

Guidance for Industry

Small Entity Compliance Guide

What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR Part 507)

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Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

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Contains Nonbinding Recommendations

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

I. INTRODUCTION

The Food Safety Modernization Act of 2011 (FSMA) directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety. On September 17, 2015, FDA published the final rule *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals* (PCAF or the rule) (80 FR 56173). FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. Law 104-121). The intent of this guide is to inform domestic and foreign animal food facilities about the PCAF regulations and enable them to better understand the requirements of the rule. It contains important information that may affect your facility.

The regulation creates new current good manufacturing practice (CGMP) requirements for animal food facilities. In addition, it creates new requirements for certain animal food facilities to establish and implement risk-based preventive controls. The regulations are found at Title 21 of the Code of Federal Regulations part 507 (21 CFR part 507). The rule became effective on November 16, 2015, but compliance dates are staggered – see section II. E “When Do I Have to Comply with the Rule?”

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

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II. OVERVIEW OF THE RULE

A. Key Requirements

Current Good Manufacturing Practice requirements (21 CFR part 507 subpart B) apply to all facilities unless an exemption applies under 21 CFR 507.5.

Unless an exemption applies (21 CFR 507.5), facilities must establish and implement a food safety system that includes a hazard analysis and implementation of risk-based preventive controls for those hazards the facility identifies as requiring a preventive control (21 CFR 507.33 and 507.34).

The rule requires a written food safety plan (21 CFR 507.31). The written plan must be prepared by (or its preparation overseen by) one or more “preventive controls qualified individuals” (21 CFR 507.31(b)) (see section VII. “Definitions”) and must include the following (21 CFR 507.31(c)):

- A hazard analysis
- Preventive controls
- A risk-based supply chain program, if appropriate
- A recall plan, if there is a hazard requiring a preventive control identified for an animal food
- Monitoring procedures
- Corrective action procedures
- Verification procedures

Receiving facilities must have a risk-based supply chain program for those raw materials and other ingredients for which an identified hazard has been controlled before receipt (a supply-chain-applied control) (21 CFR part 507, subpart E). The risk-based supply-chain program is flexible and has separate compliance dates (see section II. E. of this guidance).

B. Who Must Comply With the Rule?

The requirements of this rule apply to foreign and domestic establishments that are required to register with FDA as food facilities under section 415 of the Federal Food, Drug, and Cosmetic Act, (FD&C Act) because they manufacture, process, pack, or hold food for animal consumption in the U.S. There are exemptions from the rule or modified requirements and these are listed in section II.D of this guidance in table 2.

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C. Definitions

The PCAF rule uses a number of terms in very specific ways. A full list of these terms appears in this Guidance in section VII. “Definitions.” Table 1 lists some of the key terms.

Table 1—Key Terms Used in Part 507

Term	Definition
Animal Food	Food for animals other than man and includes pet food, animal feed, and raw materials and ingredients
Facility	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 21 CFR part 1, subpart H
Hazard	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	A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility’s food safety system.
Known or reasonably foreseeable hazard	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.
Manufacturing/Processing	Making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating animal food, including food crops or ingredients. (See section VII. “Definitions” for examples).
Preventive controls	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.

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D. Who Is Exempt From the Requirements for Hazard Analysis and Risk-Based Preventive Controls for Animal Food or Subject to Modified Requirements?

Table 2 contains information for establishments on exemptions or modified requirements for part 507.

Table 2—Exemptions and Modified Requirements for Part 507

Exemption or Modified Requirement	Conditions
Establishments that are not required to register with FDA under section 415 of the FD&C Act are exempt from 21 CFR part 507 (21 CFR 507.5(a))	Farms conducting activities on produce covered by the Produce Safety Rule will be required to comply with that rule (Title 21 Code of Federal Regulations part 117 (21 CFR part 117))
<p><i>Qualified Facilities</i> are exempt from 21 CFR part 507 subparts C and E (21 CFR 507.7(d)) and are:</p> <p><i>Very small businesses</i> (including any subsidiaries or affiliates) averaging less than \$2,500,000 (adjusted for inflation) -- in both sales of animal food <i>plus</i> the market value of animal food that is manufactured, processed, packed, or held without sale (e.g. held for a fee or supplied to a farm without sale), per year during the 3-year period preceding the current calendar year.</p> <p>OR</p> <p>A facility to which both of the following apply:</p> <ul style="list-style-type: none"> • During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at the facility that was sold directly to consumers, retailers, or restaurants (within the same state or Indian reservation or within 275 miles of the facility) was less than the monetary value of food sold by the facility (including sales by any subsidiary or affiliate) to all other purchasers; and • The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000 	<p>To be eligible for modified requirements, a qualified facility is required to notify FDA about its qualified facility status; and that it is either:</p> <ol style="list-style-type: none"> 1. Addressing identified hazards through preventive controls and monitoring the preventive controls; or 2. Complying with applicable <i>non-Federal</i> food safety regulations and notifying consumers of the name and complete business address of the facility where the animal food was manufactured or processed. 3. A qualified facility must submit these notifications to FDA during the same two year time frame that the facility is required to update its facility registration (21 CFR 507.7) <p>An otherwise Qualified Facility that does NOT notify FDA is subject to the requirements for 21 CFR part 507</p> <p>The qualified facility exemption can be withdrawn in the event of a foodborne illness outbreak. See 21 CFR part 507 subpart D--<i>Withdrawal of a Qualified Facility Exemption</i></p>
Low-risk, on-farm activities performed by small businesses (less than 500 full-time equivalent employees) or very small businesses (as defined in the rule) (21 CFR 507.5(e) and (f)) are exempt from 21 CFR part 507 subparts C and E	For specific information on which activities are covered, see section III of this guidance

