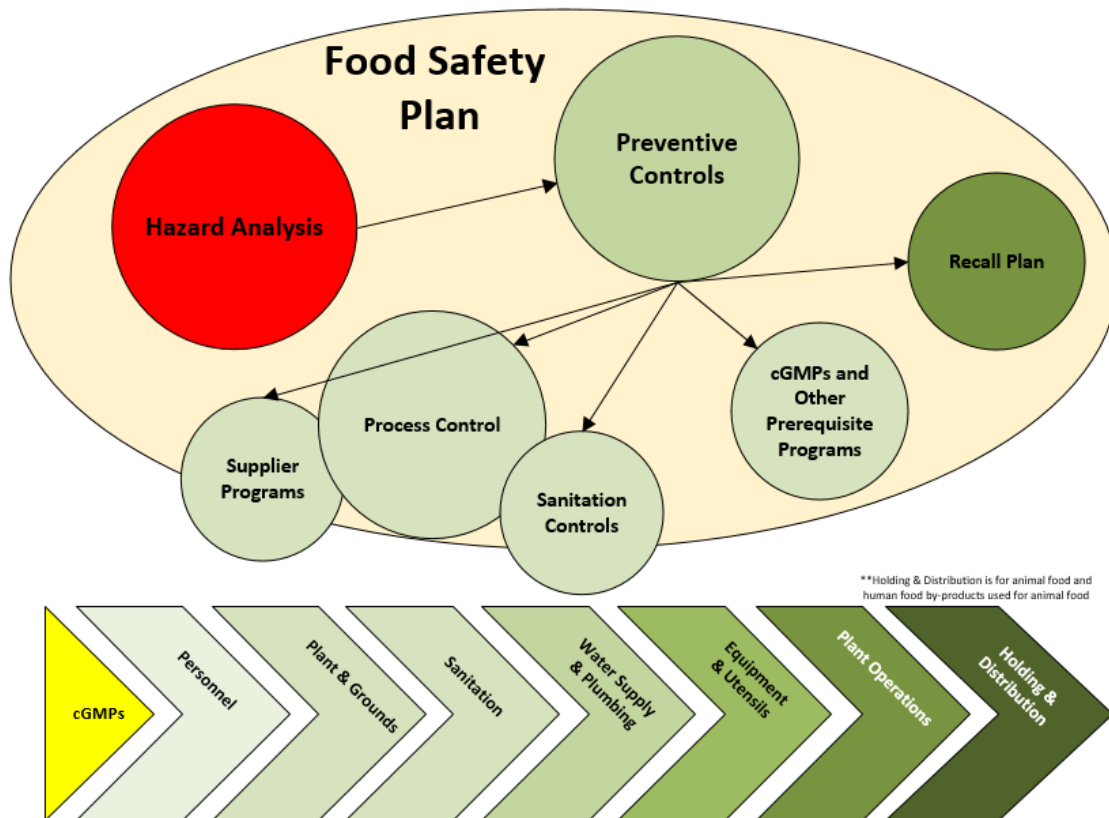




# IOWA DEPARTMENT OF AGRICULTURE & LAND STEWARDSHIP

## Food Safety Plan Guide

*These documents are for guidance purposes only and does not constitute legal advice. It is the responsibility of the commercial feed manufacturer/distributor to ensure compliance with the applicable laws and requirements. Following the guidance in these documents does not preclude regulatory or compliance action by the Iowa Department of Agriculture and Land Stewardship when authorized by state law, nor does it release any commercial feed manufacturer or distributor from legal responsibility or liability of any kind.*



