prior to the issuance of press or written notification to customers (Ref. 45). Including this guidance with the facility's recall procedures may also save time.

We decline the request to designate that it is solely the importer of a food manufactured by a foreign facility who must notify FDA if the food is recalled by the foreign facility. We are not requiring that a recall plan include procedures and assignments of responsibility for notifying FDA of recalls subject to the recall plan. Facilities should refer to our guidance in part 7 entitled ''Guidance for Industry: Product Recalls, Including Removals and Corrections'' for recommendations on conducting recalls of food that does not present a risk of serious adverse health consequences or death, including notification to FDA (Ref. 45). If the recalled food is a reportable food (*i.e.,* it does present a reasonable probability that use will cause serious adverse health consequences or death to humans or animals), then section 417 of the FD&C Act requires that the responsible party, as defined in section 417, submit a report to FDA.

We agree with comments that it is important to notify appropriate State regulatory Agencies about a recall. We generally request that FDA District Offices notify State control officials of recalls issued by animal food manufacturers. Also, State officials with responsibilities for regulating animal food can access our Web site for ''Animal and Veterinary Recalls and Withdrawals'' where we post the current and most recent recalls of animal products, including animal food (Ref. 46). We note that whatever methods are used to dispose of adulterated animal food, the methods should comply with State and local requirements.

(Comment 292) Some comments ask us to add a requirement for mock recalls on a regular basis, such as biannually. Some of these comments state that mock recalls would familiarize the staff and communications network(s) with the recall process and would improve the facility's capacity to conduct effective and efficient recalls in the event of a contamination event. Other comments assert that mock recalls would be the only way to determine the effectiveness of a recall program. Some comments note that mock recalls would be particularly critical for manufacturers that have limited experience in actual recalls.

Some comments acknowledge that a mock recall could be an important element of a recall plan but recommend that mock recalls remain voluntary, such as by including mock recalls as an example of how verification may be accomplished. Other comments note that the current recall procedures in part 7 do not recommend mock recalls. Some comments assert that a requirement to include a mock recall as a verification activity would be an excessive and inappropriate burden; that any gain in the protection of public health will not offset the resource requirements to accomplish a mock recall; that resources are better dedicated to developing a robust plan; and, use of a mock recall should be addressed in FDA guidance.

Some comments ask us to clarify the ''metrics'' for a mock recall, particularly with respect to the consequences of failing to meet an appropriate metric if a mock recall is conducted as a verification activity.

(Response 292) We agree that a mock recall would familiarize the facility with the recall process, could improve the facility's capacity to conduct effective

and efficient recalls during a contamination event, may be particularly helpful for manufacturers that have limited experience in actual recalls, and could support the development of guidance on best practices for recalls, and we encourage facilities to conduct one or more mock recalls to accomplish these goals. However, as previously discussed, a recall plan would address food that had left the facility, whereas the proposed requirements for monitoring, corrective actions, and verification would all be directed at food while it remains at the facility. Comments are mixed regarding whether the rule should require a mock recall as a verification activity for the recall plan, and we have decided to not require a facility to conduct a mock recall as a verification activity for its recall plan so that the focus of the monitoring, corrective actions, and verification in the rule remains focused on food being produced rather than on food that is distributed in commerce. We acknowledge that requiring mock recalls would go beyond our longstanding policies established in part 7. A facility that voluntarily conducts a mock recall would establish metrics appropriate to its plan and take action (such as modifications to its procedures, or additional training for its employees) if it is not satisfied with the results of the mock recall.

We note that retail companies are not subject to this rule and, thus, are not subject to the requirement to have a written recall plan.

XXIX. Comments on Proposed § 507.39—Preventive Control Management Components

We proposed preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control. Most of the comments that support the proposed provisions suggest alternative or additional regulatory text.

In the following sections, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 13 with editorial and conforming changes as shown in table 31.

TABLE 13—REVISIONS TO THE PROPOSED REQUIREMENTS FOR PREVENTIVE CONTROL MANAGEMENT COMPONENTS

Section	Description	Revision
507.39	Flexible requirements for preventive control management components.	Provide that preventive control management components take into account both the nature of the preventive control and its role in the facility's food safety system.

A. Proposed § 507.39(a)—Flexible Requirements for Monitoring, Corrective Actions and Corrections, and Verification

We proposed that, with some exceptions, the preventive controls would be subject to three preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control: Monitoring, corrective actions and corrections, and verification.

(Comment 293) Some comments support our proposal to provide flexibility in the oversight and management of preventive controls, including the explicit provision that preventive control management components take into account the nature of the preventive control. Some of these comments state that the provisions for the preventive control management components will allow facilities to tailor their food safety plans to their specific facility, product, and process and ensure that the regulatory requirements are risk-based. Other comments state that the proposed approach acknowledges the safety benefits derived from the use of prerequisite programs, such as CGMPs, and provides for a framework whereby appropriate decisions may be reached regarding hazards that require management controls that may include monitoring, corrections or corrective actions, verification, and records. Other comments state that the provisions will allow businesses to allocate resources to spend the most time and resources controlling and monitoring those hazards that pose the greatest risk to public health.

However, many of these comments also ask us to convey not only that the application of a particular management component be appropriate (*i.e.,* capable of being applied), but also that it be necessary for food safety (*i.e.,* to meet the overall FSMA food safety goals or to ensure a particular control is effective) by specifying that the preventive control management components take into account both the nature of the preventive control and its role within the facility's overall food safety system. Some of these comments ask us to make companion changes reflecting that the preventive control management components take into account both the nature of the preventive control and its role within the facility's overall food safety system throughout applicable provisions of the rule, such as the definition of ''significant hazard'' (which we now refer to as ''hazard requiring a preventive control'') and in the requirements for preventive controls, monitoring, corrective actions and corrections, and verification. Some comments ask us to consistently refer to ''the nature of the preventive control'' (rather than simply to ''the preventive control'') when communicating the flexibility that a facility has in identifying preventive controls and associated preventive control management components.

(Response 293) We agree that preventive control management components should take into account both the nature of the preventive control and its role in the facility's food safety system and have modified the regulatory text of § 507.39 to incorporate this suggestion. We reviewed the full regulatory text of proposed subpart C and made similar modifications to the regulatory text for the definition of ''hazard requiring a preventive control'' (§ 507.3); process controls (§ 507.34(c)(1)); monitoring (§ 507.40); verification (§ 507.45); validation (§ 507.47); and verification of implementation and effectiveness (§ 507.49).

(Comment 294) Some comments assert that the flexibility explicitly provided in the regulatory text could result in some facilities taking a broad approach to significant hazards and other facilities taking a more detailed approach. These comments express concern that inspectors will view the detailed approach (*e.g.,* with more preventive controls), as the standard to judge compliance with the rule. Other comments express concern that identifying a large number of preventive controls could also undermine the value of HACCP programs because treating too many controls as CCPs will pull

resources from those controls that are truly critical.

(Response 294) We agree that facilities are likely to take different approaches to complying with the rule. A facility-specific approach is consistent with FSMA, which places responsibility for hazard analysis and risk-based preventive controls on the owner, operator, or agent in charge of the facility (section 418(a) of the FD&C Act). We agree that having too many CCPs could dilute their significance, but not every hazard will require a CCP to be controlled. See table 6 in the 2014 supplemental notice for examples of preventive controls that would not be CCPs (79 FR 58476 at 58493).

During the initial stages of implementation, we expect that our investigators will ask subject matter experts in CVM to review the outcome of the facility's hazard analysis, the preventive controls established by the facility, and the associated preventive control management components that the facility has established and implemented. Over time, as our investigators gain experience, we expect that there will be fewer circumstances in which our investigators would consult CVM about such an outcome. (See also Response 2 and section LIV regarding our approach to compliance.)

(Comment 295) Some comments state that USDA's regulations (in 7 CFR 205.201(a)(3)) for the National Organic Program include regulatory text to ''ensure the effectiveness'' of measures in that program and that this regulatory text is similar to regulatory text in the requirements for preventive control management components. These comments assert that this type of regulatory text has created compliance challenges and ask us to consult with USDA about its experience with implementing effectiveness language associated with monitoring practices and procedures and ensure that the final rule uses regulatory text that will be clearly understood and readily implementable by those subject to its provisions.

(Response 295) Under the USDA regulation cited by these comments, an organic production or handling system plan must include a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to ''verify that the plan is effectively implemented.'' We have not consulted with USDA regarding its experience in evaluating compliance with this requirement because we addressed the issue likely to cause these compliance challenges for monitoring practices and procedures in an organic production or handling system plan when we established our requirements for monitoring preventive controls. Specifically, we require that a facility monitor the preventive controls with adequate frequency to ''provide assurance that they are consistently performed,'' not to ''verify that the plan is effectively implemented.'' Our requirements more clearly distinguish the purpose of monitoring and verification activities. See our previous discussion of the relationship between monitoring and verification, and our tentative conclusion to require monitoring of the performance of the preventive controls (78 FR 64736 at 64790). We are affirming that conclusion in this rule. (See Response 297.)

B. Proposed § 507.39(b)—Applicability of Preventive Control Management Components to the Supply-Chain Program

We proposed that the supplier program (which we now refer to as ''supply-chain program'') would be subject to the following preventive control management components as appropriate to ensure the effectiveness of the supplier program, taking into account the nature of the hazard controlled before receipt of the raw material or ingredient: (1) Corrective actions and corrections, taking into account the nature of any supplier non-conformance; (2) review of records; and (3) reanalysis. We address comments on the supply-chain program in sections XL through XLVII. We are finalizing the applicability of preventive control management components to the supply-chain program as proposed.

C. Proposed § 507.39(c)—Recall Plan Is Not Subject to Preventive Control Management Components

We proposed that the recall plan that would be established in § 507.38 would not be subject to the preventive control management components.

(Comment 296) As discussed in Comment 287, some comments ask us to establish requirements for a written recall plan as a CGMP requirement in subpart B rather than as a preventive control in subpart C. As a companion change, some of these comments ask us to delete our proposed provision that the recall plan would not be subject to the preventive control management components.

(Response 296) As discussed in Response 287, we are establishing the requirements as a preventive control in subpart C as proposed. Therefore, we are finalizing the provision that the recall plan not be subject to the preventive control management components.

For further discussion on comments on preventive control management components, see section XXIX in the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

XXX. Subpart C: Comments on Proposed § 507.40—Monitoring

We proposed to establish requirements for monitoring the preventive controls. We also discussed our tentative conclusion that the language of section 418 of the FD&C Act regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the ''performance'' of preventive controls.

Some comments agree with our tentative conclusion regarding the ambiguous nature of section 418. For example, some comments state that our interpretation seems appropriate because requiring monitoring of the ''effectiveness'' of the preventive controls would be redundant with required verification activities. In addition, requiring monitoring of the performance of preventive controls is consistent with applicable domestic and internationally recognized standards.

Some comments agree that facilities must be required to maintain records; but disagree regarding the scope of monitoring. One comment agrees that monitoring the performance of preventive controls would provide evidence that the preventive controls established to control the identified hazards are implemented appropriately. Some comments support the proposed provisions without change. Some comments ask us to clarify how we will interpret the provision.

In the following paragraphs, we discuss comments that disagree with our tentative conclusion or with the proposed requirements, or ask us to clarify the proposed requirements or suggest one or more changes to the proposed requirements. After considering these comments, we are affirming our tentative conclusion that the language of section 418 of the FD&C Act regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the ''performance'' of preventive controls. We also have revised the proposed requirements as shown in table 14, with editorial and conforming changes as shown in table 31.

TABLE 14—REVISIONS TO THE PROPOSED REQUIREMENTS FOR MONITORING

Section	Description	Revision
507.40	Flexibility in requirements for monitoring.	Provide that monitoring take into account both the nature of the preventive control and its role in the facility's food safety system.
507.40(c)(2)(i)	Records of monitoring	Provide that records of refrigeration temperature during storage of animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control.
507.40(c)(2)(ii)	Records of monitoring	Provide for exception records for monitoring of preventive controls other than refrigeration.

A. Our Tentative Conclusion To Require Monitoring of the Performance of Preventive Controls

(Comment 297) Some comments disagree with our tentative conclusion that it would be appropriate to require monitoring of the ''performance'' of preventive controls and assert that the concept of ''performance evaluation'' is too complex to be included in the rule.

(Response 297) These comments may have misinterpreted what we meant by ''monitoring performance of preventive controls.'' We used the term ''performance'' to mean ''the execution or accomplishment of an action, operation, or process undertaken or ordered'' (78 FR 64736 at 64790). We acknowledge that the definition of ''monitoring'' that we are establishing in this rule includes that the purpose of observations or measurements conducted as part of monitoring is to ''assess'' whether control measures are operating as intended. However, we provided examples showing that this assessment is a straightforward determination of whether a process is operating as intended and is not a complex evaluation as asserted by the comments. (See, *e.g.,* the discussion of monitoring oven temperature to ensure pathogen elimination during baking of a pet treat 78 FR 64736 at 64789 through 64790.)

(Comment 298) Some comments that support monitoring the performance of preventive controls assert that our proposed definition of ''monitoring'' (proposed § 507.3), and our preamble discussions of ''monitoring,'' have the potential to confuse ''monitoring the performance of preventive controls'' with verification activities that address ongoing implementation of control measures.

(Response 298) See Response 47 in which we discuss comments on the definition of monitoring and describe the changes we have made to that definition to address concerns about the potential to confuse ''monitoring the performance of preventive controls'' with verification activities that address ongoing implementation of control measures.

(Comment 299) Some comments assert that authority should be explicitly granted to the States to conduct food safety monitoring and that we should maintain our responsibilities for product tracing.

(Response 299) These comments misinterpret the provisions of section 418 of the FD&C Act and this rule. Section 418 places the responsibility for establishing and implementing a food safety system (including hazard analysis, risk-based preventive controls, preventive control management components (including monitoring, corrective action procedures, and verification), and recordkeeping) on the owner, operator, or agent in charge of a facility, not on FDA or any other regulatory authority. This requirement for monitoring within the framework of hazard analysis and risk-based preventive controls is distinct from regulatory oversight of animal food safety, such as during inspections and investigations of outbreaks of foodborne illness, which generally involve product tracing. We agree that it is important to coordinate regulatory oversight of animal food safety with the States and other food safety partners. As discussed in Response 2, we are working through the PFP to develop and implement a national Integrated Food Safety System consistent with FSMA's emphasis on establishing partnerships for achieving compliance (see section 209(b) of FSMA).

(Comment 300) One comment requests that routine monitoring not be required for feed mills unless they manufacture pet food.

(Response 300) We decline this request. We assume this comment is based on a presumption that pet food is a higher risk product than livestock or poultry food. The exemptions from preventive control requirements that we are establishing are specifically provided by section 103 of FSMA and we decline to apply the rule only to animal foods deemed to be of higher risk. Instead, several provisions of the rule expressly qualify that the requirements apply as appropriate to the facility, the animal food, the nature of the preventive control, and its role in the facility's food safety system, the nature of the hazard, or a combination of these factors (*e.g.,* monitoring procedures must be established as appropriate to the nature of the preventive control and its role in the facility's food safety system). For example, the hazards in a facility and historical information on the consistency of the control measure can be factors in determining the frequency of monitoring.

B. Proposed § 507.40(a) and (b)—Flexibility in Requirements for Monitoring

We proposed that, as appropriate to the preventive control, you must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls, and monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(Comment 301) Some comments agree that frequency and areas to be tested and monitored need to be determined based on each product and facility and ask us to allow each individual facility to determine the frequency and areas to be monitored based on a completed risk assessment. Some comments ask us to specify that the frequency of monitoring preventive controls must have a scientific basis.

(Response 301) It is unclear whether the comment agreeing that monitoring frequency and areas to be tested need to be determined based on each product and facility was directed to the monitoring provision or to environmental monitoring. Regardless, by requiring written procedures for monitoring, and specifying that the

procedures include the frequency with which the procedures are to be performed, the rule provides that each facility must determine the frequency of monitoring, as well as details such as the areas to be monitored. However, we decline the request to specify that these procedures be based on a completed ''risk assessment.'' The rule requires the facility to conduct a hazard analysis, which determines whether there are any hazards requiring a preventive control, and the facility would establish preventive controls for such hazards as appropriate to the facility and the animal food. The facility must consider factors associated with risk (*i.e.,* the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls) in evaluating whether any potential hazard is a hazard requiring a preventive control (§ 507.33(c)). Risk could be relevant to a facility's identification of appropriate preventive controls for a particular hazard requiring a preventive control. However, it is the nature of the preventive control, rather than the risk associated with the hazard, that is more relevant to the frequency of monitoring and the areas to be monitored. Accordingly, the rule specifies that the facility establish written procedures, and conduct monitoring, as appropriate to the preventive control rather than based on risk associated with the hazard. (See, *e.g.,* the discussion of monitoring oven temperature to ensure pathogen elimination during baking of a pet treat 78 FR 64736 at 64789 through 64790.)

We decline the request to specify that the frequency of monitoring preventive controls must have a scientific basis. Monitoring should take place with sufficient frequency to detect a problem in the performance of a preventive control. The importance of the preventive control to the safety of the animal food can be one factor in setting a frequency. We acknowledge that scientific information may be appropriate in determining the frequency of monitoring in some cases. For example, the frequency may be statistically based, such as with statistical process control. However, in some cases, factors other than scientific information may be appropriate in determining the frequency of monitoring. For example, historical information on the consistency of the control measure can be a factor in determining frequency. When variability of the process is low, the frequency may be less than with a process that has more variability. As another example, a process that is operated at a point close to a food safety parameter limit may be monitored more frequently than one where there is a large safety margin built into the process.

C. Proposed § 507.40(c)—Records

We proposed that all monitoring of preventive controls must be documented in records that are subject to verification and records review.

(Comment 302) Some comments point out that table 6 in the 2014 supplemental notice includes an example of a monitoring activity that generally would not require monitoring records (*i.e.,* monitoring for pieces of ferrous material with magnets) (see 79 FR 585476 at 58493). These comments assert that this example is in conflict with the proposed regulatory text and ask us to modify the regulatory text to provide the flexibility we acknowledged in the 2014 supplemental notice. One comment states the examples provided by FDA for monitoring performance of preventive controls pertain to preventive controls that have specific parameters. The comment states in the absence of specific parameters for a preventive control, monitoring is neither necessary nor appropriate. Other comments ask us to specify that monitoring must be documented as appropriate to the nature of the preventive control.

Some comments ask us to recognize the acceptability of monitoring systems that exclusively provide exception reports. These comments describe exception reporting as a structure where automated systems are designed to alert operators and management on an exception basis, *i.e.,* only when a deviation from food safety parameter limits are observed by the system. These comments assert that, in many cases, monitoring of preventive controls can be done by automated systems that provide exception reporting in a much more efficient manner than if performed by operators and that automated monitoring allows for increased sampling frequency (often continuous) and reduction of human error. The comments provide an example of a refrigeration temperature control that notifies on exception (*e.g.,* high temperature alarm) and may only record temperatures that exceed the specified temperature (without recording temperatures that meet control requirements). These comments acknowledge that such systems must be validated and periodically verified to ensure they are working properly. These comments ask us to clarify in the preamble to the final rule that monitoring systems can work affirmatively or by exception and that both types of systems and their related documentation are acceptable.

(Response 302) We have made several revisions to the regulatory text, with associated editorial changes, to clarify that monitoring records may not always be necessary. We agree that the exception reporting described in these comments, including validation and periodic verification to ensure that the system is working properly, would be an acceptable monitoring system in the circumstances provided in the comments, *i.e.,* for monitoring refrigeration temperature. Therefore, we have revised the regulatory text to provide that records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control. Although the comments specifically requested that we clarify our view on exception records in the preamble, we believe that clarifying the regulatory text will be more useful, both to facilities and to regulatory agencies that conduct inspections for compliance with the rule. If a facility uses ''exception records,'' the facility must have evidence that the system is working as intended, such as a record that the system has been challenged by increasing the temperature to a point at which an ''exception record'' is generated.

We also have revised the regulatory text to provide that exception records may be adequate in circumstances other than monitoring of refrigeration temperature. For example, in table 6 of the 2014 supplemental notice the example we provided of a monitoring activity that generally would not require monitoring records is monitoring for pieces of ferrous material with magnets. We believe that a magnet system that monitors for ferrous material would result in a record only when the system detects ferrous material.

XXXI. Subpart C: Comments on Proposed § 507.42—Corrective Actions and Corrections

We proposed to establish requirements for corrective actions and corrections. Some comments support the proposed requirements without change. For example, some comments assert that there is virtually no reason to have a food safety plan unless there are proper corrective actions in place so the product can be properly disposed of. Some comments agree that there should

be written procedures for corrective actions and note the importance of identifying and evaluating the problem, correcting it, and documenting the corrective action. Some comments express the view that the proposed requirement for clear corrective action in the event of an unanticipated problem, and documenting all corrective actions, contributes to a comprehensive safety plan. Some comments that support the proposed provisions suggest alternative or additional regulatory text.

In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 15 with editorial and conforming changes as shown in table 31.

TABLE 15—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CORRECTIVE ACTIONS AND CORRECTIONS

Section	Description	Revision
507.42(a)	Corrective action procedures	Clarify that corrective action procedures depend on the nature of the hazard, as well as the nature of the preventive control.
507.42(a)(1)	Corrective action procedures	Clarify that the specified list of corrective action procedures is not intended to be finite.
507.42(b)	Corrective action in the event of an unanticipated food safety problem.	Specify that the requirement applies when ''a corrective action procedure'' (rather than ''a specific corrective action procedure'') has not been established.
507.42(b)(1)(ii)	Corrective action in the event of an unanticipated food safety problem.	Specify that the requirement applies when a preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective (rather than just when a single preventive control has been found to be ineffective).
507.42(c)(2)	Corrections	Provide for additional circumstances when corrections, rather than corrective actions, are warranted.

A. Proposed § 507.42(a)(1)—Requirement To Establish and Implement Corrective Action Procedures

We proposed that, with some exceptions, as appropriate to the preventive control you must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. The corrective action procedures must include procedures to address, as appropriate, the presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing, as well as the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring.

(Comment 303) Some comments note that we proposed to list two circumstances that require written corrective active procedures (*i.e.,* product testing and environmental monitoring) and that it is not clear whether this list is intended to be exhaustive or not (*i.e.,* whether written corrective action procedures are required in only these two circumstances, or whether there may be other circumstances that require written corrective action procedures). These comments ask us to insert ''but are not limited to'' after ''must include,'' if we intend that the list is not exhaustive. Likewise, other comments state our proposal to specifically require corrective action procedures may result in a misunderstanding by some facilities about the need to take corrective actions in circumstances other than in response to testing results, other nonconformances, or other types of verification activities. These comments assert that it would be better for food safety if the regulatory requirements took a more principled approach and generally required corrective action procedures, with the importance of corrective action procedures for testing programs addressed through guidance. If, however, we conclude that specific requirements for corrective action procedures for testing programs are necessary, these comments ask us to clarify that the nature and extent of any corrective actions should be proportional to the nature of the test findings.

(Response 303) We have revised the regulatory text, with associated editorial revisions and redesignations, to clarify that the specified list of corrective action procedures is not intended to be exhaustive (*i.e.,* not limited to the two corrective action procedures that we specified in the 2014 supplemental notice). The approach we used in the modified regulatory text (*i.e.,* ''You must establish and implement written corrective action procedures . . ., including procedures to address, as appropriate . . .'') is similar to the approach used in several other provisions of the rule. (See, *e.g.,* sanitation controls (§ 507.34(c)(2)); and monitoring (§ 507.40(a)). We decline the suggestion to modify the regulatory text by adding ''but is not limited to'' after ''includes''. The word ''includes'' means to have (someone or something) as part of a group or total; to contain (someone or something) in a group or as a part of something (Ref. 47). The word ''includes'' does not need to be followed by ''but is not limited to'' to clearly communicate that a following list is not complete. We agree that the nature and extent of any corrective actions in response to the findings of testing programs should be proportional to the nature of the test findings. (See Response 304.)

(Comment 304) Some comments state that the nature and extent of the corrective actions should be proportional to the nature of the testing results. These comments ask us to require that a facility establish and implement corrective action procedures that must be taken if preventive controls are not properly implemented as appropriate to the nature of the hazard, the nature of the control measure, and the extent of the deviation.

(Response 304) We have revised the regulatory text to specify that the corrective action procedures are established and implemented based on the nature of the hazard in addition to the nature of the preventive control. We agree that the nature of the hazard plays a key role in the corrective actions that a facility would take. Although a facility's corrective action procedures likely would specify actions to take based on the extent of the deviation, we consider this a detail that does not need to be specified in the rule.

(Comment 305) Some comments ask us to revise the provisions to clarify that corrective action procedures are not always necessary when testing detects the presence of a pathogen or indicator organism. These comments assert that

the extent of the corrective actions should be proportional to the nature of the testing results themselves because the level of contamination matters for those microorganisms with thresholds that need to be taken into account and because the location of contamination in the food processing environment matters (*e.g.,* the zone in the facility where the contamination is detected). (For information about zones associated with environmental monitoring, see 78 FR 3646 at 3816.)

(Response 305) We decline this request. These comments appear to be confusing the requirement to establish and implement corrective action procedures with the content of the corrective action procedures. These comments also appear to assume that a requirement to have corrective action procedures (which describe the steps to be taken to ensure that appropriate action is taken to identify and correct a problem and, when necessary, to reduce the likelihood that the problem will recur; that all affected animal food is evaluated for safety; and that all affected animal food is prevented from entering into commerce when appropriate) predetermines the outcome of following the corrective action procedures. This is not the case. If, as the comments assert, a facility concludes, for example, that the nature of some test results do not warrant steps to reduce the likelihood that a problem will recur and that affected animal food is safe and lawful (or, in the case of finding a pathogen in some zones in the facility, that no animal food is affected), then that is what its corrective action procedures would say. The reason to have corrective action procedures is to consider the likely scenarios in advance, with appropriate input from the facility's food safety team and preventive controls qualified individual, rather than react to these scenarios on an ad hoc basis.

(Comment 306) Some comments ask us to require that corrective actions include an analysis to determine the root cause of a problem, not only identify it. These comments also ask us to require follow-up actions to ensure the corrective action was effective and assert that although the requirements address the need to reanalyze the food safety plan they do not appear to specifically address a review of the corrective action.

(Response 306) The requests of these comments do not require any revisions to the regulatory text. The rule does not use the term ''root cause'' but it does require the facility to take appropriate action, when necessary, to reduce the likelihood that the problem will recur (see § 507.42(a)(2)(ii)). Root cause analysis is simply part of a common approach to complying with this requirement. (Knowing the root cause is key to reducing the likelihood that a problem will happen again.) The rule also requires a review of records of corrective actions, but does so as a verification activity rather than as part of the corrective action procedures (see § 507.49(a)(4)).

(Comment 307) Some comments ask us to revise the proposed rule to address corrective actions in a more general way and then outline areas where specific corrective action procedures would be helpful, such as for testing programs, in guidance.

(Response 307) The proposed provisions do not prescribe the outcome of the corrective action procedures, but merely direct the facility to the types of actions that the procedures must address. In essence, the proposed provisions already do, as the comments request, address corrective actions in a general way.

(Comment 308) Some comments ask us to specify that the requirements to establish and implement written corrective action procedures also apply when a preventive control is found to be ineffective.

(Response 308) We have not revised the regulatory text as requested by these comments. The appropriate action when a preventive control is found to be ineffective is to reanalyze the food safety plan and to establish and implement a preventive control that is effective, not follow a corrective action procedure. A corrective action procedure is intended to address a problem that happens when following the procedures in a food safety plan that previously was verified to be valid, not to fix problems on an ongoing basis when a preventive control is ineffective (and, thus, the food safety plan is not valid). We agree that some of the steps that apply to corrective actions may need to be taken, such as evaluating affected animal food for safety and ensuring that adulterated animal food does not enter commerce. This is addressed by the provisions for corrective actions in the event of an unanticipated problem (§ 507.42(b)(1)), which require specific corrective actions to be taken (§ 507.42(b)(2)).

(Comment 309) Some comments requests flexibility as every facility is different from the next so prescriptive corrective actions required by rules may not be applicable or possible in all cases. Some commenters requested that documentation be maintained for corrective actions only if the corrective action was made to address an animal food safety issue. Other comments say that the animal food safety plan should outline when a corrective action is required, as well as the procedure to be followed and the requirement should only focus on animal food safety issues and not quality issues.

(Response 309) As stated in Response 304, we have revised the regulatory text to specify that the corrective action procedures are established and implemented based on the nature of the hazard in addition to the nature of the preventive control. We agree that the nature of the hazard plays a key role in the corrective actions that a facility would take. The requirement is intended to address hazards and therefore would not address animal food quality issues unless they would present a hazard (*e.g.,* if insufficient mixing would present the potential for nutrient deficiencies or toxicities). All corrective actions must be documented in records (see § 507.42(d)).

B. Proposed § 507.42(a)(2)—Content of Corrective Action Procedures

We proposed that corrective action procedures must describe the steps to be taken to ensure that: (1) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (2) appropriate action is taken to reduce the likelihood that the problem will recur; (3) all affected animal food is evaluated for safety; and (4) all affected animal food is prevented from entering into commerce, if you cannot ensure that the affected animal food is not adulterated under section 402 of the FD&C Act.

(Comment 310) Some comments assert that the corrective action procedures should not consider food to be ''affected'' if it is immediately subjected to an additional (or repeat) preventive control after determining that the initial preventive control was not properly implemented. These comments discuss an example in which there is a temperature deviation below accepted parameter limits for a given process, and the incorrectly processed product is re-processed correctly, and assert that it would be illogical to consider the food to be ''affected'' in the circumstance. Other comments ask us to modify the requirements to specify that they apply to all affected food ''if any.'' One comment states the use of the term ''all'' with ''affected'' is redundant and may contribute to unwarranted and unnecessary regulatory emphasis and requests that the word ''all'' be removed.

(Response 310) We decline the requests to modify the regulatory text to remove the word ''all'' or specify that

the requirements apply to all affected animal food ''if any.'' Animal food is ''affected'' if a preventive control is not properly implemented during its production. However, the rule does not pre-determine the consequences when animal food is ''affected.'' Instead, the rule provides for the facility to evaluate the affected animal food for safety. If, as in the example described by the comments, the facility reapplies the preventive control such that the animal food is safe and is not adulterated under section 402 of the FD&C Act, there would be no need to take steps to prevent that animal food from entering commerce.

(Comment 311) Some comments ask us to provide that requirements for corrective actions be principle-based (*e.g.,* affected product containment, control restored to operation before commencing production) rather than prescriptive.

(Response 311) The requirements for corrective actions established by this rule are principle-based in that they require the facility to describe the steps it will take rather than prescribe the steps it will take.

(Comment 312) Some comments ask us to revise the provision to make resampling and/or retesting one of the first steps in a corrective action procedure to take into account human error. These comments assert that mishandling during sampling, transport, and testing can contribute to a false positive result and that if the results of a followup test are negative, then the previous test could be considered an anomaly that could be ignored.

(Response 312) We decline this request. We disagree that an appropriate approach to positive findings of a test for contamination is to resample and retest and to consider positive findings to be an anomaly if subsequent test results are negative. Many animal food products are not homogeneous and contamination is localized. Even for homogeneous animal food products (such as liquids), the problem could be the sensitivity of the method if the level of contamination is low. For further discussion on our current thinking on presumptive positive results and additional testing, see our guidance entitled ''Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods'' (Ref. 48).

C. Proposed § 507.42(b)—Corrective Action in the Event of an Unanticipated Problem

With some exceptions, we proposed that you must take corrective action to identify and correct a problem, reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and, as necessary, prevent affected animal food from entering commerce as would be done following a corrective action procedure if any of the following circumstances apply: (1) A preventive control is not properly implemented and a specific corrective action has not been established; (2) a preventive control is found to be ineffective; or (3) a review of records finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions. We also proposed that if any of these circumstances apply, when appropriate you must reanalyze the food safety plan to determine whether modification of the food safety plan is required.

(Comment 313) Some comments ask us to delete the proposed requirement that a facility must reanalyze the food safety plan in the event of an unanticipated problem. These comments argue that FSMA does not specify reanalysis in the event of an unanticipated problem. In addition, these comments assert that the proposed requirement for reanalysis in the event of an unanticipated problem would be redundant with the proposed requirements for reanalysis as a verification activity (proposed § 507.50) and would not add value for food safety. These comments also assert that the term ''problem'' is ambiguous and ask us to replace ''problem'' with ''food safety issue'' if we retain the provision in the final rule.

(Response 313) We acknowledge that section 418 of the FD&C Act does not explicitly specify that a facility must reanalyze its food safety plan in the event of an unanticipated problem. In the 2014 supplemental notice, we clarified that reanalysis would be conducted ''when appropriate.'' For example, if a problem occurs because personnel did not understand the procedures or carry out the procedures correctly, additional training for applicable personnel may be warranted, but there likely would be no need to reanalyze the food safety plan.

We disagree that the term ''problem'' is ambiguous. The term ''problem'' signifies that something is wrong, whereas the term suggested by the comments (*i.e.,* ''issue'') may or may not signify that something is wrong. We agree that the requirements are directed to problems related to animal food safety.

We agree that there is a relationship between the requirements for corrective actions in the event of an unanticipated food safety problem and the requirements for reanalysis. To reduce redundant regulatory text, in the 2014 supplemental notice we proposed to modify the regulatory text of the requirements for reanalysis to specify that reanalysis is required when appropriate after an unanticipated food safety problem, and we are establishing that modified provision in this final rule. Importantly, the provisions for reanalysis continue to require reanalysis when a preventive control is found to be ineffective. We are not aware of any circumstances in which it would not be appropriate to reanalyze the food safety plan if a preventive control is found to be ineffective.

(Comment 314) Some comments assert that the word ''specific'' is not appropriate as a modifier for ''corrective action procedure'' because many preventive controls will have corrective action procedures that allow flexibility based upon the nature of the hazard and control. These comments also state that the term ''specific'' in this context is more appropriate for a CCP control in a HACCP system.

(Response 314) We have revised the regulatory text to delete the word ''specific.''

(Comment 315) Some comments ask us to emphasize that reanalysis is required only when a combination of two events occurs (*i.e.,* a preventive control is not properly implemented and the facility has not established a corrective action procedure).

(Response 315) In the 2014 supplemental notice, we proposed revisions to the regulatory text to clearly specify the circumstances requiring reanalysis. One such circumstance is when a preventive control is not properly implemented and a corrective action procedure has not been established, as stated in § 507.42(b)(1)(i)). The final provision includes the revisions included in the 2014 supplemental notice and is consistent with the request of these comments.

(Comment 316) Some comments ask us to add that corrective actions in the event of an unanticipated problem also apply when a preventive control is ''missing.''

(Response 316) We have revised the regulatory text to require corrective actions whenever a preventive control, combination of preventive controls, or the food safety plan as a whole, is ineffective. (See § 507.42(b)(1)(ii).) In assessing what the comment might mean by a preventive control that is ''missing,'' we concluded that an unanticipated problem could, in some cases, mean that a combination of

preventive controls, or the facility's food safety plan as a whole (rather than a single preventive control), simply was not effective. If this is the case, reanalysis would be appropriate, and we also have modified the requirements for reanalysis to specify that a facility must reanalyze its food safety plan whenever it finds that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(Comment 317) Some comments ask us to replace the term ''reanalyze'' with the term ''reassess.''

(Response 317) We decline this request. Reanalysis goes beyond assessing the validity of a preventive control or food safety plan to control a hazard. Reanalysis can also include assessing whether all hazards have been identified, whether established procedures are practical and effective, and other factors.

D. Proposed § 507.42(c)—Corrections

We proposed that you do not need to comply with the requirements for corrective actions and corrections for conditions and practices that are not consistent with specified sanitation if you take action, in a timely manner, to correct such conditions and practices.

(Comment 318) Some comments support our proposal to provide for corrections, rather than corrective actions, for sanitation controls in some circumstances. Other comments assert that situations in which ''corrections'' can be applied are not limited to sanitation controls and could include actions to address other preventive controls such as preventive maintenance controls or CGMPs. As discussed in Comment 82, some comments emphasize the importance of distinguishing between the terms ''correction'' and ''corrective action.''

(Response 318) We have revised the regulatory text, with associated editorial revisions and redesignations, to provide for corrections, rather than corrective actions and corrective action procedures, for minor and isolated problems that do not directly impact product safety. As discussed in Response 82, we also have defined the term ''correction'' to mean an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).

E. Proposed § 507.42(d)—Records

We proposed that all corrective actions (and, when appropriate, corrections) must be documented in records and that these records are subject to the verification requirements in §§ 507.45(a)(3) and 507.49(a)(4)(i). We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

XXXII. Subpart C: Comments on Proposed § 507.45—Verification

In the 2013 proposed preventive controls rule for animal food, we proposed verification activities that would include validation, verification of monitoring, verification of corrective actions, verification of implementation and effectiveness, written procedures, reanalysis, and documentation of all verification activities. We also requested comment on whether we should specify the verification activities that must be conducted for verification of monitoring (78 FR 64736 at 64796) and for verification of corrective actions (78 FR 64736 at 64796), and if so, what verification activities should be required.

To improve clarity and readability, in the 2014 supplemental notice we proposed to move the more extensive verification requirements for validation, implementation and effectiveness, and reanalysis from the single proposed section (proposed § 507.45) to separate sections (proposed §§ 507.47, 507.49, and 507.50, respectively). In addition, to address comments that asked us to provide more flexibility to facilities, including flexibility in determining whether and how to conduct verification activities, in the 2014 supplemental notice we proposed that the verification activities be performed ''as appropriate to the preventive control.''

In this section, we discuss the proposed requirements for verification of monitoring, verification of corrective actions, and documentation of verification activities. See sections XXXIII through XXXV for comments on the proposed requirements for validation, verification of implementation and effectiveness, written procedures, and reanalysis. See tables 17, 18, and 19 for a summary of the revisions to those proposed requirements.

Some comments support the proposed requirements for verification of monitoring, verification of corrective actions, and documentation of verification activities without change. For example, comments support the documentation of verification activities (see section XXXI.C). In the following paragraphs, we discuss comments on the flexibility provided for a facility to conduct verification activities as appropriate to the nature of the preventive control. We also discuss comments that address our request for comment on whether we should revise the regulatory text to specify the verification activities that must be conducted for verification of monitoring and for verification of corrective actions, or express concern that the requirements as proposed are too prescriptive. After considering these comments, we have revised the verification requirements described in § 507.45 as shown in table 16.

TABLE 16—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VERIFICATION

Section	Description	Revision
507.45(a)	Flexibility to conduct verification activities.	Provide that verification activities take into account both the nature of the preventive control and its role in the facility's food safety system.

A. Flexibility in Requirements for Verification

(Comment 319) Some comments support the flexibility provided by use of the phrase ''as appropriate to the preventive control'' in the requirement that verification activities must include, as appropriate to the preventive control, specified verification activities (*i.e.,* validation, verification that monitoring is being conducted, verification that appropriate decisions about corrective actions are being made, verification of implementation and effectiveness, and reanalysis). These comments emphasize that verification activities must be tailored to the preventive control and assert that the use of the word ''must'' is potentially confusing in light of this flexibility, *e.g.,* because not all preventive controls must be validated

for food safety, and those preventive controls that do not need monitoring would not need verification of monitoring. Other comments ask us to allow facilities flexibility to verify that preventive controls are effective in the manner prescribed by FSMA, *i.e.,* such controls should be deemed to be effective by an appropriate means as determined and supported by the facility within its food safety plan.

(Response 319) The provisions for preventive control management components make clear that all preventive control management components, including verification, are required as appropriate to ensure the effectiveness of the preventive control, taking into account the nature of the preventive control and its role in the facility's food safety system (see § 507.39). Likewise, the provisions for each of the preventive control management components (*i.e.,* monitoring, corrective actions and corrections, and verification) individually provide flexibility, either by specifying that the provisions apply as appropriate to the nature of the preventive control and its role in the facility's food safety system (*i.e.,* for monitoring and verification) or both the nature of the preventive control and the nature of the hazard (*i.e.,* for corrective actions and corrections). The word ''must'' specifies the type of activities that a facility can use to satisfy the requirements for a particular preventive control management component.

We are retaining the term ''must.'' However, we agree that the rule should provide flexibility for additional verification of implementation and effectiveness. To provide that additional flexibility, we have revised the specific requirements for verification of implementation and effectiveness to provide for other activities appropriate for verification of implementation and effectiveness (see § 507.49(a)(5)). As a conforming revision, we have revised the requirement for review of records to include a review of records of other verification activities within a reasonable time after the records are created (see § 507.49(a)(4)(ii)).

B. Proposed § 507.45(a)—Verification Activities

1. Proposed § 507.45(a)(1)—Validation

We proposed that verification activities must include, as appropriate to the preventive control, validation in accordance with § 507.47. See section XXXIII for comments on validation as a verification activity.

2. Proposed § 507.45(a)(2)—Verification of Monitoring

We proposed that verification activities must include, as appropriate to the preventive control, verification that monitoring is being conducted in accordance with § 507.40. We requested comment on whether we should specify the verification activities that must be conducted for monitoring, and if so, what verification activities should be required.

(Comment 320) Comments that address our request for comment on whether we should specify the verification activities that must be conducted for monitoring ask us to not do so because this prescriptive approach would be too limiting. These comments ask us to instead provide flexibility for the facility to determine the appropriate verification activities.

(Response 320) We agree that we should provide flexibility for the facility to determine these verification activities, and are not specifying the verification activities that must be conducted for monitoring.

3. Proposed § 507.45(a)(3)—Verification of Corrective Actions

We proposed that verification activities must include, as appropriate to the preventive control, verification that appropriate decisions about corrective actions are being made in accordance with § 507.42. We requested comment on whether this section should specify the verification activities that must be conducted for corrective actions, and if so, what verification activities should be required.

(Comment 321) Some comments ask us not to specify the verification activities that must be conducted for corrective actions because this approach would be too limiting. These comments ask us to instead provide flexibility for the facility to determine the appropriate verification activities.

(Response 321) We agree that we should provide flexibility for the facility to determine the appropriate verification activities for corrective actions, and are not specifying the verification activities that must be conducted for corrective actions.

4. Proposed § 507.45(a)(4)—Verification of Implementation and Effectiveness

We proposed that verification activities must include, as appropriate to the preventive control, verification of implementation and effectiveness in accordance with § 507.49. See section XXXIV for comments on verification of implementation and effectiveness.

(Comment 322) One comment contends that animal food facilities should not be required to conduct product testing or environmental monitoring to verify implementation and effectiveness of preventive controls. The comment states that product testing and environmental monitoring at a facility that is not using appropriate controls will not normally discover potential hazards. The comment also states that all of the safety requirements necessary to protect the health of animals are already being met because this is necessary as a good business practice and is required by customers.

(Response 322) When a food safety plan is completed by a preventive controls qualified individual, they must ensure that the preventive controls in place are adequate to provide assurance that any hazards requiring a preventive control will be significantly minimized or prevented. We have provided adequate flexibility for a preventive controls qualified individual in an animal food facility to determine if product testing or environmental monitoring is necessary considering the facility, the animal food, the nature of the preventive control, and its role in the facility's food safety system (for further discussion see section XXXIV.C and XXXIV.E).

We disagree that all food safety measures necessary to protect the health of animals are always being followed. Each year, animal food is recalled, often due to a hazard that could cause serious health consequences or death. Animal food from a facility that is required to register and for which there is a reasonable probability that use of or exposure to the food would cause serious adverse health consequences or death to humans or animals is subject to reporting to FDA under section 417 of the FD&C Act (Reportable Food Registry).

5. Proposed § 507.45(a)(5)—Reanalysis

We proposed that verification activities must include, as appropriate to the preventive control, reanalysis in accordance with § 507.50. See section XXXV for comments on reanalysis as a verification activity.

C. Proposed § 507.45(b)—Documentation of Verification Activities

We proposed that all verification activities must be documented in records. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

D. Comments on Potential Requirements Regarding Complaints

We requested comment on whether and how a facility's review of

complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards (78 FR 64736 at 64809).

(Comment 323) Some comments ask us to require review of consumer complaints as a verification activity and note that our HACCP regulations for seafood and juice require that verification activities include a review of consumer complaints to determine whether they relate to the performance of the HACCP plan or reveal the existence of unidentified CCPs. Some comments note circumstances in which consumer complaints have identified food safety problems that resulted in a company report to the RFR. Other comments assert that review of customer complaint data should not be required in the rule to verify that a facility's preventive controls are effectively minimizing the occurrence of hazards.

Some comments state that the frequency and type of complaints a facility receives is a very good indicator of the underlying issues associated with food production, reviewing these records would provide valuable insight into the type of issues that should be investigated, and this type of verification activity could therefore be extremely effective with little to no cost because the facility would already be performing this type of activity. Some comments state that many foodborne outbreaks have been identified through complaints and a review of complaints is a critical component of a food safety system. One comment says that many times customer complaints may be the first and only clue that problems exist in animal food because animal illnesses are not subject to the same reporting requirements as human illnesses, resulting in a much weaker basis for identifying, tracing, and correcting foodborne problems.

Other comments state that a food safety review of complaints is a prudent part of a food safety program but that the value of such a review is in providing information and feedback for continuous improvement of the food safety management system rather than as a verification of preventive controls. These comments caution against use of consumer complaints as a regulatory requirement for verification of the food safety plan because most complaints relate to product quality. If such a requirement is nonetheless established in the final rule, these comments recommend that the rule only require followup and documentation for the rare occurrences where consumer complaints relate to food safety issues.