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Exemption or Modified Requirement	Conditions
Activities that are subject to the “low-acid canned food” requirements (21 CFR 500.23 and part 113) are exempt from 21 CFR part 507 subparts C and E (21 CFR 507.5(b))	The exemption applies only with respect to microbiological hazards regulated under 21 CFR part 113 <i>and</i> the facility must be in compliance with part 113 (21 CFR 507.5(b)(1) and (b)(2))
Activities of a facility that are subject to Standards for Produce Safety, section 419 of the FD&C Act (21 CFR 507.5(c))	See FDA’s Produce Safety Rule (21 CFR part 112) for a description of these activities
Establishments that only store raw agricultural commodities -- <i>other than fruits and vegetables</i> -- intended for further distribution or processing (21 CFR 507.5(g)) are exempt from 21 CFR part 507 subparts C and E	Storage of raw agricultural commodities that are fruits and vegetables is not exempt
<p>Current good manufacturing practice requirements (21 CFR part 507 subpart B) do not apply to establishments that are solely engaged in:</p> <ol style="list-style-type: none"> 1. The holding and/or transportation of one or more raw agricultural commodities; 2. Hulling, shelling, drying, packing, and/or holding nuts and hulls; or 3. Ginning of cotton <p>(See 21 CFR 507.5(h))</p>	There can be no manufacturing or processing such as grinding shells or roasting nuts or extracting oil from cottonseed
Facilities solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control for pathogens (21 CFR 507.10(a))	Subparts C and E of 21 CFR part 507 do not apply
Facilities solely engaged in the storage of unexposed packaged animal food that <i>does</i> require time/temperature control for pathogens (21 CFR 507.10(b))	Subparts C and E of 21 CFR part 507 do not apply except for modified requirements in 21 CFR 507.51 to establish and implement temperature controls, monitor the temperature controls, correct any problems, calibrate temperature monitoring equipment, and review and maintain records
Holding and distribution of human food by-products for use as animal food (21 CFR 507.12)	For the human food by-products for use as animal food, the by-product is subject only to the requirements of 21 CFR 507.28 as long as the by-product does not undergo further manufacturing or processing at the human food facility, the human food facility is in compliance with 21 CFR part 117 subpart B; or, for the off-farm packing and holding of produce, in compliance with 21 CFR 117.8; and the facility is in compliance with all applicable human food safety requirements of the FD&C Act and implementing regulations.

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E. When Do I Have to Comply With the Rule?

Facilities have different compliance dates based on business size. Table 3 lists the compliance dates for the CGMP requirements in subpart B and the preventive controls requirements in subpart C of 21 CFR part 507. Table 4 lists the compliance dates for the supply-chain program in subpart E of 21 CFR part 507.

Table 3—Compliance Dates for Part 507

Business Size	Current Good Manufacturing Practice Compliance Date	Preventive Controls Compliance Date
Business other than small and very small	September 19, 2016	September 18, 2017
Small businesses, i.e., a business with fewer than 500 full-time equivalent employees	September 18, 2017	September 17, 2018
Qualified facilities (including very small businesses) as defined above	September 17, 2018	September 17, 2019, except for records to support its status as a very small business is January 1, 2017

Table 4—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

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III. WHAT ON-FARM LOW-RISK ACTIVITIES BY SMALL OR VERY SMALL BUSINESSES ARE EXEMPT FROM HAZARD ANALYSIS AND PREVENTIVE CONTROLS?