## Food Safety Plan Checklist

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### Background Information

- Assemble the Food Safety Team – Responsible for planning, developing, and implementing.
  - Select team lead – What qualifications, PC trained?
  - Select people with specific knowledge and expertise about the process and products
    - Operations, QA, Maintenance, Nutritionist, Management
- Description of facility
  - Average Tons produced
  - Integrated/Commercial
  - Species feed or product produced
  - Type of feed (mash, Mineral, Pellet)
- Describe the products, intended use, customers, and distribution.
  - What species is it intended for
  - Customer
  - Is it a Feed or ingredient
  - Is it a meal or pellet
  - Is it sacked or bulk
  - How is it stored or transported
  - Provide Ingredient list (formula)
  - Shelf Life
- Ensure prerequisites are in place
  - Documents Control Procedures should be in place, and documents are accessible to appropriate personnel
  - Based on Current Good Manufacturing Practices (21CFR 507)
    - Personnel, Plant and Grounds, Sanitation, Water Supply and Plumbing, Equipment and utensils, Plant Operations, Holding and Distribution, Holding and Distribution of human food by-products for use as animal food
  - Standard Operating Procedures for processes in the facility (*Best Practice*)
- Develop a process flow diagram of the manufacturing location.
  - Detailed process description to supplement the process flow diagram.
  - Verify that the Flow diagram is correct.
- Develop a list of ingredients used to manufacture feed

## Hazard Analysis and Preventive Controls Determination

- Hazard Analysis
  - Go through each step of the process to see if any of the steps consist of possible Biological, Chemical, Physical, and Radiological hazards.
  - Go through each ingredient used and see if they could bring any Biological, Chemical, Physical, and Radiological Hazards,
    - Toxins, pesticides, etc.
- Hazard Evaluation
  - Severity, Probability of hazard, and Method of contamination.
  - Items that must be Considered
    - Formulations, Equipment and facility, Raw materials/ingredients, Transportation practices, Manufacturing/processing procedures, Packaging and labeling activities, Storage and distribution, Intended or reasonably foreseeable use, Sanitation, Other factors, such as Temporal (weather-related) nature of hazards

## Preventive Controls and their Management Components *\*\*required, when appropriate, if hazard analysis identifies a hazard requiring a preventive control*

- Develop Preventive Controls
  - Any further procedures that may need to be in place to eliminate a hazard found.
    - Process Control
      - Utilize procedures, practices, and processes to either significantly minimize or prevent a hazard
      - Facility establish specific parameters that must be met
      - Provide for evidence-based protection
    - Sanitation
      - Cleanliness of animal food contact surfaces
      - Prevention of cross-contamination
        - From insanitary objects/personnel (shovels, scoops, openings, etc.)
        - From Raw product to processed product
    - Supply-Chain
      - Supply-Chain-Applied Control (written program)
        - Approving suppliers
        - Using only approved suppliers
        - Determining, conducting, and documenting appropriate supplier verification activities
        - Implementing appropriate preventive control management components
        - Documentation
    - Other
- Define the critical limits
  - Use research or history to find what the acceptable limits are

- Monitoring
  - Develop records and written procedures to monitor any preventative controls
  - To conduct a planned sequence of observation or measurements to assess whether control measures are operating as intended
  - Examples: Temperature, Time, Weight, Flow rate, Appearance, and pH
- Develop Corrective action and Corrections process
  - How are you going to correct if the issues that go outside of the Critical limits?
  - Establish and implement written corrective action procedures that must be taken if preventive controls are properly implemented
    - Take appropriate action is taken to identify or correct a problem that occurred during implementation
    - Take appropriate action is taken to reduce likelihood of reoccurrence
    - Evaluated affected animal food for safety
    - All affected animal food is prevented from entering into commerce if safety cannot be ensured
    - Reanalyze the food safety plan when needed
- Verification
  - Validation that the preventive controls are working
    - Done whenever a change to control measure or combination of a control measures that could affect the control of the hazard
    - Done whenever a reanalysis of the food safety plan reveals the need to do so
    - Prior to implementation, 90 calendar days, within a reasonable timeframe with written justification
    - Must include scientific and technical evidence to determine whether controls will effectively control the hazards
    - Not needed on sanitation controls, recall plan, supply-chain program, others with written justification
  - Verification that Monitoring is being conducted
  - Verification that Appropriate Decisions about Corrective Actions are being made
  - Verification of Implementation and Effectiveness -
    - Product testing
    - Environmental monitoring
    - Calibration/monitoring of thermometers, meters, and scales
- Recall Plan *\*\*\*Best practice even if not required*
  - Notify the direct consignees of animal food being recalled, How to return or dispose
  - Notify the public about hazards if presents danger to human and animal health
  - Conduct effectiveness checks to verify the recall is carried out
  - How to dispose of the recalled food (if reprocessing, reworking, destroying)
  - Common Elements
    - Defined roles and responsibilities
    - Contact lists for external notifications (Regulators, customers, public)