Other comments ask us not to require review of complaints as a verification activity. Some of these comments assert that complaints rarely relate to food safety or yield information that leads to discovery of a food safety issue. Some comments assert that requiring review of consumer complaints could result in unnecessary time and effort being spent on an activity with a limited correlation to food safety. Some comments assert that the provision would provide FDA access unnecessarily to all complaint files and lead to unproductive and subjective evaluations as to whether a given complaint pertains to the performance of the food safety plan. Other comments assert that complaints would be acted upon immediately for business reasons, and that waiting to react to complaints until conducting a review of records as a verification activity would be too late. Other comments assert that complaints are sensitive business information. Other comments assert that some consumer complaints are false or emotional (rather than factual) and have no place in development of preventive controls. Some comments assert that FSMA does not expressly direct us to require review of complaints. Some comments assert that review of complaints is not a precise scientific process, and that consumer comments are often open to different interpretations.

Some comments discuss the feasibility of consumer complaint review. Comments state that consumer complaint records are often kept at a corporate level rather than at the individual facility. One comment requests mandatory complaint monitoring for animal food manufacturers. One comment points out FDA already has access to records, including complaint files, associated with animal food, which the Agency reasonably believes to be adulterated and presenting a threat of serious adverse health consequences.

(Response 323) We are not establishing a requirement for a review of complaints as a verification activity. We agree that review of complaints is more likely to be useful in providing information and feedback for continuous improvement of the food safety system rather than as a verification of preventive controls. However, we encourage facilities to do such a review, as they occasionally do uncover animal food safety issues.

XXXIII. Subpart C: Comments on Proposed § 507.47—Validation

We proposed to establish requirements for validation of preventive controls. Some comments support the proposed requirements without change. For example, some comments agree that validation must be performed by (or overseen by) a preventive controls qualified individual and that some preventive controls (*e.g.,* sanitation controls and recall plans) do not require validation. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 17, with editorial and conforming changes as shown in table 31.

TABLE 17—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VALIDATION

Section	Description	Revision
507.47(a)	Flexibility for validating preventive controls.	Provide that validation be conducted as appropriate to both the nature of the preventive control and its role in the facility's food safety system.
507.47(b)(1)	Circumstances requiring validation	Provide that, when necessary to demonstrate the control measures can be implemented as designed, validation may be performed (1) Within 90 calendar days after production of the applicable animal food first begins or (2) within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification.

TABLE 17—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VALIDATION—Continued

Section	Description	Revision
507.47(b)(1)	Circumstances requiring validation	Add an additional circumstance requiring validation, *i.e.*, whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards requiring a preventive control.
507.47(c)	Preventive controls that do not require validation.	Clarify that a list of preventive controls that do not require validation is not an exhaustive list.

A. Flexibility in the Requirements To Validate Preventive Controls

With some exceptions (see discussion of proposed § 507.47(b)(3) in section XXXIII.D), we proposed that you must validate that the preventive controls identified and implemented in accordance with proposed § 507.36 to control the significant hazards are adequate to do (proposed § 507.47(a)).

(Comment 324) Some comments assert that the regulatory text is in conflict with the preamble discussion in the 2014 supplemental notice because the regulatory text (*i.e.,* ''(e)xcept as provided by . . .'') narrowly provides exceptions only for validation of sanitation controls, supplier controls, and the recall plan, whereas the preamble discussion provides other examples of preventive controls that would not require validation (*i.e.,* zoning, training, preventive maintenance, and refrigerated storage). These comments also assert that although the regulatory text specifies that validation requirements apply ''as appropriate to the nature of the preventive control,'' that phrase could be interpreted to mean that only the validation act itself can be tailored and that the facility does not have the flexibility to conclude that validation isn't necessary.

Some comments assert that the proposed regulatory text would prevent us from requiring validation of specific sanitation controls where it may be prudent to do so, either now or in the future as a result of a newly identified hazard, or the development of a tool, such as a test method, that would enable validation of the control for the specific hazard.

(Response 324) We have deleted ''except as provided by paragraph (b)(3) of this section'' from proposed § 507.47(a) to remove the limitation seen by the comments on the exceptions to the requirement for validation of preventive controls. We also have revised the regulatory text of § 507.47(c) to provide that a facility does not need to validate other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system. We specified that the determination that validation is not required must be made by the preventive controls qualified individual to emphasize that specialized experience is necessary to evaluate whether validation is required. We made a conforming revision to the list of responsibilities of the preventive controls qualified individual (see § 507.53(a)).

(Comment 325) Some comments ask us to separate requirements for validation from requirements for verification because verification and validation are two different concepts and combining them is confusing. One comment said that we reversed the definitions of validation and verification, compared to the common use of the terms in HACCP activities. Some comments point out that while section 418(f)(1) of the FD&C Act explicitly requires verification, it does not require validation. Some of these comments assert that our proposed requirements for validation exceed the mandate of FSMA while others argue that the lack of explicit language in section 418 of the FD&C Act gives us legal flexibility in determining whether and how to require validation.

(Response 325) Our approach is consistent with section 418 of the FD&C Act. Section 418(f)(1) of the FD&C Act requires verification of the preventive controls, and validation is an element of verification (see both the NACMCF HACCP guidelines (Ref. 49) and our HACCP regulation for juice (§ 120.3(p)). We agree that the purpose of validation is different from the purpose of other verification activities, and we have revised the definitions of both terms to make this clearer. Although we are establishing a separate regulatory section for the validation requirements, we did so to improve clarity and readability rather than as a substantive change relevant to the issues discussed in these comments. (See Response 75.)

(Comment 326) Some comments assert that validation is more appropriate for a HACCP regulation and that requiring the validation of all preventive controls does not reflect the flexibility mandated by section 418(n)(3)(A) of FSMA. Other comments assert that effective preventive measures may be identified in the future that are not amenable to validation and it would be counterproductive for them not to be employed in food safety plans because they cannot meet the validation requirements. These comments explain that certain control measures are not suitable for validation activities due to the nature of the activity or previous validation by another entity (*e.g.,* a supplier).

(Response 326) The 2013 proposed preventive controls rule for animal food would not have required the validation of all preventive controls. For example, we specifically proposed that the validation of preventive controls need not address sanitation controls and the recall plan. To emphasize that a facility has flexibility in determining which other preventive controls require validation, in the 2014 supplemental notice we revised the proposed regulatory text to require validation ''as appropriate to the nature of the preventive control.'' See Response 324 for additional revisions we have made to the regulatory text to provide flexibility for a facility to determine that validation is not necessary.

(Comment 327) Some comments ask us to allow validation of the whole system instead of individual controls.

(Response 327) See the discussion of the definition of validation in Response 75. Under the definition, validation can be directed to a control measure, combination of control measures, or the food safety plan as a whole.

(Comment 328) Some comments ask us to align validation requirements with the relative risk of operations.

(Response 328) Validation requirements apply only to preventive controls that are established and implemented based on the outcome of a hazard analysis, which requires consideration of risk. We also require

validation as appropriate to the nature of the preventive control and its role in the facility's food safety system. This provides flexibility with respect to validation and allows consideration of risk.

(Comment 329) Some comments ask us to provide guidance and clarification on topics relevant to validation, especially for small facilities that may lack the resources needed to generate studies and scientific data to validate processes. Some comments ask us to clarify our expectations for a validated process and on conducting studies for validation purposes. Some comments ask us to provide resources for validation, noting that some preventive controls will be difficult to validate and that no scientific research or data are available for certain controls. Some comments indicate that validation information provided by FDA should be in the form of non-binding guidance documents. Some comments ask us to delay enforcement for the validation requirements until a readily accessible repository of validated processes, and scientific and technical information, can be created to assist stakeholders in complying with the validation requirements.

(Response 329) We intend that the guidance we are developing will address topics such as those recommended in the comments. (See Response 1). In addition, the FSPCA is developing information for training, which may be useful to animal food facilities. We are not requiring facilities to comply with the requirements of subparts C and E of this rule, including the validation requirements, for 2, 3, or 4 years depending on the size of the facility. We expect that segments of the animal food industry will work together and with the FSPCA to develop scientific and technical information that can be used as evidence to validate a variety of preventive controls, and will be helpful to facilities.

(Comment 330) Some comments indicate that the rule lacked specifications for, and was unclear on, the process that FDA would utilize to approve or accept validation data and/or studies. Some comments ask us to develop a mechanism for industry to make sure their approach and studies meet the requirements of the rule, such as certification of process authorities or the establishment of a liaison between FDA and industry to ensure validation protocols are in compliance.

(Response 330) As discussed in Response 1, we are developing several guidance documents within FDA, including guidance on validation. In addition, as part of a collaborative effort with the FSPCA we are obtaining technical information useful for developing guidelines for preventive controls and outreach to industry, and we intend that effort to include guidance on approaches to satisfy the validation requirements of the rule. We do not intend to develop a mechanism for certification of process authorities or establish a liaison between FDA and industry to ensure validation protocols are in compliance. The guidance we are developing on validation should help industry determine whether their validation approaches are likely to be acceptable to us.

B. Proposed § 507.47(b)(1)—When Validation Must Be Performed and Role of Preventive Controls Qualified Individual in Validation

We proposed that validation of the preventive controls must be performed by (or overseen by) a preventive controls qualified individual prior to implementation of the food safety plan (or, when necessary, during the first 6 weeks of production) and whenever a reanalysis of the food safety plan reveals the need to do so.

(Comment 331) Some comments ask us to clarify whether an individual attending food safety training by an entity such as a cooperative extension or a State department of agriculture could be a ''preventive controls qualified individual'' for the purpose of performing or overseeing the validation of preventive controls.

(Response 331) See the discussion in section XXXVII.B for additional information about training applicable to a preventive controls qualified individual. We have not specified additional requirements for a preventive controls qualified individual with respect to validation. A person may be a preventive controls qualified individual through job experience, as well as training. Food safety training provided by an entity such as a cooperative extension specialist or a State department of agriculture could be appropriate training for many of the functions of the preventive controls qualified individual if the training is consistent with the standardized curriculum being developed by the FSPCA.

(Comment 332) Some comments question whether 6 weeks is enough time to perform all applicable validation studies that would address the execution element of validation. Some comments ask us to explain the basis for the proposed 6-week timeframe. Some comments ask us to align with the 90-day timeframe in the FSIS Validation Guidelines (Ref. 50). Some comments note that the seasonal nature of production of some food products may make it impractical to perform all required validations within 6 weeks. Some comments suggest that validation be performed within a specified number of production batches, such as 10 production batches. Some comments emphasize the need for flexibility and ask us to both adopt a 90-day timeframe and provide for a longer timeframe with a written justification, or provide for ongoing evidence of process validation. One comment recommends removing a required timeframe for validation or providing a compliance extension until such time as we could better support the requirements, such as in guidance. One comment asserts that the timeframe should be prior to implementation of the food safety plan. Some comments ask as us to specify that validation be performed within a reasonable time as justified by the preventive controls qualified individual. Some comments ask for more time for small businesses to perform validation studies.

(Response 332) We note that the 90-day timeframe for validation is established in FSIS' regulations at 9 CFR 304.3(b) and (c) and 9 CFR 381.22(b) and (c) (Conditions for receiving inspection for meat and meat products and poultry and poultry products, respectively). The FSIS Validation Guidelines are a companion to those regulations. We have revised the regulatory text, with associated editorial changes, to make two changes to the proposed 6-week timeframe for validation of preventive controls. First, we have adopted the 90-day timeframe already established in the FSIS' regulations by specifying that when necessary to demonstrate the control measures can be implemented as designed, validation may be performed within 90 days after production of the applicable animal food first begins. Although we had proposed a 6-week timeframe based on the 3 to 6 week timeframe suggested in the Codex Guidelines for the Validation of Food Safety Control Measures (Ref. 22), we agree that practical limitations associated with the production of some animal food products may make it difficult to perform validation within 6 weeks. The 90-day timeframe in FSIS' regulations, and incorporated into the FSIS Validation Guidelines, reflects more than 15 years of experience with validating HACCP systems for meat and poultry. Although we have provided for validation to be performed within 90 days after production of the applicable food first begins, we do not believe it would take a full 90-days of production

to determine whether the facility can provide assurances that a control measure is working as intended to control the hazard.

Second, we have provided for validation within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable animal food first begins. We acknowledge that practical limitations such as those described in the comments could prevent a facility from performing the validation within 90 days after production of the applicable animal food first begins. A timeframe that exceeds 90 days after production of the applicable animal food first begins will be the exception rather than the norm and we are requiring that the preventive controls qualified individual provide (or oversee the preparation of) a written justification for such a timeframe. We made a conforming revision to the list of responsibilities of the preventive controls qualified individual (see § 507.53(a)).

(Comment 333) Some comments ask us to add another circumstance when validation would be required, *i.e.,* whenever a change is made to the control being applied.

(Response 333) We have revised the regulatory text to require validation whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards requiring a preventive control. Under this provision, a facility would revalidate a preventive control if, for example, a different type of equipment is used to deliver a heat process, because it would be necessary to determine that the new equipment can consistently achieve the required temperature and time of the process. However, a facility would not need to revalidate a preventive control if, for example, a thermal process is changed by increasing the time or temperature, because a less stringent thermal process would already have been validated.

(Comment 334) Some comments ask us to require validation both before production and 6 weeks after production begins.

(Response 334) We decline this request. A facility has flexibility to perform validation as appropriate to the nature of the preventive controls, whether before production (*e.g.,* by obtaining and evaluating generally available scientific and technical information or by conducting studies), after production begins (to demonstrate the control measures can be implemented as designed during full-scale production), or both.

C. Proposed § 507.47(b)(2)—What Validation Must Include

We proposed that the validation of preventive controls must include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the significant hazards.

(Comment 335) Some comments assert that our discussion of validation refers to ''scientific proof'' for the validation of a processing step and ask us to define what is and is not considered scientific proof for validation.

(Response 335) We used terms such as ''scientific and technical information'' and ''scientific and technical basis'' rather than ''scientific proof'' when discussing validation. For information about what we mean by ''scientific and technical information,'' (see 78 FR 64736 at 64794 through 64795).

(Comment 336) Some comments ask us to clarify expectations of validations for basic sanitary processes. Another comment asks us to exempt the validation of CGMPs.

(Response 336) The requirements for validation only apply to preventive controls. Any practice governed by CGMPs only requires validation if a facility identifies that practice as a preventive control for a hazard. To the extent that the comment is referring to sanitary practices governed by CGMPs (such as in § 507.19), the validation requirements would not apply. To the extent that the comment is referring to sanitation controls established as a preventive control, those sanitation controls are excluded from the validation requirements (see § 507.47(c)).

(Comment 337) Some comments ask that we not require further validation of well-accepted preventive controls, such as refrigeration temperature.

(Response 337) A facility may rely on generally available scientific and technical information to demonstrate the adequacy of controls such as refrigeration but must obtain that information and establish it as a record (see § 507.45(b)).

(Comment 338) Some comments express concern that specific methods are not available to enable validation. Some comments express concern that the requirement to ''conduct studies'' might be intended, or could be interpreted, to mean that firms are required to develop or validate analytical methods (either in general or for specific food matrices). These comments assert that any such requirement would incur extreme costs and burdens without delivering commensurate public health benefits.

(Response 338) We do not intend the requirement to ''conduct studies'' to mean that firms are required to develop or validate analytical methods.

(Comment 339) Some comments recommend validation via indirect methods such as scientific publications, government documents, predictive modeling and other technical information from equipment manufacturers and other sources. Other comments assert that there are a variety of circumstances in which the collection and evaluation of scientific and technical information is not necessary (*e.g.,* the use of sieving or metal detectors to control physical hazards).

(Response 339) See Responses 324 and 326. We agree that not all preventive controls require validation, and the facility has flexibility to take into account the nature of the preventive control when determining whether to perform validation. The regulatory text, which provides for scientific and technical evidence that a control measure is capable of effectively controlling the identified hazards, provides for the use of ''indirect methods'' as recommended by the comments. However, even when sources such as scientific publications are the basis for validation, studies may be needed to demonstrate that the process used can be implemented in the facility to control the hazard.

D. Proposed § 507.47(c)(3)—Preventive Controls for Which Validation Is Not Required

We proposed that validation need not address sanitation controls, the recall plan, and the supplier program (which we now refer to as the ''supply-chain'' program).

(Comment 340) Some comments ask us to eliminate the specific list of controls that are excluded from the validation requirement and instead revise the regulatory text to provide the facility with flexibility to determine when validation is appropriate.

(Response 340) As discussed in Response 324, we have deleted ''except as provided by paragraph (b)(3) of this section'' from proposed § 507.47(a) to remove the limitation seen by the comments on the exceptions to the requirement for validation of preventive controls. We also have revised the

regulatory text of § 507.47(c) to provide that a facility does not need to validate other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system. We see no reason to also eliminate the list of those controls for which we have already determined that validation is not necessary, and require each facility to develop its own rationale for concluding that validation is not necessary based on the nature of these preventive controls. The rule would not prevent a facility from validating one of these preventive controls, such as a sanitation control, if it chooses to do so.

XXXIV. Subpart C: Comments on Proposed § 507.49—Verification of Implementation and Effectiveness

We proposed that you must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. We proposed that to do so you must conduct specified activities (*i.e.,* calibration, product testing, environmental monitoring, and review of records) as appropriate to the facility, the animal food, and the nature of the preventive control. We also proposed that you must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments, product testing, and environmental monitoring.

Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision. In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 18.

TABLE 18—REVISIONS TO THE PROPOSED REQUIREMENTS FOR VERIFICATION OF IMPLEMENTATION AND EFFECTIVENESS

Section	Description	Revision
507.49(a)	Flexibility in the requirement to conduct activities to verify implementation and effectiveness.	Provide that activities for verification of implementation and effectiveness take into account both the nature of the preventive control and its role in the facility's food safety system.
507.49(a)(1)	Verification of implementation and effectiveness for process monitoring instruments and verification instruments.	Provide for accuracy checks in addition to calibration.
507.49(a)(4)(i)	Timeframe for review of records of monitoring and corrective action records.	Provide for records review within 7 working days after the records are created, or within or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification.
507.49(a)(5)	Other activities appropriate for verification of implementation and effectiveness.	Clarify that there could be alternative verification activities of implementation and effectiveness other than those that we specify in the rule.
507.49(b)	Written procedures for verification of implementation and effectiveness.	Clarify that written procedures for verification of implementation and effectiveness are established and implemented as appropriate to the role of the preventive control in the facility's food safety system, as well as appropriate to the facility, the animal food, and the nature of the preventive control.
507.49(b)(1)	Written procedures for verification of implementation and effectiveness for process monitoring instruments and verification instruments.	Require written procedures for accuracy checks in addition to calibration.

A. Flexibility in the Requirement To Conduct Activities To Verify Implementation and Effectiveness

We proposed that you must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards by conducting specified activities as appropriate to the facility, the animal food, and the nature of the preventive control. We proposed to specify the following verification activities: (1) Calibration; (2) product testing; (3) environmental monitoring; and (4) review of records.

In the following paragraphs, we discuss comments generally directed to the need for a facility to have flexibility to apply these requirements (particularly the requirements for product testing and environmental monitoring) in a manner that works best for the facility in light of its animal food products and the nature of the preventive controls that would be verified. In sections XXXIV.B through XXXIV.F, we discuss the requirements for calibration, product testing, environmental monitoring, and review of records more specifically.

(Comment 341) Some comments express support for the flexibility provided by specifying that verification activities must be conducted ''as appropriate to the facility, the animal food, and the nature of the preventive control.'' Some comments state that the proposed provision means that, based on risk, an animal food manufacturer could decide whether or not to do product testing and, when applicable, the type of test and the testing frequency. One comment says the provision will have limited value where the presence of some levels of pathogens is expected and is not necessarily an animal food safety problem. Some comments agree with the proposed provisions because they address product testing through flexible written procedures that consider both testing and corrective action plans rather than through mandatory or prescribed requirements. Other comments agree with the proposed provisions because they require facilities to develop and use testing programs that are tailored to their facility, equipment, processes, products, and other specific circumstances, and do not prescribe specific requirements for testing, such as finished product testing. Some comments state that product testing may

not be effective in identifying the acceptability of a specific ingredient or finished product lot on any given day, but it can help assess and verify the effectiveness of a food safety plan as a whole and the facility's capability to consistently deliver against it.

Some comments assert that the preamble discussion in the 2014 supplemental notice is in conflict with the proposed regulatory text and ask us to modify the regulatory text to provide the flexibility we signaled in that supplemental notice. These comments express concern that the term ''must'' (*i.e.,* ''you must conduct activities that include the following'') could be interpreted to mean that activities listed in the regulatory text (in particular, product testing and environmental monitoring) are always required in some form. Some comments ask us to clarify whether product testing and environmental monitoring are required or optional. Other comments assert that facilities should have the flexibility to determine whether to conduct product testing and environmental monitoring based on a risk assessment. Some comments assert that there are circumstances (such as unpackaged animal food; ingredients for animal food stored in vented or open areas, in oilseed production; and rendering) where these tests would not be necessary. Some comments assert that a determination to conduct environmental monitoring should be on a case-by-case basis and that other verification activities may be used (such as process verifications or testing of intermediates) to verify implementation and effectiveness. Other comments ask us to exempt operations when their hazard analysis appropriately concludes that there is no foreseeable risk. One comment says FDA should not require routine monitoring for feed mills unless they manufacture pet food.

One comment says environmental monitoring should not be required as a verification activity for significant hazards as other controls can be used and environmental monitoring will impose undue burdens and costs to industry. Many comments state that environmental monitoring requirements should only be applied to ''significant hazards,'' if any, that are present within the firm's operation, and as with product testing, animal food facilities must be provided the flexibility to tailor their environmental monitoring programs based on risk. Comments note that in cases where the animal food is likely to undergo further processing that would minimize or eliminate any microbiological hazards, environmental pathogens would not be a significant hazard and such facilities could focus their resources on other controls. One comment says it does not agree that the potential for later processing mitigates the need for environmental monitoring because processes such as pelleting reduce but do not entirely eliminate pathogens.

(Response 341) The provisions for verification provide flexibility by specifying that they apply as appropriate to the nature of the preventive control and its role in the facility's food safety system. As noted by some comments, the provisions address testing through flexible written procedures that allow facilities to develop and use testing programs that are tailored to their facility, equipment, processes, products, and other specific circumstances. We agree that an appropriate outcome of the hazard analysis for some facilities will be that product testing and environmental monitoring are not required; it is not necessary to grant an ''exemption'' to allow a facility to achieve this outcome. For example, environmental monitoring would be required to verify effectiveness of sanitation controls when 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 because such environmental monitoring is appropriate to the facility (one manufacturing animal food), the food (such as a dry (extruded) pet food exposed to the environment), and the nature of the preventive control (sanitation controls). Animal food such as dry and raw pet food and pet treats are among the products for which manufacturing operations might need to have an environmental monitoring program when such animal food is exposed to the environment.

We discuss product testing for microbial pathogens in another FDA memorandum, including the use of pathogens and indicator organisms and microbial testing of foods for process control and for problem solving (Ref. 52). The circumstances in which product testing would be required are dependent on a variety of factors as described in the Appendix to the 2013 proposed preventive controls rule for animal food (78 FR 64736 at 64836). As with environmental monitoring, product testing must be conducted as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system. For example, a raw material or other ingredient added to an animal food after a pathogen ''kill step'' must be tested before use when the raw material or other ingredient has been associated with a pathogen and has not been treated to significantly minimize or prevent that pathogen (*e.g.,* poultry based flavoring spray applied on dry pet food). Product testing would be required because it is appropriate to the facility (one making an animal food), the food (pet food), and the nature of the preventive control (there is no control applied to the poultry based flavoring spray).

When process control testing for an indicator organism, or environmental monitoring for an indicator organism, indicates an animal food (*e.g.,* dry pet food) is reasonably likely to be contaminated with a pathogen, that animal food must be tested for the pathogen. For example, if environmental monitoring reveals animal food-contact surfaces contaminated with *Salmonella* and additional environmental monitoring following corrective actions indicates animal food-contact surfaces are still contaminated with *Salmonella,* product testing would be required because it is appropriate to the facility (one making that animal food), the animal food (pet food, which supports the growth of *Salmonella*), test results from environmental monitoring (which show the presence of an indicator organism for *Salmonella* on animal food-contact surfaces in the animal food processing environment), and the nature of the preventive control (sanitation controls to prevent contamination by environmental pathogens, which appear to be inadequate).

The word ''must'' specifies the type of activities that a facility can use to satisfy the requirements for a particular preventive control management component, and we are retaining the term ''must.'' However, we agree that the rule should provide flexibility for additional verification of implementation and effectiveness. To provide that additional flexibility, we have revised the specific requirements for verification of implementation and effectiveness to provide for other activities appropriate for verification of implementation and effectiveness (see § 507.49(a)(5)).

We believe that the performance of environmental monitoring, for an appropriate microorganism of public (human and animal) health significance or for an appropriate indicator organism, is particularly useful as a verification measure for preventive controls (*i.e.,* sanitation controls) when contamination of animal food with an environmental pathogen is a hazard

requiring a preventive control. We anticipate that facilities producing animal food that enters into the home and is frequently handled in the home will include biologic hazards of human health concerns associated with that animal food, as well as those of animal health concerns in their hazards requiring a preventive control. (See, for example, our discussion of *Salmonella* in pet food in the 2013 proposed preventive controls rule for animal food (78 FR 64736 at 64747).)

(Comment 342) Many comments ask us to issue guidance, rather than requirements, for product testing and environmental monitoring based on concerns such as the following: The value of environmental monitoring will be reduced if it becomes a minimum regulatory requirement; there are well-known limitations to product testing and negative results from product testing can create a false sense of security; negative results are likely to occur unless intensive sampling is conducted dependent upon quality sampling criteria; product testing is not preventive, would put industry into a reactive mode, and would pull valuable resources from activities focused on preventing contamination; there is limited technology available to test contaminants in some animal food matrices and limited time available for perishable commodities; any regulatory requirement will soon be outdated as products change and science improves; and product testing would vastly increase the cost of the rule and will drive many businesses out of business without necessarily improving animal food safety; and requirements for product testing would require the States to direct resources to respond to non-compliant product testing results, and such resources would be better directed to environmental monitoring.

Some of these comments emphasize the need for flexibility so that product testing and environmental monitoring are options that are available to the facility rather than requirements for all facilities. Other comments assert that guidance provides greater opportunity for industry innovation and stakeholder participation to determine the appropriate use of verification measures, and avoids a ''one-size-fits-all'' approach to regulations. Some of these comments state that we should encourage environmental monitoring to be conducted ''through facility specific food safety plans,'' which would provide the flexibility necessary to monitor risks associated with exposures of animal foods. Other comments state that operators should be given the necessary flexibility to implement any requirements in the most effective and efficient manner using a risk-based approach and taking into account the specific conditions of their facilities and operations. Some comments express concern that including a requirement makes it difficult for businesses to justify a conclusion that testing is not necessary.

Some comments ask us to solicit drafts of proposed guidance documents from the sustainable agriculture and local/regional food system community; publish a list of possible topics for future guidance each year; seek input in advance from the sustainable agriculture and local/regional food system community before preparing draft guidance (including public meetings, workshops, and formation of an advisory committee); hold public meetings on draft guidance after publication; and present draft guidance to an advisory committee including representatives from the sustainable agriculture and local/regional food system community.

Some comments suggest that an ingredient manufacturer may identify an environmental pathogen but the facility would not implement a preventive control to significantly minimize or prevent the environmental pathogen because the ingredient would be subsequently processed to control the hazard by another facility.

(Response 342) We are retaining the requirements for product testing and environmental monitoring in the rule, with the revisions, already discussed, to provide that verification activities depend on the role of the preventive control in the facility's food safety system (see Response 293); corrective action procedures depend on the nature of the hazard (see Response 304); and written procedures for product testing and environmental monitoring are established and implemented as appropriate to the role of the preventive control in the facility's food safety system. These revisions clarify in the regulatory text the flexibility that we discussed in the 2014 supplemental notice (79 FR 58476 at 58493 through 58495). Some of the comments that ask us to issue guidance rather than requirements appear to believe that only guidance can provide sufficient flexibility for product testing and environmental monitoring. This is not the case. (See Response 341.)

We disagree that environmental monitoring will become a minimum regulatory requirement in all cases; the decision to conduct environmental monitoring is made by the facility and some comments discuss specific examples of when environmental monitoring or product testing would not be warranted. If a facility relies on its customer to control an environmental pathogen then the facility must follow the requirements in subpart E for supply-chain program. Moreover, the fact that further manufacturing might be capable of eliminating an environmental pathogen that has contaminated an animal food is not a reason to not take reasonable measures to prevent contamination from the environment and to verify that such measures are effective through environmental monitoring.

We have acknowledged limitations of product testing (79 FR 58476 at 58493 through 58494) and agree that a facility should consider such limitations when determining whether to conduct product testing and keep such limitations in mind when obtaining negative results from product testing. We also agree that product testing is not preventive. However, the mere facts that there are limitations, and that product testing is itself not a preventive measure, do not eliminate all benefits of product testing; we agree with comments that although product testing may not be effective in identifying the acceptability of a specific ingredient or finished product lot on any given day, it can help assess and verify the effectiveness of a food safety plan as a whole and the facility's capability to consistently deliver against it. We agree that there is limited technology available to test for some hazards in animal food but expect that testing of animal food by a facility as the sole verification of the effectiveness its food safety plan as a whole would be the exception rather than the norm.

We disagree that regulatory requirements for product testing and environmental monitoring will soon be outdated as products change and science improves; the rule requires reanalysis of the food safety plan as a whole at least every 3 years, and requires reanalysis of the food safety plan as a whole, or the applicable preventive control, in light of new information (see § 507.50(a) and (b)). We agree that there are some costs to product testing, but the rule provides flexibility for the facility to determine when product testing is appropriate. We acknowledge that the States will be required, in many cases, to follow up on positive findings obtained during product testing but disagree that this is a reason to eliminate the proposed requirements. The States would only be directing resources when the findings indicate contamination of animal food, and doing so will protect public (human and animal) health.

We will follow the procedures in § 10.115 for issuing guidance documents. Under § 10.115(f), members of the public can suggest areas for guidance document development and submit drafts of proposed guidance documents for FDA to consider. Under § 10.115(g), after we prepare a draft guidance we may hold public meetings or workshops, or present the draft guidance document to an advisory committee for review; doing so is not common and is determined on a case-by-case basis.

(Comment 343) One comment requests that we add the additional factor of the ''intended use of the animal food'' to help further clarify that these activities should be conducted based upon the appropriate end use of the animal food as it was intended by the manufacturer, and not upon any potential use of the product not originally intended.

(Response 343) We believe the requirement as written allows the manufacturer's intended use to be taken into consideration when conducting the hazard analysis. However, to the extent that these comments are asserting that a facility can ignore consumer behavior that the facility considers contrary to principles of food safety, we disagree. For example, a facility could not conclude that it need not identify and evaluate a known or reasonably foreseeably hazard because the facility intends to provide safe handling instructions on the label of a packaged pet food. We do recognize that if a manufacturer/processor has adequately controlled a hazard and has properly packaged, held, and labeled their product, they are not responsible for unforeseeable misuse by a consumer, such as a person who intentionally feeds swine food to sheep even though the product is accurately labeled as containing copper which can be toxic for sheep. For manufacturers/processors that rely on their customer or another entity in the distribution chain to the control a hazard, they must follow the requirements in § 507.36(a)(2), (3), (4) or (5). (See Response 285 for additional information.)

B. Proposed § 507.49(a)(1)—Calibration

We proposed to require calibration of process monitoring instruments and verification instruments.

(Comment 344) Some comments distinguish ''calibration'' from an accuracy check, which the comments describe as a test to confirm that a particular equipment or measurement device is accurate. These comments assert that calibration may not be possible for certain equipment or measurement devices, and the appropriate corrective action may be replacement or application of corrective values. These comments ask us to specify that an accuracy check may be used as a verification activity in lieu of calibration.

(Response 344) We have revised the proposed requirements to require calibration of process monitoring instruments and verification instruments, or checking them for accuracy. However, if the outcome of an accuracy check is that a process monitoring instrument or verification instrument is not accurate, the facility must follow up by calibrating the device, rather than by applying corrective values, when it is practical to do so and replace the device when it is not practical to calibrate it.

C. Comments Directed to Proposed Requirements for Both Product Testing (Proposed § 507.49(a)(2) and (b)(2)) and Environmental Monitoring (Proposed § 507.49(a)(3) and (b)(3))

We proposed that to verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards you must conduct activities that include product testing and environmental monitoring, as appropriate to the facility, the animal food, and the nature of the preventive control (§ 507.49(a)(2) and (a)(3)). We also proposed that you must establish and implement written procedures for product testing and for environmental monitoring (§ 507.49(b)(2) and (b)(3)).

(Comment 345) Some comments ask us to revise the regulatory text to be explicit that there are circumstances when product testing and environmental monitoring would not be necessary. One comment supports a requirement that incoming raw materials and feed ingredients must be tested for harmful pathogens. Another comment opposes mandatory product testing for every lot of raw material received. Some comments discuss topics for us to include in guidance on procedures for product testing and environmental monitoring, such as which pathogens to test for; the range of products that should be tested; circumstances that warrant testing; what a facility would document and what factors the facility would consider before determining that product testing is not appropriate for its animal food product; frequency of sampling and number of samples to be collected; actions to take after a positive result; available test methods; reporting requirements for results; compliance strategies; and criteria for laboratories conducting the testing.

(Response 345) We decline to revise the regulatory text. The decision as to whether product testing and environmental monitoring are warranted depends on the facility and its animal food product, as well as the nature of the preventive control and its role in the facility's food safety system, and a slight variation on circumstances that would lead one facility to conclude that such testing programs were not required could lead a different facility to the opposite conclusion. Memoranda placed in the docket for the 2014 preventive controls supplemental notice for human food provide additional information on these topics requested in the comment (Refs. 51 and 52). Although directed to product testing and environmental monitoring for human food production, some of the information is relevant to animal food, as well.

(Comment 346) Some comments ask us to clarify that tests can be performed by third-party facilities or laboratories, as well as by the facility itself. Some comments ask us to clarify that we will accept test results in the same format as the format used for other purposes, such as third-party certification services.

(Response 346) The rule places no restrictions on who conducts testing. However, facilities have a responsibility to choose testing labs that will produce reliable and accurate test results. (See Response 348.) The rule does not specify the format of test results, provided that the record documenting testing satisfies the recordkeeping requirements of subpart F.

(Comment 347) Some comments express concern about requirements for product testing and environmental monitoring in light of section 202 of FSMA (section 422 of the FD&C Act (21 U.S.C. 350k)). (Section 422 of the FD&C Act addresses laboratory accreditation for the analyses of foods, including use of accredited laboratories in certain circumstances and including requirements for accredited laboratories to report the results of laboratory testing to FDA in certain circumstances.) These comments express concern that requirements for facilities to submit results of environmental monitoring to us will create an additional disincentive to looking for pathogens established in the facility. These comments assert that the results of environmental monitoring tests should be available to us for inspection but not submitted to us if product has not been distributed and that submitting the results of routine tests would be burdensome without benefit. These comments ask us to

clarify whether facilities or laboratories would be required to submit the results of environmental monitoring tests to us. Likewise, some comments ask us to clarify whether product testing (including testing of raw materials or other ingredients as part of supplier controls) is subject to the requirements of section 422 of the FD&C Act for using accredited laboratories and for reporting test results to us. Other comments ask us to establish standards and procedures for certifying laboratories that would perform the tests. These comments assert that these standards and procedures are needed to ensure the credibility of the testing and to provide direction for facilities that establish in-house testing facilities. Other comments urge us to establish regulations implementing section 422 of the FD&C Act because they would complement the requirements of the animal food preventive controls rule and because model laboratory standards that address quality controls, proficiency testing, training and education of laboratory personnel offer the protections necessary for ensuring reliable, accurate test results. Other comments assert that if laboratories are not accredited or samples are not collected in a sanitary manner, there is no guarantee the results will be scientifically valid.

(Response 347) Section 422 of the FD&C Act would require, in relevant part, that food testing be conducted by an accredited laboratory (and the results of such testing be sent directly to FDA) whenever such testing is conducted in response to a specific testing requirement under the FD&C Act or its implementing regulations when applied to address an identified or suspected animal food safety problem or to support admission of an animal food under an Import Alert that requires food testing. Although another rulemaking will address the requirements of section 422 of the FD&C Act, our current thinking is that routine product testing and environmental monitoring conducted as a verification activity is not being applied to address an identified or suspected animal food safety problem that requires food testing and would not be subject to requirements to use an accredited laboratory that would submit the results to FDA. We will review the results of environmental monitoring and product testing, if any, during inspections.

The primary concern expressed in these comments was with respect to laboratories reporting results to FDA and not with use of accredited laboratories. The rule requires a facility to establish and implement written procedures for product testing and environmental monitoring and that the procedures for such testing be scientifically valid. One way to comply with the requirement that testing procedures be scientifically valid is to use an accredited laboratory.

(Comment 348) Some comments ask us to expand the proposed requirement to identify the laboratory conducting the testing to also specify whether that laboratory is accredited and uses the appropriate standards (such as quality control, proficiency testing, and trained laboratory staff). These comments assert that such information would be useful to facilities.

(Response 348) We decline this request. These comments appear to be asking us to establish in the preventive controls for animal food rule requirements related to section 422 of the FD&C Act. Doing so in advance of regulations implementing section 422 of the FD&C Act is premature. However, facilities have a responsibility to choose testing labs that will produce reliable and accurate test results even if the rule does not require the facility to specify whether the laboratory is accredited.

(Comment 349) One comment requested the FSMA regulations regarding ISO methods for *Listeria* and *Salmonella* be changed to using BAM (Bacteriological Analytical Manual) methodology.

(Response 349) While we require scientifically valid procedures for testing, the rule does not specify a particular method be used. A laboratory could use an FDA BAM method, an ISO method, or another method that is validated in the relevant animal food matrix.

(Comment 350) Some comments say that there is little scientific data to show environmentally exposed animal food, such as raw liquid ingredients and finished liquid animal food products, as well as food for livestock creates a potential for harmful biological hazards and an evaluation of environmental pathogens should not be required as part of the hazard analysis. Other comments point out it is common practice to store ingredients with some exposure to the environment during a portion of their storage, complete outdoor storage is standard practice both at the production facility, as well as where it will be consumed without resulting in harm. Some comments say that mere exposure to the environment does not inherently increase the risk of contamination of animal food.

Some comments say environmental testing should only be required for packaged animal foods and recommend that environmental testing be required whenever animal food ingredients or finished animal foods are exposed to the environment after undergoing a process aimed at reducing pathogens (*e.g.,* a heat kill step such as rendering or the extrusion process) or other hazards that could be transmitted through the environment. These comments say processing aimed at reducing hazards will be ineffective if pathogen loads or hazard levels going into the processing are too high and are concerned that the proposed rule would not require renderers, who often handle sick and dead animals, to make sure that the plant environment is not a pathway for the recycling of pathogens into the animal food system through contaminated animal products. Many comments state that all finished animal food is ready to eat whether or not it is packaged, so it is not reasonable to limit environmental monitoring only to animal foods that may be packaged.

(Response 350) We do not expect either product testing or environmental monitoring to be common in facilities that process, pack, or hold RACs for animal consumption. We agree that there would be little or no benefit to product testing or environmental monitoring in facilities that pack or hold RACs that are rarely consumed unprocessed, such as soybeans, or for a manufacturer/processor that will rely on its customer or another entity in the distribution chain to control a hazard as specified in § 507.36(a)(2), (3), and (4). We expect that many facilities that conduct operations such as drying grain are likely to conclude, as a result of their hazard analysis, that neither product testing nor environmental monitoring are warranted and would direct their resources to food safety practices and verification measures other than environmental monitoring or product testing. While a hazard analysis must include an evaluation of environmental pathogens when animal food is exposed to the environment prior to packaging and the animal food does not include a control measure that would significantly minimize the pathogens (see § 507.33(c)(2)), we agree that holding animal food in areas exposed to the environment in some instances will present a low risk of contamination from environmental pathogens. Facilities in these instances will likely conclude there is not a hazard requiring a preventive control. However, facilities that identify an environmental pathogen requiring a preventive control would conduct environmental monitoring as appropriate to the facility, the animal food, and the nature of the preventive control.

(Comment 351) Some comments express concern about the cost of testing and suggest creation of a one-time grant program for very small businesses that would assist them in developing their initial food safety plans and testing programs. One comment says that segments of the animal food production industry currently not performing these types of activities will be challenged to interpret the requirements and develop effective programs. The comment states that inconsistent interpretations of these requirements by an industry fearful of being found in violation of the rule may lead to unnecessary testing and supplier activities and needlessly drive up the cost of compliance.

(Response 351) Very small businesses are qualified facilities that are subject to modified requirements, which do not require testing or development of a food safety plan. We intend that the guidance we are developing will be helpful to all sizes of businesses, and particularly those not currently conducting these activities, that are subject to the requirements for product testing and environmental monitoring. (See Response 1.)

D. Proposed § 507.49(a)(2)—Product Testing

(Comment 352) Some comments ask us to require finished product testing for food products designated as high-risk, particularly when the product supports pathogen growth during its shelf life. Other comments suggest that finished product or ingredient testing should be implemented as appropriate in situations where a risk has been identified and an effective preventive control cannot be implemented. Other comments ask us to require product testing if an environmental pathogen is identified as a significant hazard.

(Response 352) We decline these requests. A facility's decision to conduct product testing, and to establish the frequency of such testing, will reflect a risk-based approach consistent with its hazard analysis. Consequently, we expect that facilities that produce animal foods that have frequently been associated with outbreaks of foodborne illness (in humans or animals), or produce animal food for which an effective preventive control cannot be implemented, would establish product testing programs more often than facilities that do not produce such animal foods.

A facility that identifies an environmental pathogen as a hazard requiring a preventive control such as sanitation controls would conduct environmental monitoring. Such a facility would decide what, if any, role product testing would play as a verification activity, or as part of a corrective action as a result of positive findings from environmental monitoring, based on the facility, the animal food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system.

(Comment 353) Some comments ask us to clarify (or specify) when product testing would be directed at raw materials and other ingredients and when product testing would be directed at finished product. Some comments favor testing raw materials and other ingredients as part of ''product testing,'' whereas other comments state that testing raw materials and other ingredients should be considered part of a supplier program rather than verification of implementation and effectiveness. Other comments state that it is unclear what preventive control step would be verified by product testing and what types of facilities would be required to perform product testing. One comment states product testing for animal food should solely focus on finished products that are consumed by animals in accordance with their intended use as described in the facility's animal food safety plan.

(Response 353) We use the term ''product testing'' to mean testing any animal food product, whether raw materials or other ingredients, in-process animal foods, or finished products and, thus, product testing can be directed to any of these animal food products. For example, testing raw materials and other ingredients could be verification of a supplier; testing in-process material after a kill step could be verification of process control; testing finished product could be verification of the food safety plan as a whole, and capture a problem introduced during manufacture, including from contaminated raw materials and other ingredients, if raw materials and other ingredients had been tested before use. Product testing generally is not the most effective means of measuring the adequacy of cleaning and sanitation programs, but such testing is common to track a facility's overall hygienic production measures.

(Comment 354) Some comments assert that a facility that implements supplier verification and environmental monitoring (or other measures) should not be required to perform product testing in addition to the other controls and verification measures.

(Response 354) The facility determines whether product testing is necessary as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system. The factors mentioned by the comment are examples of factors that a facility would consider in making its determination.

(Comment 355) Some comments ask us to revise the requirement for product testing to clarify that product testing applies to significant hazards.

(Response 355) We decline this request. Product testing is a verification activity for a preventive control, and a preventive control is established for a ''significant hazard'' (which we now refer to as ''hazard requiring a preventive control''). It is not necessary to repeat, for each type of verification activity, that the activity applies to hazards requiring a preventive control.

(Comment 356) Some comments assert that the real point of product testing is to test all lots or batches. These comments explain that they would be required to retest every lot of product in order to pass an analysis of the product on to its customers, even if testing had already been performed by their vendors (*i.e.,* suppliers), because each of their customers receives a proprietary blend. These comments further explain that it is not economically or physically possible to retest small lots of product already tested by their vendors, and that the risk has already been mitigated by its vendors.

(Response 356) The situation described by these comments appears to be a supplier-customer relationship in that the customer. not this rule, has established a requirement for a certificate of analysis for every lot of received product. The product testing that this rule requires as a verification activity is to help assess and verify the effectiveness of a food safety plan and the facility's capability to consistently deliver against it, not to establish the acceptability of every lot or batch.

(Comment 357) Some comments assert product testing should primarily be used as a measure of process control, not for acceptance testing; that product testing should normally be viewed as a monitoring and review tool, not as a product conformance verification tool. The comment states testing programs for product conformance verification should be the exception rather than the rule.

(Response 357) These comments appear to have misunderstood the proposed requirements for product testing. Consistent with the views expressed by these comments, we proposed requirements for product testing as a verification measure of the food safety plan as a whole, not for product conformance.

(Comment 358) One comment says test results, whether via voluntary company programs to verify process controls or mandated by regulation, should not be required to be submitted to FDA unless they indicate serious human or animal health consequences (*i.e.,* necessitate a Class I recall) as is required under the existing requirements for the RFR. Comments state that FDA inspectors should not penalize facilities for finding potential problems through verification if appropriate corrective actions are taken.

(Response 358) This comment appears to have misunderstood the requirements for product testing, which do not include reporting product testing results to FDA. However, during an inspection, if product testing was used as a verification measure, the inspector may review the documentation for that testing and the records documenting any corrective action procedures taken as a result of that testing.

E. Proposed § 507.49(a)(3)—Environmental Monitoring

We proposed to require environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples.