Certain manufacturing, processing, packing, and holding activities are not subject to the requirements for hazard analysis and risk-based preventive controls and supply-chain program when they are conducted on-farm by small or very small businesses, if these are the only activities they conduct that would be subject to the requirements for hazard analysis and risk-based preventive controls. The exemption only applies to the low-risk activity/animal food combinations listed in the regulation. In addition, the requirements for a very small business also would not apply to very small on-farm businesses conducting only these low-risk, on-farm manufacturing, processing, packing, and holding activities. Following are the exemptions for on-farm packing and holding of animal food and the exemptions for on-farm manufacturing/processing of animal food.

A. On-Farm Packing or Holding of Animal Food

The requirements for hazard analysis and risk-based preventive controls and supply-chain program do not apply to on-farm packing or holding of animal food by a small or very small business if the packing and holding activities are limited to packing (or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of (21 CFR 507.5(e)):

- Roughage products—e.g., alfalfa meal, entire plant meal, stem meal, pomace, and pulp
- Plant protein meals—e.g., algae, coconut (copra), guar, and peanut
- 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
- Oilseed products—e.g., oil and meal of safflower, soybean, or sunflower
- Molasses—e.g., processed sugar cane, sugar beets, and citrus
- Animal protein meals—e.g., blood, feather, meat, meat and bone, and marine (e.g., crab, fish, and shrimp)
- Milk products—e.g., casein, cheese rind, and lactalbumin
- Animal tissue-derived products—e.g., fat
- Vitamins, minerals, and concentrates
- Processing aids—e.g., enzymes, preservatives, and stabilizers

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- Any other processed animal food that does not require time/temperature control for safety

B. On-Farm Manufacturing/Processing

The requirements for hazard analysis and risk-based preventive controls and supply-chain program do not apply to on-farm manufacturing/processing of animal food by a small or very small business if the only manufacturing/processing activities that the business conducts consist of the following low-risk manufacturing/processing activity/animal food combinations (21 CFR 507.5(f)):

- Chopping or shredding hay;
- 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);
- 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);
- Ensiling (including chopping, shredding, mixing, storing, or fermenting), i.e., making silage or haylage from forage (e.g., sorghum (milo), corn (maize), alfalfa, and grass), grain, culled fruits and vegetables, or roughage;
- Extracting (mechanical) or wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;
- 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
- 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.

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IV. INFORMATION FOR QUALIFIED FACILITIES

A. How Can I Tell if My Business is a Qualified Facility?

To be a qualified facility (see definitions in 21 CFR 507.3 and table 2 in section II.D of this guidance), a business must either be:

- A very small business (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)), or
- A facility to which both of the following apply:
 - 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 (consumers, or local restaurants and retail food establishments not more than 275 miles from the facility) during such period exceeded the average annual monetary value of the food sold by such facility (including sales by any subsidiary or affiliate) to all other purchasers; and
 - 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.

In determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011 (21 CFR 507.7(a)(1)).

B. How Do I Tell FDA That My Business is a Qualified Facility?

- The attestation can be submitted to FDA in one of two ways:
 - Electronically — Go to <http://www.fda.gov/furls> and follow the instructions. FDA encourages electronic submission.
 - Mail — You must use Form FDA 3942b. Send the completed paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet. To obtain a copy of this form:
 - Download it from <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm>, or

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- Write to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740 or
- Request a copy by phone at 1-800-216-7331 or 301-575-0156

C. What Other Information Must I Provide FDA?

- In the attestation you provide FDA, you must include the following:
 - You have identified 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 (21 CFR 507.7(a)(2)(i)); or
 - You are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. This attestation may be 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 (21 CFR 507.7(a)(2)(ii)).

D. When Must I Tell FDA That My Business is a Qualified Facility?

The attestation verifying that your business is a qualified facility must be submitted to FDA initially (21 CFR 507.7(c)(2)(i)) —

- By December 16, 2019, for a facility that begins manufacturing, processing, packing, or holding animal food before September 17, 2019
- Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after September 17, 2019; or

Beginning in 2020, your attestation must be submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31 (21 CFR 507.7(c)(2)(ii)).

The determination of whether a facility satisfies the definition of qualified facility must be made annually no later than July 1 of each calendar year (21 CFR 507.7(c)(1)). 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 (21 CFR 507.7(c)(3)), and

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- The facility must comply with the requirements for hazard analysis and preventive controls no later than December 31 of the applicable year, unless otherwise agreed to by FDA and the facility (21 CFR 507.7(d)).

You must maintain the records you relied upon to support the attestations. These records are subject to the record keeping requirements of the rule in 21 CFR part 507 subpart F (21 CFR 507.7(f)).