## Implementation Records

- Reanalysis of the Food Safety Plan
  - Every 3 years or when a corrective action, process change, ingredient change, product change, or more information proves needed sooner
- Recordkeeping
  - Records must be retained for at least two years
  - Records must:
    - Be kept original or electronic records
    - Contains actual values or observation
    - Be accurate, indelible, and legible
    - Being created concurrently with performance of the activity documented
    - Be as detailed as necessary to provide history of work performed
  - All Record must include:
    - Information adequate to identify the plant or facility (name and address)
    - The date and, When appropriate, the time of the activity documented
    - Signature or initials of the person performing the activity
    - Where appropriate, the identity of the product and lot code, if any
- Personnel Training
  - Annual Trainings
  - Can be sign in sheets, Signatures on SOPs or Quizzes
  - Principles of animal food hygiene and animal food safety for those involved in processes.
  - Training check-list for new employees, includes description of on the job training activities.

#235

# Current Good Manufacturing Practice Requirements for Food for Animals

## Guidance for Industry

Submit comments on this guidance at any time. Submit electronic comments to <https://www.regulations.gov/>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-1229.

For questions regarding this document, contact [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov).

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, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <https://www.fda.gov/AnimalVeterinary/default.htm> or <https://www.regulations.gov/>.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine  
October 2017**

*Contains Nonbinding Recommendations*

**Table of Contents**

I.	Introduction.....	3
II.	Background.....	3
III.	General Considerations.....	4
	A. CGMPs serve as a foundation for preventive controls.....	4
	B. Flexible CGMPs for a diverse industry.....	5
	C. Complying with the CGMPs.....	6
	D. Compliance with other regulatory requirements.....	7
IV.	Am I Subject to the CGMP Requirements? (21 CFR Part 507, Subpart A).....	7
	A. Who must follow the animal food CGMPs.....	7
	B. Who does not have to follow the animal food CGMPs.....	7
	C. CGMPs for facilities with human and animal food.....	8
	D. Facilities covered by other animal food CGMPs (21 CFR 507.1(c)).....	10
V.	CGMP Training and Qualification Requirements (21 CFR Part 507, Subpart A) and Recordkeeping (21 CFR Part 507, Subpart F).....	11
	A. Management responsibilities (21 CFR 507.4(a)(1) and 507.4(c)).....	11
	B. Qualifications and training of individuals who manufacture, process, pack or hold animal food (21 CFR 507.4(b)).....	11
	C. Training recordkeeping (21 CFR 507.4(d)).....	12
	D. Recordkeeping requirements (21 CFR Part 507, Subpart F).....	13
VI.	Current Good Manufacturing Practice for Animal Food (21 CFR Part 507, Subpart B) 14	
	A. Personnel (21 CFR 507.14).....	14
	B. Plant and grounds (21 CFR 507.17).....	16
	C. Sanitation (21 CFR 507.19).....	18
	D. Water supply and plumbing (21 CFR 507.20).....	21
	E. Equipment and utensils (21 CFR 507.22).....	23
	F. Plant operations (21 CFR 507.25).....	25
	G. Holding and distribution (21 CFR 507.27).....	30
	H. Holding and distribution of human food by-products for use as animal food (21 CFR 507.28 and 117.95).....	32
VII.	Compliance Dates.....	32
	Appendix A: Definitions for terms used in the CGMPs (21 CFR 507.3).....	34
	Appendix B: Part 507 CGMP Self-Assessment Tool.....	38