(Comment 359) Some comments ask us to specify that environmental monitoring of pathogens be executed according to a risk analysis. Many comments say environmental monitoring should be a verification tool based on a risk assessment as different animals show different susceptibility to pathogens, pathogen growth is dependent upon the animal food, and pathogens grow differently in different environments and seasons. Some comments state that the corrective actions for environmental monitoring should be risk based and take into account information such as organism threshold, sampling, and analytical methodology. One comment says the requirement should be applied only to ''significant hazards'' if any, that are present within the operation. One comment states that it is not clear who would be responsible for environmental monitoring at various points in the supply chain. The comment requests more clarification on the ''boundaries'' of responsibility for proposed measures like environmental monitoring. One comment says prior to including environmental monitoring in the regulation, methodologies and minimum standards that establish the threshold industry must meet should be developed and vetted.

(Response 359) We decline these requests. See the discussion in Response 301, which explains how risk applies to the facility's hazard analysis and the determination by the facility to establish preventive controls for hazards requiring a preventive control as appropriate to the facility and the animal food. In contrast, the requirements for environmental monitoring are a verification activity that a facility would conduct to verify that one or more preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards requiring a preventive control and would be established as appropriate to the facility, the animal food, and the nature of the preventive control rather than according to a risk analysis. The rule provides flexibility for the facility to determine appropriate test methodologies and the threshold appropriate for the environmental pathogen being monitored to verify the effectiveness of the facility's preventive control. For requirements that apply to hazards that a customer of the facility, ''or another entity in the distribution chain,'' will control. See the requirements in § 507.36 and the discussion in section XXVII.

(Comment 360) Numerous comments request that we distinguish between production of pet food and other animal food. Many comments state that FDA has publically stated that it intends environmental monitoring to apply mainly to facilities that manufacture pet food and pet treats; however, the language extends the requirement to any facility that packages animal food that does not receive a treatment to minimize pathogens. Comments say it must be made clear, through outreach, education, and compliance policy guides, that the requirement to conduct environmental monitoring is intended for a limited range of facilities, products and processes, and does not apply to livestock feed or animal food for which environmental pathogens do not pose a significant hazard in the finished animal food. Another comment expressed concern because *Salmonella* has been found in finished poultry feed. One comment says we should require *Salmonella* testing as part of an environmental program. One comment asks us to explicitly recognize in the preamble to the final rule that contamination of animal food with an environmental pathogen may be a significant hazard in many dry pet food manufacturing facilities.

(Response 360) We agree that environmental monitoring may be particularly relevant to pet food manufacturing and the majority of environmental monitoring may occur in dry or raw pet food manufacturing facilities. However, its usefulness is not limited exclusively to pet food production. Therefore, the requirement for environmental monitoring is flexible to allow a facility to determine whether environmental monitoring is needed based on the facility, the type of animal food produced, the nature of the preventive control for the environmental hazard and its role in a facility's food safety system.

We decline the request to require *Salmonella* testing as part of environmental monitoring. We believe that most facilities producing pet foods (other than those subject to part 113 that are exempt from subpart C with respect to microbiological hazards regulated under part 113) will identify *Salmonella* spp. as a known or reasonably foreseeable hazard that requires a preventive control verified by environmental monitoring. We decline the request to exempt livestock food or animal food other than pet food from the provisions for environmental monitoring. However, we believe use of environmental monitoring by a livestock or poultry food facility as a verification of a preventive control would be the exception rather than the norm.

F. Proposed § 507.49(a)(4)—Review of Records

We proposed to require review of specified records by (or under the oversight of) a preventive controls qualified individual, 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. We proposed to require review of records of monitoring and corrective action records within a week after the records are made, and review of records of calibration, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made.

(Comment 361) Some comments assert that it is not necessary for a preventive controls qualified individual to conduct or oversee review of records as a verification activity, noting that review of records in another food safety regulation (*i.e.,* the LACF requirements in part 113) can be done by persons adequately trained in recordkeeping and review of records.

(Response 361) The rule does not preclude review of records by persons other than the preventive controls qualified individual, provided that the preventive controls qualified individual provides oversight for that review. Oversight by a preventive controls qualified individual is necessary because the review of records is critical to assessing the facility's application of the preventive controls system and, thus, is fundamental to ensuring its successful operation (78 FR 64736 at 64796 through 64797). Oversight by a preventive controls qualified individual is consistent with requirements of Federal HACCP regulations for seafood, juice, and meat and poultry (Ref. 49) (78 FR 64736 at 64796 through 64797).

(Comment 362) Some comments ask us to provide for a timeframe longer than 1 week (such as 7 working days) for review of records of monitoring and corrective actions. Some comments ask us to provide the same flexibility for review of records of monitoring and corrective actions as we proposed for review of records of calibration, product testing, environmental monitoring, and supplier verification activities (''within a reasonable time'' after the records are made), *e.g.,* because some preventive controls may be monitored less frequently than is typical in a traditional HACCP plan dominated with CCPs. Some comments note that corrective actions may not be fully implemented within 7 days and ask us to provide for review of these records within a week or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce. Some comments ask us to retain the 1 week timeframe for review of records associated with perishable foods, but to extend the timeframe to 1 month for nonperishable foods.

Some comments state that some food processors that operate on a batch production basis (rather than a continuous production basis) review all records related to a particular batch all at once just before release of the batch for distribution. These comments assert that it would be inefficient, unnecessary, and needlessly complicated to require management to review a few production records in advance of the normal complete records review, particularly when laboratory testing conducted on the batch by an outside laboratory takes several weeks to complete.

(Response 362) We have revised the proposed requirement to require review of records of monitoring and corrective actions within 7 working days after the records are made or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days. A timeframe that exceeds 7 working days will be the exception rather than the norm. For example, reviewing records before release of product may be considered adequate by a facility, although this may be later than one week after the records were created. A facility may determine that all records for a lot of product will be reviewed after product testing or environmental monitoring records relevant to that lot of product are available, which may be more than a week after monitoring records were created. We made a conforming change to the list of responsibilities of the preventive controls qualified individual to address the requirement for the preventive controls qualified individual to provide (or oversee the preparation of) a written justification for such a timeframe (see § 507.53(a)).

We are not requiring that a facility review records of monitoring and corrective actions before release of product or that the timeframe for the review depends on the shelf life of the animal food. The purpose of reviewing records is not to determine whether to release product. Instead, the purpose of reviewing records is 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. However, a facility will have flexibility to review records of monitoring and corrective actions within a timeframe that exceeds 7 working days, such as before product release, provided that the facility provides a written justification for doing so. Depending on the nature of the record, a facility that reviews these types of records in a timeframe that exceeds 7 working days, and finds a problem, may be faced with recall decisions for a relatively large number of affected lots of product.

(Comment 363) Some comments ask us to revise the provisions for review of records by more generally referring to records of ''verification testing (*e.g.,* product testing and/or environmental monitoring as applicable).''

(Response 363) We have revised the regulatory text to refer to records of ''testing (*e.g.,* product testing, environmental monitoring).''

(Comment 364) Some comments refer to our request for comment on whether the regulatory text should specify the verification activities that must be conducted for corrective actions. These comments assert that if we do not further specify verification activities for corrective actions then we should eliminate the proposed requirement to review records of corrective actions.

(Response 364) Records are necessary to document all verification activities (see § 507.45(b)). The fact that the rule provides flexibility for the facility to determine the verification activities for corrective actions, rather than prescribes these verification activities, has no bearing on the requirement to document the verification activities.

(Comment 365) Some comments emphasize the importance of calibrating those instruments and monitoring devices that are critical to the preventive control, and reviewing the associated records, before validation of a lethality step and as frequently as necessary thereafter. These comments question whether requiring review of calibration records ''within a reasonable time'' will be adequate.

(Response 365) We agree that instruments and monitoring devices that are critical to a preventive control should be calibrated, and calibration records should be reviewed, before conducting studies to validate a lethality step. However, the provision is directed at verification of implementation and effectiveness of preventive controls on an ongoing basis. This rule does not prescribe specific steps that a facility must take before conducting validation studies.

A facility has flexibility to appropriately determine the frequency of reviewing calibration records based on the facility, the animal food, and the nature of the preventive control. We agree that it would be prudent to review calibration records of those instruments and monitoring devices that are critical to the preventive control more frequently than of those instruments and monitoring devices that are not critical to the preventive control. Depending on the nature of the control being calibrated, a facility that reviews calibration records infrequently, and finds a problem with calibration of process monitoring instruments and verification instruments, may be faced with recall decisions for a relatively large number of affected lots of product.

G. Proposed § 507.49(b)—Written Procedures

1. Proposed § 507.49(b)(1)—Frequency of Calibration

We proposed that you must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments.

(Comment 366) Some comments ask us to specify that an accuracy check may be used as a verification activity in lieu of calibration. These comments also ask us to specify that written procedures address the frequency of accuracy checks, as well as calibration.

(Response 366) We have revised the proposed requirement to specify that written procedures address the frequency of accuracy checks, as well as calibration.

2. Proposed § 507.49(b)(2) and (b)(3)—Product Testing and Environmental Monitoring

We proposed that you must establish and implement written procedures for product testing. We proposed that procedures for product testing must: (1) Be scientifically valid; (2) identify the test microorganism(s); (3) specify the procedures for identifying samples, including their relationship to specific lots of product; (4) include the procedures for sampling, including the number of samples and the sampling frequency; (5) identify the test(s) conducted, including the analytical method(s) used; (6) identify the laboratory conducting the testing; and (7) include the corrective action procedures required by § 507.42(a)(1).

Likewise, we proposed that you must establish and implement written procedures for environmental monitoring. Procedures for environmental monitoring must: (1) Be scientifically valid; (2) identify the test microorganism(s); (3) identify the locations from which the samples will be collected and the number of sites to be tested during routine environmental monitoring; (4) identify the timing and frequency for collecting and testing samples; (5) identify the test(s) conducted, including the analytical method(s) used; (6) identify the laboratory conducting the testing; and (7) include the corrective action procedures required by § 507.42(a)(1)(ii).

(Comment 367) Some comments express concern that the word ''valid'' in the phrase ''scientifically valid'' could be construed to mean ''validated'' because not all testing protocols can be validated within the traditional meaning of the term. These comments state their belief that what we intend is for these testing programs to be ''technically sound.'' Other comments express concern that ''scientifically valid'' may be interpreted to mean that firms are required to develop or validate analytical methods (either in general or for specific food matrices).

(Response 367) We are retaining the term ''scientifically valid'' in these provisions. We disagree that we would interpret ''scientifically valid'' to mean that facilities are required to develop or validate analytical methods. We discussed our interpretation of the term ''scientifically valid'' in the Appendix to the 2013 proposed preventive controls rule (78 FR 64736 at 64834 through 64835), and noted that this interpretation was consistent with our previous discussion of the term ''scientifically valid'' (in place of ''validated'') in the rulemaking to establish CGMP requirements for dietary supplements (68 FR 12158 at 12198, March 13, 2003). While validated methods are considered ''scientifically valid,'' methods that have not gone through formal validation processes but have been published in scientific journals, for example, may also be ''scientifically valid.'' We do expect methods used for testing to be adequate for their intended use.

Although we agree that methods that are ''scientifically valid'' would also be ''technically sound,'' we disagree that the hypothetical concern that we would construe ''scientifically valid'' to mean ''validated'' warrants changing ''scientifically valid'' to a new term (such as ''technically sound'') in light of our previous statements regarding this term and experience in the context of CGMP requirements. See the final rule establishing the dietary supplement CGMPs for additional discussion on the terms ''validated'' and ''scientifically valid'' (72 FR 34752 at 34853).

(Comment 368) Some comments support the proposed requirements for written procedures for environmental monitoring, including providing flexibility to use indicator organisms and to design the timing, location, and frequency of environmental monitoring programs in a risk-based manner, and in not prescribing specific locations (*e.g.,* food-contact surfaces or ''zone 1'') or sample quantities for testing. Other comments ask us to add details to the written procedures for product testing and environmental monitoring regarding when and where sampling is required and the number of samples to take. Some comments ask us to make sure the most current ''sampling planning science'' is used for environmental monitoring by specifying that procedures for environmental monitoring must employ sample quality criteria objectives. Other comments assert that the product testing procedure requirements are inadequate and ask us to require that procedures for product testing specify the procedures for identifying samples (including their relationship to specific lots of product); describe how sampling was conducted (to establish that the sample obtained adequately represents the lot of product the sample is intended to represent); and include the procedures for sample quality control from field to lab.

(Response 368) We decline the request to prescribe additional details, such as those described in these comments, in the requirements for written procedures for product testing and environmental monitoring. As with other procedures required by the rule, those relating to environmental monitoring and product testing must be adequate for their intended purpose. Further, procedures will not be identical in all circumstances. For example, a facility that produces products with a short shelf life may choose a different frequency of swabbing and testing than a facility that produces products with a long shelf life.

(Comment 369) Some comments ask us to provide more flexibility in product testing by not requiring establishments to provide written procedures for product testing and corrective action procedures.

(Response 369) These comments are unclear. By requiring that a facility establish its own procedures, the rule provides facilities with flexibility to develop a product testing program that works best for its facility and its products. We are retaining the requirements for written procedures for product testing, as well as for corrective action procedures.

(Comment 370) Some comments ask us to add a provision requiring that all positive results must result in corrective action being taken.

(Response 370) We decline this request. The rule requires that a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate, the presence of a pathogen or appropriate indicator organism in an animal food product detected as a result of product testing and the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring (see § 507.42(a)(1)). However, the rule does not predetermine what corrective actions a facility must take when presented with positive results from product testing or environmental monitoring. The corrective action procedures that a facility would develop, and the actual corrective actions that the facility would take, will depend on the nature of the hazard and the nature of the preventive control, as well as information relevant to the positive result (*e.g.,* pathogen or

indicator organism, product or environment, animal food-contact surface or non-animal food-contact surface).

For additional discussion of comments on verification of implementation and effectiveness, see section XXXIV of the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

XXXV. Subpart C: Comments on Proposed § 507.50—Reanalysis

We proposed to establish requirements for reanalysis of the food safety plan. Some comments support the proposed requirements without change. For example, comments agree that a preventive controls qualified individual must perform (or oversee) the reanalysis (see section XXXV.D). Some comments that support the proposed provisions suggest alternative or additional regulatory text.

In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 19, with editorial and conforming changes as shown in table 31.

TABLE 19—REVISIONS TO THE PROPOSED REQUIREMENTS FOR REANALYSIS

Section	Description	Revision
507.50(b)	Circumstances that require reanalysis	Provide for reanalysis of an applicable portion of the food safety plan (rather than the complete food safety plan) in specified circumstances.
507.50(b)(4)	Circumstances that require reanalysis	Require reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan, whenever a preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective.
507.507(c)	Timeframe to complete the reanalysis	Clarify that the requirement applies to completing the reanalysis and *validating* any additional preventive controls (as appropriate to the nature of the preventive control and its role in the facility's food safety system), rather than to completing the reanalysis and *implementing* any additional preventive controls (emphasis added).

A. Proposed § 507.50(a)—Circumstances Requiring Reanalysis

We proposed that you must conduct a reanalysis of the food safety plan: (1) At least once every 3 years; (2) whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard; (3) whenever you become aware of new information about potential hazards associated with the animal food; (4) whenever appropriate after an unanticipated animal food safety problem; and (5) whenever you find that a preventive control is ineffective.

(Comment 371) Some comments assert that the need to reanalyze the food safety plan will depend on the nature of the preventive control and its role in the food safety system. These comments also assert that if a specific preventive control is found to be ineffective, only the applicable portion of the food safety plan would need to be reanalyzed.

(Response 371) We agree and have revised the regulatory text, with associated editorial changes and redesignation, to separate the requirement to reanalyze the food safety plan as a whole every 3 years from all other circumstances when reanalysis is required ''for cause.'' When reanalysis is ''for cause,'' the regulatory text provides that reanalysis is of the food safety plan as a whole, or the applicable portion of the food safety plan.

(Comment 372) Some comments ask us to define ''reanalysis'' to mean ''a reassessment of the validity of a preventive control or food safety plan to control a hazard. Reanalysis may include a system review and, where necessary, activities to revalidate a control measure or combination of control measures.''

(Response 372) We decline this request. Reanalysis goes beyond assessing the validity of a preventive control or food safety plan to control a hazard. Reanalysis can also include assessing whether all hazards have been identified, whether established procedures are practical and effective, and other factors.

(Comment 373) Some comments ask us to require reanalysis on an annual basis, noting that annual reanalysis is required by Federal HACCP regulations for seafood, juice, and meat and poultry.

(Response 373) We decline this request. We proposed to require reanalysis at least once every 3 years as a minimum requirement in the event that there is no other circumstance warranting reanalysis (see § 507.50(b)(2) through (4)). That 3-year minimum is consistent with the statute (see section 418(i) of the FD&C Act). As a practical matter, we expect that reanalysis will occur more frequently as a result of changes in the activities conducted at a facility (§ 507.50(b)(1) through (4)).

(Comment 374) Some comments suggest editorial changes to improve the readability of the requirement to conduct reanalysis when there is a change in a preventive control.

(Response 374) We are including these editorial changes in the regulatory text, which now reads whenever ''a significant change in the activities conducted at your facility creates a reasonable potential . . .''

(Comment 375) Some comments assert that the proposed requirement to conduct reanalysis whenever you become aware of new information about potential hazards associated with the food does not align with FSMA statutory language, is ambiguous, and would establish vague compliance obligations.

(Response 375) We disagree that the proposed requirement is ambiguous and would establish vague compliance obligations. See our previous discussion regarding the emergence of the first outbreak of foodborne illness in the United States, in 2006–2007, caused by consumption of peanut butter contaminated with *Salmonella* (78 FR 64736 at 64798). Although we acknowledge that the proposed requirement is not explicit in section 418(i) of the FD&C Act, we disagree it is not in alignment with FSMA as a whole. FSMA directs the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility and identify and implement preventive controls to significantly minimize or prevent the occurrence of those hazards (see section

418(a) of the FD&C Act). In other words, FSMA focuses on a system to prevent food safety problems rather than a system to react to problems after they occur. Requiring that a facility reanalyze its food safety plan, or the applicable portion of the food safety plan, in response to information such as the emergence of a new foodborne pathogen, or an outbreak of foodborne illness from consumption of an animal food product (or handling by consumers of a pet food product) not previously associated with foodborne illness from a well-known pathogen, aligns very well with the statutory direction in FSMA.

(Comment 376) Some comments ask us to add a requirement to conduct reanalysis whenever a preventive control is found to be ''missing'' in addition to whenever a preventive control is found to be ''ineffective.''

(Response 376) We have revised the regulatory text to require reanalysis whenever a preventive control, a combination of preventive controls, or the food safety plan as a whole, is ineffective. (See § 507.50(b)(4).) A ''missing'' preventive control could be discovered during verification to establish the validity of the food safety plan as a whole or as a result of an unanticipated problem. If circumstances lead a facility to conclude that an additional (or different) preventive control is necessary, the facility would include that preventive control in its food safety plan along with associated preventive control management components, including verification to establish the validity of the food safety plan.

B. Proposed § 507.50(b)—Timeframe To Complete Reanalysis

We proposed that you must complete the reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production. We have clarified that the requirement is to complete the reanalysis and validate (rather than implement) any additional preventive controls as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(Comment 377) As discussed in Comment 332, some comments question whether 6 weeks is enough time to perform all applicable validation studies that would address the execution element of validation. Likewise, some comments question whether 6 weeks is enough time to complete reanalysis.

(Response 377) Consistent with revisions we have made to the timeframe to complete validation (see Response 332), we have revised the timeframe to complete the reanalysis and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls to be within 90 days after production of the applicable animal food first begins or within a reasonable timeframe, provided that the preventive controls qualified individual provides (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable animal food first begins. We made a conforming change to the list of responsibilities of the preventive controls qualified individual (see § 507.53(a)).

(Comment 378) Some comments state that the phrase ''before the change in activities at the facility is operative'' is ambiguous in that it is unclear if the phrase is referencing the initial change in activities that triggered the reanalysis or a change in activities subsequent to the reanalysis. These comments ask us to clarify the requirement by substituting the phrase ''before the relevant process is operative.''

(Response 378) We agree that there was ambiguity in this phrase, because changes in activities could result in the need for reanalysis and reanalysis could result in the need for changes in activities, both of which can result in a new preventive control. We have made several revisions to the regulatory text, with associated editorial changes, to clarify the requirements for reanalysis. First, we have clarified that reanalysis can be routine (at least every 3 years) or ''for cause'' (*i.e.,* a significant change that creates the potential for a new hazard or an increase in a previously identified hazard; when you become aware of new information about potential hazards associated with the animal food; when there is an unanticipated animal food safety problem; or whenever a preventive control, combination of preventive controls or the food safety plan as a whole is ineffective). Second, we have specified that the reanalysis ''for cause'' may be for the entire food safety plan or only for an applicable portion.

In addition, we have clarified that the reanalysis and the validation, as appropriate to the nature of the preventive control and its role in the facility's food safety system, of any additional preventive controls needed to address an identified hazard, would need to be completed before any change in activities (including any change in preventive controls) is operative. When additional time is necessary, we have provided for a timeframe within 90 days after production of the applicable animal food first begins or within a reasonable timeframe, provided that the preventive controls qualified individual provides (or oversees the preparation of) a written justification for a timeframe that exceeds 90 days after production of the applicable animal food first begins. In other words, if you decide to make a change, you should conduct a reanalysis before you make that change if there is potential for that change to create or increase a hazard; a reanalysis that results in changes to preventive controls should be completed and the preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, before changes in activities to produce animal food using a new preventive control are put into operation. However, we acknowledge that it may be necessary to produce product to demonstrate a revised preventive control can be implemented appropriately, and provide for an extended timeframe to make this assessment.

C. Proposed § 507.50(c)—Requirement To Revise the Written Food Safety Plan or Document Why Revisions Are Not Needed

We proposed that you must revise the written food safety plan if a significant change is made or document the basis for the conclusion that no revisions are needed. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed.

D. Proposed § 507.50(d)—Requirement for Oversight of Reanalysis by a Preventive Controls Qualified Individual

We proposed that a preventive controls qualified individual must perform (or oversee) the reanalysis. We received no comments that disagreed with this proposed requirement and are finalizing it as proposed. See section XXXVII.B for comments on the qualifications for a preventive controls qualified individual who would perform or oversee the reanalysis.

E. Proposed § 507.50(e)—Reanalysis on the Initiative of FDA

We proposed that you must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

(Comment 379) Some comments ask us to issue formal, written communications about new hazards and developments in scientific understanding. These comments express

concern that communications of this type could be inconsistent if they are communicated by individual investigators. Other comments ask us to specify in the regulatory text that it is the Commissioner of Food and Drugs who makes the determination that it is necessary to conduct a reanalysis of the food safety plan.

(Response 379) We agree that a communication from FDA about the need to reanalyze the food safety plan should be issued in a formal written manner but disagree that it is necessary to specify that it is the Commissioner of Food and Drugs who makes the determination that it is necessary to conduct a reanalysis of the food safety plan. The comment provides no basis for precluding such a determination by an organizational component (such as CVM or a component of FDA's Office of Regulatory Affairs) that has operational responsibility for animal food safety and subject matter experts to advise the managers in those organizational components.

XXXVI. Subpart C: Comments on Proposed § 507.51—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Unexposed Packaged Animal Food

We proposed that if your facility is solely engaged in the storage of packaged animal food that is not exposed to the environment, you must conduct certain activities for any such refrigerated packaged animal food that requires time/temperature controls for safety (TCS animal food) to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance. We requested comment on the proposed list of modified requirements. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In this section, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 20.

TABLE 20—REVISIONS TO THE PROPOSED MODIFIED REQUIREMENTS FOR UNEXPOSED, REFRIGERATED, PACKAGED ANIMAL FOOD

Section	Description	Revision
507.51(a)	Circumstances that make a facility subject to the modified requirements for unexposed, refrigerated packaged animal food.	Clarify that the requirements apply to a temperature control area in a facility that holds TCS animal food rather than to each product in the holding facility.
507.51(a)(2)	Modified requirements for monitoring the temperature controls.	Specify that it is the temperature controls that are consistently performed.
507.51(a)(3)	Modified requirements for corrective actions.	Clarify that corrective actions need only be taken when a loss of temperature control may impact the safety of the TCS animal food.
507.51(a)(4)(i)	Modified requirements for verification of temperature controls.	Provide additional flexibility for accuracy checks, in addition to calibration, to verify that temperature controls are consistently implemented.
507.51(a)(4)(iii)	Modified requirements for verification of temperature controls.	Provide additional flexibility for reviewing records of monitoring and corrective actions either within 7-working days after the records are made or within a reasonable timeframe.
507.51(a)(5)(i)	Records documenting the monitoring of temperature controls.	Provide additional flexibility for records documenting the monitoring of temperature controls to be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control.
507.51(a)(5)(ii)	Records documenting corrective actions.	Conforming change associated with the modified requirements for corrective actions to clarify that records of corrective actions are required when there is a loss of temperature control that may impact the safety of the TCS animal food.

A. Proposed § 507.51(a)—Modified Requirements for Unexposed Refrigerated Packaged Animal Food That Requires Time/Temperature Controls

1. Proposed § 507.51(a)(1)—Establish and Implement Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance.

We also tentatively concluded that it would be rare for a facility solely engaged in the storage of unexposed packaged animal food to not have information regarding whether a refrigerated packaged animal food is a TCS animal food and, if so, what specific temperature controls are necessary for safe storage of the food. We requested comment on this tentative conclusion.

(Comment 380) Some comments ask us to clarify that the requirement to establish and implement temperature controls applies to temperature control areas in a facility rather than to each product in a facility.

(Response 380) We agree that the requirement to establish and implement temperature controls applies to temperature control areas in a facility rather than to each product in a facility. To make this clearer, we have revised the proposed requirement to clarify that the facility must conduct activities as appropriate to ensure the effectiveness of the temperature controls rather than conduct activities ''for any such refrigerated packaged animal food.''

(Comment 381) Some comments disagree with our tentative conclusion that it would be rare for a facility solely engaged in the storage of unexposed packaged animal food to not have information regarding whether a refrigerated packaged food is a TCS animal food and, if so, what specific temperature controls are necessary for safe storage of the animal food. These comments ask us to specify that the responsibility for determining whether an animal food is a TCS animal food falls to the manufacturer of the animal food rather than the warehouse storing the animal food, because the warehouse merely provides a service. Other

comments note that the animal food product owners determine the optimal conditions for storage of their products based on their own hazard analysis and preventive controls, and that the animal food product owners can simply communicate those requirements to the warehouses that will store the products.

(Response 381) In this type of circumstance, it is appropriate for the manufacturer of the animal food to share the responsibility with the warehouse for proper storage of the animal food. The various provisions of section 418 of the FD&C Act explicitly place the responsibility for complying with the requirements for hazard analysis and risk-based preventive controls, including modified requirements, on the owner, operator, or agent in charge of a facility and, thus, a facility that is a warehouse is responsible for its own food safety plan. Regardless, the manufacturer also has responsibilities under section 418 of the FD&C Act to determine the storage conditions necessary for animal food safety and to take steps to ensure that the animal food is stored under conditions that will ensure its safety.

It is not necessary to specify this joint responsibility for determining storage conditions in the rule, because the rule already clearly specifies that its provisions apply to persons who manufacture/process animal food, as well as to persons who hold animal food. Both the warehouse and the manufacturer have flexibility in determining how to comply with the rule, including the specific mechanism whereby the warehouse would receive information about storage of an animal food product from the manufacturer or owner of the product. Moreover, a citizen petition submitted to FDA (Docket No. FDA–2011–P–056), in requesting an exemption or modified requirements for facilities solely engaged in the storage of packaged foods not exposed to the environment, asserts that such facilities work closely with food manufacturers to understand the conditions and controls needed to ensure the quality of the foods they store and distribute and that manufacturers appropriately instruct the warehouses to ensure packaged products are being properly stored (78 FR 64736 at 64768).

(Comment 382) Some comments ask us to clarify which facility, the shipping facility or the receiving facility, will be responsible for ensuring that temperature control is maintained during transportation of TCS animal foods.

(Response 382) We address specifics about the responsibilities of shipping facilities and receiving facilities in the 2014 proposed sanitary transportation rule (79 FR 7006). We will address comments regarding the responsibilities of shippers and receivers in the final sanitary transportation rule.

2. Proposed § 507.51(a)(2)—Monitor the Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed. We requested comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature.

(Comment 383) Some comments ask us to explain in the preamble of the final rule that we will accept monitoring systems that provide exception reports to satisfy the modified requirements. The comments describe exception reporting as a structure where automated systems are designed to alert operators and management when the monitoring system observes a deviation from an established limit. These comments assert that monitoring of preventive controls by automated systems can be more efficient than monitoring by personnel, and can eliminate human error.

(Response 383) We have revised the recordkeeping provisions of these modified requirements to provide that the temperature monitoring records for the modified requirements may be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control. Although the comments explicitly asked us to provide a clarification in the preamble of this rule, we decided the clarification within the regulatory text would be clearer to facilities that are subject to the requirements, as well as to investigators who will be inspecting facilities for compliance with the rule.

(Comment 384) Some comments state that written procedures for monitoring temperature are not necessary. One reason provided by the comments is that the required records (specified in proposed § 507.51(a)(5)) would provide sufficient information on the type and frequency of monitoring. Another reason is that the specific activities we proposed to ensure the effectiveness of the temperature controls already address activities that a facility would include in a written procedure.

(Response 384) We agree with the comments that we need not require that a facility develop written procedures for monitoring temperature.

3. Proposed § 507.51(a)(3)—Requirement To Take Corrective Actions

We proposed that if your facility is subject to the modified requirements, you must take appropriate corrective actions if there is a problem with the temperature controls for a TCS animal food.

(Comment 385) Some comments ask us to narrow the term ''temperature control'' to more specifically focus it on temperature controls that are relevant to food safety because some problems with the controls may not impact the product temperature (and, thus, would not impact food safety).

(Response 385) We have revised the proposed requirement (and the applicable recordkeeping requirement) to specify that corrective actions are necessary only when there is a loss of temperature control that may impact the safety of a TCS animal food.

(Comment 386) Some comments assert that the responsibility for determining any corrective actions for a TCS animal food when there is a loss of temperature control falls to the manufacturer of the food rather than to the warehouse. These comments also assert that a warehouse is a third party who is not legally empowered to make independent decisions about when and where to ship the product, or not to ship it at all. These comments ask us to clarify that the responsibility of a warehouse for ''preventing'' affected food entering commerce ends when the product is returned to the manufacturer or processor.

(Response 386) Returning affected animal food to the manufacturer/processor or owner of the animal food is one way to satisfy the requirement to prevent animal food from entering commerce if the owner, operator, or agent in charge of a warehouse cannot ensure the affected animal food is not adulterated under section 402 of the FD&C Act, either on its own or after consultation with the manufacturer or processor of the animal food. It is not necessary to specify this specific action on the part of a warehouse in the regulatory text.

4. Proposed § 507.51(a)(4)—Requirement To Verify Consistent Implementation of Temperature Controls

We proposed that if your facility is subject to the modified requirements, you must verify that temperature controls are consistently implemented by: (1) Calibrating temperature monitoring and recording devices; (2) reviewing records of calibration within

a reasonable time after the records are made; and (3) reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made.

(Comment 387) Some comments assert that the proposed requirement to ''calibrate'' devices that monitor and record temperature is inconsistent with the requirement to test such devices for accuracy in the LACF regulations in part 113. These comments assert that ''accuracy check'' is a more appropriate term to use in the modified requirements because many instruments that monitor or record temperature have very low drift values and may seldom require calibration.

(Response 387) We have revised the proposed requirements to require verification that temperature controls are consistently implemented by calibrating temperature monitoring and recording devices or checking them for accuracy. However, if the outcome of an accuracy check is that a temperature monitoring or recording device is not accurate, the facility must follow up by calibrating or replacing the device. See also Comment 344 and Response 344.

(Comment 4388) Some comments assert that reviewing records of calibration or accuracy checks is only needed if a designated tolerance is exceeded.

(Response 4388) Although we recognize that in most instances an out-of-calibration device will be identified and corrected at the time a calibration or accuracy check is performed, this is not always the case. The purpose of reviewing records of calibration or accuracy checks is to identify a problem that may have been missed or may not have been corrected rather than to react to a problem after the problem is identified. The records review is also a verification that the temperature controls were consistently implemented and that corrective actions were taken if needed.

(Comment 389) Some comments ask us to modify the frequency of checking monitoring records to specify that it be done with a frequency to demonstrate control rather than within a week after the records are made.

(Response 389) We have revised the proposed requirement to require review of records of monitoring (as well as records of corrective actions taken to correct a problem with the control of temperature) within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days.

(Comment 390) Some comments assert that the proposed verification and review activities are too prescriptive because they require reviews that are not necessary. However, these comments also assert that the proposed verification activities are too vague because they do not specify the reasons for reviewing the records. These comments ask us to focus the regulatory text on achieving the overall objective of the review (*i.e.,* ensuring the adequacy of the control) and to provide examples of meaningful review activities in guidance.

(Response 390) We disagree that the proposed verification activities would require reviews that are not necessary. The purpose of the records review is both to identify a problem with a temperature monitoring device that may not have been detected or corrected, and to verify that the temperature controls were consistently implemented and that corrective actions were taken if needed. The requirement is consistent with requirement for records review in subpart C (§ 507.49(a)(4)), which specifies records review as a verification activity 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.

5. Proposed § 507.51(a)(5)—Establish and Maintain Records

We proposed that if your facility is subject to the modified requirements, you must establish and maintain records that document monitoring, corrective actions, and verification activities.

(Comment 391) Some comments state that temperature controls in refrigerated warehouses are extremely reliable and therefore extensive record keeping and record review are not value-added. These comments ask us to revise the proposed provision to require a record only if a deviation in the environmental temperature from the prescribed limits was noted.

(Response 391) We have revised the regulatory text to provide that temperature monitoring records may be kept either as affirmative records demonstrating temperature is controlled or as exception records demonstrating loss of temperature control. The revised provision is consistent with the more general requirement for monitoring records of refrigeration temperature during storage of TCS animal food (see § 507.40(c)(2)).

B. Proposed § 507.51(b)—Records

We proposed that the records that a facility must establish and maintain for the proposed modified requirements are subject to the requirements that would be established in proposed subpart F. We received no comments that disagreed with our proposal, and are finalizing proposed § 507.51(b) without change.

XXXVII. Subpart C: Comments on Proposed § 507.53—Requirements Applicable to a Preventive Controls Qualified Individual and a Qualified Auditor

We proposed to establish requirements for the qualifications of a preventive controls qualified individual and a qualified auditor. Some comments support the proposed requirements without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text.

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the provisions as proposed with conforming changes as shown in table 31.

A. Proposed § 507.53(a) and (b)—What a Preventive Controls Qualified Individual or Qualified Auditor Must Do or Oversee

We proposed to list the functions that must be performed by one or more preventive controls qualified individuals (*i.e.,* preparation of the food safety plan; validation of the preventive controls; review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions; and reanalysis of the food safety plan) or by a qualified auditor (*i.e.,* conduct an onsite audit). We proposed to list these functions for simplicity (*i.e.,* to make it easy to see all of the requirements in a single place). We specified that this list of functions already proposed to be established in applicable sections of the rule did not in itself impose any additional requirements.

(Comment 392) Some comments ask us to clarify whether the preventive controls qualified individual must be on the premises during operating hours. Other comments ask us to clarify that the preventive controls qualified individual is not responsible for performing laboratory testing, because the preventive controls qualified individual may not be appropriately educated and trained for laboratory testing.

(Response 392) The rule does not require that the preventive controls qualified individual be onsite during operating hours. The rule also does not require that the preventive controls qualified individual be responsible for performing laboratory testing, although review of testing records (*e.g.,* records of product testing or environmental testing) must be conducted or overseen by a preventive controls qualified individual.

(Comment 393) Some comments ask us to consider the implication of having the preventive controls qualified individual serve as the process authority, serve as the auditor, and offer final sign off on a validation and corrective actions, and suggest that a third party may be necessary to ensure that uniform standards are applied.

(Response 393) To the extent that the comment suggests that the functions of the preventive controls qualified individual create a conflict of interest, we disagree. The rule focuses on the need for applicable training and experience to perform certain functions. The preventive controls qualified individual must develop (or oversee the development of) the food safety plan that controls the identified hazards and then ensures through review of records that the plan is being implemented as designed. The rule does not require that a facility engage a third party to provide oversight of any individual, including a preventive controls qualified individual, but does not preclude a facility from doing so if it chooses.

B. Proposed § 507.53(c)—Qualification Requirements

1. Proposed § 507.53(c)(1)—Preventive Controls Qualified Individual

We proposed that to be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. We also proposed that this individual may be, but is not required to be, an employee of the facility.

(Comment 394) Some comments express concern that there is lack of specificity on what constitutes appropriate training and experience for a preventive controls qualified individual and ask us to clarify what FDA's standardized curriculum for preventive controls qualified individuals will consist of, what experience will be recognized as meeting the requirement, how FDA will recognize the experience and whether and how FDA will recognize industry providers of training programs. Some comments state that currently industry members may choose from many private organizations and academia to obtain training under established HACCP based training programs and audit training programs. Some comments ask us to allow flexibility for industry to continue current training programs without receiving express approval from the FSPCA.

(Response 394) As discussed in Response 1, the FSPCA is establishing a standardized curriculum. The curriculum will focus on the specific requirements of the preventive controls rule. Training providers do not need approval from the FSPCA to use the curriculum.

(Comment 395) Some comments ask who will assess the qualifications of a particular preventive controls qualified individual or determine whether particular individuals are in fact ''qualified.'' Some comments ask us to use an outcome-based demonstration of competency. Some comments ask us to specify that all work experience must be comparable or that a preventive controls qualified individual must pass a proficiency test. Some comments ask us to establish minimum standards for competency. Some comments ask us to clarify what job experiences would be sufficient. Some comments ask how we will verify that reported training and experience are true.

(Response 395) We are not establishing minimum standards for competency and do not intend routinely to directly assess the qualifications of persons who function as the preventive controls qualified individual, whether by their training or by their job experience. Instead, we intend to focus our inspections on the adequacy of the food safety plan. As necessary and appropriate, we will consider whether deficiencies we identify in the food safety plan suggest that the preventive controls qualified individual may not have adequate training or experience to carry out the assigned functions, including whether reported training and experience is accurately represented.

(Comment 396) Some comments ask us to provide for competency requirements to be met through on-the-job experience in lieu of traditional classroom training. Some comments ask us to clarify what we mean by training that is ''at least equivalent'' to that received under a standardized curriculum recognized as adequate by FDA. Some comments ask us to clarify whether individuals who have successfully completed training in the development and application of risk-based preventive controls through programs delivered and recognized under the International HACCP Alliance would be considered to have completed training ''equivalent'' to that recognized by FDA for the development and application of risk-based preventive controls.

(Response 396) The requirements do provide for qualification through appropriate job experience, such as experience with successfully implementing HACCP systems or other preventive-based food safety systems. It is the responsibility of the owner, operator, or agent in charge of the facility to determine whether any individual who prepares (or oversees the preparation of) the food safety plan has appropriate qualifications to do so, whether by on-the-job experience or by training.

There are some differences in the requirements of the animal food preventive controls rule compared to the requirements of HACCP regulations for seafood, juice, and meat and poultry such that training provided by the International HACCP Alliance may not be equivalent. To avoid unnecessary duplication of training, such an individual may only need to attend partial, supplemental courses in order to meet the training requirements. Alternatively, a person who has received the International HACCP Alliance training and has implemented a HACCP plan may be qualified through job experience.

(Comment 397) Some comments ask us to emphasize that a standardized curriculum in the development and application of risk-based preventive controls may not provide a preventive controls qualified individual with sufficient expertise to design and conduct robust, scientific validation studies to support the adequacy of control measures.

(Response 397) We acknowledge that a single training course may not provide adequate training for every function of the preventive controls qualified individual for the animal foods produced by a facility. In some cases an individual may gain the full complement of knowledge and experience through multiple, specific training courses; in other cases an individual may gain the full complement of knowledge and experience through job experience or through a combination of training and job experience.

(Comment 398) Some comments ask us not to establish requirements that are

overly strict because there is a finite supply of food safety experts in the country and many facilities will need multiple preventive controls qualified individuals.

(Response 398) We disagree that the requirements applicable to the preventive controls qualified individual should be designed to match any current limitations in the number of individuals who have the knowledge and skill to prepare (or oversee the preparation of) a food safety plan. We expect that market forces will act to increase the number of preventive controls qualified individuals to match the demand generated by this rule. In addition, as discussed in section LIII.A, we are further staggering the compliance dates for subparts C and E of the rule, so that those businesses that are not small will need to comply with subparts C and E of the rule within 2 years, and small businesses will need to comply with subparts C and E of the rule within 3 years. Very small businesses are not required to develop a food safety plan or conduct other activities that require oversight by a preventive controls qualified individual.

2. Proposed § 507.53(c)(2)—Qualified Auditor

We proposed that to be a qualified auditor, a preventive controls qualified individual must have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

(Comment 399) Some comments object to the proposed requirement that a qualified auditor must be a preventive controls qualified individual with certain technical auditing expertise. One comment asserts that a qualified auditor should not be required to have the broader skills of a preventive controls qualified individual.

(Response 399) We have revised the definition of ''qualified auditor,'' and the requirements applicable to a ''qualified auditor,'' such that a ''qualified auditor'' means a person who is a ''qualified individual'' as that term is defined in this final rule, rather than a ''preventive controls qualified individual,'' because some auditors may be auditing businesses (such as produce farms) that are not subject to the requirements for hazard analysis and risk-based preventive controls, and it would not be necessary for such an auditor to be a ''preventive controls qualified individual.''

(Comment 400) Some comments ask us to consider specifying training for qualified auditors. These comments also ask us to consider certain industry documents in any guidance we may issue regarding qualified auditors.

(Response 400) At this time, we are not planning to specify a training curriculum for qualified auditors. If we develop guidance related to qualified auditors, we will consider industry documents that are already available.

C. Proposed § 507.53(d)—Records

We proposed that all applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained. For clarity, we have revised the requirement to specify the type of training that must be documented, *i.e.,* applicable training in the development and application of risk-based preventive controls (see 78 FR 64736 at 64804).

(Comment 401) Some comments ask us to explain how job experience should be documented in records to prove qualifications.

(Response 401) The rule does not require documentation of job experience. A facility has flexibility to determine whether and how to document a preventive controls qualified individual's job experience. For example, a facility could ask a preventive controls qualified individual to provide a resume documenting applicable experience. As discussed in Response 395, we intend to focus our inspections on the adequacy of the food safety plan. As necessary and appropriate, we will consider whether deficiencies we identify in the food safety plan suggest that the preventive controls qualified individual may not have adequate experience to carry out the assigned functions.

For further discussion on comments received to the proposed rule for preventive controls rule for human food, see the final rule of the human food preventive controls rule published elsewhere in this issue of the **Federal Register**.

XXXVIII. Subpart C: Comments on Proposed § 507.55—Implementation Records

We proposed to list all records documenting implementation of the food safety plan in § 507.55(a). We noted that proposed § 507.55(a) would not establish any new requirements but merely make it obvious at a glance what implementation records are required under proposed part 507, subpart C. We received no comments that disagreed with this proposed provision and are finalizing it as proposed.

We proposed that the records that you must establish and maintain are subject to the requirements of proposed subpart F (''Requirements Applying to Records that Must be Established and Maintained''). (Proposed subpart F would establish requirements that would apply to all records that would be required by the various proposed provisions of proposed part 507.) We received no comments that disagreed with this proposed provision and are finalizing it as proposed.

XXXIX. Subpart D: Comments on Proposed New Provisions for Withdrawal of a Qualified Facility Exemption

In the 2013 proposed animal food preventive controls rule, we proposed to establish procedural requirements that would govern our withdrawal of an exemption for a qualified facility (proposed subpart D; the withdrawal provisions). In the 2014 supplemental notice, we discussed several comments we received on these withdrawal provisions and proposed modifications and additions to them. Some of the reproposed provisions would modify the provisions that we included in the 2013 proposed preventive controls rule (such as the timeframe for compliance with an order withdrawing an exemption), whereas others would be new provisions (such as a procedure to reinstate an exemption that had been withdrawn). In this section of this document we discuss comments that we received on the withdrawal provisions in the 2013 proposed preventive controls rule, but did not address in the 2014 supplemental notice. We also discuss comments that we received on the re-proposed withdrawal provisions in the 2014 supplemental notice.

Most of the comments support the proposed provisions, suggest alternative or additional regulatory text, or ask us to clarify how we will interpret the provision.

For several provisions, we received no comments that disagreed with our proposal, and are finalizing the provisions without change. These provisions are § 507.75 (Presiding officer for an appeal and for an informal hearing); § 507.77 (Timeframe for issuing a decision on an appeal); § 507.80 (Revocation of an order to withdraw a qualified facility exemption); and § 507.83 (Final agency action).

In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with or suggest one or more changes to the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 21 with editorial and conforming changes as shown in table 31.