E. Withdrawal of a Qualified Facility Exemption

FDA may withdraw a qualified facility exemption —

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility (21 CFR 507.60(a)(1)); or
- 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 (21 CFR 507.60(a)(2)).

Before FDA issues an order to withdraw a qualified facility exemption, FDA —

- 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 (21 CFR 507.60(b)(1));
- 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 (21 CFR 507.60(b)(2)); and
- Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption (21 CFR 507.60(b)(3)).

V. CURRENT GOOD MANUFACTURING PRACTICE (CGMP)

A. Personnel

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 necessary to protect against the contamination of animal food (21 CFR 507.14), including:

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- Maintaining adequate personal cleanliness;
- Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;
- Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;
- Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and
- Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials

B. Plant and Grounds

Grounds — 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 (21 CFR 507.17(a)):

- 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;
- Maintaining driveways, yards, and parking lots so that they do not constitute a source of contamination in areas where animal food is exposed;
- Adequately draining areas that may contribute contamination to animal food by seepage, foot-borne filth, or providing a breeding place for pests; and
- Treating and disposing of waste so that it does not become a source of contamination in areas where animal food is exposed.

Plant construction and design — 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, i.e., the plant must (21 CFR 507.17(b)):

- Provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;
- Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;

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- 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;
- 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
- 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.

Animal food stored outdoors in bulk — The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including (21 CFR 507.17(c)):

- Using protective coverings where necessary and appropriate;
- Controlling areas over and around the bulk animal food to eliminate harborage for pests; and
- Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.

C. Sanitation

- 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 (21 CFR 507.19(a)).
- 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 (21 CFR 507.19(b)):
 - 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
 - In wet processing of animal food, when cleaning and sanitizing are necessary to protect against the introduction of undesirable microorganisms, 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.

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- Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use (21 CFR 507.19(c)).
- Only the following toxic materials may be used or stored in a plant where animal food is processed or exposed (21 CFR 507.19(d)(1)) –
 - Those 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.
- Those toxic materials that are allowed to be used or stored in the plant area where animal food is manufactured, processed, or exposed must be identified, used, and stored in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials (21 CFR 507.19(d)(2));
- Other toxic materials, such as fertilizers and pesticides, must be stored in an area of the plant where animal food is not manufactured, processed, or exposed (21 CFR 507.19(d)(3));
- Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas of a plant 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 (21 CFR 507.19(e)); and
- 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 (21 CFR 507.19(f)).

D. Water Supply and Plumbing

- Water must be adequate for the operations and must be derived from an adequate source (21 CFR 507.20(a)(1)).
- Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for (21 CFR 507.20(a)(2)):
 - Manufacturing, processing, packing, or holding of animal food;
 - Cleaning of equipment, utensils, and animal food-packaging materials; and

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- 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 (21 CFR 507.20(a)(3));
- Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food (21 CFR 507.20(a)(4));
- Plumbing must be designed, installed, and maintained to (21 CFR 507.20(b)):
 - 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, 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 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.
- Sewage and liquid disposal waste must be disposed of through an adequate sewerage system or through other adequate means (21 CFR 507.20(c));
- 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 (21 CFR 507.20(d)); and
- 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 (21 CFR 507.20(e)).

E. Equipment and Utensils

- All plant equipment and utensils used in manufacturing, processing, packing, or holding animal food, 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 (21 CFR 507.22(a)(1));

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- 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 (21 CFR 507.22(a)(2));
- Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces (21 CFR 507.22(a)(3));
- 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, cleaning procedures, and sanitizing agents (21 CFR 507.22(a)(4));
 - Made of nontoxic materials;
 - Maintained to protect animal food from being contaminated.
- 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 (21 CFR 507.22(b));
- Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device (21 CFR 507.22(c));
- 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 (21 CFR 507.22(d)); and
- 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 (21 CFR 507.22(e)).

F. Plant Operations—Management

- Management of the establishment must ensure that (21 CFR 507.25(a)):
 - 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 rule;
 - Animal food, including raw materials, other ingredients, or rework is accurately identified;

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- Animal food-packaging materials are safe and suitable;
- The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;
- 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;
- Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;
- 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
- 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.

G. Plant Operations—Raw Materials and Other Ingredients

- All raw materials and other ingredients 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 (21 CFR 507.25(b)(1)). In addition:
 - 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;
 - Raw materials must be cleaned as necessary to minimize contamination;
 - 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.
- Raw materials and other ingredients (21 CFR 507.25(b)(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

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- 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.