## **Current Good Manufacturing Practice Requirements for Food for Animals**

### **Guidance for Industry**

*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**

This guidance is intended for domestic and foreign facilities that are required to register as food facilities under the Federal Food, Drug and Cosmetic Act (the FD&C Act) because they manufacture, process, pack, or hold animal food for consumption in the U.S. This guidance contains information to help these facilities determine whether they need to comply with the current good manufacturing practice (CGMP) requirements for animal food established in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule published on September 17, 2015 (80 FR 56170) (the final rule). This guidance also provides additional information and recommendations for compliance with the CGMP requirements for animal food, as well as compliance with related requirements such as training and recordkeeping. The CGMP requirements are codified in 21 CFR part 507, subpart B (subpart B), and some related requirements are codified in 21 CFR part 507, subparts A and F (subparts A and F).

FDA's (hereinafter also referred to as "Agency", "we", or "our") guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

#### **II. Background**

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353). This law enables FDA to better protect public health by helping to ensure the safety and security of the animal food supply by focusing on prevention of food safety problems rather than reacting to problems after they occur. As part of our implementation of FSMA, we established risk-based preventive control requirements for the production of animal food by food facilities required to register under section 415 of the FD&C Act (see section 418 of the FD&C Act). At the same time, we established Current Good Manufacturing Practice requirements (CGMPs) for the manufacturing, processing, packing, and holding of animal food under section 402(a)(3) and (4) of the FD&C Act and sections 311, 361, and 368 of the Public Health Service Act.

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In October 2013, we proposed to establish baseline standards in the form of CGMPs that would apply to most facilities manufacturing, processing, packing, or holding animal food. These CGMPs were proposed to provide baseline food safety standards that would complement the proposed requirements for hazard analysis and risk-based preventive controls for food for animals authorized by FSMA (78 FR 64736). In September 2014, we issued a supplemental notice of proposed rulemaking based on extensive stakeholder input on the proposed rule, which revised key provisions of the proposed rule, including the CGMP provisions (79 FR 58475). In September 2015, we issued a final rule that established for facilities that are required to register with FDA because they manufacture, process, pack, or hold animal food for consumption in the U.S.: (1) CGMP regulations in 21 CFR part 507, subpart B; and (2) hazard analysis and risk-based preventive controls regulations in 21 CFR part 507, subpart C.

This guidance is intended to provide general information on the CGMP requirements established in the final rule, as well as other provisions related to the CGMP requirements, such as training and recordkeeping. Guidances related to other provisions of the final rule, such as general guidance on hazard analysis and preventive controls, are being developed separately.

### **III. General Considerations**

#### **A. CGMPs serve as a foundation for preventive controls**

The CGMPs in 21 CFR part 507, subpart B provide baseline safety and sanitation standards for the manufacturing, processing, packing, and holding of animal food. For definitions of manufacturing/processing, packing, and holding, please see Appendix A: Definitions for terms used in the CGMPs (21 CFR 507.3). These CGMPs address general animal food safety and sanitation concerns. The preventive controls requirements in 21 CFR part 507, subpart C relate to a facility's identification and evaluation of hazards in their animal food and measures to control hazards requiring preventive controls.

We consider CGMPs to be one of many prerequisite programs that can support an effective animal food safety plan. A facility must follow specific steps when conducting its hazard analysis to determine if there are any hazards requiring a preventive control, including evaluating known or reasonably foreseeable hazards (21 CFR 507.33).

As part of its evaluation of known or reasonably foreseeable hazards, a facility must consider any relevant factors, such as the effect of manufacturing/processing procedures, on the safety of the finished animal food for the intended animal (21 CFR 507.33(d)). A facility's use of prerequisite programs, such as CGMPs, could be a relevant factor. A facility may determine that properly implementing a prerequisite program, such as CGMPs, will decrease the probability that a known or reasonably foreseeable hazard will occur in the absence of a preventive control or decrease the severity of the illness or injury if the hazard were to occur.