TABLE 21—REVISIONS TO THE PROPOSED PROVISIONS FOR WITHDRAWAL OF A QUALIFIED FACILITY EXEMPTION

Section	Description	Revision
507.60(b)(2)	Timeframe for a qualified facility to respond to a notification from FDA about circumstances that may lead FDA to withdraw the facility's exemption.	Allow 15 calendar days, rather than 10 calendar days, for the facility to respond.
507.65(c)	Contents of an order to withdraw a qualified facility exemption.	Editorial changes to clarify that the order will specify which of two circumstances that may lead FDA to withdraw a qualified facility exemption apply, or whether both of these two circumstances apply.
507.65(d)(1)	Contents of an order to withdraw a qualified facility exemption.	Specify that the timeframe for the qualified facility to comply with the order is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order.
507.65(d)(2)	Timeframe for a qualified facility to appeal an order withdrawing the facility's exemption.	Allow 15 calendar days, rather than 10 calendar days, for the facility to appeal the order.
507.65(e)	Contents of an order to withdraw a qualified facility exemption.	Include a statement informing the facility that it may ask us to reinstate an exemption that was withdrawn by following the procedures in § 507.85.
507.67	Compliance with, or appeal of, an order to withdraw a qualified facility exemption.	Specifies that a qualified facility that loses its exemption would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption.
507.67(a)(1) and (c)(1).	Compliance with, or appeal of, an order to withdraw a qualified facility exemption.	Specify that the timeframe for the qualified facility to comply with the order is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order.

A. Proposed § 507.60—Circumstances That May Lead FDA To Withdraw a Qualified Facility Exemption

We proposed that we may withdraw the exemption that would apply to a qualified facility in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility, or if we determine that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility. We also proposed that before we issue an order to withdraw an exemption, we: (1) May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak; (2) must notify you, in writing, of circumstances that may lead us to withdraw the exemption, and provide an opportunity for you to respond in writing, within 10 calendar days of the date of receipt of the notification, to our notification; and (3) must consider your actions to address the circumstances that may lead us to withdraw the exemption.

(Comment 402) Some comments agree with the proposed provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified facility exemption. For example, some comments agree that other regulatory actions should be considered before withdrawing a qualified facility exemption, and some comments agree that it is appropriate to assess corrective actions taken by a qualified facility in response to an animal food safety problem when considering whether to withdraw its exemption. Other comments agree that these provisions are reasonable and will provide qualified facilities due process and greater clarity on the withdrawal process, but suggest that we could issue guidance rather than include these provisions in the rule to allow us greater flexibility should we have to act quickly to protect the public (human or animal) health.

Other comments disagree with these proposed provisions and ask us to delete them from the final rule. These comments assert that FSMA does not require us to describe the actions that we may take prior to withdrawing a qualified facility exemption and that it is not necessary to do so because it is customary for us to work with an animal food facility to address problems before taking enforcement actions. These comments also express concern that listing possible regulatory actions before we would issue an order to withdraw a qualified facility exemption could create an expectation that we will always exercise such regulatory actions before issuing the order. These comments also express concern that being bound by these provisions could prevent us from acting quickly to protect public health.

(Response 402) We are retaining the provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified facility exemption. We agree that it is customary for us to work with an animal food facility to address problems before taking enforcement actions, but disagree that specifying this customary practice in the rule would prevent us from acting quickly to protect public (human or animal) health. As previously discussed, we consider that issuing an order to withdraw an exemption would be a rare event, in part because alternative actions such as those described in these provisions may provide a more expeditious approach to correcting a problem than withdrawing an exemption (79 FR 58524 at 58553). We also disagree that the rule binds us to take alternative regulatory action before issuing an order to withdraw a qualified facility exemption, other than to notify the facility in writing of circumstances that may lead us to withdraw the exemption, provide an opportunity for the facility to respond in writing, and consider the actions taken by the facility to address the circumstances we describe. The rule clearly specifies that regulatory actions such as a warning letter, recall, administrative detention, suspension of registration, refusal of animal food offered for import, seizure, and injunction are actions that we ''may'' (not ''must'') take before issuing an order to withdraw a qualified facility

exemption. Providing the facility with an opportunity to correct the problems before we take steps to withdraw an exemption has the potential to save Agency resources associated with preparing an order, responding to an appeal of the order and request for a hearing, and administering a hearing. Directing resources to help a facility correct problems, rather than to administer a withdrawal process that could be resolved by the time of a hearing, is appropriate public health policy.

(Comment 403) Some comments ask us to specify that the notification of circumstances that may lead FDA to withdraw the exemption must include facts specific to the situation and information about how the facility can remedy the situation.

(Response 403) By specifying that we must notify the facility of circumstances that may lead us to withdraw an exemption, we mean that we would include facts specific to the situation. It is the responsibility of the facility, not FDA, to remedy the situation.

(Comment 404) Some comments ask us to state affirmatively that we must not withdraw the exemption if the facility has satisfactorily addressed the problematic conditions or conduct at the facility. These comments assert that, without this affirmative statement, the requirement that we ''consider the actions taken by the facility'' remains unclear.

(Response 404) We decline this request. If the facility has satisfactorily addressed the problematic conditions or conduct, there would be no problematic circumstances for us to describe in the order withdrawing the qualified facility exemption.

(Comment 405) Some comments ask us to provide additional time for a qualified facility to respond, in writing, to a notification of circumstances that may lead us to withdraw its exemption. Comments suggest timeframes of 60, 90, and 120 days as a reasonable or appropriate period of time for a qualified facility to compile information and documentation of facts and to respond to a notification of circumstances that may cause us to withdraw its exemption. Some of these comments express concern that the proposed deadline is too short, and that the short timeframe violates the intent of the exemption. Some comments ask us to establish graduated response times, with less response time allowed for more serious animal food safety concerns.

(Response 405) We have revised the provision to provide for 15 calendar days, rather than 10 calendar days, for a facility to respond in writing to our notification. The 15-day timeframe is the same as the timeframe for responding to a warning letter. Circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility, just as circumstances that lead us to issue a warning letter require prompt action.

(Comment 406) Some comments ask us to clarify how an exemption can be revoked (and restored) on diversified farms that produce both exempt and non-exempt products.

(Response 406) We assume that this comment is referring to a farm mixed-type facility that produces some products (such as forage products or plant protein meals) that are exempt from the requirements for hazard analysis and risk-based preventive controls, as well as some products that are not exempt from these requirements. Neither withdrawing nor reinstating a qualified facility exemption would have any impact on products that are not subject to the requirements for hazard analysis and risk-based preventive controls. In contrast, administrative procedures such as injunction and suspension of registration likely would apply to all animal food production by the facility.

(Comment 407) Some comments ask us to consistently use either ''calendar days'' or ''working days'' throughout the provisions directed to withdrawal of an exemption. Some comments ask us to use ''business days'' rather than ''calendar days'' or ''working days.''

(Response 407) We have expressed the timeframes for all of the withdrawal provisions in calendar days.

(Comment 408) Some comments ask us to clarify that the decision to withdraw a qualified facility exemption is an individualized determination and will not be applied to a class of farmers by stating this clearly in the preamble.

(Response 408) The decision to withdraw a qualified facility exemption is an individualized determination and will not be applied to a class of facilities or farmers.

(Comment 409) Some comments assert that the timeframes for responding to a notification that an exemption may be withdrawn should be the same regardless of whether the notification is sent to a qualified facility subject to the human or animal food preventive controls rule or a farm subject to the produce safety rule. These comments state that many small farms do value-added processing and will be subject to both rules.

(Response 409) Although the produce safety rule is not yet final, we intend to make the administrative procedures associated with withdrawal of an exemption consistent to the extent practicable, including the timeframe for responding to a notification.

(Comment 410) Some comments ask us to expand the scope of the withdrawal provisions to include facilities that would satisfy criteria for an exemption from the requirements for hazard analysis and risk-based preventive controls for low-risk activity/food combinations (*i.e.,* the exemptions in proposed §§ 507.5(e) and (f)).

(Response 410) We decline this request. Section 418 of the FD&C Act does not provide for withdrawal of the exemptions established in § 507.5(e) and (f). The withdrawal provision in section 418(l)(3) of the FD&C Act is limited to qualified facilities.

B. Proposed § 507.62—Issuance of an Order To Withdraw a Qualified Facility Exemption

We proposed procedures for the steps we would take to issue an order to withdraw an exemption applicable to a qualified facility, including procedures that would: (1) Emphasize that a senior FDA official (such as an FDA District Director, the Director of the Division of Compliance in CVM, or a more senior FDA official) must approve an order to withdraw the exemption before the order is issued; (2) provide that any officer or qualified employee of FDA may issue the order after it has been approved; (3) specify that we would issue the order to the owner, operator, or agent in charge of the facility; and (4) require that the order be in writing and be signed and dated by the officer or qualified employee of FDA who is issuing the order.

(Comment 411) Some comments ask us to include in the procedures timeframes for: (1) Submitting an order after an initial determination that criteria for withdrawing an exemption are met; (2) approval or denial by the FDA District Director; (3) issuing the withdrawal (with automatic revocation of order if FDA does not issue the order within the specified timeframe); and (4) delivery of the order to the owner, operator, or agent in charge of the facility. Other comments recommend that the procedures for issuing an order specify that we send the order in a way that ensures its receipt, such as through certified mail with confirmation of delivery to ensure the facility operator receives the order.

(Response 411) We are not establishing timeframes for the steps we take before a facility receives an order for withdrawal of an exemption. The timeframes surrounding our internal

process for developing an order have no bearing on the time that a facility will need to respond to the order or on the information it will need to do so. We agree that it is appropriate to specify timeframes for the procedural steps that follow a facility's receipt of an order, and the withdrawal procedures include such timeframes.

We are not specifying that we send an order in a way that ensures its receipt. Although certified mail with confirmation of delivery is one way to ensure receipt, other methods are available, including delivery through private carriers that provide mechanisms to document receipt. In light of the provision (which we included in the 2014 supplemental notice) linking the timeframes for a facility to comply with, or appeal, an order to the date of receipt of the order (rather than to the date of the order), it will be up to us to deliver the order in a way that provides us with evidence of receipt.

C. Proposed § 507.65—Contents of an Order To Withdraw a Qualified Facility Exemption

We proposed specific information that would be included in an order to withdraw an exemption, including (1) The date of the order and the name, address, and location of the qualified facility; (2) a brief, general statement of the reasons for the order, including information relevant to the circumstances that led us to issue the order; (3) a statement that the facility must either comply with subpart C within 120 calendar days of receipt, or appeal the order within 10 calendar days of receipt; (4) the text of section 418(l) of the FD&C Act and of the withdrawal provisions in part 507, subpart D; (5) information about an informal hearing on an appeal of the order; and (6) contact information for appropriate senior FDA officials, as well as the name and the title of the FDA representative who approved the order.

(Comment 412) Some comments recommend that the order specify which of the two circumstances that could lead us to issue the order apply.

(Response 412) We have made editorial changes to the regulatory text to make it more clear that the provision requires us to specify which circumstance applies. (*i.e.,* an active investigation of foodborne illness, or conduct or conditions associated with the qualified facility), or whether both of these two circumstances apply. See the revised regulatory text for § 507.65(c).

(Comment 413) Some comments ask us to add more specific requirements for the content of an order to withdraw an exemption, including specific evidence about the circumstances leading to the order. The comments maintain that doing so would help the facility respond with particularity to the facts and issues contained in the order if the facility appeals the order. The comments also recommend that the order include the evidence on which the order is based including, as applicable, evidence linking the active investigation of a foodborne illness outbreak directly to the facility or measurable evidence (collected using generally accepted scientific standards) indicating the presence in the facility of pathogens that pose an imminent threat to public (human or animal) health, or conduct or conditions that are material to the safety of animal food. The comments also recommend that the order include, when applicable, a statement explaining how altering the conduct or conditions would prevent or mitigate a foodborne illness outbreak.

(Response 413) We agree that the order must provide sufficient information to enable a facility to respond with particularity to specific evidence about the circumstances leading to the order. However, we disagree that the order must do so by including the specific information recommended by the comments, and we have not revised the proposed withdrawal provisions to incorporate the suggestions of these comments. The comments appear to be more focused on whether the circumstances that lead us to issue an order meet an evidentiary standard than on explaining the problem so that a facility can both understand the problem and respond with particularity to the facts and issues contained in the order. The withdrawal provisions that we are establishing in this provision require the order to include a brief, general statement of the reasons for the order, including information relevant to: (1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or (2) conditions or conduct associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at the facility. The requirements that we are establishing in this provision would enable a qualified facility to both understand the problem and respond to it. In addition, because other requirements in these withdrawal provisions specify that we must notify a qualified facility of circumstances that may lead us to withdraw its exemption before we issue the actual order, the order withdrawing the exemption would be the second time that the facility hears about the problems (see § 507.60(b)(2)). We intend that the process of responding to the notification that we must send before issuing an order to withdraw an exemption, including discussing the problems with FDA as warranted, would provide additional information to the facility to enable the facility to both understand the problem and respond to it.

(Comment 414) Some comments ask us to provide 15 ''business days'' from date of receipt of the order, rather than the proposed 10 calendar days from date of receipt of the order, for the facility to appeal the order.

(Response 414) We have revised the provision to provide for 15 calendar days, rather than 15 business days, for a facility to appeal the order. We also have made conforming changes to establish the same 15 calendar day timeframe in all provisions that specify the timeframe to appeal the order (*i.e.,* §§ 507.67(a)(2), 507.69(a)(1), and 507.71(a)(2)). We also extended the timeframe for the hearing to be held to be within 15 calendar days, rather than the proposed 10 calendar days, after the date the appeal is filed to provide more time for the facility to prepare for the hearing (see § 507.73(a)). The timeframe for the hearing to be held continues to provide for an alternative timeframe agreed upon in writing by both the facility and FDA; a facility that would have preferred the proposed timeframe of 10 calendar days could request that the hearing be held more quickly than 15 calendar days.

The 15-day timeframe is the same as the timeframe for responding to a warning letter. Circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility, just as circumstances that lead us to issue a warning letter require prompt action.

(Comment 415) Some comments support the proposed timeframe of 120 calendar days for a qualified facility whose exemption has been withdrawn to comply with the animal food preventive controls rule, but ask us to make the timeframe for complying with a FSMA rule the same regardless of whether the exemption is withdrawn from a qualified facility subject to the animal food preventive controls rule or from a farm subject to the produce safety rule. Other comments ask us to extend the timeframe to come into compliance, *e.g.,* to 1 or 2 years. Some of these comments suggest that qualified facilities should have 120 days to develop a plan of action, but 2 years to fully comply. Some of the comments argue that large farms and

manufacturers are given a year to come into compliance, and that requiring small and very small businesses to comply in a shorter time period would effectively drive them out of business. Other comments ask us to consider provisions that would require compliance with only those portions of the rule that formed the basis for the revocation.

(Response 415) We continue to believe that the 120-day timeframe is adequate, but we have added flexibility such that a facility may request, with a justification in writing to FDA, a reasonable timeframe for compliance that exceeds 120 calendar days from the receipt of the order. FDA must grant the request for the facility to receive the extended timeframe. We are not generally extending the timeframe because circumstances that could lead us to withdraw a qualified facility exemption require prompt action on the part of a facility. A qualified facility that receives an order to withdraw its exemption would have received advance notification of the circumstances leading to the order and would have had an opportunity to correct the problems rather than have us proceed to issue the order (see § 570.60(b)). If the facility requests a hearing, more than 40 days could elapse between the date that the facility receives the order and the date that the presiding officer for the hearing confirms the order to withdraw the exemption. Given that the circumstances that would lead us to issue the order involve either: (1) An active investigation of a foodborne illness outbreak that is directly linked to the qualified facility or (2) a determination that withdrawal of the exemption is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at the facility, a delay of 1 to 2 years to comply with the rule is not warranted. We also do not believe that it would be appropriate to require a facility to come into compliance with only those provisions that formed the basis of the revocation. The provisions of subparts C and E are interrelated and operate as a system and therefore are not optimized through piecemeal implementation. However, FDA may consider staggered implementation as an option in granting a request for an extension of the timeframe to comply with an order to withdraw the exemption for a qualified facility.

As already discussed, the new requirements for hazard analysis and risk-based preventive controls are not ''one-size-fits-all.'' Although each facility subject to the rule must prepare and implement a food safety plan, the preventive controls that the facility would establish and implement would depend on the facility, the animal food, and the outcome of the facility's hazard analysis. In addition, the preventive control management components that a facility would establish and implement for its preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's animal food safety system.

Although the produce safety rule is not yet final, we intend to make the administrative procedures associated with withdrawal of an exemption consistent to the extent practicable, including the timeframe to comply with the applicable rule if an exemption is withdrawn.

(Comment 416) Some comments ask us to include in the order a statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 507.85.

(Response 416) We have revised the requirements for the contents of an order as requested by these comments.

D. Proposed § 507.67—Compliance With, or Appeal of, an Order To Withdraw a Qualified Facility Exemption

We proposed that: (1) You must either comply with applicable requirements of part 507 within 120 calendar days of receipt, or appeal the order within 10 calendar days of receipt; (2) submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action unless the Commissioner of FDA, as a matter of discretion, determines that delay or a stay is in the public interest; and (3) if you appeal the order, and we confirm the order, you must comply with applicable requirements of part 507 within 120 calendar days of confirmation of receipt of the order.

(Comment 417) Some comments ask us to specify that a qualified facility that loses its exemption from the requirements for hazard analysis and risk-based preventive controls would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption.

(Response 417) A qualified facility that loses its exemption from the requirements for hazard analysis and risk-based preventive controls would no longer need to comply with the modified requirements that apply to qualified facilities that have an active exemption. To make this clearer, the final withdrawal procedures now include this information (see the regulatory text for § 507.67(c)).

E. Proposed § 507.69—Procedure for Submitting an Appeal

We proposed that (1) To appeal an order, you must submit a written appeal to FDA within 15 calendar days of receipt and respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely; and (2) In your written appeal, you may include a written request for an informal hearing.

(Comment 418) Some comments ask us to rely on records kept in the normal course of business for documentation that will be sufficient to respond to an order to withdraw a qualified facility's exemption, rather than requiring a facility to ''respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.'' These comments assert that we should not require a facility that submits a written appeal to provide documents and records that they are not required to keep.

(Response 418) We decline this request. In a withdrawal action, FDA is providing a qualified facility multiple opportunities to persuade FDA that withdrawal is not appropriate. If the facility relies on documentation as part of its response, it is reasonable to require that this documentation be provided to FDA.

F. Proposed § 507.71—Procedure for Requesting an Informal Hearing

We proposed that if you appeal the order: (1) You may request an informal hearing, and must do so together with your written appeal (within 15 calendar days of the date of receipt of the order and (2) a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted; you would receive written notice of the presiding officer's determination, explaining the reason for the denial.

(Comment 419) Some comments ask us to guarantee a hearing so that a qualified facility can present its case in

person before having its exemption revoked.

(Response 419) We decline this request. We agree that a qualified facility has a right to appeal an order to withdraw an exemption, and we have provided for a right to appeal.

G. Proposed § 507.73—Requirements Applicable to an Informal Hearing

We proposed that if you request an informal hearing, and we grant the request: (1) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and by us; (2) the presiding officer may require that the hearing be completed within 1 calendar day; and (3) we must conduct the hearing in accordance with part 16 (21 CFR part 16), with some specified modifications, including that no party shall have the right, under § 16.119, to petition FDA for reconsideration or a stay of the presiding officer's final decision.

(Comment 420) Some comments object to our proposal that no party shall have the right, under § 16.119 to petition FDA for reconsideration or a stay of the presiding officer's final decision. These comments assert that our justification (*i.e.,* that the circumstances that would lead to a withdrawal merit prompt action and that a facility has the opportunity for judicial review in accordance with 21 CFR 10.45) is not a sufficient argument for justifying the removal of the option to file a motion for reconsideration or stay. These comments ask us to revise proposed § 507.73(c)(6) to specify that the qualified facility shall have the right to file a motion for reconsideration or stay.

(Response 420) We decline this request. In the 2014 supplemental controls notice, we proposed an additional mechanism for a qualified facility to present its view that its exemption should not be withdrawn, *i.e.,* by providing advance written notification to a qualified facility if we are considering withdrawing an exemption and providing an opportunity for the facility to respond before we issue an order to withdraw an exemption. We also proposed to provide an opportunity for reinstatement of an exemption that had been withdrawn. We believe the multiple opportunities now available to a facility provide adequate opportunities for a facility's views to be considered, and further mechanisms are not warranted.

H. Proposed § 507.85—Reinstatement of a Qualified Facility Exemption That Was Withdrawn

We proposed four provisions for reinstating a withdrawn qualified facility exemption. First, we proposed that if the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in CVM) determines that a facility has adequately resolved problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or in the case of a foreign facility, the Director of the Division of Compliance in CVM) will, on his own initiative or on the request of a facility, reinstate the exemption (proposed § 507.85(a)).

Second, we proposed that you may ask FDA to reinstate an exemption that has been withdrawn by following specific steps (§ 507.85(b)(1) and (2)). Third, we proposed that if your exemption was withdrawn in the event of an active investigation of a foodborne illness outbreak that is directly linked to your facility and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your qualified facility exemption and will notify you in writing that your exempt status has been reinstated.

We proposed that if your exemption was withdrawn both in the event of an active investigation of a foodborne illness outbreak that is directly linked to your facility and because FDA had determined that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with your facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility, and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified facility exemption.

(Comment 421) Some comments agree with our tentative conclusion that the absence of a specific provision in section 418 of the FD&C Act for the reinstatement of an exemption that is withdrawn does not preclude us from providing for such a process (79 FR 58524 at 58553). Other comments disagree with that tentative conclusion and assert that Congress crafted the withdrawal provision as a ''one strike, you're out'' provision. These comments also assert that including the withdrawal provision as a ''one strike, you're out'' provision was an essential part of the legislative agreement that allowed for adoption of the qualified facility exemption. These comments also assert that reinstatement would undermine the intent of the withdrawal provision because it would reduce the incentive for small animal food processors to ensure that the products they sell are as safe as possible. These comments also assert that a recognized principle of statutory interpretation provides that exemptions to statutes should be strictly construed, particularly when the statute addresses public health and safety, and that we are giving the exemption an impermissibly broad construction.

Some comments ask why we believe that a business deserves a ''second bite of the apple'' in light of the understanding (under proposed § 507.60(b) and (c)) that we will first seek to correct problems before considering withdrawal. These comments also question at what point a facility would apply for reinstatement, and ask why we would allow a facility that has already come into compliance with FSMA's requirement to implement preventive controls to abandon those controls in favor of reinstating its exempt status. These comments ask us to eliminate the proposed provisions allowing for reinstatement.

Some comments do not support the proposed reinstatement provisions when an animal food facility has been directly linked to a foodborne illness outbreak. Some comments support the proposed reinstatement provisions only when we determine, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the facility that had its exemption withdrawn.

(Response 421) We disagree that the proposed reinstatement provisions would give the exemption an impermissibly broad construction. The express statutory language of section 418(l) of the FD&C Act does not support the comments' assertion that the withdrawal provision is a ''one strike, you're out'' provision. We also disagree that reinstatement would undermine the intent of the withdrawal provision because it would reduce the incentive for small animal food processors to ensure that the products they sell are as

safe as possible. We expect that the withdrawal provision itself provides a big incentive for small animal food processors to ensure that the products they sell are as safe as possible because of the business disruption that would occur if they are subject to withdrawal of the exemption. We proposed that a facility would need to present data and information to demonstrate that it has adequately resolved the problems with the conditions or conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility, such that continued withdrawal of the exemption is not necessary to protect public (human or animal) health and prevent or mitigate a foodborne illness outbreak.

We disagree that we should categorically refuse to consider reinstating a qualified facility exemption if we had withdrawn the exemption because an animal food facility had been directly linked to a foodborne illness outbreak. First, if information later comes to light to raise considerable doubt that a qualified facility had, indeed, been directly linked to a foodborne illness outbreak, and conditions and conduct at the facility do not otherwise warrant withdrawing the facility's exemption, it would be appropriate for us to reinstate the facility's exemption. Second, we would only reinstate the exemption if we determined that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human or animal) health and prevent or mitigate a foodborne illness outbreak.

(Comment 422) Some comments that support the reinstatement of a withdrawn exemption ask us to establish a timeframe within which FDA will reinstate an exemption. Some comments ask us to specify in the regulatory text that the reinstatement would occur in a reasonable period of time, both in circumstances where FDA has decided on its own initiative to reinstate the exemption and in circumstances where a facility submits a request for reinstatement. Some comments suggest 10 days is a reasonable period of time within which FDA should reinstate an exemption.

(Response 422) We decline the requests to establish a timeframe for reinstatement in the regulatory text. If we determine on our own initiative to reinstate an exemption (*e.g.,* because we later determine, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the facility), our determination would be effective immediately. If we receive a request to reinstate a withdrawn exemption, we intend to respond in a reasonable timeframe consistent with available resources. In some cases, we may respond that we need more information in order to evaluate your request.

(Comment 423) Some comments ask that the process for reinstatement include at least one level of administrative appeal if we deny a facility's request for reinstatement.

(Response 423) We have not revised the regulatory text to provide for an administrative appeal if we deny a facility's request for reinstatement. Existing procedures allow a facility to ask for a meeting with applicable FDA officials (see § 10.65(c)) and appeal our decision if we deny the request (see § 10.75).

(Comment 424) Some comments ask us to establish a 1-year probationary period before the withdrawn qualified facility exemption could be fully reinstated.

(Response 424) We decline this request. We intend to act on a request for reinstatement based on the merits of the data and information presented in the request, not after a pre-determined timeframe.

I. Conforming Amendment to 21 CFR Part 16

We proposed to amend § 16.1(b)(2) to include part 507, subpart D, relating to the withdrawal of an exemption applicable to a qualified facility, to the list of regulatory provisions under which regulatory hearings are available. We received no comments that disagreed with this proposed provision, and are finalizing it as proposed.

J. Other Comments on the Withdrawal Provisions

(Comment 425) Several comments ask us to provide clarification through guidance, issued for public comment, on a variety of topics associated with the withdrawal provisions.

(Response 425) We will consider the need for guidance in the future. At this time, we consider that withdrawing an exemption would be both rare and dependent upon the circumstances. We need to direct our resources to developing guidance on issues that would apply more broadly, and more generally, than the withdrawal provisions.

(Comment 426) Some comments ask detailed questions about how we would coordinate the withdrawal process with the States.

(Response 426) In general, we work with our State partners and other government counterparts in dealing with enforcement actions, including coordinating actions or deferring to each other when one department has authority to swiftly act to protect the consumer. In the specific case of this rule, we are working through the PFP to develop and implement a national Integrated Food Safety System consistent with FSMA's emphasis on establishing partnerships for achieving compliance (see Response 2 and section 209(b) of FSMA).

(Comment 427) Some comments ask us to add provisions regarding notification of the appropriate State regulatory agency when a qualified facility exemption is withdrawn and reinstated.

(Response 427) We decline this request. As previously noted, we are sensitive to the time required for various inspection activities and intend to communicate with States regarding our expectations for how to verify whether a facility is a qualified facility. The status of a facility as a qualified facility principally affects the requirements that it is subject to, and will be most useful to FDA and our food safety partners when preparing for inspection. At this time we do not intend to establish a system notifying the applicable State authorities at a point in time when the status of a facility as a qualified facility changes, whether as a result of withdrawal or reinstatement of a qualified facility exemption or because the facility's business has grown to the point where it exceeds the financial for very small business.

XL. Subpart E: General Comments on Proposed Requirements for a Supply-Chain Program

In the 2014 supplemental notice, we provided an opportunity for public comment on potential requirements for a supplier program as a preventive control. The supplier program for a receiving facility would be limited to those raw materials and other ingredients for which the receiving facility has identified a significant hazard (which we now refer to as a ''hazard requiring a preventive control''). Under the definitions established in this rule, ''supplier'' means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de

minimis nature; ''receiving facility'' means a facility that is subject to subparts C and E and that manufactures/processes a raw material or other ingredient that it receives from a supplier (see § 507.3).

We previously explained our understanding that, particularly for RACs, there may be multiple establishments, including cooperatives, packing houses, and distributors, between a receiving facility and the establishment that would be considered the supplier, which would make supplier verification very challenging under certain circumstances (79 FR 58476 at 58497). We requested comment on what verification activities would be appropriate for receiving facilities to conduct when a raw material or ingredient passes through more than one facility that would not be required to verify control of hazards if supplier programs are limited to manufacturers/processors. We discussed an example in which a receiving facility is a feed mill that receives oats from a distributor, who receives grains from a cooperative, and neither the distributor nor the cooperative is required to establish supplier controls for the farms, where the hazards are being controlled, and asked what supplier controls should be applied for the grains coming from the farms. We requested comment on whether and how the requirements for supplier verification should address such situations. We also requested comment regarding whether (and, if so, how) the final preventive controls rule for animal food should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain, and Point B in the supply chain is a facility that only packs or holds animal food, but does not manufacture/process animal food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain.

In the remainder of this section, we discuss comments that address our request for comment on complex supply-chain scenarios such as those described in the 2014 supplemental notice. We also describe our reasons for revising the proposed requirements for a supplier program to provide additional flexibility for an entity other than the receiving facility to determine, conduct, and document the appropriate supplier verification activities. When an entity other than the receiving facility determines, conducts, or both determines and conducts the appropriate supplier verification activities, the receiving facility must review and assess that entity's applicable documentation, and document the receiving facility's review and assessment. Providing this additional flexibility required a series of changes to multiple proposed provisions. To improve clarity and readability, we redesignated proposed § 507.36 into eight distinct sections of regulatory text in a newly established subpart E (Supply-Chain Program), with editorial changes associated with the new structure of the redesignated regulations. See table 22 for the section numbers and titles in subpart E. See table 23 for an overview of the major revisions to the proposed requirements for a supply-chain program. See sections XLI through XLVII for a discussion of the specific provisions of the final requirements for a supply-chain program, and tables 24 to 29 for more detailed summaries of revisions to these specific provisions. Because table 23 is an overview, the changes identified in table 23 appear again in, tables 24 to 29. Because the editorial changes associated with the redesignation are extensive, we do not list them in table 31.

The title of subpart E is ''Supply-Chain Program'' rather than ''Supplier Program.'' As shown in table 23 and discussed in more detail in section XLI.D, we have added one requirement applicable to non-suppliers. ''Supply-chain program'' is a more appropriate term to reflect a subpart that includes a requirement applicable to nonsuppliers in addition to the requirements applicable to suppliers. In the remainder of this document, we use the phrase ''supply-chain program'' in section headings and when referring to the provisions of the final rule. We continue to use the term ''supplier program'' when describing the proposed provisions and the comments regarding the proposed provisions.

TABLE 22.4—REDESIGNATION OF THE REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM IN SUBPART E

[Supply-chain program]

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.

TABLE 23.5—OVERVIEW OF REVISIONS TO THE PROPOSED REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
Throughout	Throughout	The type of preventive control applicable to the supply-chain program.	Refer to ''supply-chain-applied control'' rather than ''preventive control'' or variations such as ''hazard requiring a preventive control when the hazard is controlled before receipt of the raw material or other ingredient.''
507.36(a)(2) (in subpart C).	507.37(a)(1)(ii)	A supply-chain program is not required when the hazard will be controlled by the receiving facility's customer in the distribution chain.	Shifted to be in provisions outside the framework of the supply-chain program in subpart E.

TABLE 23.5—OVERVIEW OF REVISIONS TO THE PROPOSED REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Revision
507.105(a)(2)	N/A	Circumstances that do not require a supply-chain program.	The receiving facility does not need a supply-chain program when the receiving facility is an importer, is in compliance with the forthcoming FSVP requirements, and has documentation of verification activities conducted under the forthcoming FSVP program.
507.105(a)(3)	N/A	Exemption from the requirements for a supply-chain program.	Exemption for animal food supplied for research or evaluation.
507.105(c)	N/A	Requirements applicable to non-suppliers	When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (*e.g.*, when a nonsupplier applies controls to certain produce (*i.e.*, produce that will be subject to the forthcoming produce safety rule), 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 in the supply chain, review and assess the entity's applicable documentation, and document that review and assessment.
507.110(c)	507.37(a)(3)(ii)	Purpose of the supply-chain program	Specify only that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.
507.110(d)	507.37(b)	Factors that must be considered in determining appropriate supplier verification activities.	• Clarification that these factors must be considered in approving suppliers, as well as in determining appropriate supplier verification activities. • Flexibility in the factors that must be considered if a supplier is a qualified facility, a produce farm that will not be subject to the forthcoming produce safety rule on the basis of size and/or direct farm marketing, or a shell egg producer that is not subject to the requirements of 21 CFR part 118 (production, storage, and transportation of shell eggs) because it has less than 3,000 laying hens.
507.115(a)	N/A	Responsibilities of the receiving facility	Provide flexibility for an entity other than the receiving facility to determine, conduct, and document supplier verification activities, provided that the receiving facility reviews and assesses applicable documentation from that entity and documents the receiving facility's review and assessment.
507.115(b)	N/A	Responsibilities of the receiving facility	Specify documentation that a receiving facility may not accept from a supplier to satisfy the receiving facility's responsibilities for its supply-chain program.
507.120(a)	507.37(a)(3)(i)	Approval of suppliers	Explicit requirement for a receiving facility to approve its suppliers.
507.120(b)	507.37(a)(3)(i)	Approval of suppliers	Explicit requirement for a receiving facility to establish and follow written procedures for receiving raw materials and other ingredients.
507.130(e)	N/A	Alternative supplier verification activity	Provide for an alternative supplier verification activity when the supplier is a shell egg producer with less than 3,000 laying hens.
507.130(f)	N/A	Independence of the supplier	Specify that there must not be any financial conflicts of interests that influence the results of the verification activities listed in § 507.110(b) and payment must not be related to the results of the activity.

TABLE 23.5—OVERVIEW OF REVISIONS TO THE PROPOSED REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Revision
507.135(c)(1)	507.37(e)	Substitution of an inspection for an audit	Provide additional flexibility for domestic inspection by representatives of other Federal Agencies (such as USDA), or by representatives of State, local, tribal, or territorial agencies.
507.175	507.37(g)	Records documenting the supply-chain program.	List additional records associated with the revised provisions.

(Comment 428) Several comments ask us to issue guidance rather than establish requirements for a supplier program in the rule. Some comments assert that the benefits of a supplier verification program do not outweigh the costs; that we did not consider the effects of such a requirement on farms and small businesses; and that FSMA does not actually contain a requirement for a supplier verification program. Conversely, other comments support including a mandatory supplier program in the rule for hazards that are controlled in raw materials and other ingredients before receipt by the receiving facility, although many comments assert that a supplier verification program should be viewed as a verification activity rather than a preventive control. Some comments assert that a mandatory domestic supplier program is necessary to provide parity with the requirements of the FSVP rule authorized by FSMA, while other comments assert that FSMA's authorization of foreign supplier verification should not be used to justify a domestic supplier program. Some of these comments single out our request for comment, in the proposed FSVP rule, on whether to allow an entity that would be both an importer (under the FSVP rule) and a receiving facility (under the animal food preventive controls rule) to be deemed in compliance with the FSVP rule if it was in compliance with the supplier verification provisions of the animal food preventive controls rule, and agree with such an approach (78 FR 45730 at 45748).

(Response 428) We agree that it is necessary to include a mandatory supply-chain program in the rule to ensure the safety of animal food where hazards are controlled in raw materials and other ingredients before receipt by a receiving facility, and we are finalizing such a requirement in this rule. The statute specifically identifies supplier verification activities as a preventive control (see section 418(o)(3) of the FD&C Act). Further, we believe a supply-chain program is a measure that a person knowledgeable about food safety would establish and implement in order to significantly minimize or prevent hazards requiring a preventive control in an incoming raw material or other ingredient.

Supplier verification is sufficiently important for the control of hazards in both domestic and imported animal foods that FSMA contains provisions for both domestic and foreign supplier verification (sections 418(o)(3) and 805 of the FD&C Act). Because we have aligned the provisions for supplier verification in the FSVP rule with the provisions for a supply-chain program in this rule, we are allowing importers and receiving facilities to take advantage of that fact in considering compliance with both part 507 and our forthcoming FSVP regulations that we proposed to establish in part 1, subpart L, so that they do not have to duplicate verification activities (see § 507.105(a)(2)).

(Comment 429) Some comments that addressed questions we asked in the 2013 proposed preventive controls rule for animal food and the 2014 supplemental notice recommend that we add flexibility to the requirements for a supplier program such that any entity in the supply chain between the supplier and the receiving facility can perform supplier verification activities. Some comments ask us to allow a receiving facility to have a supplier program established for it by another entity. Other comments assert that it would be too burdensome for a receiving facility to consider any information related to the supplier's supplier or to go further back in the supply chain beyond the entity that is one back from the receiving facility. Other comments assert that we should eliminate any requirements for a supplier program from the rule because a supplier program involving more entities than just the receiving facility and the supplier would become too complex. Some comments express concern that we would be creating ''an environment where our supply chain is required to be disclosed to our customers via product testing, audits and supplier verification,'' asserting that this would discourage customers from buying from entities such as repackers when they could go to the source. Some comments state that we have not taken into account the low-risk nature of some industries. Other comments ask us to confirm that distributors and warehouses are not included in the requirements for a supplier program because they would not likely meet the definition of a receiving facility or a supplier.

(Response 429) We agree with comments recommending additional flexibility in the supply-chain program with regard to who can perform certain activities and have added this flexibility to the final rule (see § 507.115). Because the receiving facility and the supplier may be separated by several entities in a supply chain, we are allowing such entities (*e.g.,* distributors, brokers, aggregators) to determine, conduct, and document supplier verification activities as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. However, because the approval of suppliers is ultimately the responsibility of the receiving facility, the rule specifies that only a receiving facility can approve suppliers (see §§ 507.115(a)(1) and 507.120(a) and Response 430).

We disagree that complex supply chains make a supply-chain program too difficult and that a receiving facility cannot be expected to reach further back in a supply chain than the entity immediately before it in the supply chain. Supply-chain programs are currently used by facilities as a standard business practice and we understand that some of those supply chains are complex, with entities between the receiving facility and the supplier. We acknowledge that complex supply chains present a challenge because information will need to flow through several entities to allow the link between the receiving facility and the

supplier. However, we believe a supply-chain program is a critical preventive control for receiving facilities that will rely on suppliers to control hazards in raw materials and other ingredients. Although distributors, brokers, and other entities in the supply chain between a receiving facility and its supplier are not required to have a role in supplier verification, they have the option to determine, conduct, and document supplier verification activities as a service to the receiving facility if they so choose. If these entities choose not to participate in supplier verification, the receiving facility will need to reach back in the supply chain past them. In such situations, it may be necessary for the entities between the receiving facility and the supplier to provide the identity of the supplier to the receiving facility, if that identity is not available on the raw material or other ingredient or otherwise apparent. In such cases, the role that distributors, brokers, aggregators and similar entities would play in supplier verification would be minimal. We cannot determine whether having to provide the identity of the supplier to the receiving facility would change buying practices. However, we believe that manufacturers consider a number of factors in determining who they will purchase from, including the services provided, and that there will continue to be a role for aggregators, repackers, brokers and others. We have provided flexibility for these entities to play a role in supplier verification if the receiving facility and the business entity determine there is a benefit to do so.

See also the discussion in section XLIII regarding the specific provisions of § 507.115. Although comments focus on flexibility for an entity in the supply chain between the supplier and the receiving facility to perform supplier verification activities, and such entities are the most likely to be determining, conducting, and documenting supplier verification activities, the flexibility provided by the rule is not limited to such entities.

(Comment 430) Some comments ask us to establish a general requirement for a supplier program without specifying roles and responsibilities for the various entities involved. Other comments ask us to define ''supplier'' as the entity with which the receiving facility has a commercial relationship.

(Response 430) We disagree that we should establish a general requirement for a supply-chain program without specifying roles and responsibilities for the various entities involved. Although we have added flexibility to provide that an entity other than the receiving facility may determine, conduct, and document supplier verification activities (see § 507.115), we continue to believe it is important to clearly define two roles in the supply chain that share the primary responsibility in the supplier verification process—*i.e.,* the receiving facility and the supplier. In all cases where we have added flexibility for participation by an entity other than the receiving facility, the responsibility for the supply-chain program is clearly lodged with the receiving facility, and linked to the supplier (see § 507.115). To emphasize the responsibility of the receiving facility and its link to the supplier, the final rule clearly states that the receiving facility must approve its suppliers before receiving raw materials and other ingredients (see § 507.120(a)).

For the supply-chain program to be meaningful and robust, there must be an exchange of information between these two entities—the entity receiving the animal food and the entity that controlled the hazard—even when an entity other than the receiving facility participates by determining, conducting, and documenting some supplier verification activities. The ultimate responsibility for supplier verification rests with the receiving facility through its determination in approving suppliers and in reviewing and assessing applicable documentation provided by another entity. Therefore, we also disagree that the definition of ''supplier'' should be revised to be the next entity back in a supply chain (*e.g.,* the entity with which a receiving facility has a commercial relationship). The entity with which a receiving facility has a commercial relationship might be a distributor, broker or aggregator. A distributor, broker or aggregator does not control an identified hazard and, therefore, cannot assume the same role as an establishment that manufactures/processes the animal food, raises the animal, or grows the food.

(Comment 431) Some comments ask us to provide flexibility in the content of the supplier program. Some comments assert that specifying the content of the supplier program would result in duplicative requirements on suppliers, who must first comply with certain regulations and then demonstrate that compliance in order to comply with a different regulation.

(Response 431) We disagree that a requirement for a supply-chain program in which compliance with an underlying regulation is demonstrated is duplicative with the need to comply with the underlying regulation. The requirement for a supply-chain program is not mandating that the facility or farm comply twice with the animal food preventive controls rule or the produce safety rule; it is merely requiring that the compliance by the facility or the farm with the applicable regulation be verified to ensure that hazards requiring a preventive control are being controlled.

We are continuing to specify the basic content of a supply-chain program, *i.e.,* using approved suppliers; determining appropriate supplier verification activities; conducting supplier verification activities; and establishing records documenting these activities (see § 507.110(a)). However, the rule provides flexibility in the choice of supplier verification activities and how often such activities must be performed. (See §§ 507.110(b)(4) and 507.130(b)(2), (c), (d), and (e)). In addition, the rule provides for an alternative supplier verification activity for certain entities (see § 507.130(c), (d), and (e) regarding alternative supplier verification activities for qualified facilities, certain produce farms, and certain shell egg producers, respectively).

XLI. Subpart E: Comments on Requirement To Establish and Implement a Supply-Chain Program

We proposed that the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient (proposed § 507.37(a)). We also proposed circumstances when a receiving facility would not be required to have a supplier program.

In the following sections, we discuss comments that ask us to clarify the proposed requirement to establish and implement a written supplier program or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the regulatory text as shown in table 24.

TABLE 24—REVISIONS TO THE PROPOSED REQUIREMENTS TO ESTABLISH AND IMPLEMENT A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
N/A	507.37(a)(1)(ii)	A supplier program is not required when there are no hazards requiring a preventive control.	Deleted as unnecessary.
N/A	507.37(a)(1)(ii)	A supplier program is not required when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards requiring a preventive control.	Deleted as unnecessary.
507.36(a)(2)	507.37(a)(1)(ii)	A supplier program is not required when the hazard will be controlled by the receiving facility's customer in the distribution chain.	Shifted to be in provisions outside the framework of the supply-chain program in subpart E.
507.105(a)(2)	N/A	Circumstances that do not require a supply-chain program even though the receiving facility's hazard analysis determines that a hazard requires a supply-chain-applied control.	A receiving facility is an importer, is in compliance with the FSVP requirements, and has documentation of verification activities conducted under the FSVP program.
507.105(a)(3)	N/A	Exemption from the requirements for a supply-chain program.	Exemption for animal food supplied for research or evaluation.
507.105(c)	N/A	Requirements applicable to non-suppliers	When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier, the receiving facility must (1) verify the supply-chain-applied control; or (2) obtain documentation of an appropriate verification activity from another entity in the supply chain, review and assess the entity's applicable documentation, and document that review and assessment.

A. Requirement for a Written Supply-Chain Program (Final § 507.105(a)(1) and (b))

We proposed that the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient. We also proposed that the supplier program must be written. (See proposed § 507.37(a)(1)(i) and (2).) To improve clarity, we have revised the provision to substitute the phrase ''hazard requiring a supply-chain-applied control'' for the phrase ''significant hazard when the hazard is controlled before receipt of the raw material or ingredient.'' We have added a definition for the term ''supply-chain-applied control'' to mean 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 § 507.3) and use the more specific term '' supply-chain-applied control,'' rather than the broader term ''preventive control,'' throughout the provisions for a supply-chain program.

(Comment 432) As discussed in Comment 428, several comments ask us to issue guidance rather than establish requirements for a supplier program in the rule.

(Response 432) See Response 428 for a discussion of our reasons for declining this request and establishing requirements for a supply-chain program in the rule.

(Comment 433) Some comments ask us to revise the regulatory text to remove the condition that all hazards be foreseeable so that the supplier program can address economically motivated adulteration.

(Response 433) This comment is unclear. The requirement for a supply-chain program applies when the outcome of a hazard analysis is that a known or reasonably foreseeable hazard requires a preventive control, and the hazard would be controlled by the receiving facility's supplier. The requirement applies regardless of whether the hazard requiring a preventive control is, or is not, a hazard that would be introduced into a food for the purposes of economic gain.