H. Plant Operations—General

- For the purposes of manufacturing, processing, packing, and holding operations, the following apply (21 CFR 507.25(c)(1)-(8)):
 - 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;
 - 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 water activity (a_w)) must be adequate to prevent adulteration of animal food;
 - Work-in-process and rework must be handled so that it is protected against contamination and the growth of undesirable microorganisms;
 - 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;
 - Filling, assembling, packaging, and other operations must be performed in a way that protects against the contamination of animal food and the growth of undesirable microorganisms;
 - 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;
 - 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
 - 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 rule.

I. Holding and Distribution

- Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following (21 CFR 507.27(a)):

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- 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
- Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.
- The labeling for the animal food ready for distribution must contain, when applicable, information and instructions for safely using the animal food for the intended animal species (21 CFR 507.27(b));
- 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 (21 CFR 507.27(c));
- 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 (21 CFR 507.27(d)); and
- Unpackaged or bulk animal food must be held in a manner that does not result in unsafe cross contamination with other animal food (21 CFR 507.27(e)).

J. Holding and Distribution of Human Food By-Products for Use as Animal Food

Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor must be held under conditions that will protect against contamination, including the following (21 CFR 507.28(a)):

- 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;
- 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
- During holding, human food by-products for use as animal food must be accurately identified.

In addition:

- Labeling that identifies the product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed (21 CFR 507.28(b)); and

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- 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 (21 CFR 507.28(c)).

VI. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

A. Hazard Analysis

The first step in developing your food safety plan is to conduct a hazard analysis. You must conduct the hazard analysis to identify and evaluate known or reasonably foreseeable hazards (hazards that are known to be, or have the potential to be, associated with the facility or the animal food) for each type of animal food manufactured, processed, packed, or held at your facility. The identification and evaluation are based on experience, illness data, scientific reports, and other information. The next step is to determine whether any of the identified known or reasonably foreseeable hazards require a preventive control (21 CFR 507.33(a)(1)). These hazards may occur naturally, may happen unintentionally, or may be intentionally introduced for economic gain. (See 21 CFR 507.33(b)(2).) The hazard analysis must be written, regardless of its outcome, as part of the written food safety plan (21 CFR 507.33(a)(2)).

1. What categories of hazards must you consider?

There are three categories of hazards--biological, chemical (including radiological), and physical that you must consider in your hazard analysis (21 CR 507.33(b)(1)). Table 5 lists these categories with examples of each for animal food.

Table 5—Categories of hazards

Category	Description
Biological hazards	Microbiological hazards such as parasites, environmental pathogens, and other pathogens (e.g., <i>Salmonella</i> spp. or <i>Listeria monocytogenes</i>)
Chemical (including radiological) hazards	Hazards such as pesticide and drug residues, natural toxins (such as mycotoxins), decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food or excessive copper in food for sheep)
Physical hazards	Hazards such as stones, glass, and metal fragments

2. What must your hazard evaluation include?

Your hazard evaluation must include consideration of the severity of the illness or injury caused to humans or animals if the identified hazards were to occur and the probability that the hazards will occur without preventive controls (21 CFR 507.33(c)). The evaluation must consider the

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effect of various factors on the safety of the finished food for the intended animal (21 CFR 507.33(d)). Table 6 lists these factors.

Table 6—What Factors the Hazard Evaluation Must Consider

Factors to Consider	Description
Formulation of the animal food	Nutrient deficiencies and toxicities (such as lack of thiamine in cat food or too much copper in sheep food) can result in illness or injury to animals. Certain ingredients such as acids and preservatives inhibit growth of, or even kill, microorganisms of public health significance.
Condition, function, and design of the facility and equipment	Equipment with close-fitting parts may be difficult to clean and could allow pathogens to become established. Equipment with metal-to-metal contact may generate metal fragments.
Raw materials and other ingredients	Contaminated ingredients can introduce hazards such as pathogens or chemical toxins (e.g., mycotoxins).
Transportation practices	Failure to adequately clean animal-food contact surfaces of transportation equipment could result in contamination of an animal food.
Manufacturing/processing procedures	Improper cooling or holding of certain animal food, such as pet food, can result in contamination of the animal food with environmental pathogens.
Packaging and labeling activities	Failure to include on the labeling instructions for safe use for the intended species could result in unsafe use in a different species.
Storage and distribution	Some animal food requires refrigerated storage or moisture controls to maintain safety.
Intended or reasonably foreseeable use	Food for cattle containing copper could be a safety concern if fed to sheep.
Sanitation, including employee hygiene	Animal food, such as raw pet food, may be subject to contamination in an unclean facility, from unclean equipment, or from poor employee hygiene.
Other relevant factors	Factors which may create hazards, e.g., weather's effect on levels of some natural toxins such as mycotoxins.