When the probability of a hazard occurring or the severity of the illness or injury is sufficiently reduced due to proper implementation of a prerequisite program, a facility may conclude that the hazard does not require a preventive control. If the facility concludes in its hazard analysis that

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the hazard is not a "hazard requiring a preventive control," the facility does not need to establish preventive controls, or preventive control management components, for these hazards.<sup>1</sup>

In some situations, implementation of a prerequisite program alone may not be sufficient for a facility to determine that a hazard does not require a preventive control. If a facility determines that a hazard requires a preventive control, the facility must identify and implement a preventive control to significantly minimize or prevent the hazard and include that preventive control in its written food safety plan (21 CFR 507.34(a)(1) and (b)). The hazard analysis and risk-based preventive controls in 21 CFR part 507, subpart C require a facility to identify and control hazards specific to the facility and the animal food it produces which, based on the hazard analysis, are not sufficiently mitigated by CGMPs or other prerequisite programs in place at the facility. In establishing a preventive control for a hazard, the facility may choose to use a procedure that it is already performing, such as a CGMP procedure alone or in combination with other procedures, as the preventive control. This procedure would then be subject to all of the applicable requirements for a preventive control, including monitoring, corrective actions, verification, and validation (21 CFR 507.39).

For example, a facility may use a flushing procedure as a sanitation measure to clean and maintain equipment surfaces to meet CGMP requirements. If a facility determines that cross-contamination between batches of certain types of animal foods may result in a hazard requiring a preventive control, the facility may wish to use a flushing procedure as their preventive control. In that situation, the flushing procedure would need to be identified as the preventive control in the food safety plan. The flushing procedure would then need to be monitored, verified, and validated when it is being used as a preventive control.

### **B. Flexible CGMPs for a diverse industry**

The CGMPs serve as baseline standards for producing safe animal food for various types of animal food facilities and animal foods. As the CGMPs were developed, we considered the diversity of the industry and the ultimate goal of animal food safety. We added flexibility where appropriate to address the diversity of facilities, the wide range of animal food activities a facility might engage in, and the potential safety risks posed by some animal foods. These flexible CGMP requirements can be applied in various animal food production settings. In particular, there may be significant differences in how these CGMPs are implemented in facilities where undesirable microorganisms are a food safety concern for the type of animal food produced compared to facilities producing an animal food that is not as likely to be affected by undesirable microorganisms. This guidance provides additional explanation and examples for facilities to implement these CGMPs based on their unique facility and type of animal food.

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<sup>1</sup> We intend to provide more information regarding our current thinking on the evaluation and documentation of prerequisite programs in a hazard analysis in Draft Guidance for Industry (GFI) #245 – Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.

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### **C. Complying with the CGMPs**

CGMPs serve as baseline standards for producing safe animal food, including preventing insanitary conditions in the production of animal food. Animal food that is not manufactured, processed, packed, and held according to CGMPs may be considered adulterated (21 CFR 507.1(a)(1)(i-ii) and section 402(a)(3) and (4) of the FD&C Act). Full compliance with the CGMP provisions should reduce the likelihood that the animal food will be manufactured/processed, packed, or held under insanitary conditions (conditions that may cause the animal food to become contaminated or rendered injurious to health) or be otherwise unfit for food. An animal food does not need to contain a harmful substance to be adulterated. Compliance with CGMPs also should reduce the likelihood that the animal food will be adulterated within the meaning of section 402(a)(1) of the FD&C Act.<sup>2</sup> FDA will consider the risk and impact to public health in determining whether to pursue regulatory action because of a CGMP violation.

The FD&C Act prohibits introducing or delivering for introduction into interstate commerce adulterated animal food (section 301(a) of the FD&C Act). The FD&C Act also prohibits doing an act (e.g., violating CGMPs) that causes animal food to become adulterated after receipt of that food or its components in interstate commerce while the food is held by a facility for sale (section 301(k) of the FD&C Act). Among other remedies, the government has authority to file actions in court to remove adulterated animal food from the marketplace (seizure) and/or to prevent a firm from continuing to manufacture and distribute adulterated food (injunction) (sections 304 and 302 of the FD&C Act). Following the CGMP requirements for animal food is important because it may help prevent you from producing and distributing adulterated animal food.