(Comment 434) Some comments ask us to specify that a Certificate of Analysis or other documentation of the existence and/or level of a hazard could be provided to the receiving facility to indicate the potential for an actual existence of a hazard so that the receiving facility could evaluate whether the hazard requires a preventive control. Some comments state that chemical hazards such as nutrient imbalances are not controlled through easily described ''procedures'' but are instead controlled through factors such as product formulation (*e.g.,* controlling the levels of required or contaminating chemicals in each ingredient depending on the proportion of the ingredient in the finished animal food) and the amount fed. For example, some comments explain that mineral content of certain raw materials or ingredients may require control in some situations (*e.g.,* copper content in food for sheep) but not in other situations (*e.g.,* copper content in swine food). One comment expresses concern about whether customers would be willing to provide the receiving facility with confidential information about the customer's own hazard analysis with respect to sensitive topics. Furthermore, in such cases the receiving facility will not even know whether the chemical contaminant constitutes an actual ''hazard'' for the purposes of the customer's finished food. This comment also asserts that a Certificate of Analysis provided to a receiving facility constitutes ''control before receipt of the raw material or ingredient.''

(Response 434) We do not understand the concern of this comment. A receiving facility and a supplier do not need to share all of the details of product formulation for a receiving facility to communicate its requirements to a supplier. In the example provided by the comment, the receiving facility could provide the supplier with a

written specification for a contaminant such as lead, and the supplier could demonstrate that it satisfied the receiving facility's specification by providing a Certificate of Analysis showing the results of laboratory testing for lead. Neither the written specification provided by the receiving facility, nor the Certificate of Analysis provided by the supplier, would disclose confidential information about the formulations or procedures of either entity.

This comment also appears to misunderstand the applicability of the supply-chain program. The rule requires a supply-chain program when the receiving facility has identified, through its hazard analysis, that there is a hazard requiring a supplier-applied control. In the circumstances described by the comment, a Certificate of Analysis or other documentation of test results from the supplier to the receiving facility could demonstrate that the supplier has controlled the hazard to the receiving facility's specifications, but would not overturn the outcome of the receiving facility's hazard analysis that there is a hazard requiring a preventive control, and that the appropriate control is applied by the supplier. On the contrary, the Certificate of Analysis simply demonstrates that the supply-chain-applied control functioned as intended.

(Comment 435) One comment asks us to specify in the regulatory text that the supplier program must be written ''if required'' because there are specified circumstances when a supplier program is not required.

(Response 435) We decline this request. Although the rule provides circumstances when a supply-chain program is not required (see § 507.105(a)(2)), it is not necessary to specify, for all other provisions of the supply-chain program, that the provision only applies ''if required.''

B. Circumstances That Do Not Require a Written Supply-Chain Program (Final § 507.105(a)(2))

We proposed that the receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which there are no significant hazards; the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or the receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. (See proposed § 507.37(a)(1)(ii)(A), (B), and (C).)

We are deleting the proposed provision that a supplier program is not required for raw materials and ingredients for which there are no ''significant hazards'' (which we now refer to as ''hazards requiring a preventive control'') because it is unnecessary. The supply-chain program is required when a hazard identified in the receiving facility's hazard analysis identifies a hazard requiring a supply-chain-applied control; it is not necessary to also state the converse. Likewise, we are deleting the proposed provision that a supplier program is not required if the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards. In such a case, the outcome of the hazard analysis would not be that the hazard requires a supply-chain-applied control.

As discussed in section XXVII, after considering comments, we are shifting the provision in which the receiving facility relies on its customer to control the hazard from the requirements for a supply-chain program to a series of provisions that apply when a manufacturer/processor identifies a hazard requiring a preventive control, but can demonstrate and document that the hazard will be controlled by an entity in its distribution chain (see §§ 507.36 and 507.37). However, as discussed in Response 428 and section XLI.C, we also are establishing two additional circumstances when a supply-chain program is not required (see § 507.105(a)(2) and (3)).

(Comment 436) As noted in Comment 428, some comments single out our request for comment, in the proposed FSVP rule, on whether to allow an entity that would be both an importer (under the FSVP rule) and a receiving facility (under animal food the preventive controls rule) to be deemed in compliance with the FSVP rule if it was in compliance with the supplier verification provisions of the animal food preventive controls rule, and agree with such an approach (78 FR 45730 at 45748).

(Response 436) As noted in Response 428, we have aligned the provisions for supplier verification in the FSVP rule with the provisions for a supply-chain program in this rule, and we are allowing importers and receiving facilities to take advantage of that fact in considering compliance with our forthcoming FSVP regulations that we proposed to establish in in part 1, subpart L, so that they do not have to duplicate verification activities (see § 507.105(a)(2)).

(Comment 437) Some comments support the specified criteria for when a receiving facility would not be required to establish and implement a supplier program. Other comments express concern that these criteria suggest no supplier verification is needed at all in some circumstances despite supplier verification activities being potentially informative about a particular supplier. These comments ask us to establish some general requirement to perform verification activities for all suppliers.

(Response 437) We decline this request because it is neither risk-based nor consistent with the nature and purpose of the supply-chain program, which is to provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented (see the regulatory text of § 507.110(c)). We agree that some degree of verification of all suppliers may prove useful to a receiving facility for various purposes, and the rule would not prevent a receiving facility from establishing a supply-chain program for all of its suppliers regardless of risk and regardless of whether the applicable hazard in a raw material or other ingredient is controlled before its receipt.

(Comment 438) Some comments ask us to specify that a ''kill step'' would be an adequate indicator to significantly minimize or prevent significant hazards identified by the receiving facility when the receiving facility controls the hazard.

(Response 438) These comments appear to misunderstand the applicability of the supply-chain program. The rule requires a supply-chain program when the receiving facility has identified, through its hazard analysis, that there is a hazard requiring a preventive control and the receiving facility's manufacturing/processing will not control the hazard. In the circumstances described by the comment, the receiving facility is controlling the hazard and a supply-chain program for the raw material or other ingredient is not required. It is not necessary to specify the types of controls that the receiving facility may use to control the hazard.

(Comment 439) Some comments ask us to specify that a receiving facility need not establish and implement a supplier program for raw materials and ingredients if those raw materials or ingredients were received from an affiliated party within the same corporate or controlling entity.

(Response 439) We decline this request. With the revisions we have made to the proposed requirements for a supplier program, the supply-chain program that we are establishing in this rule provides ample opportunities for an affiliated party within the same corporate or controlling entity to establish and implement a supply-chain program that is suited to its relationship to these entities. For example, as discussed in Response 458, a receiving facility might be able to determine and document a justification for a supplier verification activity other than an annual audit when a supplier is an affiliated party based on the receiving facility's knowledge of the corporate policies regarding animal food safety practices (see § 507.130(b)(2)). In addition, as discussed in Response 461, we have agreed that the corporate parent of a facility can be active in developing and implementing the facility's food safety plan (see section XXIV.A). If, for example, a corporate headquarters establishes and implements a supply-chain program for use company-wide, a receiving facility could rely on supplier verification activities conducted by its corporate headquarters, with applicable documentation available during inspection.

C. Exemption for Animal Food Supplied for Research or Evaluation (Final § 507.105(a)(3))

We are establishing an exemption from the requirement for a receiving facility to establish and implement a supply-chain program when it receives animal food for the purposes of research or evaluation, provided that certain conditions are met (see § 507.105(a)(3)). Those conditions are that the animal food: (1) Is not intended for retail sale and is not sold or distributed to the public; (2) is labeled with the statement ''Animal food for research or evaluation use''; (3) 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; and (4) 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. The exemption is analogous to an exemption we proposed for the FSVP rule under section 805(f) of the FD&C Act. (See proposed § 1.501(c), 78 FR 45730 at 45745.) We believe it is not necessary to conduct supplier verification activities when animal food is obtained in this limited circumstance.

D. Additional Requirements for Non-Suppliers (Final § 507.105(c))

As discussed in section IV.B of this rule and in section IV.B of the final rule for preventive controls for human food as published elsewhere in this addition of the **Federal Register,** the final rule for preventive controls for human food includes several revisions to the ''farm'' definition in response to comments. One change includes adding a new definition for a ''secondary activities farm,'' which provides for practices such as packing by cooperatives and packing houses under the ownership of multiple growers to remain within the ''farm'' definition (see Response 25 in the final rule for preventive controls for human food). Another change to the ''farm'' definition accommodates business models in which one operation grows crops but does not harvest them, and another operation, not under the same management, harvests crops but does not grow them (see Response 32 in the final rule for preventive controls for human food). This revision is a change from the ''farm'' definition established in the section 415 registration regulations in 2003, and the proposed revisions to the ''farm'' definition in the 2013 proposed human food preventive controls rule and the 2014 supplemental human food preventive controls notice, which all describe a ''farm'' as an entity ''devoted to the growing *and* harvesting of crops'' (emphasis added).

We proposed the requirements for a supplier program in the context of a single business entity ''*devoted to the growing and harvesting of crops''* (emphasis added) in which packing operations were often done by that same business entity. The final ''farm'' definition accommodates business models where growing, harvesting, and packing operations will be done by different business entities. Harvesting and packing operations include some supply-chain-applied controls, such as controls on worker hygiene, quality of water used during harvesting and packing operations, and establishing and following water-change schedules for recirculated water, even though the harvesting and packing operations do not fall within the definition of ''supplier.''

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 animal food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act (see section 418(c) of the FD&C Act and § 507.34(a)). That obligation includes responsibilities for raw materials and other ingredients when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier. To clarify the receiving facility's responsibilities when a supply-chain-applied control is applied by a non-supplier, we are establishing a requirement specifying that when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier, the receiving facility must: (1) Verify the supply-chain-applied control or (2) obtain documentation of an appropriate verification activity from another entity in the supply chain, review and assess the entity's applicable documentation, and document that review and assessment. See § 507.105(c). Because § 507.105(c) refers to provisions in a future produce safety rule, we will publish a document in the **Federal Register** announcing the effective date of that provision when we finalize the produce safety rule.

We do not expect the receiving facility to follow all of the requirements of subpart E applicable to ''suppliers'' when verifying a control by a ''non-supplier,'' as required by § 507.105(c). Instead, we expect the receiving facility to take steps such as a review of the non-supplier's applicable food safety records. For example, if a receiving facility receives produce from a supply chain that includes a separate grower, harvester, and packer, the grower is the supplier and the requirements of subpart E applicable to ''suppliers'' apply to the grower. To verify controls applied by the harvester, the receiving facility could review the harvester's records, such as records of training for harvest workers and records of agricultural water quality used in harvest operations. To verify controls applied by the packer, the receiving facility could review the packer's records, such as records of agricultural water quality used in packing operations. As discussed in Response 429, we are allowing entities such as distributors, brokers, and aggregators to determine, conduct, and document verification activities that apply to suppliers as a service to the receiving facility, provided that the receiving facility reviews and assesses applicable documentation provided by the other entity and documents that review and assessment. Likewise, under § 507.105(c)(2) a receiving facility could obtain documentation of review of applicable records maintained by the harvester or packer from another entity, review and assess the entity's applicable

documentation, and document that review and assessment.

We recognize that 507.105(c) may have limited applicability to raw material and other ingredients used in animal food. At this time, we do not have an example of when we would expect an animal food manufacturer to verify non-supplier controls for its raw materials or other ingredients. Although we do not have examples and expect limited applicability of § 507.105(c)(2), we have included these provisions to provide for instances when an animal food facility identifies situations in which controls applied by a ''non-supplier'' need to be verified as part of the facility's supply-chain program.

E. Proposed General Requirements for the Supply-Chain Program That We Are Not Including in the Final Rule (Proposed § 507.37(a)(4) and (5))

We proposed that when supplier verification activities are required for more than one type of hazard in a food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards. We also proposed that for some hazards, in some situations it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented. We have concluded that these provisions are largely self-evident and need not be included in the regulatory text. Therefore, we are not finalizing these proposed provisions. We will consider whether it will add value to discuss the principles in these proposed provisions in guidance that we intend to develop for the supply-chain program.

XLII. Subpart E: Comments on General Requirements for the Supply-Chain Program

We proposed several requirements generally applicable to the supplier program (such as factors to consider in determining appropriate supplier verification activities (proposed § 507.37(b)), as well as several requirements more narrowly targeted to specific aspects of the supplier program (such as requirements applicable to onsite audits). As part of the redesignation of proposed § 507.37 into subpart E, with eight distinct sections, we are establishing the more general requirements in § 507.110 (see table 25).

Most comments that support the proposed provisions suggest alternative or additional regulatory text. In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the regulatory text as shown in table 25.

TABLE 25—REVISIONS TO THE PROPOSED GENERAL REQUIREMENTS APPLICABLE TO A SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Revision
507.110(a)	507.37(a)(3)	What the supply-chain program must include.	Add that the supply-chain program includes, when applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment.
507.110(b)	507.37(c)(1)	Appropriate supplier verification activities.	N/A.
507.110(c)	507.37(a)(3)(ii)	Purpose of supplier verification activities for raw materials and other ingredients.	Specify only that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.
507.110(d)	507.37(b)	Factors that must be considered when approving suppliers and determining appropriate supplier verification activities for raw materials and other ingredients.	Clarify that the factors apply in approving suppliers, as well as in determining appropriate supplier verification activities.
507.110(d)	507.37(b)	Factors that must be considered when approving suppliers and determining appropriate supplier verification activities for raw materials and other ingredients; Supplier performance..	• Specify that three of the factors relate to ''supplier performance'' • Specify ''The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control'' rather than ''Where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier's supplier''. • Add ''other FDA compliance actions related to food safety'' as an example of information relevant to the supplier's compliance with applicable FDA food safety regulations. • Clarify that consideration of supplier performance includes, 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.

TABLE 25—REVISIONS TO THE PROPOSED GENERAL REQUIREMENTS APPLICABLE TO A SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Revision
			• Provide flexibility in the factors that must be considered if a supplier is a qualified facility, a produce farm that will not be subject to the forthcoming produce safety rule on the basis of size and/or direct farm marketing, or a shell egg producer that is not subject to the requirements of 21 CFR part 118 (production, storage, and transportation of shell eggs) because it has less than 3,000 laying hens.
507.110(e)	507.37(f)	Supplier non-conformance	N/A.

A. Description of What the Supply-Chain Program Must Include (Final § 507.110(a))

We proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers) (proposed § 507.37(a)(3)(i)). We also proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities. We also proposed requirements applicable to the determination and documentation of appropriate supplier verification activities (proposed § 507.37(b)). We also proposed specific documentation requirements for records associated with the supplier program (proposed § 507.37(g)).

The final rule specifies that the supply-chain program must include: (1) Using approved suppliers; (2) determining appropriate supplier verification activities (including determining the frequency of conducting the activity); (3) conducting supplier verification activities; and (4) documenting supplier verification activities. For clarity, § 507.110(a) states this general requirement for the supply-chain program and §§ 507.120, 507.125, 507.130, 507.135, and 507.175 provide the specific requirements for using approved suppliers, determining appropriate supplier verification activities, conducting verification activities, specific requirements for onsite audits, and records, respectively. See the discussion of the specific requirements of §§ 507.120, 507.125, 507.130, 507.135, and 507.175 in sections XLIV, XLV, XLVI, and XLVII, respectively.

As discussed in section XLI.D, the final rule establishes a verification requirement when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (see § 507.105(c)). For clarity, § 507.110(a) states this general requirement for the supply-chain program in § 507.105(a)(5), and § 507.105(c) provides the specific requirements that apply when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

B. Appropriate Supplier Verification Activities ((Final § 507.110(b))

We proposed to require that appropriate supplier verification activities include: (1) Onsite audits; (2) sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility; (3) review by the receiving facility of the supplier's relevant food safety records; or (4) other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier (proposed § 507.37(c)(1)).

(Comment 440) Some comments support the inclusion of onsite audits as an appropriate supplier verification activity. However, other comments oppose it, and ask us to remove the onsite audit requirement from the supplier verification program, stating that Congress prohibited FDA from requiring third parties to verify or audit compliance with the rules. These comments express concern that the supplier verification program effectively imposes an ''entire second layer of regulation'' on farms that are supplying ingredients to processors, and claim this is an unnecessary burden that is not authorized by FSMA.

(Response 440) We are retaining onsite audits as an appropriate supplier verification activity. Onsite audits may be less commonly used by the animal food industry than the human food industry. However, onsite audits provide the opportunity to review the food safety plan and written procedures and to observe the implementation of animal 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 animal food safety measures for which they are responsible. Thus, an audit can provide for a more comprehensive assessment of animal food safety implementation by a facility. Comments that oppose including onsite audits as a verification activity are concerned that farms will be required to have audits to verify that they are in compliance with produce safety standards or facilities will be required to have audits to verify preventive controls. These comments apparently refer to the provision in section 419(c)(1)(E) of the FD&C Act that the regulation issuing standards for the safety of produce ''not require a business to hire a consultant or other third party to identify, implement, certify compliance with these procedures, processes and practices,'' or the provision in section 418(n)(3)(D) of the FD&C Act that the preventive controls regulation ''not require a facility to hire a consultant or other third party to identify, implement, certify or audit preventative controls.'' The regulations proposed under section 419 of the FD&C Act would not impose such requirements. The requirements for supplier verification in this rule (under section 418 of the FD&C Act) provide for audits as one supplier verification activity. Although the rule does specify an annual onsite audit as the appropriate supplier verification activity 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, the receiving facility is not required to hire a third

party to conduct the audit. Any qualified auditor, other than the supplier, may conduct the audit, including an employee of the receiving facility or another entity, such as an entity in the supply chain between the supplier and the receiving facility. The rule also provides that a receiving facility may determine and document that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (see § 507.130(b)(1) and (2)). Audits already conducted on a supplier's facility or operation for other business purposes may meet the requirement for supplier verification. In addition, the rule provides alternative requirements for verification of suppliers that are farms that grow produce and are not a covered farm under part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5 (see § 507.130(d)). Finally, we have also provided that inspections may substitute for an audit under specified circumstances (see § 507.135(c)).

While we realize that some farms may receive audits under the supplier verification provisions of part 507, we anticipate that onsite audits will be used as a verification activity more frequently for non-farm facilities because hazards associated with commercial animal food production are not typically controlled by the farm, but rather during manufacture or processing of the animal food.

(Comment 441) Some comments support the inclusion of sampling and testing of the raw material or other ingredient as an appropriate supplier verification activity, and note that verification testing is more effective when conducted by the supplier than the receiving facility because the supplier can control the lot of product tested. However, other comments oppose it, stating that sampling and testing is not useful for products for various reasons such as the non-homogeneous distribution of some hazards, or statistical limitations because of practical limits on number of samples or limited shelf life of some products.

(Response 441) We are retaining sampling and testing as an appropriate supplier verification activity. As noted in the FDA memorandum on supplier programs, sampling and testing are commonly used by industry in the verification of supplier performance (Ref. 53). We have previously discussed factors that impact the utility and frequency of raw material/ingredient testing (see the Appendix published in the 2013 proposed preventive controls rule for animal food (78 FR 64736 at 64836)). We agree that there are benefits in having sampling and testing conducted by the supplier, because the supplier can then take appropriate action with respect to the findings, including not shipping contaminated product. However, because contamination with some hazards is likely to be non-homogeneous and for microbial pathogens or microbial toxins the numbers are likely to be low, a negative test result does not guarantee the absence of contamination. This should be taken into account when deciding which verification activity (or activities) is appropriate. Because of the limitations of sampling and testing, the controls the supplier has in place to minimize contamination, and the management of those controls, are key in determining when sampling and testing is appropriate as a verification activity. For short shelf life products, where holding product pending test results can negatively impact product quality and usefulness, an onsite audit to verify control of hazards may be more appropriate than sampling and testing.

(Comment 442) Some comments ask us to specify in the regulatory text that sampling and testing can be conducted by or on behalf of the supplier or the receiving facility.

(Response 442) The provisions of § 507.115 specify the responsibilities of the receiving facility, and allow a receiving facility to conduct all supplier verification activities, including sampling and testing. These provisions also provide that a supplier, or an entity other than the receiving facility (such as an entity in the supply chain between the supplier and the receiving facility), can conduct sampling and testing, provided that the receiving facility reviews and assesses the documentation provided by the supplier. The rule places no restrictions on when a receiving facility, a supplier, or an entity other than the receiving facility could have a business relationship with a third party (such as a contract laboratory) to conduct sampling and testing.

(Comment 443) Some comments suggest that, for a facility regularly undergoing audits, reviewing a ''supplier's relevant food safety records'' should allow for the receiving facility to review documentation related to pre-existing audits. These comments ask us to revise the provision to add ''including, but not limited to, records related to audits previously performed on the supplier's facility.''

(Response 443) We decline this request. The comment misinterprets what we mean by a ''supplier's relevant food safety records.'' The rule provides for onsite audits as a verification activity, as well as reviewing a ''supplier's relevant food safety records.'' When an annual audit is determined to be an appropriate verification activity (see § 507.130(b)(1)), the audit would be reviewed by the receiving facility, but a review of this audit is not what we meant by a ''supplier's relevant food safety records.'' As described in an FDA memorandum on supplier programs, food safety records are records documenting that the food safety procedures that have been established to control hazards are being followed and are adequately controlling such hazards (Ref. 53). Thus, a receiving facility may obtain documentation of a supplier's control measures for a particular lot of a raw material or other ingredient provided to the receiving facility, such as the records created when a process control measure was applied. The food safety records may also include supplier records that show that the supplier's supplier has controlled a hazard. Such records may include audits, for example, when the supplier's supplier controls the hazard and the supplier's records include records of an audit conducted with respect to the hazard control activities of the supplier's supplier. To emphasize that the review of a supplier's relevant food safety records can include records other than records of audits, we have revised the documentation requirements applicable to review of a supplier's food safety records to specify that the documentation must include the general nature of the records reviewed (see § 507.175(c)(9)). By ''general nature of the records reviewed'', we mean information such as ''records of process controls.''

(Comment 444) Some comments support the inclusion of other appropriate supplier verification activities based on the risks associated with the ingredient and the supplier, because it provides flexibility for facilities to design risk-based programs that are appropriate for their operations. Comments suggest other verification activities may include receiving raw materials and other ingredients from a supplier without a full audit report if the supplier maintains certification to a standard recognized by the Global Food Safety Initiative (GFSI); providing for documentary verification (such as fact-specific questionnaires and representations exchanged between the supplier and the receiving facility); and confirming that a facility, especially a small manufacturing facility, is licensed

by the appropriate State or local regulatory authority.

(Response 444) We are retaining this provision to allow other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient (§ 507.110(b)(4)). We have revised the regulatory text to refer to ''supplier performance and the risk associated with the raw material or other ingredient'' because ''supplier performance'' is more appropriate than ''risk associated with the supplier.'' We use the term ''risk'' as defined by the Codex Alimentarius Commission to be ''a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food'' (Ref. 54). As discussed in section XLII.D, the considerations for supplier performance, which can be related to the probability of a hazard in the raw material or ingredient and the severity of adverse health effects that can result, are broader than this.

We do not believe that a supplier maintaining certification to an industry standard would, by itself, serve as verification that a supplier is controlling the hazard; however we agree that this can be a consideration in the determination of the type and frequency of the verification activity conducted. Similarly, fact-specific questionnaires and representations exchanged between the supplier and the receiving facility can be a consideration in the determination of the type and frequency of the verification activity conducted. Confirming that a facility is licensed by the appropriate State or local regulatory authority should not serve as the only verification that a supplier is controlling the hazard, because the requirements for a license and the degree of inspectional oversight could vary greatly. We do provide for modified supplier verification activities for qualified facilities, which are very small businesses (§ 507.130(c)).

C. Purpose of Supplier Verification Activities for Raw Materials and Other Ingredients (Final § 507.110(c))

We proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities, to verify that: (1) The hazard is significantly minimized or prevented; (2) the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act of the FD&C Act; and (3) the incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations (proposed § 507.37(a)(3)(ii)). We have revised the provision to specify that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. If the supply-chain program provides assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented, it is not necessary to also specify that the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act. We also have deleted the requirement that the verification activities must verify that the incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations and instead focused that requirement as a factor that must be considered in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted rather than as one of the stated purposes of the supply-chain program. See the regulatory text of § 507.110(d)(i)(iii)(B).

(Comment 445) Some comments ask us to revise this provision to state that the receiving facility's use of the incoming raw material or ingredient will not cause the finished food to be adulterated under section 402 of the FD&C Act. These comments assert that FSMA does not mandate, nor is it reasonable to expect, that incoming raw materials and ingredients will not be adulterated under section 402, and that it is acceptable for a receiving facility to control the ''adulterating hazard,'' even if it relies on the supplier to control other hazards.

(Response 445) We decline this request. We acknowledge that in some circumstances a receiving facility may rely on the supplier to control certain hazards, while controlling other hazards itself. For example, a receiving facility that produces dry dog food that contains corn could rely on its supplier for the control of the chemical hazard aflatoxin, but control the biological hazard *Salmonella* through its own heat-treatment process. However, the supply-chain program applies to hazards requiring a supply-chain-applied control, and the purpose relates to those hazards. In the example where the receiving facility is relying on the supplier to control aflatoxin, the provision would require the receiving facility to verify that the hazard (aflatoxin) has been significantly minimized or prevented by the supplier and that the level of aflatoxin in the corn does not render it adulterated under the FD&C Act.

D. Factors That Must Be Considered When Approving Suppliers and Determining Appropriate Supplier Verification Activities for Raw Materials and Other Ingredients (Final § 507.110(d))

We proposed that in determining and documenting the appropriate verification activities, the receiving facility must consider the following: (1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients; (2) where the preventive controls for those hazards are applied for the raw material and ingredients, such as at the supplier or the supplier's supplier; (3) the supplier's procedures, processes, and practices related to the safety of the raw material and ingredients; (4) 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 the animal food; (5) the supplier's food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and (6) any other factors as appropriate and necessary, such as storage and transportation practices (proposed § 507.37(b)).

As discussed in Responses 429 and 430 and section XLIV.A, we have revised the regulatory text regarding use of approved suppliers to more explicitly state that the receiving facility must approve suppliers. The factors that must be considered in determining the appropriate supplier verification activities are equally relevant to approving suppliers, and the final rule requires that these factors must be considered in approving suppliers, as well as in determining appropriate supplier verification activities. For clarity and consistency with terms used throughout the final provisions for a supply-chain program, the final rule specifies ''the entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control'' rather than ''Where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier's supplier.''

As discussed in Response 444, we are using the term ''supplier performance,'' rather than ''risk of supplier,'' when discussing factors associated with

suppliers. The final rule groups three of the proposed factors as ''supplier performance.'' As a companion change to emphasize that ''supplier performance'' applies to all three of these factors, we refer to the supplier's ''food safety history'' rather than ''food safety performance history.''

We also have revised the regulatory text to clarify that consideration of supplier performance includes, 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. We made this change because the final rule includes several provisions that acknowledge that some animal food establishments, including animal food establishments that are ''suppliers'' as that term is defined in this rule, operate in a foreign country. (See, *e.g.,* the definition of ''qualified auditor'' in § 507.3 and §§ 507.7(a)(2)(ii), 507.7(e), 507.105(a)(2), 507.130(c), 507.135(c)(1)(ii), 507.135(c)(2), and 507.175(c)(15)). Some of these provisions (*e.g.,* §§ 507.105(a)(2), 507.130(c), 507.135(c)(1)(ii), 507.135(c)(2), and 507.175(c)(15)) are in the requirements for a supply-chain program. 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, a receiving facility may substitute the written results of an inspection by the applicable food safety authority for an audit, provided that certain conditions are met (see § 507.135(c)(1)(ii) and (2)). However, as of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food. The final rule provides flexibility for alternative verification requirements for certain entities (see § 507.130(c), (d), and (e)). We have revised the factors that must be considered regarding supplier performance to reflect the flexibility the rule provides for conducting supplier verification activities for these entities (see § 507.110(d)(2)).

(Comment 446) Some comments support the flexibility for receiving facilities to determine the appropriate supplier verification activities and frequency with which to conduct these activities. Some comments state that not all of the factors that we proposed a receiving facility consider are relevant for the process of selecting the verification activity. These comments suggest changing the regulatory text to require a receiving facility to consider ''both food and supplier related risks, including the following, as appropriate'' and then listing the factors as proposed. Other comments suggested similar changes to the regulatory text.

(Response 446) We disagree that not all of the factors that we proposed a receiving facility to consider are relevant to determining the appropriate verification activity. Every factor might not be determinative in all cases, and our requirement merely to consider each factor does not assume so. However, any one of these factors could be crucial depending on the animal food, the hazard, and the nature of the preventive control. We continue to consider it appropriate to require receiving facilities to consider each of these factors in making their determinations about the appropriate verification activities.

(Comment 447) Some comments ask us to clarify that the phrase ''the nature of the hazard'' means the nature of the hazard requiring control.

(Response 447) We have revised the regulatory text to specify ''the nature of the hazard controlled before receipt of the raw material or other ingredient.'' The revised regulatory text is consistent with regulatory text in the provisions for the preventive control management components (see § 507.39(b), which specifies ''taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient'').

(Comment 448) Some comments agree that a receiving facility must consider where the preventive controls for hazards are applied for the raw materials and ingredients, such as at the supplier or the supplier's supplier. Other comments assert that this consideration should not be used to determine if supplier oversight is needed. Other comments state that it may be hard to review the procedures used by a supplier's supplier and beyond and ask us to provide clear flexibility regarding requirements for the content and performance of a receiving facility's supplier program.

(Response 448) The purpose of the requirement to consider where the hazard is controlled is to assist a receiving facility in determining what supplier verification activities are appropriate, not to determine whether supplier oversight is needed. Once a receiving facility has determined that a hazard requiring a preventive control is controlled before receipt of a raw material or other ingredient, supplier oversight is needed.

We recognize that there is need for additional flexibility regarding conducting supplier verification activities. As discussed in Response 429, we are providing significant additional flexibility to address this situation in the final rule.

(Comment 449) Some comments object to the proposed requirement to consider 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 the food. These comments assert that it is difficult for a receiving facility to know a supplier's compliance status, because it is not easy to obtain this kind of information in a timely fashion. Some comments ask us to develop an online database to house this information to help make it easier to find. Some comments ask us to replace the broad requirement to consider applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations with a narrower requirement to only consider any FDA warning letter or import alert relating to the safety of the food.

(Response 449) We are retaining the broad requirement to consider applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations. Such information is relevant to supplier performance regardless of whether there is an applicable warning letter or import alert.

We currently have a searchable online database for warning letters (Ref. 55) and another searchable online database for import alerts (Ref. 56). Both of these databases are available to the public from our homepage at *http://www.fda.gov*. We also publicize actions to suspend a facility's registration, such as in our 2012 suspension of registration due to *Salmonella* contamination of nut butter and nut products (including ingredients used in animal foods) manufactured, processed, packed, and held by the facility (Ref. 57). Under the requirement to consider supplier performance with respect to applicable food safety regulations, a receiving facility cannot ignore published information relating to a supplier's compliance with applicable FDA food safety regulations in determining the appropriate verification activities, such as publicized information regarding suspension of registration. To

emphasize this point, we have revised the regulatory text to specify that the applicable information includes ''other FDA compliance actions related to animal food safety.'' We also have revised the regulatory text to specify that the compliance relates to an FDA warning letter or import alert relating to the ''safety of animal food,'' rather than the ''safety of the animal food,'' to provide flexibility for a receiving facility to identify information that may raise a question about a supplier's compliance history in a more general way, rather than only with respect to a particular animal food.

(Comment 450) Some comments state we should only require consideration of the supplier's food safety performance history relevant to the hazards requiring control in the raw materials or ingredients that the receiving facility receives from the supplier.

(Response 450) Consideration of the supplier's animal food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier will be focused on the hazard that the supplier is controlling because that is the food safety information the receiving facility will consider to be relevant and for which the receiving facility would develop a history. The information could indicate that certain verification activities may be more appropriate than others for verifying the control of the hazard at that particular supplier or provide information useful in determining a frequency for the verification activity. However, we decline to revise the provision to specify that consideration should be limited to the hazards requiring control. Even though this is the most relevant information, a facility may become aware of information with respect to a raw material or other ingredient provided to another customer of the supplier that may suggest the need to conduct a different verification activity. For example, if the receiving facility is obtaining mineral premix from a supplier that is controlling for a nutrient imbalance of copper and molybdenum and becomes aware that mineral premixes from this supplier have been associated with a recall due to contamination with a physical hazard, the receiving facility would determine that it should implement verification activities related to controlling for physical hazards.

(Comment 451) Some comments ask us to replace the phrase ''examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation'' with ''such as storage and transportation.''

(Response 451) We have made this editorial change.

E. Supplier Non-Conformance (Final § 507.110(e))

We proposed that if the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the FD&C Act (proposed § 507.37(f)).

(Comment 452) Some comments object to the use of the word ''significant'' in this proposed provision, recommending that we replace it with ''requiring control by the supplier.'' These comments reason that these activities are only necessary if the receiving facility is relying on the supplier to control the specific hazards.

(Response 452) We have revised the regulatory text to state ''a hazard requiring a supply-chain-applied control'' rather than ''significant.''

XLIII. Subpart E: New Requirement Specifying the Responsibilities of the Receiving Facility (Final § 507.115)

As discussed in Response 429, after considering comments we are providing flexibility for an entity other than the receiving facility to determine, conduct, and document the appropriate supplier verification activities, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents the receiving facility's review and assessment. We are specifying that flexibility in § 507.115. We have titled this section ''Responsibilities of the receiving facility'' to emphasize the responsibility of the receiving facility for its supply-chain program. (See Responses 429 and 430.) Although comments focus on flexibility for an entity in the supply chain between the supplier and the receiving facility to perform supplier verification activities, and such entities are the most likely entities to be the entities determining, conducting, and documenting supplier verification activities, the flexibility provided by the rule is not limited to such entities.

The rule does, however, set some bounds on the flexibility for determining, conducting, and documenting appropriate supplier verification activities. For example, as discussed in Responses 429 and 430, only the receiving facility can approve its suppliers. As another example, although it would not be appropriate for a supplier to determine the appropriate supplier verification activities for itself, we had proposed that it would be appropriate for a supplier to conduct sampling and testing of raw materials and ingredients as a supplier verification activity (proposed § 507.37(c)(1)(ii)), and we are retaining that provision in the final rule (see § 507.115(a)(4)). Likewise, it is common industry practice for a supplier to arrange for an audit by a third party (Ref. 53), and the new flexibility provision does not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with the requirements of the rule applicable to audits (§ 507.135). See § 507.115 for the full text of this new flexibility provision.

XLIV. Subpart E: Comments on Using Approved Suppliers and Determining Appropriate Supplier Verification Activities

We proposed requirements for the use of approved suppliers (proposed § 507.37(a)(3)(i)) and for determining and documenting appropriate supplier verification activities (proposed § 507.37(b)). See table 26 for a description of the final provisions and the changes we have made to clarify the requirements.

TABLE 26—REVISIONS TO THE PROPOSED REQUIREMENTS FOR APPROVING SUPPLIERS AND FOR DETERMINING AND DOCUMENTING APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES

Final section designation	Proposed section designation	Description	Revision
507.120(a)	507.37(a)(3)(i)	The receiving facility must approve suppliers and document that approval.	Explicit statement of this requirement.

TABLE 26—REVISIONS TO THE PROPOSED REQUIREMENTS FOR APPROVING SUPPLIERS AND FOR DETERMINING AND DOCUMENTING APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES—Continued

Final section designation	Proposed section designation	Description	Revision
507.120(b)(1)	507.37(a)(3)(i)	Written procedures for receiving raw materials and other ingredients must be established and followed.	Explicit requirement for written procedures.
507.120(b)(2)		The purpose of the written procedures is to 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 the receiving facility subjects to adequate verification activities before acceptance for use).	N/A.
507.120(b)(3)	507.37(a)(3)(i)	Use of the written procedures for receiving raw materials and other ingredients must be documented.	Conforming change associated with the explicit requirement to establish and follow written procedures.
507.125	507.37(b)	Requirement to determine and document appropriate supplier verification activities.	N/A.

A. Using Approved Suppliers (Final §§ 507.120)

We proposed to require that a supplier program include verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use) (proposed § 507.37(a)(i)).

This proposed requirement included an implicit requirement that a facility must approve suppliers. For clarity, we make that requirement, and documentation of that approval, explicit in the final rule. (See § 507.120(a)).

The rule continues to require that a receiving facility ensure raw materials and other ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or other ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subject to adequate verification activities before acceptance for use), but we revised the provision to specify that the receiving facility must do so by establishing and following written procedures, and require documentation that these procedures were followed. To simplify the provisions, we also established a definition for 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), and use that term throughout subpart E. For example, a facility could design a checklist for employees to use when raw materials and other ingredients are delivered to the facility. We decided to specify use of written procedures for receiving raw materials and other ingredients in light of the flexibility the final rule provides for an entity other than the receiving facility (such as an entity in the supply chain between the supplier) to conduct this activity (see § 507.115(a)(2)). Although we agree that such an entity can do this as a service to the receiving facility, a written procedure is appropriate to ensure a robust and meaningful verification. As a companion change, we revised the associated documentation requirement to specify documentation of use of the written procedures.

(Comment 453) Some comments support the requirement to approve suppliers. Other comments ask us to provide guidance for use of unapproved suppliers on a temporary basis, because the use of unapproved suppliers could be a high risk situation. Other comments emphasize that if the final supplier approval process is significantly changed compared to the proposed supplier approval process, industry must have enough time to plan and develop supplier verification plans and a process for unapproved sources.

(Response 453) We will consider including guidance for use of unapproved suppliers on a temporary basis in guidance that we intend to issue regarding the supply-chain program. We do not believe that the final requirements regarding the use of approved suppliers will require increased implementation time. The principal change is to allow flexibility for entities in the supply chain other than the receiving facility to establish written procedures for receiving raw materials and other ingredients and document that written procedures for receiving raw materials and other ingredients are being followed.

B. Determining Appropriate Verification Activities (Final § 507.125)

The rule requires that a supply-chain program include determining appropriate supplier verification activities (including determining the frequency of conducting the activity) (see § 507.110(a)(2)). Comments that addressed the proposed provision for determining appropriate verification activities (which provides flexibility to the facility to determine the appropriate verification activities) did not disagree with it. The rule also requires that certain factors must be considered in determining appropriate verification activities (§ 507.110(d)). We discuss those factors, and comments that addressed those factors, in section XLII.D. Both of these provisions (*i.e.,* § 507.110(a)(2) and § 507.110(d)) derive from the proposed requirement regarding factors that must be considered in determining appropriate supplier verification activities (proposed § 507.37(b)). To give prominence to both the responsibility and the flexibility to determine appropriate supplier verification activities, and emphasize the factors

that must be considered in addressing this responsibility, new § 507.125 specifies that appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 507.110(d).

XLV. Subpart E: Comments on Conducting Supplier Verification Activities for Raw Materials and Other Ingredients

We proposed requirements applicable to conducting supplier verification activities (proposed § 507.37(c)). Most comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision. In the following sections, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 27.

TABLE 27—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CONDUCTING SUPPLIER VERIFICATION ACTIVITIES FOR RAW MATERIALS AND OTHER INGREDIENTS

Final section designation	Proposed section designation	Description	Revision
507.130(a)	507.37(c)(1)	Requirement to conduct one or more appropriate supplier verification activities.	Add reference to an additional provision that provides for alternative supplier verification activities for shell egg producers that have less than 3,000 laying hens.
507.130(b)(1)	507.37(c)(2)(i)	Requirement to conduct an onsite audit as the supplier verification activity when the hazard being controlled by the supplier 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.	N/A.
507.130(b)(2)	507.37(c)(2)(ii)	Exception to the requirement to conduct an annual onsite audit with a written determination.	N/A.
507.130(c)	507.37(c)(3)	Alternative supplier verification activity when the supplier is a qualified facility.	• Modify the regulatory text to better align with the responsibilities of a qualified facility to submit an attestation to FDA about its food safety practices or its compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. • Clarify that the date for a receiving facility to obtain written assurance that a supplier is a qualified facility is 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. • Provide for written assurance that, when applicable, the supplier is producing the raw material or other ingredient in compliance with 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.
507.130(d)	507.37(c)(4)	Alternative supplier verification activity when the supplier is a farm that is not a ''covered farm'' under part 112 in accordance with § 112.4(a) or in accordance with §§ 112.4(b) and 112.5.	• Clarify that the applicable farms are ''not covered farms'' rather than ''not subject to part 112'' because some of these farms are subject to modified requirements in § 112.6. • Clarify that the date for a receiving facility to obtain written assurance from the farm about its status is 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.

TABLE 27—REVISIONS TO THE PROPOSED REQUIREMENTS FOR CONDUCTING SUPPLIER VERIFICATION ACTIVITIES FOR RAW MATERIALS AND OTHER INGREDIENTS—Continued

Final section designation	Proposed section designation	Description	Revision
			• Clarify that the written assurance from the farm is an acknowledgement that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).
507.130(e)	N/A	Alternative supplier verification activity when the supplier is a shell egg producer that has fewer than 3,000 laying hens.	Specify an additional situation where the receiving facility can consider an alternative supplier verification activity.

A. Requirement To Conduct One or More Supplier Verification Activities (Final § 507.130(a))

With two exceptions, we proposed that the receiving facility must conduct and document one or more specified supplier verification activities for each supplier before using the raw material or ingredient and periodically thereafter (proposed § 507.37(c)(1)). See section XLII.B for a discussion of comments regarding the appropriate verification activities (*i.e.,* onsite audits, sampling and testing, records review, and other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient). See sections XLV.C and XLV.D for a discussion of the proposed exceptions to this requirement to conduct and document verification activities. As discussed in section XLV.E, the final rule provides for an additional circumstance in which an alternative supplier verification activity may be conducted, *i.e.,* when the supplier is a shell egg producer that has fewer than 3,000 laying hens.

B. Requirement for an Onsite Audit as a Verification Activity When a Hazard Has a Reasonable Probability of Resulting in Serious Adverse Health Consequences or Death to Humans or Animals (Final § 507.130(b))

We proposed that when a hazard in a raw material or 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, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter. We also proposed that this requirement does not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. (Proposed § 507.37(c)(2)).

(Comment 454) Some comments support the provision for audits when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. Some of these comments state that audits should be the default verification activity in order to eliminate facilities choosing the lowest cost option regardless of whether it was best for food safety. Other comments state that audits would be the best option for facilities that cannot visit each supplier annually and that onsite inspection can identify problems in ways that paperwork reviews cannot.

However, other comments oppose this requirement. Some of these comments state that facilities should have flexibility in choosing verification activities, regardless of whether or not the hazards could result in serious adverse health consequences or death to humans or animals and express concern that this requirement does not allow the necessary flexibility for a facility to tailor an effective supplier program based upon risk. Other comments express concern that the provision sets a precedent that annual audits are the preferred or most effective verification measure and that other verification activities often can help paint a more accurate picture of a supplier over time. Other comments express concern that audits only give a ''snapshot'' of a supplier's performance at a given time and ask that we not overemphasize audits.

(Response 454) We are retaining this provision as proposed. As we indicated in the Appendix of our 2013 proposed preventive controls rule, an increasing number of establishments are requiring, as a condition of doing business, that their suppliers become certified to food safety management schemes that involve third-party audits (78 FR 64736 at 64836 through 64837). We agree that onsite audits can identify problems in ways that paperwork reviews cannot. Because an audit involves more than simply observing the facility producing an animal food product, we believe it is more than just a ''snapshot'' of the supplier's programs. As discussed in Response 440, onsite audits can include observations, records review and employee interviews.

The requirement to conduct an annual audit in specified circumstances is risk-based because the specified circumstances are limited to situations where there is a reasonable probability that exposure to the hazard in the raw material or other ingredient will result in serious adverse health consequences or death to humans or animals. The food safety controls applied by suppliers of such raw materials or other ingredients are more important than for other types of hazards because of the serious adverse health consequences that can occur if the hazards are not controlled. Annual audits are required of certification schemes that are benchmarked to the Global Food Safety Initiative Guidance Document for GFSI recognition (Ref. 58). We disagree that this requirement does not provide flexibility in choosing verification activities; in recognition that other verification activities can help paint a more accurate picture of a supplier over time, we have provided for alternative verification activities or audit frequencies if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (see § 507.130(b)(2)).

(Comment 455) Some comments ask us to define those products that may trigger the requirement for an audit, especially with respect to farms. These comments question how to assess whether a hazard could result in serious adverse health consequences or death to humans or animals.

(Response 455) We decline this request. Any list of such products would be extensive and it is unlikely we could capture all the circumstances in which this could apply. Hazards for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death 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). Examples of such hazards that, in some circumstances, have resulted in serious adverse health consequences or death to humans or animals include pathogens or their toxins in animal food. Animal food containing 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 are considered reportable foods; examples of foods FDA has considered to present a reasonable probability of serious adverse health consequences or death can be found in our Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Refs. 19 and 20).

(Comment 456) Some comments ask us to clarify the role of third-party audits and the Good Agricultural Practice (GAP) program and ask us to allow GAPs to be a voluntary mechanism to satisfy buyer demands for food safety certification.

(Response 456) Although the rule would not require a receiving facility to hire a third party to conduct an audit, onsite audits can include third-party audits. There are likely to be benefits for suppliers having a third-party audit, because the same audit may be acceptable to multiple receiving facilities as an appropriate supplier verification activity. For farms, GAPs audits may be viewed as an appropriate supplier verification activity. GAPs audits and other third-party audits would need to comply with the requirements of this rule applicable to onsite audits (see § 507.135).

(Comment 457) Some comments assert that we should delete this provision entirely, stating that this requirement for an audit is ''outside the scope of FSMA.''

(Response 457) We disagree that a requirement for an audit is ''outside the scope of FSMA.'' See the discussion in Response 440 regarding the provision in section 419(c)(1)(E) of the FD&C Act that the regulation issuing standards for the safety of produce ''not require a business to hire a consultant or other third party to identify, implement, certify compliance with the procedures, processes and practices'' and the provision in section 418(n)(3)(D) of the FD&C Act that the preventive controls regulation ''not require a facility to hire a consultant or other third party to identify, implement, certify or audit preventive controls.'' As noted in that response, a facility is not required to hire a third party to conduct an audit.