B. Preventive Controls

Your written food safety plan must identify the preventive controls you have implemented to ensure that any hazards requiring a preventive control will be significantly minimized or prevented (21 CFR 507.34(a)). These controls include those at critical control points (CCPs) if there are any, or controls other than at CCPs as appropriate for animal food safety. Preventive controls may include any or all of the following (21 CFR 507.34(c)):

- Process controls
- Sanitation controls

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- Supply-chain controls
- Recall plan.

The types of preventive controls you must use will depend on the facility and the animal food:

- Process controls are procedures, practices, and processes to ensure the control of operations such as heat processing, acidifying, irradiating, and refrigerating foods. When applying a process control, you must specify the parameter that is monitored (e.g., the temperature, the pH of the animal food) and the minimum or maximum value that ensures control (e.g., a minimum of 375°F (for a heat treatment), a maximum of 41°F (for refrigerated storage). (See 21 CFR 507.34(c)(1).)
- Sanitation controls are procedures, practices, and processes to ensure that the facility's sanitation practices are adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling (21 CFR 507.34(c)(2)). Sanitation controls must address:
 - The cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment;
 - 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; and
 - The sanitation controls do not include all sanitation procedures used in the facility, only those that are used to control a hazard requiring a preventive control.
- Supply-chain controls are activities taken to verify that suppliers that are controlling hazards are doing so effectively. This will be covered in section VI.E on Supply Chain Program for Receiving Facilities (21 CFR 507.34(c)(3)).
- A recall plan is required for any animal food with a hazard requiring a preventive control (21 CFR 507.38). It must be written and must include steps to take and the person responsible for taking the steps to:
 - Notify your direct customers;
 - Notify the public, if necessary;
 - Check the effectiveness of the recall; and
 - Appropriately dispose of the recalled animal food.

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C. Oversight and Management of Preventive Controls

The PCAF rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise. These procedures or management components are designed to provide assurance that preventive controls are effective and consistently performed (21 CFR 507.39). Table 7 provides information on these management components and recordkeeping.

Table 7— Preventive Control Management Components

Management Components	Explanation
Monitoring	You must have written procedures for monitoring each preventive control, including how often these procedures are to be performed (21 CFR 507.40)
Corrective actions and corrections	Procedures taken to identify and correct a problem that occurs during animal food production. Corrective actions include steps taken when a problem occurs with implementation of a preventive control, steps taken to reduce the likelihood the problem will recur, steps taken to evaluate the affected animal food for safety, and steps taken to prevent it from entering commerce. Corrective actions must be documented in records. Corrections that don't include all these steps may be taken in certain situations, such as for minor problems that don't affect the safety of the animal food (21 CFR 507.42)
Verification & Validation	These are activities to ensure that preventive controls are consistently applied and effective in controlling the hazards. It is critical to verify that controls are carried out and, where necessary, to validate with scientific evidence that a control measure effectively controls an identified hazard. Verification activities include calibration (or accuracy checks) of process monitoring and verification instruments (such as thermometers) and reviewing records to verify that monitoring is being conducted and appropriate corrective actions are taken (if necessary) (21 CFR 507.45 and 507.47)
Product testing and environmental monitoring	These are verification activities for implementation and effectiveness of preventive controls. Environmental monitoring generally would be required if contamination of a finished animal food with an environmental pathogen is a hazard requiring a preventive control (21 CFR 507.49)

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Management Components	Explanation
Records	<p>Records may be originals, true copies – i.e., reproductions of originals – or electronic (21 CFR 507.202(a)(1)) and must be made promptly available to an authorized representative of the Secretary of Health and Human Services (such as an FDA investigator or State inspector conducting inspections for FDA) (21 CFR 507.200(c)). The following apply to records:</p> <ul style="list-style-type: none">• Records include your food safety plan itself, i.e., hazard analysis and preventive controls development; recall plan; and monitoring, corrective action and verification procedures• Records include implementation records, i.e., monitoring data, corrective actions taken, validation documentation, verification activity records, supply-chain program execution, and personnel training• Your records must include information to identify your plant or facility, the date when the activity was documented, and product or lot code if applicable (21 CFR 507.202(b))• Records must be kept for at least 2 years after the date prepared, or as long as necessary for those records used to support your status as a qualified facility (21 CFR 507.208(a))• Existing records you use to comply with other Federal, State, or local regulations do not need to be duplicated if they satisfy the record keeping requirement. Existing records may be supplemented where needed to satisfy the requirements for part 507 (21 CFR 507.212(a))