In order to assist facilities in reviewing the implementation of CGMP requirements at their facility, we have included a Part 507 CGMP Self-Assessment Tool in Appendix B of this guidance. This tool groups the CGMPs in a way that may be useful when conducting a walk-through review of your facility. The tool describes the CGMP requirements and provides a blank "notes" box that a facility could use to take notes about their implementation of the CGMP requirements. A facility could use this information to determine additional CGMP implementation steps and to track their CGMP implementation over time. This tool may be useful to review your facility's implementation of the CGMPs initially and on a periodic basis, but a facility is not required to use this tool.<sup>3</sup>

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<sup>2</sup> Section 402(a)(1) of the FD&C Act states: "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

<sup>3</sup> Facilities are not required to use this tool and the tool is not subject to FDA requirements for: recordkeeping, submission to FDA, or disclosure to third parties or the public. Facilities may adapt this tool or create or use alternative tools that organize the requirements in a different way to review implementation of the CGMPs in their facility, but are not required to do so.

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### **D. Compliance with other regulatory requirements**

The CGMP regulations in 21 CFR part 507, subpart B contain FDA's minimum standards for current good manufacturing practice requirements for animal food. Compliance with other food safety regulations is discussed in this guidance, see section IV.D. Facilities covered by other animal food CGMPs (21 CFR 507.1(c)). In some cases, other regulatory requirements may apply to certain aspects of your animal food facility. Some examples include: zoning or land use requirements, building requirements, water supply requirements, liquid and solid waste disposal requirements, and occupational safety requirements. Animal food facilities should be aware of, and in compliance, with these other regulatory requirements that may apply to their facility.

## **IV. Am I Subject to the CGMP Requirements? (21 CFR Part 507, Subpart A)**

### **A. Who must follow the animal food CGMPs**

Establishments that are required to register as a food facility under section 415 of the FD&C Act because they manufacture, process, pack or hold animal food (which includes animal food ingredients) for consumption in the United States are required to follow these CGMPs, unless they qualify for an exemption (21 CFR 507.5(a) and (h)). (See Appendix A: Definitions for terms used in the CGMPs (21 CFR 507.3) for the definition of a facility for purposes of 21 CFR part 507.) We explain in this guidance who is exempt from these requirements, or subject to limited requirements; see section IV.B. Who does not have to follow the animal food CGMPs.

### **B. Who does not have to follow the animal food CGMPs**

#### **1. Animal food establishments that are not required to register (21 CFR 507.5(a))**

Establishments that are not required to register under section 415 of the FD&C Act do not have to follow these CGMP requirements. Establishments are not required to register if they do not meet the definition of a facility found in 21 CFR 1.227, or if they qualify for one of the exemptions from food facility registration found in 21 CFR 1.226.

Examples of establishments that do not have to register include: (1) farms; (2) facilities that are regulated exclusively, throughout the entire facility, by the United States Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act; (3) retail food establishments; (4) restaurants (pet shelters, kennels and veterinary facilities that provide food to animals are considered restaurants); (5) foreign facilities if the food undergoes further manufacturing/processing by another facility outside the United States; (6) transport vehicles that hold food only in the usual course of business as carriers; and (7) the private residence of an individual (21 CFR 1.226 and 1.227).<sup>4</sup> "Farm" has a specific definition in 21 CFR 1.227.

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<sup>4</sup> For more information about food facility registration, consult FDA's regulations found in 21 CFR part 1, subpart H, and guidance available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm331959.htm>.

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### **2. Activities not subject to the CGMP requirements (21 CFR 507.5(h))**

Some facilities that are required to register may meet one of the exemptions from the CGMP requirements in 21 CFR 507.5. Facilities solely engaged in the following activities are not subject to the CGMP requirements in 21 CFR part 507, subpart B: (1) holding and/or transportation of one or more raw agricultural commodities; (2) hulling, shelling, drying, packing and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); or (3) ginning cotton (without manufacturing/processing, such as extracting oil from cottonseed) (21 CFR 507.5(h)). Certain terms used in this exemption, such as "raw agricultural commodity," "holding," and "manufacturing/processing," are defined in 21 CFR 507.3. (See Appendix A: Definitions for terms used in the CGMPs (21 CFR 507.3) for selected definitions.)