(Comment 458) Some comments support the flexibility to not conduct an annual onsite audit if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. Other comments question how a facility would prove that alternative measures are equally effective as an annual audit, when it is not known how effective an annual audit is. Other comments assert that the provision is meaningless because a farm or facility would not take the legal risk of verifying it has received ''adequate assurance,'' because this would be subject to an FDA inspector's interpretation.

(Response 458) This provision requires a facility to use a verification activity that provides adequate assurance that a hazard is controlled, not to determine how effective an audit is and assess whether alternative measures are equally effective.

As an example of using an alternative approach to an annual onsite audit, consider the situation in which a receiving facility is part of a large corporation, is making a pet food, and obtains meat and bone meal from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as the receiving facility. The receiving facility 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 and bone meal is adequately controlled. The facility could support its decision by documenting this determination, including the procedures in effect at the supplier and the activities used by the corporation to verify that the subsidiary operates in accordance with corporate food safety policies and practices to ensure that hazards are adequately controlled.

We disagree that the provision is meaningless because a farm or facility would see a legal risk in using an alternative to annual onsite audits as a supplier verification activity. First, a farm would be a supplier and would not be the entity that would determine whether an onsite audit or some other supplier verification activity is appropriate. As established in § 507.115, determining the appropriate supplier verification activity would be the responsibility of a receiving facility, and although appropriate supplier verification activities could be determined by another entity in the receiving facility's supply chain as a service, the supplier verification activities could not be determined by the supplier itself. Second, although there is always a potential for differences in interpretation between an FDA inspector and an inspected firm, we are establishing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance. For example, FDA intends to deploy specialized investigators, backed up by technical experts, to assess the soundness and performance of a facility's food safety system (Ref. 10). In addition, a central element of FDA's strategy to gain industry compliance is to help make available to farmers, food processors, and importers, especially small businesses, the education and technical assistance they need to understand and implement FSMA's new prevention-oriented standards (Ref. 5). The new inspection paradigm and the assistance and training for industry should help minimize different interpretations between industry and regulators.

(Comment 459) Some comments ask us to require facilities to notify us when they determine that an alternative to an audit is an appropriate supplier verification activity and be able to justify and document how an alternative verification activity provides the same level of assurance as an onsite audit.

(Response 459) We decline this request. We will assess a facility's supplier verification activities during a facility inspection, including the documentation that an alternative verification activity provides the same level of assurance as an onsite audit.

(Comment 460) Some comments ask us to specify the type of documentation required for our investigators to determine when the activities are ''in

compliance with the law and sufficient to protect public health.''

(Response 460) We decline this request. The facility's approach to the determination, and the applicable documentation required to support that determination, would depend on the circumstances. For example, in Response 458, we discuss a possible approach in a situation in which a receiving facility is part of a corporation and obtains an ingredient from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as the receiving facility. Another situation could be when a receiving facility has many years of experience with the same supplier, but the approach and documentation in that situation likely would be different from an approach and documentation used when the supplier and the receiving facility are part of the same corporation.

(Comment 461) Some comments ask that we not limit the determination for a supplier verification activity other than an onsite audit to a determination by the receiving facility. These comments explain that the corporate parent of a facility can be the entity that makes this determination. These comments suggest that we can account for the role of the corporation by specifying that a facility documents ''the determination'' (rather than ''its'' determination).

(Response 461) We have agreed that the corporate parent of a facility can be active in developing and implementing the facility's food safety plan (see section XXIV.A). However, the specific suggestion of these comments is not necessary to achieve the outcome requested by the comments because of editorial changes we made to provide for entities other than the receiving facility to determine and conduct the appropriate supplier verification activities.

C. Alternative Verification Activity When the Supplier Is a Qualified Facility (Final § 507.130(c))

We proposed that if a supplier is a qualified facility the receiving facility need not comply with the specified verification requirements if the receiving facility: (1) Documents, at the end of each calendar year, that the supplier is a qualified facility and (2) obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the animal food.

This rule has several provisions that require written assurances. We have established specific elements that each of these written assurances must include, *i.e.,* the effective date; printed names and signatures of authorized officials; and the applicable assurance (see § 507.215).

We have revised the provision to clarify that the receiving facility must have written assurance that a facility is a qualified facility: (1) Before first approving the supplier for an applicable calendar year and (2) by December 31 of each calendar year (rather than ''at the end of the calendar year'') and that the written assurance is regarding the status of the qualified facility for the following calendar year. By specifying ''by December 31,'' a receiving facility can 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. See also Responses 76, 139, 140, the requirements in § 507.7(a) for an annual determination of the status of a facility as a qualified facility, and the requirements in § 507.7(d) that apply when the status of a facility changes from ''qualified facility'' to ''not a qualified facility.'' A receiving facility and its suppliers have 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 their specific business relationship.

As discussed in section XLII.D, we have revised the requirements for considering supplier performance to provide that the receiving facility may, when applicable, 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, and information relevant to the supplier's compliance with those laws and regulations, rather than consider applicable FDA food safety regulations and information relevant to the supplier's compliance with applicable FDA food safety regulations. We have made a conforming change to the alternative verification activities for a qualified facility (see the regulatory text of § 507.130(c)(2)).

(Comment 462) Some comments support this alternative supplier verification activity because it provides flexibility. Other comments ask us to revise the provision so that it only requires that the supplier document its status as a qualified facility. Still other comments ask us to remove all provisions on qualified facilities because they view these provisions as effectively adding a second layer of regulations on produce farms, and claim this is not authorized by FSMA. Other comments ask us to delete the requirement that the written assurance include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

(Response 462) We have revised the provisions for an alternative verification activity for a qualified facility to better align with the responsibilities of a qualified facility to submit an attestation to FDA about its food safety practices (§ 507.7(a)(2)(i)) or its compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries (§ 507.7(a)(2)(ii)) (see the regulatory text of § 507.130(c)). Importantly, a qualified facility is still subject to CGMPs and the FD&C Act, and, if the qualified facility is a supplier controlling a hazard, it is reasonable for a receiving facility to expect the qualified facility to provide to the receiving facility, an assurance that reflects an attestation the facility has made to FDA. As modified, one possibility is for a qualified facility to provide a receiving facility with a brief description of the preventive controls it is implementing to control the applicable hazard, consistent with an attestation of its food safety practices in accordance with § 507.7(a)(2)(i). For example, the qualified facility could state that its manufacturing processes include a lethality step for microbial pathogens of concern. As required by § 507.7(f), a qualified facility that submits an attestation to FDA about its animal food safety practices would have documentation of those practices to support its attestation to FDA and, thus, would have documentation to support its written assurance to the receiving facility. Although a qualified facility that submits an attestation to FDA about its food safety practices also would have documentation of monitoring the performance of the preventive controls to ensure that such controls are effective as required by § 507.7(a)(2)(i), we are not requiring the qualified facility to describe its monitoring of the performance of preventive controls to ensure that they are effective. Alternatively, a qualified facility could provide a receiving facility with 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.

We disagree that the alternative verification activity for produce farms would add a second layer of regulations on produce farms and are retaining this provision.

(Comment 463) Some comments ask us to remove the requirement that the written assurance be obtained at least every 2 years. Other comments ask us to revise the purpose of the written assurance from ''the raw material or ingredient is not adulterated'' to ''the receiving facility's use of the raw material or ingredient will not cause the finished food to be adulterated.''

(Response 463) We decline these requests. A supplier verification activity needs to consider supplier performance on an ongoing basis. Procedures and practices evolve over time, and it is appropriate for a receiving facility that is obtaining written assurance from a supplier as an alternative verification activity to be aware of both procedures and practices that have changed, as well as procedures and practices that have stayed the same. The specified timeframe for updating the written assurance, *i.e.,* at least every two years, is reasonable.

A supplier can only provide assurance about raw materials and other ingredients that it supplies to the receiving facility, not about the animal food product that the receiving facility will produce using the supplier's raw material or other ingredients.

D. Alternative Verification Activity When the Supplier Is a Produce Farm That Is Not a ''Covered Farm'' for the Purposes of the Future Produce Safety Rule (Final § 507.130(d))

We proposed that if a supplier is a farm that is not subject to the requirements that we have proposed to be established in the produce safety rule in accordance with proposed § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with the verification requirements if the receiving facility: (1) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to the produce safety rule and (2) obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act. See also § 507.215, which establishes specific elements that this written assurance must include, *i.e.,* the effective date; printed names and signatures of authorized officials; and the applicable assurance.

Produce farms that are not ''covered farms'' under § 112.4 of the forthcoming produce safety rule have less than $25,000 in annual sales averaged over the previous 3-year period, or satisfy the requirements for a qualified exemption in § 112.5 and associated modified requirements in § 112.6 based on average monetary value of all food sold (less than $500,000) and direct farm marketing (during the previous 3-year period, the average annual monetary value of food sold directly to qualified end users exceeded the average annual monetary value of the food sold to all other buyers). In the 2014 supplemental notice, we erroneously referred to these farms as farms ''not subject to the requirements established in part 112.'' While produce farms that make less than $25,000 are not subject to the requirements in part 112, produce farms that satisfy the requirements for a qualified exemption are not subject to the full requirements of part 112, but they do have certain modified requirements that they must meet, as described in § 112.6. We have corrected the description of these farms in § 507.130(d).

We have revised the provision to clarify that the receiving facility must have documentation that the raw material or other ingredient provided by the supplier is not subject to part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5: (1) Before first approving the supplier for an applicable calendar year and (2) by December 31 of each calendar year (rather than ''at the end of the calendar year'') and that the documentation is regarding the status of supplier for the following calendar year. By specifying ''by December 31,'' a receiving facility can 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. See also the discussion in section XLV.C regarding a similar revision we made when the supplier is a qualified facility.

(Comment 464) Some comments support the proposed alternative supplier verification activity. Other comments support applying the proposed alternative supplier verification activity more broadly, *i.e.,* to any farm that will not be subject to part 112 (*e.g.,* a farm that grows wheat), stating that both small and large non-produce farms should have the same option as farms that are exempted under § 112.4. Some comments ask us to revise the alternative verification requirements to apply to raw materials from farms that do not grow and harvest ''produce'' as we proposed to define it in § 112.3(c) so that the alternative verification requirements would apply to grain. Some comments assert that it is not possible to receive ''written assurances'' of compliance from growers of grain because there is no safety standard for grain growers, and that any such documents would be essentially meaningless.

Some comments ask us to revise the requirement to obtain written assurance so that it does not apply to ''food not subject to the requirements of part 112 of this chapter pursuant to part 112.2.'' Other comments assert that a documentation requirement for commodities that will be exempt from the produce safety rule would increase recordkeeping burdens without added benefit because produce that will be exempt from the produce safety rule is low risk.

Some comments assert that farms should not have to provide written assurances because the requirement is ambiguous. These comments assert that exempt farmers are small-scale producers who are subject primarily to state and local laws and this provision would require them to provide written assurances that they are complying with unspecified Federal regulations. The comments claim that, without seeking legal counsel, many exempt farmers would be unable to provide such assurances, limiting the ability of these farmers to market their products to non-exempt facilities (the overwhelming majority of the food market).

(Response 464) We have revised the to specify that the written assurance from the farm must state 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). Any business that introduces food into interstate commerce is subject the prohibited acts provisions in section 301 of the FD&C Act, and is accountable if it produces food that is adulterated.

As discussed in Response 284, new § 507.36(a) allows a manufacturer/processor to not implement a preventive control if it determines and documents that the type of animal food (*e.g.,* soybeans) could not be consumed without application of the appropriate control. We believe most receiving facilities will take advantage of this provision, and not establish supply-chain controls under the supply-chain

program in subpart E for some specific RACs.

This alternative supplier verification activity is intended to minimize the burden on suppliers that are small farms. The amount of food produced by such farms is small, and the exposure to food from such farms therefore is low. We disagree that a written assurance from such a farm would be meaningless. Any business that distributes food in interstate commerce is subject to the FD&C Act, and must produce food that is in compliance with the FD&C Act, regardless of whether FDA has established a specific regulation governing the production of the food.

(Comment 465) Some comments ask us to delete this alternative supplier verification activity because they see it as a contradiction to the traceability provisions of the Bioterrorism Act and FSMA, because ''trace back'' is only required for ''one step back'' or for a single supplier for a particular shipment of food.

(Response 465) The supply-chain program that is being established in this rule is a preventive control for the ongoing production of safe animal food, not a ''trace back'' provision, established under the Bioterrorism Act, to help address credible threats relating to food that is reasonably believed to be adulterated and to present a threat of serious adverse health consequences or death to humans or animals.

(Comment 466) Some comments ask us to specify 3 options for verification if a supplier is a farm subject to the requirements of part 112: (1) Documentation at the end of each calendar year that the raw material or ingredient provided by the supplier is subject to part 112; (2) written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under the FD&C Act; or (3) evidence that the supplier is certified to a recognized third-party GAP/GHP/GMP/HACCP audit scheme. (We note that we are assuming that ''GHP'' is an abbreviation for ''Good Hygienic Practice.'')

(Response 466) We decline this request. Documenting that a raw material or other ingredient is subject to the produce safety rule has no bearing on whether the farm is complying with that rule to control the hazards. With respect to all farms subject to the requirements of part 112 providing a written assurance, as discussed in Response 464, the amount of food produced by the small farms that could provide written assurance to a receiving facility is small, and the exposure to food from such farms therefore is low. We disagree that it is appropriate to extend this alternative supplier verification activity to larger farms because such farms provide a larger volume of produce.

A farm that has been subject to an audit that complies with the requirements of this rule can provide the results of the audit; a mere statement that the farm has been certified based on an audit is insufficient.

E. Alternative Verification Activity When the Supplier Is a Shell Egg Producer That Has Less Than 3,000 Laying Hens (Final § 507.130(e))

We are establishing an additional alternative supplier verification activity when a supplier is 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. See the regulatory text of § 507.130(e). The provision is analogous to the alternative supplier verification activity when a supplier is a farm that meets the criteria in § 507.130(d) and would account for a very small amount of eggs in the food supply. See also § 507.215, which establishes specific elements that the required written assurance must include, *i.e.,* the effective date; printed names and signatures of authorized officials; and the applicable assurance.

F. Independence of Persons Who Conduct Supplier Verification Activities (Final § 507.130(f))

In the 2014 supplemental notice, we requested comment on whether we should include in the final preventive controls rule requirements to address conflicts of interest for individuals conducting verification activities and, if so, the scope of such requirements.

(Comment 467) Some comments request that requirements to address conflicts of interest should not be implemented or ask that conflict of interest provisions not be written too broadly, and be limited to circumstances where the individual employee carrying out the verification activities has a direct personal financial interest in or financial ties to the supplier (*e.g.,* owns a substantial amount of stock in the supplier or is personally paid directly by the supplier). Comments state that it would not be uncommon for a receiving facility to have a shared financial interest in the supplier (*e.g.,* partial ownership of one by the other or both being owned by the same parent company). Thus, employees that have an indirect financial interest (*e.g.,* owning stock in a supplier because they own stock in their own company, which in turn owns an interest in the supplier) should not be disqualified from performing verification activities. Comments also indicate that a laboratory analyst performing ingredient testing should not be precluded from testing ingredients from a supplier in which the analyst has a potential conflict of interest, as long as the analyst is not aware of the identity of the supplier at the time the test is performed.

(Response 467) We are establishing a requirement that there must not be any financial conflicts of interests that influence the results of the verification activities listed in § 507.110(b) and payment must not be related to the results of the activity. This does not prohibit employees of a supplier from performing the functions specified in § 507.115 in accordance with § 507.115. 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. The provisions would not prevent a person who is employed by a receiving facility from having an indirect financial interest in a supplier (*e.g.,* if a company in which the employee owns stock owns an interest in the supplier).

(Comment 468) Comments ask that we not preclude a supplier from hiring an outside party to perform onsite audits, food certifications, or sampling and testing.

(Response 468) We have specified that the requirements do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor (see § 507.115(c)). We also have specified that a 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 the documentation to the receiving facility (see § 507.115(a)(4)). This acknowledges that it is common for suppliers to include Certificates of Analysis for tests conducted on specific lots of product along with the shipment to the receiving facility.

XLVI. Subpart E: Comments on Onsite Audit

We proposed requirements that would apply to an onsite audit. Most comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision. In the following sections, we

discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 28.

TABLE 28—REVISIONS TO THE PROPOSED REQUIREMENTS FOR ONSITE AUDITS

Final section designation	Proposed section designation	Description	Revision
507.135(a)	507.37(d)(1)	An onsite audit of a supplier must be performed by a qualified auditor.	N/A.
507.135(b)	507.37(d)(2)	An onsite audit must consider applicable FDA regulations.	Clarify that, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.
507.135(c)(1)(i)	507.37(e)(1)	Substitution of inspection for domestic suppliers.	Broaden the list of applicable inspections to include inspections by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies.
507.135(c)(1)(ii) and 507.135(c)(2)	507.37(e)(2)	Substitution of inspection for foreign suppliers.	N/A.
507.135(d)	N/A	Use of a third-party auditor that has been accredited in accordance with regulations that will be established in the forthcoming third-party certification rule.	If the onsite audit is solely conducted to meet the requirements of the animal food preventive controls rule by an audit agent of a certification body that is accredited in accordance with regulations that will be established in part 1, subpart M, the audit is not subject to the requirements in those regulations.

A. Requirements Applicable to an Onsite Audit (Final § 507.135(a) and (b))

We proposed that an onsite audit of a supplier must be performed by a qualified auditor. If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit would need to consider such regulations and include a review of the supplier's written plan (*e.g.,* HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited (proposed § 507.37(d)). We have revised ''including its implementation'' to ''and its implementation'' to emphasize that implementation of the plan is distinct from the plan itself (*e.g.,* § 507.31(c) establishes the recordkeeping requirement for the food safety ''plan,'' and § 507.55 lists implementation records.)

As discussed in section XLII.D, we have revised the requirements for considering supplier performance to provide that the receiving facility may, when applicable, 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, and information relevant to the supplier's compliance with those laws and regulations, rather than consider applicable FDA food safety regulations and information relevant to the supplier's compliance with applicable FDA food safety regulations. We have made a conforming change to the requirements for an onsite audit to clarify that 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. However, as of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food.

(Comment 469) Comments support a requirement that an onsite audit be performed by a qualified auditor, provided that we finalize provisions (in proposed § 507.37(e)) whereby an inspection by certain authorities could substitute for an audit. Some comments ask us to specify that the rule permits the use of audits conducted by private third-party food safety auditing firms. Other comments ask us to provide a list of recognized private third-party food safety schemes and consider making third-party food safety certification to a recognized audit scheme mandatory for all food operations that grow, pack, hold and manufacture/process food for wholesale markets. Other comments ask us to further specify that FDA will audit all food facilities no less than once every 5 years to verify that private third-party audits are consistent with FDA audits and findings.

(Response 469) See our discussion in section XLVI.B of the final provisions governing substitution of inspection for an audit. We agree that onsite audits may be conducted by third parties, but disagree that it is necessary to specify this in the rule. Nothing in this rule prevents a facility from hiring a third party to conduct audits.

We decline the requests to provide a list of recognized private third-party food safety schemes or to make third-party food safety certification to a recognized audit scheme mandatory for all food operations that grow, pack, hold and manufacture/process animal food for wholesale markets. The rule provides flexibility regarding use of third-party auditors and the information is easily obtained from other sources.

Private third-party food safety audit schemes are a function of the private sector, not a function of the Federal government. Likewise, we decline the request to specify that FDA will ''audit'' all food facilities no less than once every 5 years to verify that private third-party audits are consistent with FDA audits and findings. We will inspect food facilities for compliance with this rule, not to verify the findings of a third-party audit, with a frequency consistent with our responsibilities under the FD&C Act.

(Comment 470) Some comments express concern about the multiple audits that facilities are subject to each year and ask us to encourage those subject to the rule to accept an audit performed by any of the ''bona fide authorities'' where it is warranted. Other comments note that food manufacturers conduct their own audits and have developed extensive expertise in doing so, and oppose any supplier verification requirement that would affect those audits. Other comments ask us to allow audits to industry standards (such as GFSI or ISO) to satisfy supplier verification requirements to avoid adding a new audit to audits currently being conducted. Some comments assert that audits to industry standards (such as GFSI or ISO) and other similarly accredited audits should be considered equivalent to onsite audits. Some comments express concern that requiring a new audit in addition to audits already being conducted could lead to auditor shortages and unnecessary additional costs.

(Response 470) We expect that a facility will adopt an approach to audits that works best for the facility and minimizes the number of audits conducted for the same facility. An employee of a receiving facility may perform an audit, provided that the employee satisfies the criteria established in the rule for qualified auditors. Under § 507.3 and § 507.53, a qualified auditor is a qualified individual (as defined in § 507.3) and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. For additional information, see Response 700 in the final rule for preventive controls for human food published elsewhere in this issue of the **Federal Register**, in which we discuss auditor qualifications with respect to the GFSI's auditor competency model.

(Comment 471) Some comments ask us to delete the proposed requirement for a review of the supplier's written plan as part of an audit because review of the supplier's food safety plan should be part of an overall supplier verification program when the supplier is controlling a hazard that could cause serious adverse health consequences or death, but should not be tied to an audit. These comments state that receiving facilities may choose to use an unannounced audit program where the auditor spends time focusing on the actual conditions on the production floor, with a review of the supplier's food safety plan being done as a separate verification activity.

(Response 471) We decline this request. We agree that review of an applicable food safety plan should be part of an overall supplier verification program and that the review of the food safety plan may be conducted separately from the observation of actual conditions on the production floor, provided that both are conducted within the annual timeframe. However, we believe it important that the audit address whether the food safety plan is being implemented as designed and other comments to this rule support that view. For example, as discussed in Comment 493 regarding our inspection of a food facility, some comments assert that our access to company records must be conducted onsite in the course of an authorized inspection so that we may understand the full context of what the records show. Thus, the onsite observations and the food safety plan review cannot be entirely separated, as the comment seems to suggest.

We note that the requirement to include a review of the supplier's food safety plan only applies when the supplier has a food safety plan. For example, we did not propose a requirement for a farm that would be subject to the forthcoming produce safety rule to have a food safety plan.

B. Substitution of Inspection by FDA or an Officially Recognized or Equivalent Food Safety Authority

We proposed that instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, the food that is the subject of the onsite audit would need to be within the scope of the official recognition or equivalence determination, and the foreign supplier would need to be in, and under the regulatory oversight of, such country (proposed § 507.37(e)).

As of August 30 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority for animal food. A signed systems recognition agreement for human food does not apply to animal food.

(Comment 472) Some comments ask us to allow State or local inspection reports, as well as FDA inspection reports, to substitute for an onsite audit for small and very small facilities. Other comments ask us to create a ''safe harbor'' provision in which a supplier providing a copy of permits obtained from the most recent inspection done by Federal, State, or local health authorities satisfies the supplier verification requirement; if there are no permits, review of relevant records and/or sampling of raw material based on scale of production should be adequate.

(Response 472) We have revised the regulatory text to provide for an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as USDA), or by representatives of State, local, tribal, or territorial agencies. We are specifying that the inspection must be ''appropriate'' and be conducted for compliance ''with applicable FDA food safety regulations'' to make clear that the inspection must be sufficiently relevant to an onsite audit to credibly substitute for an onsite audit. For example, inspection by USDA to determine whether a farm satisfies the requirements of the produce safety rule could constitute an appropriate inspection that could substitute for an audit, but an inspection by USDA to determine whether a farm satisfies the requirements of the National Organic Program could not.

We have not provided for substitution of a ''permit obtained from the most recent inspection'' for an onsite audit. We do not see how a ''permit'' could shed light on whether a business is complying with specific applicable FDA regulations. We have provided for an alternative verification activity to the annual onsite audit (such as a review of relevant records and/or sampling of raw material) with a written justification (see § 507.130(b)). The rule would not preclude an appropriate review of records, or sampling and testing of raw

materials, by other Federal Agencies, or by representatives of State, local, tribal, or territorial agencies, provided that the receiving facility satisfies the requirements for an adequate written justification.

(Comment 473) Some comments ask us to clarify what we mean by ''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.'' These comments also ask whether a specific country qualifies and whether HACCP certificates issued by a specific foreign government agency would replace an onsite audit.

(Response 473) 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. Information on FDA systems recognition can be found on the FDA Web site (Ref. 59). As of August 30 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food. We would not accept a HACCP certificate issued by a foreign government as a substitute for an onsite audit, but a receiving facility could consider whether such a certificate could be part of its justification for conducting another supplier verification activity in lieu of an annual onsite audit, or for conducting an audit on a less frequent basis than annually.

(Comment 474) Some comments ask us to clarify that the applicable standards will be those applied by the food safety authority of a country with a food safety system recognized as comparable or equivalent rather than having to achieve compliance with the applicable U.S. FDA food safety regulations.

(Response 474) The applicable standards will be those applied by the food safety authority of a country with a food safety system recognized as comparable or equivalent to that of the United States. As of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food.

C. Onsite Audit by a Third-Party Auditor Accredited for the Purposes of Section 808 of the FD&C Act

We have proposed to establish regulations (in part 1, subpart M) to provide for accreditation of third-party auditors/certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications (78 FR 45782, July 29, 2013). The purpose of the proposed third-party certification rule is to help us ensure the competence and independence of third-party auditors/certification bodies who conduct foreign food safety audits and to help ensure the reliability of food and facility certifications issued by third-party auditors/certification bodies that we will use in making certain decisions relating to imported animal food, such as animal food certifications required by FDA as a condition of granting admission to an animal food determined to pose a safety risk.

(Comment 475) Comments support use of third-party auditors, but emphasize that such auditors need not be accredited under the requirements to be established under our forthcoming third-party certification rule.

(Response 475) We agree that a third-party auditor who conducts an audit as a supplier verification activity to satisfy the requirements of this rule need not be accredited under our forthcoming third-party certification rule. In addition, we see no reason that any requirements of our forthcoming third-party certification rule should apply to an audit merely because it was conducted by a person who had been accredited under that rule. To make this clear, we have added a provision to specify that if an onsite audit is solely conducted to meet the requirements of this rule 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. See § 507.135(d). Because § 507.135(d) refers to provisions in a future third-party certification rule, we will publish a document in the **Federal Register** announcing the effective date of § 507.135(d) when we finalize the third-party certification rule.

XLVII. Subpart E: Comments on Records Documenting the Supply-Chain Program (Final § 507.175)

We proposed to require documentation of verification activities in records, including minimum requirements for records documenting an audit, records of sampling and testing, and records documenting a review by the receiving facility of the supplier's relevant food safety records. We also proposed that the receiving facility must review such records in accordance with the requirements applicable to review of records as a verification activity (*i.e.,* in accordance with § 507.49(a)(4)).

We did not receive comments on the documentation requirements associated with a written supplier program, determination of appropriate supplier verification activities, review of records, supplier verification activities other than an annual onsite audit when the hazard being controlled by the supplier 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, alternative supplier verification activity when the supplier is a qualified facility, substitution of inspection for an audit, or supplier nonconformance (proposed § 507.37(g)(1), (2), (7), (9), (10), (12), and (13), respectively). We are finalizing these documentation requirements with editorial and conforming changes associated with the final requirements of the supply-chain program.

The supply-chain program includes two provisions that are explicit requirements of the final animal food preventive controls rule, but had been implicit requirements of the 2014 supplemental notice. The first of these provisions is the explicit requirement that the receiving facility must approve suppliers in accordance with the requirements of § 507.110(d), and document that approval, before receiving raw materials and other ingredients from those suppliers (see § 507.120(a)). The second of these requirements is that written procedures for receiving raw materials and other ingredients must be established and followed (see § 507.120(b)(1)). We are including in § 507.175 the documentation associated with these requirements (see § 507.175(c)(3) and (4)).

The supply-chain program includes four provisions that were not in the 2014 supplemental notice: (1) A receiving facility that is an importer can comply with the foreign supplier verification requirements in the FSVP rule rather than conduct supplier verification activities for that raw material or other ingredient under this rule (§ 507.105(a)(2)); (2) a receiving facility may use an alternative verification activity for a supplier that is

a shell egg producer that is not subject to the requirements established in part 118 because it has less than 3,000 laying hens (§ 507.130(e)); (3) when applicable, a receiving facility must verify a supply-chain-applied control applied by an entity other than the receiving facility's supplier (§ 507.105(c)); and (4) entities other than the receiving facility may determine, conduct, and document certain specified supplier verification activities, provided that the receiving facility reviews and assesses the other entity's applicable documentation, and documents its review and assessment (§ 507.115). We are establishing the associated documentation requirements in § 507.175(c)(2), (14), (17), and (18), respectively.

In the following sections, we discuss comments on the proposed records for the supplier program. After considering these comments, we have revised the proposed requirements as shown in table 29.

TABLE 29—REVISIONS TO THE PROPOSED REQUIREMENTS FOR RECORDS FOR THE SUPPLY-CHAIN PROGRAM

Final section designation	Proposed section designation	Description	Did we receive comments regarding the proposed requirement?	Did we revise the documentation requirement other than editorial and conforming changes associated with the final requirements for the supply-chain program?
507.175(a)	N/A	The records documenting the supply-chain program are subject to the requirements of subpart F.	N/A	Consequential change associated with establishing the requirements for a supplier in subpart E rather than subpart C.
507.175(b)	507.37(g)	The receiving facility must review the records in accordance with § 507.49(a)(4).	Yes	No.
507.175(c)(1)	507.37(g)(1)	The written supply-chain program	No	N/A.
507.36(b)(2)	507.37(g)(3)	Annual written assurance from a receiving facility's customer.	Yes	Shifted to be in provisions outside the framework of the supply-chain program in subpart E.
507.175(c)(2)	N/A	Documentation obtained from an importer	N/A	N/A.
507.175(c)(3)	507.37(g)(1)	Documentation of the approval of a supplier.	No	No.
507.175(c)(4)	507.37(g)(1)	Written procedures for receiving raw materials and other ingredients.	No	No.
507.175(c)(5)	507.37(g)(4)	Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients.	Yes	Yes.
507.175(c)(6)	507.37(g)(2)	Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients.	No	No.
507.175(c)(7)	507.37(g)(5)	Documentation of the conduct of an onsite audit.	Yes	Added a requirement for the documentation to include the name of the supplier subject to the onsite audit.
507.175(c)(8)	507.37(g)(6)	Documentation of sampling and testing conducted as a supplier verification activity.	Yes	Specify that the documentation include the date(s) on which the test(s) were conducted and the date of the report.
507.175(c)(9)	507.37(g)(7)	Documentation of the review of the supplier's relevant food safety records.	No	Specify that the documentation must include the general nature of the records reviewed and conclusions of the review.
507.175(c)(10)	507.37(g)(8)	Documentation of other appropriate supplier verification activities.	Yes	Specify that the other appropriate supplier verification activities are based on supplier performance and the risk associated with the raw material or other ingredient.
507.175(c)(11)	507.37(g)(9)	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.	No	No.

TABLE 29—REVISIONS TO THE PROPOSED REQUIREMENTS FOR RECORDS FOR THE SUPPLY-CHAIN PROGRAM—Continued

Final section designation	Proposed section designation	Description	Did we receive comments regarding the proposed requirement?	Did we revise the documentation requirement other than editorial and conforming changes associated with the final requirements for the supply-chain program?
507.175(c)(12)	507.37(g)(10)	Documentation of an alternative verification activity for a supplier that is a qualified facility.	No	Provide for documentation, when applicable, of a written assurance that the supplier is producing the raw material or other ingredient in compliance with 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.
507.175(c)(13)	507.37(g)(11)	Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient that would not be a covered farm subject to the forthcoming produce safety rule.	Yes	No.
507.175(c)(14)	N/A	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 because it has less than 3,000 laying hens.	N/A	N/A.
507.175(c)(15)	507.37(g)(12)	The written results of an appropriate inspection of the supplier by FDA, by representatives of other Federal Agencies (such as USDA), 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.	No	No.
507.175(c)(16)	507.37(g)(13)	Documentation of actions taken with respect to supplier non-conformance.	No	No.
507.175(c)(17)	N/A	Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier.	N/A	N/A.
507.175(c)(18)	N/A	When applicable, documentation of the receiving facility's review and assessment of documentation of a supplier verification activity provided by a supplier or by an entity other than the receiving facility.	N/A	N/A.

A. Applicability of the Recordkeeping Requirements of Subpart F

We have added new § 507.175(a) to specify that the records documenting the supply-chain program in subpart E are subject to the requirements of subpart F. Under the 2014 supplemental notice, the documentation requirements would have been in subpart C, and the applicability of subpart F was specified in § 507.55 in subpart C. The new provision specifying the applicability of subpart F to the records associated with the supply-chain program is a consequential change associated with establishing the requirements for a supply-chain program in subpart E, rather than in subpart C.

B. Requirement To Review Records of the Supply-Chain Program (Final § 507.175(b))

We proposed that a receiving facility must review records documenting the supplier program in accordance with the requirements applicable to review of records as a verification activity (*i.e.,* in accordance with § 507.49(a)(4)). (Proposed § 507.37(g).)

(Comment 476) Some comments ask us to provide consideration for records associated with the supplier program to be administered and maintained at corporate headquarters rather than at individual facilities, because this is common industry practice.

(Response 476) We are aware that certain programs are administered, and records are maintained, at corporate headquarters rather than at individual facilities. The rule provides that offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review and electronic records are considered to be onsite if they are accessible from an onsite location (see § 507.208(c)). We expect that the facility would be able to access information and records relevant to the supply-chain program within 24 hours (*e.g.,* electronically) when the records are maintained at corporate headquarters. As necessary and appropriate, we intend to work with facilities on a case-by-case basis to determine the best way to review records associated with the supply-chain program when the supply-chain program is administered at the corporate level.

(Comment 477) Some comments ask us to clarify in the regulatory text that the required records are ''as appropriate to the supplier program.''

(Response 477) We have revised the regulatory text to specify that the required records are ''as applicable to its supply-chain program'' (see § 507.175(c)).

C. Documentation Demonstrating Use of the Written Procedures for Receiving Raw Materials and Other Ingredients (Final § 507.175(c)(5))

We proposed to require documentation demonstrating that products are received only from approved suppliers (proposed § 507.37(g)(4)).

(Comment 478) Some comments support the proposed requirement with no changes. Other comments ask us to specify ''raw materials and ingredients'' rather than ''products'' in the regulatory text.

(Response 478) We have revised the regulatory text to specify ''raw materials and other ingredients'' with associated conforming changes.

D. Documentation of the Conduct of an Onsite Audit (Final § 507.175(c)(7))

We proposed to require documentation of an onsite audit. This documentation must include: (1) Documentation of audit procedures; (2) the dates the audit was conducted; (3) the conclusions of the audit; (4) corrective actions taken in response to significant deficiencies identified during the audit; and (5) documentation that the audit was conducted by a qualified auditor. For clarity, we have revised the regulatory text to specify documentation of the ''conduct'' of an audit and added a requirement for the documentation to include the name of the supplier subject to the onsite audit.

(Comment 479) Some comments ask that we add ''if applicable'' to the requirement to maintain documentation of an audit because an audit may not be necessary if a receiving facility has documented that other verification activities are appropriate.

(Response 479) We decline this request. The documentation is always necessary if an audit is used as a verification activity. The provision is about maintaining documentation when an audit is conducted, not about when an audit needs to be conducted.

(Comment 480) Some comments ask us to maintain the confidentiality of audit reports and exempt such audit reports from disclosure under the Freedom of Information Act (FOIA).

(Response 480) These comments are similar to comments we received related to disclosure of other records required by this part (see Comments 490 and 491). We would establish the status of supply-chain program records, such as audit reports, as available for, or protected from, public disclosure on a case-by-case basis. As discussed in Response 491, we primarily intend to copy such records when we conduct an inspection for cause or if the preliminary assessment by our investigator during a routine inspection is that regulatory followup may be appropriate (*e.g.,* if the report indicates that a significant food safety problem was noted). See Response 491 for a discussion of situations in which records would, or would not, be protected from disclosure.

(Comment 481) Some comments express concern about maintaining documentation of the conclusions of an audit and documentation of corrective actions taken in response to significant deficiencies identified during the audit. These comments explain that FDA's access to such documentation during inspection might discourage suppliers from allowing unannounced audits. These comments ask us to delete these proposed requirements. If the requirement regarding documentation of corrective actions remains in the final rule, these comments ask us to limit such documentation to situations in which the identified deficiencies posed a risk to public health.

(Response 481) We are retaining these documentation requirements as proposed. These comments appear to be suggesting that documentation requirements be established based on whether a business entity would want us to see information during inspection rather than on the utility and value of the documentation. We expect that receiving facilities, in general, maintain documentation of the conclusions of audits that they have conducted or arranged to have conducted. A receiving facility must approve all of its suppliers, and documentation of corrective actions taken in response to significant deficiencies identified during an audit has value to a receiving facility in determining whether to approve a supplier before first receiving any raw materials or other ingredients and then on an ongoing basis.

The rule does not require that onsite audits be unannounced, although we acknowledge that some receiving facilities may see value in unannounced audits. We decline the request to require a receiving facility to maintain documentation of corrective actions only if the identified deficiencies posed a risk to public (human and animal) health. The purpose of an audit, like the purpose of all the supplier verification activities, is broader than identifying deficiencies that pose a risk to public (human and animal) health and includes verifying whether a raw material or other ingredient is adulterated under section 402 of the FD&C Act and is produced in compliance with applicable FDA food safety regulations (see § 507.110(c)). If, for example, a supplier's facility has filthy conditions or the raw materials and other ingredients it supplies are contaminated with filth, a receiving facility may find it inappropriate to approve that supplier. Even though filth often does not pose a risk to public (human and animal) health, a food may be deemed to be adulterated under section 402(a)(4) of the FD&C Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.

E. Documentation of Sampling and Testing (Final § 507.175(c)(8))

We proposed to require records of sampling and testing. These records must include: (1) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested; (2) identification of the test(s) conducted, including the analytical method(s) used; (3) the date(s) on which the test(s) were conducted and the date of the report; (4) the results of the testing; (5) corrective actions taken in response to detection of hazards; and (6) information identifying the laboratory conducting the testing.

(Comment 482) Some comments ask us to not apply the requirement to maintain records related to sampling and testing to the receipt of RACs because sampling and testing of RACs is neither common nor effective for detecting biological or chemical hazards, especially in raw, intact produce.

(Response 482) We decline this request. These comments appear to suggest that documentation requirements be established based on the frequency and utility of sampling and testing a particular commodity rather than on a determination by a receiving facility that sampling and testing is an appropriate supplier verification activity for a particular supplier. We disagree with such a suggestion. A receiving facility that has determined that sampling and testing is an appropriate supplier verification activity needs to maintain records of those results as it would for any other supplier verification activity. To the extent that these comments are concerned that the supply-chain

program requires sampling and testing of RACs, we emphasize that this is not the case. See also Response 350 for a discussion of the usefulness of sampling and testing as a verification measure for RACs.

(Comment 483) Some comments ask us to allow documentation of testing to include the date the test results were reported as an alternative to the date(s) on which the test(s) were conducted.

(Response 483) We have revised the provision to require ''The date(s) on which the test(s) were conducted and the date of the report.'' We agree that the date on which the test results are reported can be important, but it should not be a replacement for the date of the test.

(Comment 484) Some comments ask us to add ''if necessary'' to the end of the proposed requirement for documentation of corrective actions taken in response to detection of hazards.

(Response 484) We decline this request. The documentation is always necessary if corrective actions are taken. The provision is about maintaining documentation when corrective actions are taken, not about the fact that corrective actions may not always be needed.

F. Documentation of Other Appropriate Supplier Verification Activity (Final § 507.175(c)(10))

We proposed to require records of other appropriate verification activities based on the risk associated with the ingredient. For clarity and consistency, we have revised the proposed requirement to specify ''documentation'' of the other appropriate supplier verification activity rather than ''records'' of the activity. As a conforming change associated with using the term ''supplier performance,'' rather than ''risk of supplier,'' when discussing factors associated with suppliers, the final requirement specifies that the other appropriate supplier verification activities are based on the supplier performance and the risk associated with the raw material or other ingredient.

(Comment 485) Some comments ask us to also specify that an ''other'' appropriate supplier verification activity be based on the risk associated with raw materials and suppliers.

(Response 485) We have revised the regulatory text to specify ''Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient.'' The revised regulatory text of the documentation tracks the regulatory text of this ''other'' appropriate supplier verification activity (see § 507.110(b)(4)). As discussed in Response 444, ''supplier performance'' is more appropriate than ''risk associated with the supplier.''

G. Documentation of an Alternative Verification Activity for a Supplier That Is a Farm That Is Not a ''Covered Farm'' for the Purposes of the Future Produce Safety Rule (Final § 507.175(c)(13))

We proposed to require documentation of an alternative verification activity for a supplier that is a farm that is not a ''covered farm'' for the purposes of the future produce safety rule, including: (1) The documentation that the raw material or ingredient provided by the supplier is not subject to the produce safety rule and (2) the written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the FD&C Act. We have revised the documentation to reflect the final requirements of § 507.130(d)—*i.e.,* to require: (1) Written assurance that the supplier is not a covered farm under part 112 in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter and (2) 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). However as of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food.

(Comment 486) Some comments ask us to delete this documentation requirement because RACs except fruits and vegetables should be exempt from supplier verification.

(Response 486) See Response 464. This alternative supplier verification activity is intended to minimize the burden on suppliers that are small farms.

(Comment 487) Some comments ask us to include a cross-reference to the applicable requirement.

(Response 487) We have not added this cross-reference. We agree that adding the cross-reference has the potential to be helpful, but it also has the potential to clutter the regulatory text. We considered it would be more useful to specify what the documentation needs to be rather than to specify the cross-reference to the applicable alternative supplier verification activity.

XLVIII. Subpart F: Comments on Proposed New Recordkeeping Requirements

We proposed to establish in subpart F requirements that would apply to all records that would be required by the various provisions of proposed part 507, including general requirements related to the content and form of records; additional requirements specific to the food safety plan; requirements for record retention; requirements for official review of records by FDA; and public disclosure.

Some comments support the proposed requirements without change. Some comments that support the proposed provisions suggest alternative or additional regulatory text or ask us to clarify how we will interpret the provision.

In the following paragraphs, we discuss comments that disagree with or suggest one or more changes to the proposed requirements. After considering these comments, we have revised the proposed requirements as shown in table 30 with editorial and conforming changes as shown in table 31.

TABLE 30—REVISIONS TO THE PROPOSED RECORDKEEPING REQUIREMENTS

Section	Description	Revision
507.200(b)	Requirements for public disclosure	Specify that the requirement applies to records ''obtained by FDA.''
507.200(c)	Requirements for official review	Clarify that FDA may copy records upon oral or written request by a duly authorized representative of the Secretary of Health and Human Services.

TABLE 30—REVISIONS TO THE PROPOSED RECORDKEEPING REQUIREMENTS—Continued

Section	Description	Revision
507.202(b)	General requirements applying to records.	Provide that the time of an activity being documented only include the time of the activity when appropriate.
507.202(c)	General requirements applying to records.	Specify that electronic records are exempt from the requirements of 21 CFR part 11.
507.208(a)(2)	Requirements for record retention	Specify that records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility for as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.
507.208(c)	Requirements for record retention	Provide for offsite storage of all records other than the food safety plan, provided that the offsite records can be retrieved and provided onsite within 24 hours of request for official review.
507.208(d)	Requirements for record retention	Provide that the food safety plan may be transferred to some other reasonably accessible location if the plant or facility is closed for a prolonged period, provided that it is returned to the plant or facility within 24 hours of request for official review.
507.215	Special requirements applicable to a written assurance.	• Establish requirements applicable to all written assurances required by the rule. • Establish additional requirements applicable to written assurances that are required when a food product distributed by manufacturer/processor requires further processing for food safety by a subsequent manufacturer.

A. Proposed § 507.200—Records Subject to the Requirements of Subpart F and Requirements for Official Review

We proposed that all records required by part 507 would be subject to all requirements of subpart F, except that certain specific requirements (proposed § 507.206) would apply only to the written food safety plan. We also proposed that certain proposed requirements (*e.g.,* for records to contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities) would not apply to the records that would be kept by qualified facilities. We proposed that records required by proposed part 507 are subject to the disclosure requirements under part 20 (21 CFR part 20). We proposed that all records required by proposed part 507 be made promptly available to a duly authorized representative of the Secretary of HHS upon oral or written request. We also asked for comment on whether we should require a facility to send records to us rather than make the records available for review at a facility's place of business and, if so, whether we should require that the records be submitted electronically.

(Comment 488) Some comments disagree with the proposal to exempt the records that would be kept by qualified facilities from requirements to keep accurate, detailed records. The comments note that the proposed exemption would apply to qualified facilities regardless of whether they operate under the first option for documentation (*i.e.,* food safety practices) plans or under the second option for documentation (*i.e.* compliance with non-Federal food safety laws). These comments assert that the proposed detailed record keeping requirements should apply to records relating to monitoring food safety practices and ask us to revise the proposed requirements so that this exemption would apply only to those qualified facilities that operate under non-Federal food safety laws.

(Response 488) We decline this request. We based the proposed exemption on a statutory provision that a qualified facility is not subject to certain requirements, including the statutory recordkeeping requirements (see section 418(l)(2) of the FD&C Act). Although the requirements that apply to a qualified facility require submission of certain attestations to FDA (see § 507.7(a) and (b)), and these attestations must be supported by documentation (see § 507.7(f)), the rule does not require that records kept by a qualified facility to support its attestations be the same type of records that would be kept by a facility subject to subparts C and E. For example, if the facility attests that it has identified the potential hazards associated with the animal food being produced, implemented preventive controls to address the hazards, and is monitoring the performance of the preventive controls, the qualified facility might support its attestation by having a standard operating procedure for monitoring preventive controls rather than detailed records of actual monitoring.