D. Circumstances When a Preventive Control is Not Required

If you are a manufacturer/processor, you are not required to implement a preventive control for an identified hazard if any of the following circumstances apply (21 CFR 507.36):

- You determine and document that the animal food in question could not be consumed without application of an appropriate control.
- You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls to ensure that the identified hazard will be significantly minimized or prevented, and you:
 - Disclose in documents accompanying the animal food, in accordance with trade practice, that the animal food is “not processed to control [identified hazard]”; and,
 - Annually obtain from your customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard, unless your customer has determined that the identified hazard is not a hazard in the animal food intended for use for a specific animal species and your customer's written assurance provides this determination, specifying the animal species and why the identified hazard is not a hazard.

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- You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls (e.g., because the customer is a qualified facility subject to modified requirements or some other business not subject to the requirements) to provide assurance the customer is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and you:
 - Disclose in documents accompanying the animal food, in accordance with trade practice, that the animal food is “not processed to control [identified hazard]”, and
 - Annually obtain from your customer written assurance that your customer is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements.
- 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:
 - Disclose in documents accompanying the animal food, in accordance with trade practice, that the animal food is “not processed to control [identified hazard]”; and
 - Annually obtain from your customer written assurance that your customer:
 - Will disclose in documents accompanying the animal food, in accordance with trade practice, that the animal food is “not processed to control [identified hazard]”; and
 - Will only sell to another entity that agrees, in writing, that it will:
 - Follow identified procedures that will significantly minimize or prevent the identified hazard – if the entity is covered by hazard analysis and risk-based preventive controls requirements – or, if it is not so covered, it will manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements; or
 - Obtain a similar written assurance from the entity's customer.
- You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the identified hazards in the animal food product you distribute and you document the implementation of that system.

E. Supply-Chain Program for Manufacturing/Processing Facilities

If a manufacturing/processing facility (i.e., receiving facility) has identified in its raw materials and ingredients a hazard that requires a preventive control and the receiving facility relies on a control applied in the supply chain before receipt, the facility must have a supply-chain program (21 CFR part 507 subpart E). Manufacturing/processing facilities that control all identified

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hazards with their own preventive controls, or who follow requirements applicable when relying on a commercial customer to control hazards, do not need to have a supply-chain program for such animal food.

Animal food facilities subject to the supply-chain program requirements of this rule are responsible for ensuring that raw materials and other ingredients for their products are received only from approved suppliers, or — if received on a temporary basis from unapproved suppliers — ensuring those materials are subject to verification activities before being accepted for use (21 CFR 507.110(d)(1), 507.115(a)(1) and 507.120).

1. Requirements

- a. The supply-chain program must be written (21 CFR 507.105(b)) and must include:
 - Using suppliers approved by the receiving facility (21 CFR 507.110(a)(1), 507.115(a)(1), and 507.120);
 - Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) (21 CFR 507.110(a)(2) and 507.125);
 - Conducting supplier verification activities (21 CFR 507.110(a)(3), 507.130 and 507.135);
 - Documenting supplier verification activities (21 CFR 507.110(a)(4) and 507.175); and
 - 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 (21 CFR 507.110(a)(5) and 507.175).
 - Other entities in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess the entity's documentation verifying control of the hazard and document this review (21 CFR 507.110(a)(5)).
- b. Supplier verification activities (21 CFR 507.110(b)(1)-(4)) include:
 - Onsite audits;
 - Sampling and testing of raw materials or other ingredients;
 - Review of the supplier's relevant food safety records; and
 - Other appropriate supplier verification activities based on the risk associated with the raw material or other ingredient and supplier performance.

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2. Exceptions

- A receiving facility that is an importer, is in compliance with the foreign supplier verification requirements, and has documentation of verification activities which provide assurance that the hazards requiring a supply-chain-applied control for a raw material or other ingredient have been significantly minimized or prevented, does not need to conduct supplier verification activities for that raw material or other ingredient (21 CFR 507.105(a)(2)).
- The requirements in subpart E do not apply to animal food that is supplied for research or evaluation use (21 CFR 507.105(a)(3)).

F. Compliance Dates for the Requirements of the Supply–Chain Program

Separate compliance dates have been established for the supply-chain program provisions so that an animal food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the PCAF rule or the produce safety rule (if applicable). See table 4 in section II.E for the compliance dates.

G. Education and Training

Establishments subject to subpart C of this rule must ensure that the individual (preventive controls qualified individual) who prepares or oversees preparation of their animal food safety system has 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 an animal food safety system (21 CFR 507.31 and 507.53(c)(1)).