(Comment 489) Some comments assert that the proposed requirements governing public disclosure are not aligned with other risk-based preventive controls programs, such as HACCP programs. These comments argue that these proposed requirements should be realigned with other risk-based preventive controls programs to preserve the privacy of information maintained in required records unless that information has been otherwise made publicly available. Some comments suggest that we revise the proposed requirements to be analogous to the public disclosure requirements in our HACCP regulations for seafood and juice (see §§ 123.9(d) and 120.12(f), respectively).

(Response 489) We disagree that the proposed provisions governing public disclosure are not aligned with the public disclosure provisions of our HACCP regulations for seafood and juice. Our regulations in part 20 regarding public information apply to all Agency records, regardless of whether a particular recordkeeping requirement says so. In the case of the recordkeeping requirements for our HACCP regulations for seafood and juice, we framed the provisions regarding public disclosure by providing specific details about how particular provisions in part 20 (*i.e.,* § 20.61 (Trade secrets and commercial or financial information which is privileged or confidential) and § 20.81 (Data and information previously disclosed to the public)) would apply to the applicable records. In the case of the recordkeeping requirements for this

rule, we framed the provisions regarding public disclosure by more broadly referring to all the requirements of part 20, consistent with our more recent approach for framing the provisions regarding public disclosure in the rule ''Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation'' (part 118; see § 118.10(f)). Provisions such as § 20.20 (Policy on disclosure of Food and Drug Administration records) apply to all records that we have in our system, including HACCP records, even though the HACCP regulations do not specify that this is the case.

(Comment 490) Some comments ask us to clarify that the disclosure requirements of part 20 include protections for trade secrets and privileged or confidential commercial information and financial information. Other comments ask us to clarify that written food safety plans and associated records are not subject to public disclosure because they represent trade secret or confidential commercial information. Other comments ask us to clarify how the disclosure requirements of part 20 would apply to verification records (such as testing records).

(Response 490) The questions raised in these comments are similar to some of the questions raised during the rulemaking to establish FDA's HACCP regulation for seafood (see the discussion at 60 FR 65096 at 65137 through 65140, December 18, 1995). FDA's experience in conducting CGMP inspections in processing plants, our experience with enforcing the HACCP regulations for seafood and juice, and our understanding from the Final Regulatory Impact Analysis (FRIA) for this rule (Ref. 60) make it clear that food safety plans will take each facility some time and money to develop. Thus, we conclude that food safety plans generally will meet the definition of trade secret, including the court's definition in *Public Citizen Health Research Group* v. FDA, 704 F.2d 1280 (D.C. Cir. 1983). Plans that incorporate unique regimens or parameters to achieve product safety, which are the result of considerable research and effort, will surely meet this definition.

We would establish the status of verification records, such as the results of product testing and environmental monitoring, as available for, or protected from, public disclosure on a case by case basis. As discussed in Response 491, we primarily intend to copy such records when we conduct an inspection for cause. We also intend to copy such records if the preliminary assessment by our investigator during a routine inspection is that regulatory followup may be appropriate (*e.g.,* if these records demonstrate that an environmental pathogen has become established in a niche environment in an animal food processing plant).

(Comment 491) Some comments assert that we should not copy documents as part of routine investigations so as to prevent critical documents from release under the FOIA. These comments are particularly concerned that our ability to copy verification records (such as testing records) and potentially release these records under the FOIA would discourage facilities from testing as a verification activity. These comments also express concern that some facilities would include in their food safety plans elements, not required by the proposed rule, that address food defense, as well as food safety, and that disclosure of such a food safety plan without proper redaction could provide useful information to persons seeking to defeat the facility's food defense strategies. In addition, these comments express concern that the task of reviewing all of these records and redacting trade secrets and confidential information would further set back FDA's already overburdened FOIA offices and create even longer delays in responding to FOIA requests.

(Response 491) We have revised the proposed requirement to specify that all required records must be made promptly available ''for official review and copying'' to increase the alignment of the recordkeeping requirements of this rule with those of our HACCP regulations for seafood and juice. The issues raised by these comments are similar to some of the issues raised by comments during the rulemaking to establish our HACCP regulations for seafood (see the discussion at 60 FR 65096 at 65137 through 65140) and our regulations in part 118 for the prevention of *Salmonella* Enteritidis in shell eggs. We intend to copy records on a case-by-case basis as necessary and appropriate. We may consider it necessary to copy records when, for example, our investigators may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate followup regulatory actions.

We primarily intend to copy records such as the results of product testing or environmental monitoring when we conduct an inspection for cause, *e.g.,* as a result of an outbreak investigation, violative sample results, or followup to a consumer complaint. See Response 490 for a discussion of how the FOIA would apply to records, such as records of testing as a verification activity, that we copy during an inspection and maintain in our system.

(Comment 492) Some comments ask us to modify the proposed requirement to clarify that it is ''records required by this part and provided to the Agency,'' rather than ''records obtained by the Agency'' that are subject to public disclosure.

(Response 492) We agree that it is appropriate to specify that the disclosure requirements of this rule apply to information that we maintain as a record (see the description of ''record'' in § 20.20(e)). (See also the discussion (in the proposed rule to establish our seafood HACCP regulation, 59 FR 4142 at 4160, January 28, 1994) that there are significant legal and practical questions as to whether FDA has the authority to require disclosure of industry records that are not in FDA's possession.) However, we see no meaningful distinction between records ''provided to FDA'' and records ''obtained by FDA,'' and have revised the provision to specify that records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20. The revised regulatory text makes clear that the requirements of part 20 attach to those documents obtained by FDA. To the extent that these comments are addressing the difference between records provided during inspection and records submitted to us, as already discussed we have decided not to require submission of certain records to us (see Response 493).

(Comment 493) Some comments strongly oppose any requirement for submission of records to FDA remotely and assert that there is no basis in FSMA for such a requirement. Some comments express concern about our ability to protect confidential information (such as supplier and customer records received by a facility under the protection of confidentiality agreements) that is transmitted electronically (*e.g.,* the information that might be released through computer hacking or leaks). Some comments note that inadvertent disclosure of information related to specific products, hazards, and preventive controls implemented at food facilities could both prove harmful from a commercial or competitive standpoint and expose existing vulnerabilities in the U.S. food supply, thus potentially rendering food facilities susceptible to malicious attack.

Some comments express concern over any potential requirements to submit

reports from third-party audits to FDA. The comments state that a requirement to submit audit reports, which may be included as voluntary or required components of a facility's food safety plan, would not be of public health benefit and could potentially impact a facility's willingness to use audits in their food safety program.

Some comments offered that instead of submission of the food safety plan, a facility should submit a ''certification'' that the facility has a food safety plan during the course of the facility registration process.

Some comments oppose the concept of a ''desk audit'' whereby our investigators conduct their inspections from a remote office without actually visiting the facility and assert that our access to company records must be conducted on-site in the course of an authorized inspection so that we may understand the full context of what the records show. Some comments point out that there would be challenges associated with credential validation when we asked for records to be sent remotely, such as in an email request. Some comments ask that we modify the proposed requirement to specify that records would only be made available to us during a facility inspection.

(Response 493) We have decided not to establish any requirements for a facility to send records to us. We will review records when we are onsite in the course of an authorized inspection, and copy records as necessary and appropriate.

We are not modifying the proposed requirement to specify that records would only be made available to us during a facility inspection because it is not necessary to do so. The regulatory text specifying that the records be made available to a duly authorized representative of the Secretary of HHS provides the context that the records would be made available during inspection.

B. Proposed § 507.202—General Requirements Applying to Records

We proposed that the records must: (1) Be kept as original records, true copies, or electronic records (and that electronic records must be kept in accordance with part 11 (21 CFR part 11)); (2) contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities; (3) be accurate, indelible, and legible; (4) be created concurrently with performance of the activity documented; (5) be as detailed as necessary to provide history of work performed; and (6) include the name and location of the plant or facility, the date and time of the activity documented, the signature or initials of the person performing the activity, and, where appropriate, the identity of the product and the production code, if any.

We have revised the provision to require information adequate to identify the plant or facility (*e.g.,* the name, and when necessary, the location of the plant or facility) rather than to always require both the name and location of the plant or facility (see § 507.202(b)(1)). In some cases, the name of the plant or facility will be adequate to identify it, *e.g.,* when a plant or facility is not part of a larger corporation that has facilities at more than one location. In other cases, the name of the plant or facility may not, by itself, be adequate to identify the plant or facility, *e.g.,* when a plant or facility is part of a larger corporation with more than one location and the ''name'' of each plant or facility is the same.

(Comment 494) Some comments express concern about ''apparent mandates'' that we will require records to be kept as paper copies, even if the records were generated electronically, for 2 years.

(Response 494) We did not propose to require that all records must be kept as paper copies. A facility has the choice to keep records as original records, true copies, or electronic records.

(Comment 495) Some comments assert that compliance with part 11 for the secure operation of many systems currently in use is unnecessary and would create the need to redesign and recreate existing systems, thus leading to considerable cost and complexity. These comments identify the requirement for hardware and software to be validated as a key cost concern and assert that validation activities would be difficult to maintain and would not deliver added value. As an example, these comments explain that an expectation for validation of electronic recordkeeping software and hardware would be particularly problematic because software patches and security updates are distributed on a nearly weekly basis, and express the view that validation procedures are most appropriately applied before use of a new system and after major software changes or updates. These comments also assert that it would be costly, burdensome, and require specialized resources to modify or replace existing electronic systems to comply with part 11. These comments provide an example in which a facility needed more than 9 months to upgrade one system alone to comply with part 11, and note that it would not be unusual for companies to employ multiple systems, so the burden and cost would exponentially increase. These comments ask us to instead require facilities that use electronic records to a use secure system that ensures records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Other comments express concern about the financial burden for small facilities such as farm mixed-type facilities and ask us to either modify requirements for farm mixed-type facilities, very small businesses, and small businesses or provide that such facilities be fully exempt from part 11 requirements for electronic records. Other comments state that, as with the recordkeeping requirements under the Bioterrorism Act, such requirements are disproportionate to the regulatory need.

Some comments state that major advances in software technology have been made since part 11 published in 1997, and such advances must be carefully considered in evaluating any potential expansion or new applications of part 11. These comments also state that we already are in the process of reevaluating part 11 for the regulations for which it currently applies, citing industry guidance issued more than 10 years ago in which we acknowledged that part 11 is unworkable in many respects and decided to exercise enforcement discretion for part of the regulations and announced plans to reexamine part 11 as a whole.

Some comments recommend that we develop guidance, with input from key stakeholders, to describe the kinds of systems and steps that can be used to assure records meet the required standard. This guidance should clearly establish that specific security needs will depend on the circumstances, including the system at issue, its intended use, the criticality of the preventive control or other food safety measure it is used to manage, and other relevant factors. For example, these comments explain that a quality system used to manage CCP documentation would have greater security needs than a review of a Certificate of Analysis for a non-sensitive ingredient.

(Response 495) In light of the substantial burden that could be created by the need to redesign large numbers of already existing electronic records and recordkeeping, we are providing in new § 507.202(c) that records that are established or maintained to satisfy the requirements of part 507 and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. As we did in the section 414 recordkeeping

regulations, we also are specifying that records that satisfy the requirements of part 507, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. The rule provides that a facility may rely on existing records to satisfy the requirements of this rule, and this rule does not change the status under part 11 of any such records if those records are currently subject to part 11. As we did in the rulemaking to establish the section 414 recordkeeping regulations, we are establishing a conforming change in part 11 to specify in new § 11.1(j) that part 11 does not apply to records required to be established or maintained under part 507, and that records that satisfy the requirements of part 507, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

Although we are not specifying that part 11 applies, facilities should take appropriate measures to ensure that records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(Comment 496) Some comments assert that certain production and associated activities are not time-sensitive and would not require documentation of the time the activity is performed. These comments ask us to modify the proposed requirements so that the records would only require the time of the activity documented where appropriate for food safety.

(Response 496) We agree that certain activities (*e.g.,* record review and verification activities) are not time-sensitive and, thus, would not need to include the time that the activity was performed. The final rule provides flexibility for the facility to determine when to document the time by specifying that the time be documented ''when appropriate'' (see § 507.202(b)(2)).

(Comment 497) Some comments assert that concurrent record creation will prove difficult in many animal food-processing environments. These comments ask us to modify the proposed requirement that records be created concurrently with the performance of the activity documented to qualify that the requirement only applies where feasible, and that the records could be created as soon as possible thereafter under circumstances where concurrent record creation is not feasible.

(Response 497) We decline this request. The comments did not provide any examples of activities where concurrent record creation in animal food manufacturing/processing, packing, or holding environments would prove difficult, and we are not aware of any such example. For example, we are not aware of any difficulty complying with longstanding similar requirements associated with our HACCP regulations for seafood and juice (see §§ 123.9(a)(4) and 120.12(b)(4), respectively).

C. Proposed § 507.206—Additional Requirements Applying to the Food Safety Plan

We proposed that the food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.

(Comment 498) Some comments ask for clarification on who can sign and date the food safety plan. Some comments state that the proposed rule would exclude the preventive controls qualified individual from signing and dating the food safety plan unless the preventive controls qualified individual is the owner, operator, or agent in charge of the facility. These comments ask us to revise the rule to allow the preventive controls qualified individual to sign and date the food safety plan (*e.g.,* because it is the preventive controls qualified individual who prepares (or oversees the preparation of) the food safety plan). One comment suggests that ''agent in charge'' be defined to include all preventive controls qualified individuals. Some comments ask us to require that any preventive controls qualified individuals who prepare (or oversee the preparation of) specific sections of the food safety plan sign and date applicable sections.

(Response 498) We decline these requests. The statute expressly directs the owner, operator, or agent in charge of a facility to prepare the food safety plan (see section 418(h) of the FD&C Act). As previously discussed, such a signature would provide direct evidence of the owner, operator or agent's acceptance of the plan and commitment to implementation of the plan (78 FR 64736 at 64816). A facility has flexibility to require the signature of one or more preventive controls qualified individuals who prepared, or oversaw the preparation of, its food safety plan in addition to the minimum signature requirement specified in the rule. Likewise, a facility also has flexibility to require the signature of one or more members of its food safety team who contributed to the preparation of the food safety plan, even if those individuals are not serving as the preventive controls qualified individual for the facility.

D. Proposed § 507.208—Requirements for Record Retention

We proposed that: (1) All required records must be retained at the plant or facility for at least 2 years after the date they were prepared; (2) records relating to the general adequacy of equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued; (3) except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the records were made if such records can be retrieved and provided onsite within 24 hours of request for official review; and (4) if the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

(Comment 499) Some comments ask us to clarify that the 2-year record retention requirement only applies to records created after the compliance date for the final rule.

(Response 499) The retention requirements only apply to records created after the applicable compliance date for the final rule. See Response 76 and section LIII.A, which explain that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. See also Response 502, which explains that we have revised the record retention provisions to specify that records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility for as long as necessary to support the status of facility as a qualified facility during the applicable calendar year.

(Comment 500) Some comments ask us to delete the proposed requirement to keep records on site for 6 months or 2 years (depending on the record) and assert that it should suffice to require that records be available within 24 hours of request or within a reasonable period of time. Some comments assert that records should be able to be kept in the location where they are created, which may be at corporate headquarters. Other comments state that it may be difficult to obtain records within 24 hours and requested additional time. Comments also assert that specifying the location for record storage will increase costs but will not contribute to improvements in public health. Some

comments ask us to permit offsite storage for all records over 6 months old, in contrast to the 2-year retention period we proposed for records relating to the general adequacy of equipment or processes being used by a facility, including the results of scientific studies and evaluations.

(Response 500) We have revised the provisions to provide for offsite storage of all records (except the food safety plan), provided that the records can be retrieved and made available to us within 24 hours of request for official review. We have determined that in order to maintain inspectional efficiency, 24 hours is a reasonable period to allow for retrieval of any offsite records. We expect that many records will be electronic records that are accessible from an onsite location and, thus, would be classified as being onsite (see § 507.208(c)). As a companion change, we have revised the proposed provision directed to the special circumstance of storing records when a facility is closed for prolonged periods of time so that it only relates to the offsite storage of the food safety plan in such circumstances (see § 507.208(d)).

(Comment 501) Some comments assert that a 2-year retention period for records is much longer than needed for animal food products, as animal food is often consumed within a short time after manufacture. These comments ask us to establish a 1-year period for record retention, which would be similar to record retention periods required in other FDA regulations. Some comments assert that records should be required to be kept for the shelf life of the product plus an additional 6 months, for certain animal foods such as pet foods.

(Response 501) We decline these requests. The proposed 2-year retention period is authorized by the statute (see section 418(g) of the FD&C Act). Moreover, the reasons discussed by the comments for linking the retention period to shelf life are more relevant to the record retention requirements for the purpose of tracking potentially contaminated food (part 1, subpart J; see § 1.360) than to the record retention requirements for the purpose of evaluating compliance with this rule.

(Comment 502) Some comments ask us to require that qualified facilities keep financial and sales records for 3 or 4 years, because a qualified facility must document that the average value of food it sold over the prior 3 years did not exceed $500,000 annually.

(Response 502) We have revised the record retention provisions to specify that records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year. As discussed in section VIII.A, the definition of very small business established in this rule is based on an average (of sales plus market value of animal food held without sale) during the 3-year period preceding the applicable calendar year. Thus, both of the criteria for the qualified facility exemption are based on financial records associated with the preceding 3-year period. The actual retention time necessary to support the status of a qualified facility during the applicable calendar year could be as long as 4 years. For example, if we inspect a facility on May 1, 2024, the facility would have retained the records from 2021 to 2023 for 3 years and 4 months. If we inspect the facility on December 28, 2024, the facility would have retained the records from 2021 to 2023 for nearly 4 years.

E. Proposed § 507.212—Use of Existing Records

We proposed that existing records (*e.g.,* records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of subpart F. We also proposed that the information required by part 507 does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by part 507 may be kept either separately or combined with the existing records.

Comments that address this proposed requirement support it. For example, some comments state that this provision would provide flexibility to facilities to comply with the record requirements in an efficient manner. Other comments state that this provision would prevent companies from having to duplicate records or create new records solely to satisfy recordkeeping requirements.

(Comment 503) Some comments state that food safety plan records are a ''web of related documents'' that may be used in other programs and cannot be collected or reduced to a ''binder.''

(Response 503) We agree that food safety plan records could be considered a ''web of related documents,'' *i.e.,* a set of records that could include documents used in other programs. We also agree that the food safety plan records need not be collected in a single location or ''reduced to a binder.'' Likewise, the records documenting implementation of the plan could be a ''web of related documents.'' For example, a facility that collects samples of product and sends them to a laboratory for testing would have records documenting its collection of samples, as well as records documenting the laboratory's test results. Consistent with the requirements of the rule for written procedures for product testing (§ 507.49(b)(2)) and the general recordkeeping requirements of subpart F (§ 507.202), the sampling records would contain information such as the name and location of the facility, the date when the samples were collected, the signature or initials of the person collecting the samples, and the identity and lot code of the sampled product.

Likewise, the laboratory report would contain information identifying the laboratory, the product tested (and associated lot code), the test analyte, the test(s) conducted (including the analytical method(s) used), the date of the test(s), the test results, and the signature or initials of the person who conducted the test. Alternatively, it would be acceptable to have the signature or initials of the person who approved the release of the test results from the laboratory. Together, these records contain all the required information to associate them with a facility, a specific lot of product, and the results of laboratory testing on that product.

Although the provisions for use of existing records provide flexibility, there are some limitations. For example, monitoring records must be created concurrently with the monitoring activity and contain the signature or initials of the person conducting the monitoring. If the facility has an existing form that it uses to document the monitoring activity, and that form does not provide (or have space to add) information adequate to identify the plant or facility (*e.g.,* the name and, when necessary, the location of the facility), and does have (or have space to add) a place for the signature of the person performing the activity, we expect the facility to modify the form rather than use the existing form. The provisions for ''supplementing'' existing records do not extend to providing information identifying the facility, or signatures, on separate pages.

(Comment 504) Some comments state that our review of records should be limited to issues under our jurisdiction, regardless of the other information that may be contained in the record. Other

comments ask us to ensure that inspectors are adequately trained on how to review facility records for the requisite information across multiple sets of documents, as needed.

(Response 504) Section 418(h) of the FD&C Act requires that the written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418, together with the documentation of monitoring of preventive controls, instances of nonconformance material to food safety, the results of testing and other means of verification, instances when corrective actions were implemented and the efficacy of preventive controls and corrective actions, be made available to FDA. Our inspectors will be trained to focus on the written food safety plan and the records documenting implementation of the plan during inspections. Our inspectors have experience in the review of records that an animal food business establishes and maintains for more than one purpose—*e.g.,* during the review of records kept under the section 414 recordkeeping regulations during the investigation of an outbreak of foodborne illness.

For further discussion of comments received on recordkeeping requirements, see section XLI in the final rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

F. Final § 507.215—Special Requirements Applicable to a Written Assurance

As discussed in section XXVII, new § 507.215 establishes requirements applicable to the written assurance a manufacturer/processor obtains from its customer. New § 507.215(a) applies to all written assurances required by the rule, *i.e.,* the assurance must contain the effective date; printed names and signatures of authorized officials; and the applicable assurance.

The provisions of § 507.215(b), together with another new provision (§ 507.37), establish legal responsibilities under the rule for a facility that provides a written assurance regarding a food product that a manufacturer/processor distributes without application of a preventive control that is needed to control a hazard. This responsibility exists even for a facility that is not itself a manufacturer/processor, such as for a facility that is a distributor. We are establishing legal responsibilities for the facilities that provide these written assurances because following these assurances is critical to ensuring that required preventive controls are applied to the food by an entity in the distribution chain before the food reaches consumers.

XLIX. Comments by Foreign Governments and Foreign Businesses

We received several comments from foreign governments and foreign businesses covering a wide range of issues. Many of those comments were similar to comments made on certain topics by domestic stakeholders, so we are addressing those comments in other sections throughout this preamble. In this section, we are responding to comments that are primarily focused on international issues, such as the obligations of the United States under the World Trade Organization Agreement (WTO).

(Comment 505) Some comments by foreign government representatives ask us to provide extended periods of time for the implementation of the rule for facilities in foreign countries.

(Response 505) The concept of special and differential treatment is incorporated in the WTO Agreements. Article 10.2 of the WTO Sanitary and Phytosanitary (SPS) Agreement states: ''Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction . . . longer timeframes for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.''

In 2001, at the WTO Ministerial Conference in Doha, WTO Members issued a Ministerial Decision that interpreted the special and differential obligations of the SPS Agreement (Ref. 61). The Ministerial Decision defined ''longer timeframe for compliance'' to normally mean a period of not less than 6 months.

We recognize that businesses of all sizes may need more time to comply with the new requirements established under this rule. As discussed in section LIII, the compliance date for implementation of subpart C, Hazard Analysis and Preventive Controls is extended one year beyond the compliance date for the implementation of subpart B, Current Good Manufacturing Practice. Businesses other than small and very small businesses will have 1 year after the date of publication to comply with the CGMP requirements and 2 years after publication to comply with preventive controls requirements. Small businesses will have 2 years after publication to comply with the CGMP requirements and 3 years after publication to comply with preventive controls requirements. Very small businesses will have 3 years after publication to comply with the CGMP requirements and 4 years after publication to comply with preventive controls requirements. We anticipate that these extended implementation periods for small businesses and very small businesses will apply to a number of businesses in developing countries. Because all of these time periods are longer than the 6 month minimum defined in the WTO Ministerial Decision, we believe these implementation periods are sufficient to address the needs of businesses in developing countries, particularly for small and very small businesses in such countries.

In addition to the extended time periods for compliance for small and very small businesses, we have also established modified requirements for very small businesses, which we define as 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). These modified requirements for very small businesses are less burdensome and are described in § 507.7 of this regulation.

In addition to the extended and staggered time periods for compliance for all firms, and modified requirements for very small businesses, we intend to work with the animal food industry, education organizations, USDA, the United States Agency for International Development, and foreign governments to develop tools and training programs to facilitate implementation of this rule.

(Comment 506) Some comments assert that the food safety systems of the European Union and other countries afford a similar level of food safety protection and must therefore be recognized by FDA as equivalent under the WTO SPS Agreement. These comments urge FDA to accept the HACCP plans and other steps taken to comply with European food safety laws as being sufficient to comply with this rule.

(Response 506) The concept of ''equivalence'' for food safety regulatory measures is contained in Article 4 of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the ''SPS Agreement'') (Ref. 62). That article provides that WTO Member countries ''shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from

those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.'' This provision of the SPS Agreement envisions a process in which the exporting country provides evidence to the food safety regulator in the importing country in order to ''objectively demonstrate'' that the food safety system in the exporting member meets the level of food safety protection established by the importing country. To date, FDA has considered equivalence as most appropriately applied to the assessment of a foreign government's specific programs for specific types of foods, such as shellfish and dairy products. In that context, the equivalence assessment provides a very detailed comparison of each measure that a country applies in controlling risks associated with the particular commodity under review. FDA continues to have latitude to engage in equivalence determinations for market access and as required by our regulations for certain commodities.

In contrast to the assessment of equivalence for the regulation of specific foods based upon a detailed review of an individual food safety measure or group of measures applied to a specific food, FDA has established a process of assessing foreign food safety systems to identify systems that offer a comparable level of public health protection as the U.S. food safety system for FDA regulated foods. We refer to that process as ''systems recognition,'' which we discuss in Response 507.

(Comment 507) Some comments urge FDA to include a provision in this rule that would reflect a determination made by FDA in the ''systems recognition'' process so that FDA's compliance framework, including audit and inspection activities, takes into account the effectiveness of the regulatory or administrative control of food safety systems. These comments ask us to include a provision in this rule establishing that an affirmative systems recognition determination by FDA for an exporting country would be a sufficient basis to exempt exporting businesses from that country from their obligation to comply with the requirements of this rule. Another comment urges FDA to utilize the systems recognition process to recognize the effectiveness of the European Union (EU) system in order to avoid unnecessary or duplicative requirements and controls on food imports from the EU. Another comment requests that FDA coordinate inspection and audits with the relevant competent authority.

(Response 507) We agree, in part, with this comment. We agree that the systems recognition program can allow FDA to take into account the effectiveness of a foreign food safety regulatory system as we develop a compliance framework for imported foods from a country for which we have made an affirmative determination of comparability via the systems recognition program. While we decline to add an exemption for food imported from a country with affirmative systems recognition determination by FDA, we note that the systems recognition program is based upon the concept that foreign food businesses can meet U.S. food safety requirements by providing assurances that these foods are produced according to the food safety standards of a country that FDA has found to be comparable or equivalent to that of the United States. Several provisions of the supply-chain program specifically provide for consideration 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 (see §§ 507.110(d)(1)(iii)(B); 507.130(c)(2), (d)(2), and (e)(2); and 507.135(b) and (c)(1)(ii)). However, as of August 30, 2015, FDA has not developed a systems recognition program for animal food; therefore, we have no signed systems recognition agreements with any foreign food safety authority relating to animal food. The currently existing systems recognition agreement relates solely to human food and does not apply to animal food. For further discussion of the systems recognition program, see Response 718 of the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

We also note that we intend to publish a final FSVP rule in the near future. There, we intend to establish modified requirements for food imported from a foreign supplier in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as ''comparable'' to that of the United States.

Section 507.105(a)(2) of this rule provides the option for a receiving facility that is an importer to comply with the supplier verification requirements in this rule or with the foreign supplier verification program requirements that we will establish in part 1, subpart L for a raw material or other ingredient. We intend that the final FSVP rule will contain a similar provision (derived from proposed § 1.502), so that only one supplier verification procedure needs to be undertaken in order to comply with both rules when the specified conditions are met.

(Comment 508) Some comments assert that a proper harmonization is needed with international standards and ask us to harmonize the FSMA requirements for the food safety plan with international and domestic HACCP programs. These comments also ask us to explain any differences between the FSMA food safety plan and the existing HACCP programs and ask us to provide exporters with background information and specific examples of differences, including how firms are directed to set their CCPs and critical limits.

(Response 508) We currently have no HACCP requirements applicable to animal food. For discussion of this comment, see Response 725 in the final rule for preventive controls for human food, published elsewhere in this issue of the **Federal Register**.

L. Editorial and Conforming Changes

The revised regulatory text includes several changes that we have made to make the requirements more clear and improve readability. The revised regulatory text also includes several conforming changes that we have made when a change to one provision affects other provisions. We summarize the principal editorial and conforming changes in table 31.

TABLE 31—PRINCIPAL EDITORIAL AND CONFORMING CHANGES

Designation in the revised regulatory text (§)	Revision	Explanation
• 11.1(j)	Specify that part 11 does not apply to records required to be established or maintained under part 507, and that records that satisfy the requirements of part 507, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.	Conforming change associated with the recordkeeping requirements in § 507.202, which provide that part 11 does not apply to records required to be established or maintained under part 507.
Throughout part 507	• Substitute the term ''adequate'' for the term ''sufficient''. • Substitute the term ''inadequate'' for the term ''insufficient''.	Conforming change associated with our proposal, in the 2014 supplemental animal preventive controls notice, to make this substitution so that the rule consistently uses the term ''adequate.''
Throughout part 507	Substitute the term ''pathogen'' for the term ''microorganism of public health significance''.	Conforming change associated with the definition of ''pathogen.''
Throughout part 507	Substitute the term ''preventive controls qualified individual'' for the term ''qualified individual''.	Conforming change associated with adding the term ''preventive controls qualified individual''.
Throughout part 507	Substitute the term ''unexposed packaged animal food'' for the phrase ''packaged animal food that is not exposed to the environment''.	Conforming change associated with the definition of ''unexposed packaged animal food''.
Throughout part 507	Substitute the phrase ''chemical (including radiological) hazards'' for phrases such as ''chemical and radiological hazards''.	Conforming change associated with the definition of ''hazard''.
Throughout part 507	Substitute the term ''hazard requiring a preventive control'' for the term ''significant hazard''.	Conforming change associated with the proposed definition of ''significant hazard'' (which we now refer to as ''hazard requiring a preventive control'').
Throughout part 507	Shorten ''raw agricultural commodity as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act'' to ''raw agricultural commodity''.	Conforming change associated with the new definition of ''raw agricultural commodity''.
507.1(a)	Redesignate subparagraphs to distinguish between applying the provisions in determining whether animal food is adulterated and applying the provisions in determining whether there is a violation of the PHS Act.	Improve clarity.
507.3	Substitute ''apply'' for ''are applicable'' in the introductory paragraph.	Improve clarity.
507.3	Alphabetize the examples of harvesting activities in the definition of ''harvesting''.	Improve clarity.
507.3	Alphabetize the examples of manufacturing/processing activities in the definition of ''manufacturing/processing''.	Improve clarity.
507.3	Specify that the definition of ''very small business'' includes any subsidiaries and affiliates.	Give prominence to this aspect of the definition of ''very small business.'' The relevance of subsidiaries and affiliates to the definition of ''very small business'' is established in the definition of ''qualified facility,'' but including it again in the definition of ''very small business'' will help to ensure that it is considered when determining whether the business is within the dollar threshold established in the definition of ''very small business''.
• 507.3 • 507.5 • 507.7(d) • 507.10(a) • 507.65(d)(1)	Substitute ''subparts C and E'' for ''subpart C''.	Conforming change associated with the redesignation of the requirements for a supply-chain program in new subpart E.

TABLE 31—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (§)	Revision	Explanation
507.7(a)(2)(ii)	Editorial change to place the clause ''including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight'' at the end of the provision, rather than in a parenthetical at the beginning of the provision.	Improve clarity.
• 507.14 • 507.17(a) • 507.20(d) • 507.202(b)	Conforming changes associated with the definition of ''plant''.	The definition of ''plant'' focuses on the building, structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food. The term ''establishment'' focuses on a business entity rather than on buildings or other structures.
507.20(d)	Refer to ''employees'' rather than ''its employees''.	Editorial change.
• 507.25(a)(2) through(b)(1) • 507.33(d)(3) • 507.105(a)(1) • 507.110(b) through (e) • 507.115(a) • 507.120(a) and (b) • 507.130 • 507.175(c)	Changes to consistently refer to raw materials and ''other ingredients''.	Conforming change with preventive controls rule for human food.
507.31(b)(3), 507.34(c)(3), 507.39(b), 507.47(c)(3), 507.55(a)(5).	Refer to ''supply-chain program'' rather than ''supplier program''.	Conforming change associated with the title of final subpart E (proposed § 507.37).
• 507.47(b)(2) • 507.50(b)(4)	Conforming changes associated with the definition of ''validation''.	Improve clarity; consistency with the requirements for validation.
507.49(a)(4)(ii)	Refer to ''supply-chain verification activities,'' as well as ''supplier verification activities''.	Consequential change as a result of the requirement in § 507.105(c) for verification of an entity that is in the supply-chain but is not a supplier.
507.49(b)(1)	Changes to require written procedures for method and frequency of accuracy checks for process monitoring instruments and verification instruments.	Conforming change associated with the requirements to calibrate process monitoring instruments and verification instruments (or check them for accuracy).
507.50(c)(2)	Conforming changes associated with the timeframe for validating preventive controls.	Consistency with the requirements for validating preventive controls.
507.50(d)	Editorial changes to the requirement to revise the written food safety plan or document why revisions are not needed.	Improve clarity.
507.51(a)(2)	Editorial change to specify ''provide assurance that the temperature controls are consistently performed'' rather than ''provide assurance that they are consistently performed''.	Improve clarity.
• 507.51(a)(4)(ii) • 507.51(a)(4)(iii)	Substitute the phrase ''records are created'' for the phrase ''records are made''.	Consistency with other recordkeeping requirements of the rule.
507.51(a)(4)(iii)	Change ''within a week'' to ''within 7 working days''.	Conforming change associated with review of records of monitoring and corrective action records.
507.53(a)(3)	Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for validation.	Conforming change associated with flexibility to determine the timeframe for validation of a preventive control.
507.53(a)(4)	Change to specify the role of the preventive controls qualified individual in determining that validation is not required.	Conforming change associated with flexibility to determine that validation of a preventive control is not required.
507.53(a)(6)	Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for review of records of monitoring and corrective actions.	Conforming change associated with flexibility to determine the timeframe for review of records of monitoring and corrective actions.

TABLE 31—PRINCIPAL EDITORIAL AND CONFORMING CHANGES—Continued

Designation in the revised regulatory text (§)	Revision	Explanation
507.53(a)(8)	Change to specify the role of the preventive controls qualified individual in determining an alternative timeframe for completing reanalysis.	Conforming change associated with flexibility to determine the timeframe for completing reanalysis.
Subpart D (title) 507.60 507.62 507.65 507.67 507.80 507.85	Substitute the term ''qualified facility exemption'' for the phrase ''exemption applicable to a qualified facility'' or the phrase ''exemption applicable to a qualified facility under § 507.5(d)''.	Conforming change associated with the definition of ''qualified facility exemption''.
507.60(b)(1)	Change ''import alert'' to ''refusal of animal food offered for import''.	Align with statutory language regarding imports rather than with specific procedures that FDA uses for refusing admission to animal foods offered for import.
507.62(a)	Change ''FDA official senior to such Director'' to ''FDA official senior to either such Director''.	The provision refers to two ''Directors'' and the clause applies to either Director.
507.65(c)(2)	Refer to ''conditions or conduct'' rather than ''conduct or conditions''.	Consistency with regulatory text in § 507.60(a)(2).
• 507.67(a)(2) • 507.69(a)(1) • 507.71(a)(2), • 507.73(a)	Change ''within 10 calendar days'' to ''within 15 calendar days''.	Conforming change to reflect a timeframe of 15 calendar days, rather than 10 calendar days, in the order withdrawing a qualified facility exemption.
• 507.85(a) • 507.85(b)(2)	Specify ''any problems with the conditions and conduct'' rather than ''problems with the conditions and conduct'' or ''problems with the conditions or conduct''.	Clarify that reinstatement of a qualified exemption that was withdrawn requires resolution of any problems, regardless of whether the problems related to conditions, conduct, or both conditions and conduct.
507.202	Refer to ''lot code'' rather than ''production code''.	Consistency with the definition of ''lot''.
507.206	Editorial changes to present the requirement in active voice.	Improve clarity.

LI. Comments on FSMA's Rulemaking Provisions

A. Comments on Section 418(m) of the FDA&C Act Regarding Modified Requirements for Facilities Solely Engaged in the Production of Food for Animals Other Than Man

Section 418(m) of the FD&C Act authorizes the Secretary, by regulation, to modify the requirements for compliance under the section with respect to facilities that are solely engaged in the production of food for animals other than man. We tentatively concluded that the requirements of section 418 of the FD&C Act are needed to ensure the safety of animal food and in turn the health of animals, the health of humans who are exposed to animal food, and the safety of animal derived products for human consumption. We proposed certain limited exemptions, described elsewhere in this rule, as provided by section 103 of FSMA. We sought comment on whether the requirements in section 418 of the FD&C Act should be modified further for facilities that are solely engaged in the production of food for animals other than man, based on scientific and public health principles (78 FR 64736 at 64745).

(Comment 509) Some comments agree with our proposal to establish only minor modifications to the requirements of section 418 of the FD&C Act for facilities solely engaged in the production of food for animals other than man. Other comments ask that we consider proposing more extensive modified requirements for animal food, or exempting feed mills, using the authority under section 418(m).

(Response 509) We did not receive comments that provided sufficient data and rationale to support changing our proposed modifications to the requirements in section 418 of the FD&C Act. However, the final rule provides risk-based flexibility in the preventive controls requirements and their management components by recognizing the importance of the facility, the food, the nature of the preventive control, and its role in the facility's food safety system. For our approach to feed mills, see our discussion in section IV.

B. Comments on Requirements in Section 418(n)(3) of the FD&C Act Regarding Content

FSMA specifies that this rule acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods (section 418(n)(3)(C) of the FD&C Act).

(Comment 510) Some comments agree that the proposed preventive controls requirements reflect a risk-based approach and recognition that a ''one-size-fits-all'' approach is not appropriate in the application of hazard analysis and risk-based preventive controls across the entire domestic and international food industry. These comments ask us to retain this flexibility in the final rule by describing the required and expected results of the program, but not going as far as prescribing the process and methodology taken to get there. Other comments emphasize that the final rule must provide sufficient flexibility to allow facilities to adopt practices that are practical and effective for their specific, individual operations. One comment expressed the opinion that

different manufacturing and distribution practices are necessary to ensure the safety of human food, pet food, and livestock food.

(Response 510) The final rule directs the owner, operator, or agent in charge of a facility to establish and implement a food safety plan that includes a written hazard analysis, preventive controls that the facility identifies to control hazards requiring a preventive control, and establish and implement appropriate preventive control management components to ensure the effectiveness of the preventive controls, taking into account the facility, the food, the nature of the hazard, the nature of the preventive control and its role in the facility's food safety system. As requested by the comments, the rule does not prescribe the process and methodology to ''get there.''

(Comment 511) Some comments interpret the statutory direction in section 418(n)(3)(C) of the FD&C Act to mean that Congress granted us authority to provide flexibility for businesses of all sizes and types (*i.e.,* not just small businesses), as well as to acknowledge differences in risk. These comments assert that section 418(n)(3)(C) grants us authority to exempt distribution centers from the requirements for hazard analysis and risk-based preventive controls because: (1) Distribution centers are very low-risk facilities and (2) requiring distribution centers to comply with those requirements would not be practicable.

(Response 511) We disagree with these comments. A pet food distribution center must register as a food facility because it holds food for animal consumption and does not satisfy any of the criteria for entities that are not required to register (see § 1.226). The preventive controls that such a facility would establish and implement would depend on the facility, the animal food, and the outcome of the facility's hazard analysis, and any preventive control management components associated with a facility's preventive controls would be established as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system. In the case of a facility that is a pet food distribution center, the facility would, as part of its evaluation, determine whether any preventive controls are necessary for unexposed, non-refrigerated packaged animal foods. The facility might determine that the modified requirements in § 507.51 for unexposed, refrigerated, packaged TCS animal foods are appropriate to apply to such foods that it holds. If so, the facility could establish its food safety plan by building on the provisions established in § 507.51.

LII. Comments on Proposed Conforming Amendments

We proposed a series of conforming amendments to current regulations to add a reference to part 507. The affected sections in Title 21 CFR Chapter 1 are:

- § 11.1 Scope;
- § 16.1 Scope;
- § 117.95 Holding and distribution of human food by-products for use as animal food;
- § 225.1 Current good manufacturing practice;
- § 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers; and
- § 579.12 Incorporation of regulations in part 179.

We received no comments that disagree with the proposed conforming changes. Therefore, at this time we are amending each of these current regulations so that they refer to part 507 except for the amendment to part 225. We proposed to add a new paragraph (d) in § 225.1 stating that ''In addition, nonmedicated feed is subject to part 507 of this chapter.'' All animal food facilities that are required to register as a food facility under section 415 of the FD&C Act are subject to the requirements of part 507. This would include those facilities that manufacture medicated animal feed, nonmedicated animal feed, or both. Because of this, we do not think the conforming change to part 225 is necessary and we are not finalizing this conforming change.

LIII. Effective and Compliance Dates

A. Effective and Compliance Dates for Part 507

We proposed that the final rule based on proposed part 507 would become effective 60 days after its date of publication in the **Federal Register**, with staggered compliance dates (78 FR 64736 at 64751). We tentatively concluded that it was reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small and very small businesses to comply with the rule. We also tentatively concluded that it was reasonable to allow for 2 years after the date of publication of the final rule for small businesses to comply with the rule, and 3 years after the date of publication of the final rule for very small businesses to comply with the rule.

We received one comment agreeing with our proposed compliance dates. In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, these proposed compliance dates. After considering these comments, we have concluded that additional time is needed for the animal food industry to comply with this final rule. Therefore, the compliance date for implementation of subpart C, Hazard Analysis and Preventive Controls and subpart E, Supply-Chain Program, is extended one year beyond the compliance date for the implementation of subpart B, Current Good Manufacturing Practice. Businesses other than small and very small businesses will have 1 year after the date of publication to comply with the CGMP requirements and 2 years after publication to comply with preventive controls and supply-chain requirements. Small businesses will have 2 years after publication to comply with the CGMP requirements and 3 years after publication to comply with preventive controls and supply-chain requirements. Very small businesses will have 3 years after publication to comply with the CGMP requirements and 4 years after publication to comply with preventive controls requirements.

In addition, we are establishing an earlier compliance date for the financial records that a facility maintains to support its status as a very small business that is eligible for the qualified facility exemption in § 507.5(d). Specifically, the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017. (See Response 76.)

We are also establishing separate compliance dates for the supply-chain program provisions. As discussed in Response 515, a receiving facility's compliance date for the supply-chain program provisions of this rule is the later of: (1) The receiving facility's compliance date for the other preventive controls requirements under this rulemaking; (2) for a raw material or other ingredient from a supplier subject to the preventive controls requirements of this rule, six months after the receiving facility's supplier of that raw material or ingredient is required to comply with the preventive controls requirements of this rule; or (3) for a raw material or other ingredient that from a supplier subject to CGMPs, but not the preventive controls requirements of this rule, 6 months after the receiving facility's supplier of that animal food is required to comply with the CGMP requirements of this rule. See tables 32 and 33 for a summary of these compliance dates.

TABLE 32—COMPLIANCE DATES FOR THE REQUIREMENTS OF PART 507 OTHER THAN THE REQUIREMENTS FOR A SUPPLY-CHAIN PROGRAM (SUBPART E)

Size of business	Compliance date for subpart B and related requirements	Compliance date for subpart C and § 507.7
Qualified facility (including very small business) as defined in § 507.3.	September 17, 2018	September 17, 2019, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2017.
Small business as defined in § 507.3	September 18, 2017	September 17, 2018.
All other businesses	September 19, 2016	September 18, 2017.

TABLE 33—COMPLIANCE DATES FOR THE REQUIREMENTS OF THE SUPPLY-CHAIN PROGRAM (SUBPART E)

Situation	Compliance date:
A receiving facility is a small business and its supplier will be subject to the CGMPs, but not the preventive control requirements, of the animal food preventive controls rule.	6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule.
A receiving facility is a small business and its supplier is subject to the animal food preventive controls rule.	The later of: September 17, 2018 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with this rule.
A receiving facility is not a small business or a very small business and its supplier will be subject to CGMPs, but not the preventive control requirements, of the animal food preventive controls rule.	6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule.
A receiving facility is not a small business or a very small business and its supplier will be subject to the animal food preventive controls rule.	The later of: September 18, 2017 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.

We also are establishing two additional compliance dates applicable to qualified facilities. We are establishing *December 16, 2019* first as the compliance date for the initial submission of the attestation by a facility that it is a qualified facility (see § 507.7(a)(1)) and the attestation by a qualified facility about its food safety practices (see § 507.7(a)(2)(i)), or that it is in compliance with non-Federal food safety law (see § 507.7(a)(2)(ii)), and second as the compliance date for the notification requirement of § 507.7(e)(1). A qualified facility that submits an attestation that it is in compliance with applicable non-Federal food safety law must notify consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (see § 507.7(e)). If an animal food packaging label is required, the required notification must appear prominently and conspicuously on the label of the animal food (see § 507.7(e)(1)). This notification requirement may require some qualified facilities to update the labels of their packaged animal food products.

(Comment 512) Some comments disagree with the proposed compliance dates and our tentative conclusion that concepts in the CGMP regulations would not be new to the animal food industry. Comments state that both large and small facilities would need to expend considerable resources to implement the practices and procedures to comply with the new requirements. A few comments note that the complexity of the proposed regulation presents a challenge for compliance within the proposed timeframes. Because both CGMPs and preventive controls are new for the animal food industry, comments request additional time to comply with the regulations. Some comments also note that manufacturers of human food have had many years to comply with CGMPs, and the expectation that the animal food industry will comply with both CGMP and preventive controls requirements in a narrow timeframe is not reasonable. The majority of comments agree that the implementation dates for the CGMP regulations should come before the implementation date of the preventive controls regulations.

(Response 512) We agree with the comments and are extending the compliance date for implementation of the preventive controls regulations 1 year beyond the compliance date for the implementation of CGMP requirements. Because both the CGMP and preventive controls regulations are new to the animal food industry, we understand that these facilities would have been learning and implementing many new requirements during the proposed timeframe. With an extra year before they must implement preventive controls requirements, animal food facilities will be able to focus on developing and implementing the applicable CGMPs for their facilities. Many of these CGMPs are considered prerequisites for a preventive controls program. Having CGMPs well in place before having to implement the preventive controls requirements will provide the facility with a better understanding of the additional controls that might be needed to significantly minimize or prevent any significant hazards associated with the animal food that the facility has identified. In addition, facilities will have more time to educate and train their employees on the preventive controls requirements the facility will need to implement. FDA intends to work closely with the animal food industry, extension and education organizations, and state partners to develop the tools and training programs needed to facilitate implementation of the final rule.

(Comment 513) Some comments recommend that compliance dates for the preventive controls rule for animal food be set for 3 years after the 60-day effective date of the rule, regardless of firm size.

(Response 513) We disagree with this comment. Although the requirements in this final regulation are new for the animal food industry, some individual animal food facilities, either individually or through feed industry associations, have implemented some procedures that are consistent with the proposed requirements. Not all concepts

and processes are new to the entire animal food industry, especially the larger facilities. Therefore, we conclude that these larger facilities should not need 3 years to comply with the requirements of this final regulation, in contrast to some of the very small businesses.

(Comment 514) Some comments ask us to clarify when a very small business would need to comply with the rule if the business starts up after the rule goes into effect.

(Response 514) A very small business that is operating as of the date of publication of the final rule, or begins operating any time before the compliance date for very small businesses, must comply with the rule by the compliance date for very small businesses. A very small business that begins operation any time after the compliance date for very small businesses must comply with the rule when it begins operation, and should plan accordingly.

(Comment 515) Some comments request that compliance dates for the proposed preventive controls rule coincide with the requirements of the proposed foreign supplier verification program rule.

(Response 515) We are finalizing separate compliance dates for the supply-chain program provisions of this rule. While this adds complexity, we are doing this for two main reasons. First, we are aligning, to the extent feasible, the compliance dates of the supply-chain program provisions of this rule with the compliance dates of the forthcoming FSVP rule, which we intend to publish in the coming months. This will provide greater coordination across the programs, particularly with respect to the verification of domestic and imported raw materials and other ingredients. Second, we want to minimize the likelihood that a receiving facility will be required to comply with the supply-chain program provisions of this rulemaking before its supplier is required to comply with applicable new food safety regulations implementing FSMA. Our goal is to avoid a situation in which a receiving facility would be required to develop a supply-chain program for an animal food from a particular supplier and then be required to revise this supply-chain program shortly thereafter once the supplier is subject to an applicable new food safety regulation—specifically, the preventive controls rule for animal food. Therefore, the compliance dates for the supply-chain program have been revised. A receiving facility's compliance date for the supply-chain program provisions of this rule is the later of: (1) The receiving facility's compliance date for the other preventive controls requirements under this rulemaking; (2) for a raw material or other ingredient from a supplier subject to the preventive controls requirements of this rule, 6 months after the receiving facility's supplier of that raw material or ingredient is required to comply with the preventive controls requirements of this rule; or (3) for a raw material or other ingredient that from a supplier subject to CGMPs, but not the preventive controls requirements of this rule, 6 months after the receiving facility's supplier of that animal food is required to comply with the CGMP requirements of this rule.

B. Effective Dates for Conforming Amendments

The conforming amendments to regulations in parts 500 and 579 are technical amendments that add a cross-reference to part 507. The conforming amendment to part 11 adds a reference to the scope of part 11 that the records required under part 507 are not subject to part 11. The conforming amendment to part 16 adds a reference to the scope of part 16 for new procedures in part 507, subpart D that provide a person with an opportunity for a hearing under part 16. These conforming amendments are effective on November 16, 2015, the same date as the effective date of part 507. We are not establishing compliance dates for these conforming amendments. As a practical matter, compliance dates will be determined by the dates for compliance with part 507.

C. Delayed Effective Dates for Provisions That Refer to the Forthcoming Rules for Produce Safety and Third-Party Certification

The following provisions refer to provisions we intend to establish in the near future in part 112 (Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption): §§ 507.12(a)(1)(ii), 507.105(c), 507.110(d)(2)(ii), 507.130(d), and 507.175(c)(13). In addition, paragraph (2) of the definition of ''qualified auditor'' in § 507.3 and § 507.135(d) refers to provisions we intend to establish in the near future in part 1, subpart M (Accredited Third-Party Food Safety Audits and Food or Facility Certification). In addition, §§ 507.105(a)(2) and 507.175(c)(2) refer to provisions we intend to establish in the near future in part 1, subpart L (Foreign Supplier Verification Programs for Food Importers). We will publish a document in the **Federal Register** announcing the effective dates of paragraph (2) of the definition of ''qualified auditor'' in § 507.3, and §§ 507.12(a)(1)(ii), 507.105(a)(2), 507.105(c), 507.110(d)(2)(ii), 507.130(d), 507.135(d), 507.175(c)(2) and 507.175(c)(13).

LIV. Compliance and Enforcement

Gaining industry compliance with the provisions of this rule is as important as establishing the provisions. A central element of our strategy to gain industry compliance is to help make available to facilities subject to this rule the education and technical assistance they need to understand and implement the requirements (Ref. 5). Within the Agency we are establishing a Food Safety Technical Assistance Network and seeking funding to increase FDA staffing to provide a central source of information to support industry understanding and implementation of FSMA standards (Ref. 5). This will allow us to respond in a timely and consistent way to industry questions on preventive controls technical and compliance issues (Ref. 5).

We also are working in collaboration with the FSPCA to develop training materials and establish training and technical assistance programs (Ref. 4) and (Ref. 6). The FSPCA includes members from FDA, State food protection agencies, the animal food industry, and academia. It is funded by a grant to the Illinois Institute of Technology's Institute for Food Safety and Health, a nationally-recognized leader in food safety. In addition to developing a standardized preventive controls training curriculum, the FSPCA is developing selected sections of model food safety plans for several animal food types that will provide needed instructional examples. Although we have provided funding to the FSPCA to develop a standardized preventive controls training curriculum, we are unable to fund training for individual groups who might need particular training materials.

We also are partnering with the NIFA of USDA to administer the FSMA-mandated National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, a grant program to provide technical assistance for FSMA compliance to owners and operators of small and medium-size farms and small food processors (Ref. 7). Such efforts will help ensure widespread voluntary compliance by encouraging greater understanding and adoption of established food safety standards, guidance, and protocols.

With regard to inspections, we will conduct regular inspections of domestic facilities to ensure that facilities subject to this rule are adequately implementing

the required preventive controls and supply-chain program, pursuant to our inspection authority under section 704 of the FD&C Act. Our inspections will verify that such facilities are implementing systems that effectively protect against animal food contamination, and in particular, that they comply with the rule by implementing preventive controls, including supply-chain programs, to provide assurances that any hazard requiring a preventive control or supply-chain applied control has been significantly minimized or prevented.

In order to effectively carry out this new paradigm of animal food safety, we will need to reorient and retrain our staff. To this end, we are seeking additional funding, including for the training of more than 2,000 FDA inspectors, compliance officers, and other staff involved in food safety activities (Ref. 10).

We also plan to leverage the resources of State, local, tribal, and territorial governments to conduct domestic verification activities. We are working with officials from these governments through the PFP to develop and implement a national Integrated Food Safety System, which will focus on establishing partnerships for achieving compliance (see section 209(b) of FSMA), and which will allow us to utilize the thousands of State, local, and tribal inspectors available to help with the domestic verification process.

Section 201 of FSMA mandates that FDA inspect domestic high-risk facilities no less than once every 3 years. Consistent with FSMA, FDA will use its current resources, new resources that it obtains, and its partnerships to conduct regular inspections of covered facilities, focusing on those facilities that pose the highest risk to animal food safety.

LV. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A tribal summary impact statement has been prepared that includes a summary of tribal officials' concerns and how FDA has addressed them (Ref. 63). Persons with access to the Internet may obtain the tribal consultation report at *http://www.fda.gov/pcafrule* or at *http://www.regulations.gov*. Copies of the tribal summary impact statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

LVI. Economic Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. FDA has developed an FRIA that presents the benefits and costs of this final rule (Ref. 60). The Office of Management and Budget (OMB) has determined that this final rule is an economically significant regulatory action as defined by Executive Order 12866.

The summary analysis of benefits and costs included in this document is drawn from the detailed FRIA (Ref. 60) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–N–0922), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. Because the final rule would impose annualized costs that range from $25,000 to $34,000 on many small entities, the Agency determined that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule will likely result in a 1-year expenditure that will meet or exceed this amount.

LVII. Analysis of Environmental Impact

FDA has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment (Ref. 64). Therefore, neither an environmental assessment nor an environmental impact statement is required.

LVIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in this section with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.

Description: Regulations issued in the final rule entitled, ''Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,'' implement section 418 of the FD&C Act, as amended by the FDA Food Safety Modernization Act (FSMA). The regulations establish science-based minimum standards for conducting a hazard analysis, documenting hazards requiring preventive controls, implementing preventive controls, and documenting the implementation of the preventive controls by domestic and foreign animal food facilities registered with FDA under section 415 of the FD&C Act. The regulations also establish current good manufacturing practice for the manufacturing, processing, packing, and holding of animal food.

The preventive controls regulations require animal food facilities to have a written food safety plan that includes a hazard analysis; a description of preventive controls (including recall procedures); a supply-chain program, a description of procedures for monitoring the preventive controls; corrective action if preventive controls are not properly implemented; and a description of procedures for verifying implementation and effectiveness of the preventive controls.

The regulations further require facilities to establish and implement verification procedures for product testing and environmental monitoring, and require that the hazard analysis and risk-based preventive controls for animal food take into account the possibility of economically motivated adulteration of animal food. Facilities that manufacture, process, pack, or hold food for animals and foods for human consumption and are subject to part 117 (as finalized elsewhere in this issue of the **Federal Register**) may choose to comply with part 117 with respect to the animal food, provided the food safety plan addresses the hazards specific to animal food where applicable.

The final rule also establishes certain exemptions, under applicable regulations. The rule imposes specific reporting requirements on facilities claiming the very small business qualified facility exemption.

Description of Respondents: Facilities that manufacture, process, pack, or hold food for animals. Generally, a facility is required to register if it manufactures, processes, packs, or holds animal food for consumption in the United States. At the time of this analysis, the number of animal food facilities registered with the Agency was 7,469.

In the **Federal Register** of October 29, 2013 (78 FR 64736), FDA published a proposed rule including a Paperwork Reduction Act (PRA) analysis of the information collection provisions found in the regulations. In the **Federal Register** of September 29, 2014 (79 FR 58476), FDA published a supplemental notice of proposed rulemaking also including a PRA analysis. Although FDA did not receive comments specifically addressing the four information collection topics solicited in both the 2013 proposed preventive controls rule for animal food and the 2014 supplemental notice, we have revised our burden estimate consistent with finalization of the rule's requirements.

FDA estimates the burden for this information collection as follows:

Reporting Burden

Table 34 shows the total estimated annual reporting burden associated with this final rule. This estimate is a revision from reporting estimates found in our proposed rulemaking, reflecting an updated count of the number of facilities registered with the Agency as animal food facilities, and resulting in an overall decrease from our previous estimate.

TABLE 34—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
507.7 exemption: submit attestation that facility is a qualified facility and attestation of preventive controls or compliance with non-Federal food safety laws	1,120	.5	560	*.5	280
507.67, 507.69, and 507.71; submission of an appeal, including submission of a request for an informal hearing	1	1	1	4	4
507.85(b); requests for reinstatement of exemption	1	1	1	2	2
Total					286

[1] Capital and other costs of implementation and compliance for this final rule are discussed in the FRIA (Ref. 60).
* (30 minutes).

Out of 7,469 animal food facilities registered with FDA, we estimate approximately 15% (1,120) could be ''qualified'' facilities under the ''very small business'' definition as discussed in the FRIA (Ref. 60), and thus eligible for certain limited exemptions under the applicable regulations. Section 507.5 exempts qualified facilities from subpart C and E of the regulations, which includes all of the hazard analysis and preventive controls requirements, including supply-chain program requirements. The number of respondents in table 34, row 1 is derived from Agency estimates of the number of qualified animal food facilities that must report their status as such a facility every 2 years. The number of total annual responses is calculated by multiplying the number of respondents by the number of responses submitted annually. The average hourly time burden per response found in table 34, column 5 is based on FDA's assumption that a facility will report its status electronically through a Web portal maintained by FDA, and that this will take approximately 0.5 hours (30 minutes).

The estimated burden associated with the requirements under §§ 507.67, 507.69, and 507.71 of the regulations is reflected in table 34, row 2. Based on the limited data on foodborne illness outbreaks originating at very small animal food facilities, FDA does not expect to withdraw many qualified facility exemptions and expects the number of appeals to be even fewer. The estimated number of respondents is based on the Agency's expectation that the number of appeals will be very few. The number of responses per respondent reflects that the rule only requires one submission per appeal. Given that facilities must respond with particularity to the facts and issues contained in the withdrawal order, the Agency estimates an average burden of 4 hours per response.

The estimated burden associated with the requirements under § 507.85(b) is reflected in table 34, row 3. The Agency expects few, if any, requests for reinstatement of an exemption that has been withdrawn under the regulations and thus is providing an estimate of only 1 per year at this time. We estimate the time necessary for making such a request to be no more than 2 hours, which includes submitting the written request and presenting information that the animal food safety problems were adequately resolved and continued withdrawal of the exemption is not necessary to protect public (human and animal) health.

Recordkeeping Burden

Table 35 shows the total estimated annual recordkeeping burden associated with this final rule. This estimate is a revision from the recordkeeping estimates found in our proposed rulemaking, reflecting an updated count of the number of registered animal food facilities, as well as additional recordkeeping requirements associated with the various preventive control provisions and recordkeeping

requirements associated with the supply-chain program implemented at Subpart E.

TABLE 35—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR part 507; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Subpart A—General Provisions					
507.7(e); records attesting that the facility is a "qualified" facility.	1,120	.5	560	.1 (6 minutes)	56
507.4(d); documentation of animal food safety and hygiene training.	7,469	0.75	5,579	0.04 (2 minutes) ..	279
Subpart C—Hazard Analysis and Risk-Based Preventive Controls					
507.31–507.55; food safety plan, including hazard analysis, preventive controls, and procedures for monitoring, corrective actions, and verification; recall plan; validation; reanalysis; modifications; and implementation records.	7,469	519	3,876,411	.10 (6 minutes)	387,641
Subpart E—Supply-Chain Program					
507.105–507.175; written supply-chain program, including records documenting program.	7,469	519	3,876,411	.10 (6 minutes)	387,641
Subpart F—Requirements Applying to Records					
507.200–507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.	7,469	519	3,876,411	.10 (6 minutes)	387,641
Total	.....	.....	11,629,793	.....	1,163,258

[1] Capital and other costs of implementation and compliance with this final rule are discussed in the FRIA (Ref. 60).

Under the final rule, we estimate a total of 7,469 respondents (the number of registered animal food facilities) are subject to recordkeeping requirements found in the applicable regulations. Although FDA believes that, in some cases, all respondents will incur new recordkeeping activities as a result of the final rule (*e.g.,* documentation of training in the principles of animal food hygiene and safety), we believe other provisions may apply only to certain respondents (*e.g.,* documentation of a supply-chain program), depending upon the applicable regulation. With regard to the hazard-analysis and risk-based preventive controls, the supply-chain program, and the requirements applying to records under part 507 subparts C, E, and F, respectively, we have provided a cumulative burden and averaged burden per recordkeeping that we believe will be incurred by the respondents under this final rule based on information available to us at this time. After allowing for implementation of the final rule and upon seeking reauthorization for its information collection provisions, FDA will reassess its burden estimate accordingly.

Third-Party Disclosure Burden

Table 36 shows the total estimated third-party disclosure burden associated with the final rule. This figure has been revised from the third-party disclosure estimates found in our proposed rulemaking. This revision reflects fewer than anticipated third-party disclosure requirements under the final rule and results in an overall decrease to our total estimated annual third-party disclosure burden by 36,315 hours.

TABLE 36—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species.	330	10	3,300	0.25 (15 minutes).	825
507.7(e)(1); change labels on products with labels	1,526	4	6,104	1	6,104
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	1,329	1	1,329	1	1,329
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	330	312	102,960	.01 (1 minute)	1,030

TABLE 36—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

21 CFR Section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
507.28(b); holding and distribution of human food by-products for use as animal food.	40,798	2	81,596	0.25 (15 minutes).	20,399
Total					29,687

[1] Capital and other costs of implementation and compliance for this final rule are discussed in the FRIAs (Ref. 60).

Under the final rule, we estimate all (7,469) respondents are subject to third-party disclosure requirements found in the applicable regulations. The number in column 2 represents an estimated annual number of those respondents we believe will incur third-party disclosure burdens under the respective regulation shown in column 1. This figure is derived from our familiarity with third-party burden associated with similar FDA regulations. Upon implementation of the final rule, the Agency will reevaluate its estimate accordingly.

To calculate the number of annual disclosures, we multiplied the number of respondents in column 2 by an estimated number of disclosures in column 3. This figure represents the estimated annual number of disclosures per respondent we attribute for the respective requirement. To calculate the annual hourly burden, we multiplied the number of annual disclosures by an estimated hourly burden in column 5. This figure represents the amount of time we attribute to conducting the respective disclosure activities identified in column 1.

Section 507.7(a)(2) provides that qualified facilities must either submit to FDA attestation of hazard identification, preventive controls implementation, and monitoring, or attestation that the facility is in compliance with applicable non-Federal food safety law.

Section 507.7(e) requires a qualified facility that chose the latter to notify consumers of the name and business address of the facility where the animal food was manufactured or processed: (1) On the label if a package label is required by other provisions of the FD&C Act or (2) on labeling at the point of purchase if no label is required.

Section 507.25(a)(2) provides that the management of the plant must ensure that animal food, including raw materials, other ingredients, or rework, is accurately identified as part of plant operations. (See §§ 7.49 and 7.42(b)(1) and (2) (21 CFR 7.49 and 7.42(b)(1) and (2)).)

Section 507.38(b)(1) and (2) does not add to the estimated hourly burden because facilities initiating recalls may notify consignees and the public. (See §§ 7.49 and 7.42(b)(1) and (2)).)

Under section 507.28(b), labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-product for use as animal food when distributed. The estimated number of disclosures per respondent and average burden per disclosure assumes that 60 percent of the 67,996 domestic human food manufacturing facilities (Ref. 65) or 40,798 facilities are affected, and that two sets of labeling per facility per year will be required. We estimate 0.25 hours per disclosure to prepare labeling, and affix to the containers, for a total of 20,399 burden hours.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

LIX. Federalism

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

LX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov*. (FDA has verified the Web site addresses in this section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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64. Environmental Review of Final Rule: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, August 28, 2015.
65. FDA, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Human Food—Preliminary Regulatory Impact Analysis,'' 2013. See Reference 23 in the 2014 supplemental notice.

List of Subjects

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCB's).

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 579

Animal feeds, Animal foods, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 1. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. In § 11.1, add paragraph (j) to read as follows:

§ 11.1 Scope.

* * * * *

(j) This part does not apply to records required to be established or maintained by part 507 of this chapter. Records that satisfy the requirements of part 507 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 4. In § 16.1(b)(2), add the following entry in numerical order to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 507.60 through 507.85 (part 507, subpart D of this chapter) relating to withdrawal of a qualified facility exemption.

* * * * *

PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

■ 5. The authority citation for 21 CFR part 117 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 6. Add § 117.95 to subpart B to read as follows:

§ 117.95 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in § 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

PART 500—GENERAL

■ 7. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 8. Revise § 500.23 to read as follows:

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

Except as provided in § 507.5(b) of this chapter, the provisions of parts 507 and 113 of this chapter apply to the manufacturing, processing, or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

■ 9. Add part 507 to read as follows:

PART 507—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

Subpart A—General Provisions

Sec.

Subpart B—Current Good Manufacturing Practice

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

Subpart D—Withdrawal of a Qualified Facility Exemption

Subpart E—Supply-Chain Program

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 507.1 Applicability and status.

(a) The criteria and definitions in this part apply in determining whether an animal food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of this part and § 507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

(d) Except as provided by § 507.12, if a facility is required to comply with subpart B of part 507 and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food and animal food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 507 and is also required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, provided the food safety plan also addresses hazards for the animal food, if applicable, that require a preventive control. When applying the requirements of part 117 of this chapter to animal food, the term ''food'' in part 117 includes animal food.

§ 507.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

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

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

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 a supplier's food safety processes and procedures.

Calendar day means every day shown on the calendar.

Correction means an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

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 part 1, subpart H of this chapter.

Farm means farm as defined in § 1.227 of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

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.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.,* 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as animal food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.,* foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that 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 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.

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, extruding, 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.

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.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

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 this part and has technical expertise obtained through education, training, or experience (or the 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 of this chapter.

Qualified end-user, with respect to food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located:

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable

calendar year was less than $500,000, adjusted for inflation.

Qualified facility exemption means an exemption applicable to a qualified facility under § 507.5(d).

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.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiving facility means a facility that is subject to subparts C and E of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Rework means clean, unadulterated animal food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

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

Small business means, for purposes of this part, a business employing fewer than 500 full-time equivalent employees.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

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.

Unexposed packaged animal food means packaged animal food that is not exposed to the environment.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

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, for purposes of this part, 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).

Water activity (a_w) means a measure of the free moisture in an animal food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

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).

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

§ 507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food.

(a)(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F of this part are qualified to perform their assigned duties; and

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F of this part are qualified to perform their assigned duties.

(b) Each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 507.3, *i.e.,* have 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; and

(2) Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.

(c) Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food.

(d) Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part.

§ 507.5 Exemptions.

(a) This part does not apply to establishments, including ''farms'' (as defined in § 1.227 of this chapter), that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Subparts C and E of this part do not apply with respect to activities that are subject to § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at an animal food facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to those activities.

(2) The exemption in paragraph (b)(1) of this section is applicable only with respect to those microbiological hazards regulated under part 113 of this chapter.

(c) Subparts C and E of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(d) Except as provided in subpart D of this part, subparts C and E of this part do not apply to a qualified facility. Qualified facilities are subject to the requirements in § 507.7.

(e) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm packing or holding of processed animal food, and § 507.7 does not apply to on-farm packing or holding of processed animal food by a very small business, if the only packing or holding activities subject to section 418

of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/animal food combinations—*i.e.,* packing (or repacking) (including weighing or conveying incidental to packing or repacking); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(1) Roughage products (*e.g.,* alfalfa meal, entire plant meal, stem meal, pomace, and pulp);

(2) Plant protein meals (*e.g.,* algae, coconut (copra), guar, and peanut);

(3) Grain by-products and processed grain products (*e.g.,* bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal);

(4) Oilseed products (*e.g.,* oil and meal of safflower, soybean, or sunflower);

(5) Molasses (*e.g.,* processed sugar cane, sugar beets, and citrus).;

(6) Animal protein meals (*e.g.,* blood, feather, meat, meat and bone, and marine (*e.g.,* crab, fish, shrimp));

(7) Milk products (*e.g.,* casein, cheese rind, and lactalbumin);

(8) Animal tissue-derived products (*e.g.,* fat);

(9) Vitamins, minerals, and concentrates;

(10) Processing aids (*e.g.,* enzymes, preservatives, and stabilizers); and

(11) Any other processed animal food that does not require time/temperature control for safety.

(f) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and § 507.7 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts consists of the following low-risk manufacturing/processing activity/animal food combinations:

(1) Chopping or shredding hay;

(2) Cracking, crimping, flaking, pearling, peeling, shelling, or wafering—grain (*e.g.,* barley, sorghum, corn, oats, rice, rye, and wheat) or oilseed (*e.g.,* beans, canola, cottonseed, linseed, soybeans, and sunflowers);

(3) Crushing, dry rolling, grinding, milling, pulverizing—grain, oilseed, grain by-products and processed grain products, oilseed products, hay, ensiled material, culled fruits and vegetables, roughage (*e.g.,* cobs, hulls, husks, and straws), or roughage products;

(4) Ensiling (including chopping, shredding, mixing, storing, or fermenting), that is, making silage or haylage from forage (*e.g.,* sorghum (milo), corn (maize), alfalfa, and grass), grain, culled fruits and vegetables, or roughage;

(5) Extracting (mechanical) or wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;

(6) Labeling roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety; and

(7) Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety.

(g) Subparts C and E of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(h) Subpart B of this part does not apply to any of the following:

(1) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(2) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and

(3) Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed).

§ 507.7 Requirements that apply to a qualified facility.

(a) A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) An attestation that you have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation 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, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) The attestations required by paragraph (a) of this section must be submitted to FDA by any one of the following means:

(1) *Electronic submission.* To submit electronically, go to *http://www.fda.gov/furls* and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) *Submission by mail.* (i) You must use Form FDA 3942b. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from *http://www.fda.gov/pcafrule*;

(B) Write to the U.S. Food and Drug Administration (HFS–681), 5100 Paint Branch Parkway, College Park, MD 20550; or

(C) Request a copy of this form by phone at 1–800–216–7331 or 301–575–0156.

(ii) Send a paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS–681), 5100 Paint Branch Parkway, College Park, MD 20550. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c)(1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By *December 16, 2019* for a facility that begins manufacturing, processing, packing, or holding animal food before *September 17, 2019;*

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after *September 17, 2019;* or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from ''not a qualified

facility'' to ''qualified facility'' based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from ''qualified facility'' to ''not a qualified facility'' based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year.

(d) When the status of a facility changes from ''qualified facility'' to ''not a qualified facility,'' the facility must comply with subparts C and E of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. Box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities) as follows:

(1) If an animal food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the animal food.

(2) If an animal food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f)(1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

§ 507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.

(a) Subparts C and E of this part do not apply to a facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(b) A facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 for any unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food.

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production, or the off-farm packing and holding of raw agricultural commodities, that are packed or held by that human food facility for distribution as animal food if:

(1)(i) The human food facility is subject to and in compliance with subpart B of part 117 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; or

(ii) For the off-farm packing and holding of produce (as defined in part 112 of this chapter), the human food facility is subject to and in compliance with § 117.8 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and

(2) The human food facility does not further manufacture or process the by-products intended for use as animal food.

(b) The human food by-products for use as animal food identified in paragraph (a) of this section must be held and distributed by that facility in accordance with § 507.28 and § 117.95 of this chapter.

Subpart B—Current Good Manufacturing Practice

§ 507.14 Personnel.

(a) The management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food.

(b) The methods for conforming to hygienic practices and maintaining cleanliness include:

(1) Maintaining adequate personal cleanliness;

(2) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;

(3) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;

(4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and

(5) Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

§ 507.17 Plant and grounds.

(a) The grounds around an animal food plant under the control of the management of the establishment must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.

(b) The plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, including that the plant must:

(1) Provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;

(2) Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;

(3) Provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors (*e.g.,* steam) and fumes in areas where they may contaminate animal food and in a manner that minimizes the potential for contaminating animal food;

(4) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured,

processed, packed, or held, and areas where equipment or utensils are cleaned; and

(5) Provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage.

(c) The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including:

(1) Using protective coverings where necessary and appropriate;

(2) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and

(3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.

§ 507.19 Sanitation.

(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated.

(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:

(1) When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use; and

(2) In wet processing of animal food, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.

(d) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in the plant area where animal food is manufactured, processed, or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic materials described in paragraph (d)(1) of this section (*e.g.,* cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials; and

(3) Other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.

(e) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of pesticides in the plant is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(f) Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests.

§ 507.20 Water supply and plumbing.

(a) The following apply to the water supply:

(1) Water must be adequate for the operations and must be derived from an adequate source;

(2) Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities;

(3) Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use; and

(4) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(b) Plumbing must be designed, installed, and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid being a source of contamination to animal food, water supplies, equipment, or utensils, or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.

(c) Sewage and liquid disposal waste must be disposed of through an adequate sewerage system or through other adequate means.

(d) Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

§ 507.22 Equipment and utensils.

(a) The following apply to plant equipment and utensils used in manufacturing, processing, packing, and holding animal food:

(1) All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;

(4) Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;

(ii) Made of nontoxic materials; and

(iii) Maintained to protect animal food from being contaminated.

(b) Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way to protect against the contamination of animal food.

(c) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device.

(d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, a_w, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.

(e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food.

§ 507.25 Plant operations.

(a) Management of the establishment must ensure that:

(1) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;

(2) Animal food, including raw materials, other ingredients, or rework is accurately identified;

(3) Animal food-packaging materials are safe and suitable;

(4) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

(5) Adequate precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food-packaging materials;

(6) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;

(7) Animal food that has become adulterated is rejected, disposed of, or if appropriate, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and

(8) All animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food.

(b) Raw materials and other ingredients:

(1) Must be examined to ensure that they are suitable for manufacturing and processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration. In addition:

(i) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be examined upon receipt to determine whether contamination or deterioration of animal food has occurred;

(ii) Raw materials must be cleaned as necessary to minimize contamination; and

(iii) Raw materials and other ingredients, including rework, must be stored in containers designed and constructed in a way that protects against contamination and deterioration, and held under conditions, *e.g.,* appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated;

(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans; and

(3) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.

(c) For the purposes of manufacturing, processing, packing, and holding operations, the following apply:

(1) Animal food must be maintained under conditions, *e.g.,* appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;

(2) Measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (*e.g.,* heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling a_w) must be adequate to prevent adulteration of animal food;

(3) Work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms;

(4) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food;

(5) Filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms;

(6) Animal food that relies principally on the control of water activity (a_w) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe a_w level;

(7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(8) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

§ 507.27 Holding and distribution.

(a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of animal food; and

(2) Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.

(b) The labeling for the animal food product ready for distribution must contain, when applicable, information and instructions for safely using the animal food product for the intended animal species.

(c) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food.

(d) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

(e) Unpackaged or bulk animal food must be held in a manner that does not

result in unsafe cross contamination with other animal food.

§ 507.28 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 507.31 Food safety plan.

(a) You must prepare, or have prepared, and implement a written food safety plan.

(b) One or more preventive controls qualified individuals must prepare, or oversee the preparation of, the food safety plan.

(c) The written food safety plan must include:

(1) The written hazard analysis as required by § 507.33(a)(2);

(2) The written preventive controls as required by § 507.34(b);

(3) The written supply-chain program as required by subpart E of this part;

(4) The written recall plan as required by § 507.38(a)(1);

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);

(6) The written corrective action procedures as required by § 507.42(a)(1); and

(7) The written verification procedures as required by § 507.49(b).

(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 507.33 Hazard analysis.

(a)(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and

(2) The hazard analysis must be written regardless of its outcome.

(b) The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep); and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

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

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal 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.

(d) The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and other ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors such as the temporal (*e.g.,* weather-related) nature of some hazards (*e.g.,* levels of some natural toxins).

§ 507.34 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(2) Preventive controls required by paragraph (a)(1) of this section include:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for animal food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and animal food:

(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes for the:

(i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food-contact surfaces and from raw product to processed product.

(3) Supply-chain controls. Supply-chain controls include the supply-chain program as required by subpart E of this part;

(4) A recall plan as required by § 507.38; and

(5) Other preventive controls. These include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

(1) You determine and document that the type of animal food could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part to ensure that the identified hazard will be significantly minimized or prevented; and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard (except as provided in paragraph (c) of this section);

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements;

(4) You rely on your customer to provide assurance that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that your customer:

(A) Will disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and

(B) Will only sell to another entity that agrees, in writing, it will:

(*1*) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part), except as provided in paragraph (d) of this section, or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part); or

(*2*) Obtain a similar written assurance from the entity's customer, subject to the requirements of § 507.37, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5)You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the animal food product you distribute and you document the implementation of that system.

(b) You must document any circumstance specified in paragraph (a) of this section that applies to you, including:

(1) A determination in accordance with paragraph (a) of this section that the type of animal food could not be consumed without application of an appropriate control;

(2) The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;

(3) The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;

(4) The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the animal food product you distribute.

(c) For the written assurance required by paragraph (a)(2)(ii) of this section, if your customer has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, your customer's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.

(d) For the written assurance required by paragraph (a)(4)(ii)(B) of this section, if the entity in the distribution chain subsequent to your customer is subject to subpart C of this part and has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, that entity's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance that the identified hazard will be significantly minimized or prevented.

§ 507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4).

A facility that provides a written assurance under § 507.36(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 507.38 Recall plan.

(a) For animal food with a hazard requiring a preventive control you must:

(1) Establish a written recall plan for the animal food; and

(2) Assign responsibility for performing all procedures in the recall plan.

(b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:

(1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;

(3) Conduct effectiveness checks to verify the recall has been carried out; and

(4) Appropriately dispose of recalled animal food, *e.g.,* through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.

§ 507.39 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.34 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

(1) Monitoring in accordance with § 507.40;

(2) Corrective actions and corrections in accordance with § 507.42; and

(3) Verification in accordance with § 507.45.

(b) The supply-chain program established in subpart E of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:

(1) Corrective actions and corrections in accordance with § 507.42, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 507.49(a)(4)(ii); and

(3) Reanalysis in accordance with § 507.50.

(c) The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section.

§ 507.40 Monitoring.

As appropriate to the nature of the preventive control and its role in the facility's food safety system you must:

(a) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(b) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(c)(1) You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 507.45(a)(2) and records review in accordance with § 507.49(a)(4)(i);

(2)(i) Records of refrigeration temperature during storage of animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control; and

(ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

§ 507.42 Corrective actions and corrections.

(a) As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

(i) The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected animal food is evaluated for safety; and

(iv) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a corrective action procedure has not been established;

(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or

(iii) A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem;

(ii) Reduce the likelihood that the problem will recur;

(iii) Evaluate all affected animal food for safety;

(iv) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and

(v) When appropriate, reanalyze the food safety plan in accordance with § 507.50 to determine whether modification of the food safety plan is required.

(c) You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:

(1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the sanitation controls in § 507.34(c)(2)(i) or (ii); or

(2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.

(d) All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 507.45(a)(3) and records review in accordance with § 507.49(a)(4)(i).

§ 507.45 Verification.

(a) Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:

(1) Validation in accordance with § 507.47;

(2) Verification that monitoring is being conducted as required by § 507.39 (and in accordance with § 507.40);

(3) Verification that appropriate decisions about corrective actions are being made as required by § 507.39 (and in accordance with § 507.42);

(4) Verification of implementation and effectiveness in accordance with § 507.49; and

(5) Reanalysis in accordance with § 507.50.

(b) All verification activities conducted in accordance with this section must be documented in records.

§ 507.47 Validation.

(a) You must validate that the preventive controls identified and implemented in accordance with § 507.34 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a preventive controls qualified individual:

(i)(A) Prior to implementation of the food safety plan or;

(B) When necessary to demonstrate the control measures can be implemented as designed:

(*1*) Within 90 calendar days after production of the applicable animal food first begins;

(*2*) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins;

(ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and

(iii) Whenever a reanalysis of the food safety plan reveals the need to do so.

(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards.

(c) You do not need to validate:

(1) The sanitation controls in § 507.34(c)(2);

(2) The recall plan in § 507.38;

(3) The supply-chain program in subpart E of this part; and

(4) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

§ 507.49 Verification of implementation and effectiveness.

(a) You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring and verification instruments (or checking them for accuracy);

(2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure 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:

(i) Monitoring and corrective action records within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days; and

(ii) Records of calibration, testing (*e.g.,* product testing, environmental monitoring), and supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and

(5) Other activities appropriate for verification of implementation and effectiveness.

(b) As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section;

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1)(ii).

§ 507.50 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years.

(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(2) Whenever you become aware of new information about potential hazards associated with the animal food;

(3) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and

(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or,

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable animal food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food.

(a) If a facility that is solely engaged in the storage of unexposed packaged animal food stores any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, pathogens;

(2) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;

(3) If there is a loss of temperature control that may impact the safety of such refrigerated packaged animal food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);

(ii) Reviewing records of calibration within a reasonable time after the records are created; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days;

(5) Establish and maintain the following records:

(i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

§ 507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 507.31(b));

(2) Validation of the preventive controls (§ 507.47(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food;

(4) Determination that validation is not required (§ 507.47(c)(4));

(5) Review of records (§ 507.49(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7-working days;

(7) Reanalysis of the food safety plan (§ 507.50(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food.

(b) A qualified auditor must conduct an onsite audit (§ 507.135(a)).

(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility; and

(2) 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.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Implementation records required for this subpart.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 507.36(b), of the basis for not establishing a preventive control in accordance with § 507.36(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;
(vi) Environmental monitoring;
(vii) Records review; and
(viii) Reanalysis;
(5) Records that document the supply-chain program; and
(6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.
(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Withdrawal of a Qualified Facility Exemption

§ 507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption.

(a) FDA may withdraw a qualified facility exemption under § 507.5(d):
(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or
(2) If FDA determines that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.
(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:
(1) May consider one or more other actions to protect the public (human or animal) health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, refusal of animal food offered for import, seizure, and injunction;
(2) Must notify the owner, operator, or agent in charge of the facility, in writing of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and
(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

§ 507.62 Issuance of an order to withdraw a qualified facility exemption.

(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.
(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.
(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.
(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 507.65 Contents of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption under § 507.5(d) must include the following information:
(a) The date of the order;
(b) The name, address, and location of the qualified facility;
(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:
(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or
(2) Conditions or conduct associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.
(d) A statement that the facility must either:
(1) Comply with subparts C and E of this part on the date that is 120 calendar days after the date of receipt of the order or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or
(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.
(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 507.85.
(f) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart;
(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 507.73;
(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine); and
(i) The name and the title of the FDA representative who approved the order.

§ 507.67 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.

(a) If you receive an order under § 507.65 to withdraw a qualified facility exemption, you must either:
(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or
(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.
(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.
(c) If you appeal the order, and FDA confirms the order:
(1) You must comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and
(2) You are no longer subject to the requirements in § 507.7.

§ 507.69 Procedure for submitting an appeal.

(a) To appeal an order to withdraw a qualified facility exemption, you must:
(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order;
(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely.
(b) In a written appeal of the order withdrawing an exemption provided under § 507.5(d), you may include a

written request for an informal hearing as provided in § 507.71.

§ 507.71 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 507.69 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to you explaining the reason for the denial.

§ 507.73 Requirements applicable to an informal hearing.

If you request an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

(3) Section 507.75, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under paragraph (c)(4) of this section are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1) through (3), and (a)(5), of this chapter, and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 507.75 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 507.77 Timeframe for issuing a decision on an appeal.

(a) If you appeal the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If you appeal the order and request an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 507.80 Revocation of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption is revoked if:

(a) You appeal the order and request an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) You appeal the order and request an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) You appeal the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 507.83 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 507.85 Reinstatement of a qualified facility exemption that was withdrawn.

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case

of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(2) Present data and information to demonstrate that you have adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 507.60(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 507.5(d), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 507.60(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding and you may ask FDA to reinstate your exemption under § 507.5(d) in accordance with the requirements of paragraph (b) of this section.

Subpart E—Supply-Chain Program

§ 507.105 Requirement to establish and implement a supply-chain program.

(a)(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(2) A receiving facility that is an importer, is in compliance with the foreign supplier verification requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides assurance that the hazards requiring a supply-chain-applied control 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.

(3) The requirements in this subpart do not apply to animal food that is supplied for research or evaluation use, provided that such animal food:

(i) Is not intended for retail sale and is not sold or distributed to the public;

(ii) Is labeled with the statement ''Animal food for research or evaluation use'';

(iii) 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; and

(iv) 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.

(b) The supply-chain program must be written.

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (*e.g.,* when a non-supplier applies controls to certain produce (*i.e.,* produce covered by part 112 of this chapter), 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.

§ 507.110 General requirements applicable to a supply-chain program.

(a) The supply-chain program must include:

(1) Using approved suppliers as required by § 507.120;

(2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 507.125;

(3) Conducting supplier verification activities as required by §§ 507.130 and 507.135;

(4) Documenting supplier verification activities as required by § 507.175; and

(5) 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.

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) Onsite audits;

(2) Sampling and testing of the raw material or other ingredient;

(3) Review of the supplier's relevant food safety records; and

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

(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.

(d)(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

(i) The hazard analysis of the animal food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;

(ii) The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;

(iii) Supplier performance, including:

(A) The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;

(B) 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); and

(C) 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; and

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

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:

(i) A qualified facility as defined by § 507.3;

(ii) A farm that grows produce and 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; or

(iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens.

(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or other ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

§ 507.115 Responsibilities of the receiving facility.

(a)(1) The receiving facility must approve suppliers.

(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.

(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:

(i) Establish written procedures for receiving raw materials and other ingredients by the entity;

(ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and

(iii) Determine, conduct, or both determine and conduct, the appropriate supplier verification activities, with appropriate documentation.

(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, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

(b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity:

(1) A determination by its supplier of the appropriate supplier verification activities for that supplier;

(2) An audit conducted by its supplier;

(3) A review by its supplier of that supplier's own relevant food safety records; or

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 507.110(b)(4).

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135.

§ 507.120 Using approved suppliers.

(a) The receiving facility must approve suppliers in accordance with the requirements of § 507.110(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers;

(b)(1) Written procedures for receiving raw materials and other ingredients must be established and followed;

(2) 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); and

(3) Use of the written procedures for receiving raw materials and other ingredients must be documented.

§ 507.125 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).

Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 507.110(d).

§ 507.130 Conducting supplier verification activities for raw materials and other ingredients.

(a) Except as provided by paragraphs (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 507.110(b), as determined under § 507.110(d), must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter.

(b)(1) Except as provided by paragraph (b)(2) of this section, 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) The appropriate supplier verification activity is an onsite audit of the supplier; and

(ii) The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

(2) The requirements of paragraph (b)(1) of this section do not apply if 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.

(c) If a supplier is a qualified facility as defined by § 507.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 507.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains 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:

(i) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the animal food; or

(ii) A statement that the facility is in compliance with State, local, county, tribal or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign counties.

(d) If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility:

(1) Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(f) There must not be any financial conflicts of interest that influence the results of the verification activities listed in § 507.110(b) and payment must not be related to the results of the activity.

§ 507.135 Onsite audit.

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

(b) 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.,* Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(c)(1) The following may be substituted 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:

(i) 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), or by representatives of State, local, tribal, or territorial agencies; or

(ii) 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.

(2) 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.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

§ 507.175 Records documenting the supply-chain program.

(a) The records documenting the supply-chain program are subject to the requirements of subpart F of this part.

(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 507.49(a)(4).

(c) The receiving facility must document the following in records as applicable to its supply-chain program:

(1) The written supply-chain program;

(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification activities conducted under § 1.506(e) of this chapter;

(3) Documentation of the approval of a supplier;

(4) Written procedures for receiving raw materials and other ingredients;

(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;

(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(7) Documentation of the conduct of an onsite audit. This documentation must include:

(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;

(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;

(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;

(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;

(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;

(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);

(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 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 Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(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 Federal Food, Drug, and Cosmetic 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);

(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 United States 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;

(16) Documentation of actions taken with respect to supplier non-conformance;

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and

(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.

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

§ 507.200 Records subject to the requirements of this subpart.

(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart.

(b) Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

(d) The requirements of § 507.206 apply only to the written food safety plan.

(e) The requirements of § 507.202(a)(2), (4), and (5) and (b) do not apply to the records required by § 507.7.

§ 507.202 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(2) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) Information adequate to identify the plant or facility (*e.g.,* the name, and when necessary, the location of the plant or facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.

(c) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 507.206 Additional requirements applying to the food safety plan.

The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification.

§ 507.208 Requirements for record retention.

(a)(1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(2) Records that a facility relies on during the 3-year period preceding the

applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (*e.g.,* because the facility has updated the written food safety plan (§ 507.31) or records that document validation of the written food safety plan (§ 507.45(b))).

(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

§ 507.212 Use of existing records.

(a) Existing records (*e.g.,* records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 507.215 Special requirements applicable to a written assurance.

(a) Any written assurance required by this part must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) The applicable assurance under:

(i) § 507.36(a)(2);

(ii) § 507.36(a)(3);

(iii) § 507.36(a)(4);

(iv) § 507.130(c)(2);

(v) § 507.130(d)(2); or

(vi) § 507.130(e)(2).

(b) A written assurance required under § 507.36(a)(2), (3) or (4) must include:

(1) Acknowledgement that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the written assurance; and

(2) Provision that if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination.

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

■ 10. The authority citation for 21 CFR part 579 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

■ 11. In § 579.12, add the following sentence to the end of the paragraph to read as follows:

§ 579.12 Incorporation of regulations in part 179.

* * * Any facility that treats animal feed and pet food with ionizing radiation must comply with the requirements of part 507 of this chapter and other applicable regulations.

Dated:*August 31, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21921 Filed 9–10–15; 8:45 am]

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