In addition, each individual (including temporary and seasonal personnel) engaged in (or supervising) manufacturing, processing, packing, or holding animal food covered by this rule must:

- Be a qualified individual, i.e., have the education, training, or experience (or a combination of these) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties (21 CFR 507.4(b)(1)); and
- 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 (21 CFR 507.4(b)(2)).

Additional qualifications for supervisory personnel: responsibility for ensuring compliance with the requirements of this rule must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination of these) necessary to supervise subordinates in the production of safe animal food (21 CFR 507.4(c)).

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Records documenting required training in the principles of animal food hygiene and animal food safety must be established and maintained (21 CFR 507.4(d)).

H. Reanalysis of Your Food Safety Plan

You must reanalyze your food safety plan at least once every 3 years (21 CFR 507.50(a)). You must also conduct a reanalysis whenever:

- A significant change in the activities at your facility creates a potential for a new hazard or a significant increase in a previously identified hazard (21 CFR 507.50(b)(1));
- You become aware of new information about potential hazards associated with the animal food (21 CFR 507.50(b)(2));
- It is appropriate after an unanticipated animal food safety problem (21 CFR 507.50(b)(3)); and
- You find that a preventive control(s) or the food safety plan as a whole is ineffective (21 CFR 507.50(b)(4)).

VII. DEFINITIONS

Adequate: That which is needed to achieve the intended purpose in keeping with good public (human and animal) health practice.

Affiliate: Any facility that controls, is controlled by, or is under common control with another facility.

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

Audit: The systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Calendar day: Every day shown on the calendar.

Correction: 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: 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.

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Environmental pathogen: 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 rule include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility: 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 21 CFR part 1, subpart H.

Farm: As modified by The Human Food Preventive Controls rule and found in 21 CFR 1.227:

- (1) *Primary production farm.* A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:
 - (i) Pack or hold raw agricultural commodities;
 - (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
 - (iii) Manufacture/process food, provided that:
 - (A) All food used in such activities is consumed on that farm or another farm under the same management; or
 - (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
 - (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
 - (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

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(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) *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 raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities 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 as described in paragraphs (1)(ii) and (iii) of this definition.

FDA: The Food and Drug Administration.

Food: As defined in section 201(f) of the FD&C Act (articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article), and includes raw materials and ingredients.

Food-contact surfaces: Surfaces that contact animal food, and surfaces from which drainage – or other means of transfer – onto the animal food, or onto surfaces that contact the animal food – ordinarily occurs during the normal course of operations. *Food-contact surfaces* include utensils and animal food-contact surfaces of equipment.

Full-time equivalent employee: Represents 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: Activities on farms and farm mixed-type facilities 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 FD&C 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, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

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

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Hazard requiring a preventive control : A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food, and components and 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: Storage of animal food and 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 FD&C Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks.

Known or reasonably foreseeable hazard: 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: The animal food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing: 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: Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites, including 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.

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Mixed-type facility: 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. An example is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require it to be registered.

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

Packing: Placing animal food into a container other than packaging the animal food and also includes re-packing and activities performed incidental to packing or re-packing an animal food, e.g., activities performed for the safe or effective packing or re-packing of that animal food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act.

Pathogen: A microorganism of public (human or animal) health significance.

Pest: Any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant: The building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

Preventive controls: 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: 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: A person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. Examples of potential qualified auditors include:

- (1) A government employee including a foreign government employee; and
- (2) An audit agent of a certification body that is accredited in accordance with regulations in 21 CFR part 1, subpart M “Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.”

Qualified end-user: With respect to a food, it 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 21 CFR 1.227) that:

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- (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 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: a facility that is a very small business: (when including the sales by all its subsidiaries or affiliates, if it has any; or of the entity of which the facility itself is a subsidiary or affiliate, if it is either); OR a facility to which both of the following conditions 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 the facility that is sold directly to qualified end-users (as defined above) exceeded the average annual monetary value of the food sold by the 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: An exemption applicable to a qualified facility.

Qualified individual: A person who has the education, training, or experience (or a combination of these) 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: Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

Receiving facility: A facility that is subject to Hazard Analysis and Risk-Based Preventive Controls and the Supply-Chain Program, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Rework: 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: 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 and humans.

Significantly minimize: To reduce to an acceptable level, including to eliminate.

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Small business: For purposes of this rule, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Subsidiary: A company which is owned or controlled directly or indirectly by another company.

Supplier: 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: 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: A packaged animal food that is not exposed to the environment.

Validation: 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: 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: For purposes of this rule, 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): 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: 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: For purposes of the rule, is the owner, operator, or agent in charge of a facility.