The term "facility" is defined in 21 CFR 1.227, which says in part:

Facility means any establishment, structure, or structures under one ownership at one general physical location ... that manufactures/processes, packs, or holds food for consumption in the United States.... A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership....

One facility could have several operations in separate physical structures. For example, a facility may hold raw agricultural commodities in one structure and manufacture animal food in another structure. If a facility performs any activity subject to CGMP requirements (such as manufacturing/processing), in addition to those activities described in the exemptions to the CGMPs, then the entire facility is subject to the CGMP requirements<sup>5</sup>.

For more information about these exemptions, please see draft Guidance for Industry "Application of the "Solely Engaged" Exemptions in Parts 117 and 507" at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm580204.htm>.

### **C. CGMPs for facilities with human and animal food**

#### **1. Facilities with both human and animal food (21 CFR 507.1(d))**

Some facilities manufacture, process, pack, or hold food for both humans and animals. For example, a facility that manufactures salt may process some salt meeting certain specifications for human use and other salt meeting certain specifications for animal use.

In situations where a facility is required to follow both the human food CGMPs found in 21 CFR part 117, as well as the animal food CGMPs found in 21 CFR part 507, we are allowing the facility the choice between: (1) following the CGMPs in part 117 for its human and animal food;

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<sup>5</sup> For further explanation, see comment/response 212 in the preamble of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (80 FR 55908 at 55984-86 (Sept. 17, 2015)).

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or (2) following the CGMPs in part 117 for the human food and the CGMPs in 21 CFR part 507 for the animal food (21 CFR 507.1(d)).

In deciding which CGMPs to follow, we recommend that facilities consider how they are manufacturing, processing, packing, or holding the human and animal food. For example, if a facility has separate employees, production lines, and holding areas, it might prefer to follow 21 CFR part 117 for the human food and 21 CFR part 507 for the animal food. However, if a facility is using common employees, production lines, or holding areas for the human and animal food, it might prefer to follow 21 CFR part 117 for both the human and animal food.

### **2. Certain by-products of human food for use as animal food (21 CFR 507.12 and 507.28)**

In the process of producing human food, some facilities may generate by-products that can be used for animal food. Examples might include:

- wheat middlings generated while processing wheat for flour;
- grain products (e.g., hulls, bran, and germ) from other grain processing operations;
- peels, rinds, pomace, pulp, culls, or other similar material generated from processing fruits or vegetables for human consumption; or
- human food such as potato chips, cookies, bread, pastry products, and pasta that is not adulterated and is safe for use as animal food, but is not acceptable as human food for quality reasons such as the wrong size, shape, color, or texture.

In these situations, a human food facility may only be subject to limited holding and distribution CGMPs for by-products of human food production or the off-farm packing and holding of produce that is packed or held by that human food facility for distribution as animal food, if two conditions are met. First, the human food facility must be:

- (1) subject to and in compliance with 21 CFR part 117, subpart B and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations, or
- (2) subject to and in compliance with 21 CFR 117.8 (providing regulatory options for the off-farm packing and holding of produce) and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations.

Second, the facility must not further manufacture or process the human food by-products for use as animal food (21 CFR 507.12).

If the facility meets those two conditions, then once the by-product for use as animal food is separated from the human food, the facility must follow the limited requirements found in both 21 CFR 117.95 and 507.28<sup>6</sup> for the holding and distribution of the human food by-products for use as animal food (21 CFR 507.12(b)). These provisions do not apply to:

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<sup>6</sup> Sections 117.95 and 507.28 are identical and appear in both places for the convenience of the facilities to which the provisions apply.

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- a human food that is rejected for food safety reasons (i.e., because it has, or potentially has, been contaminated or adulterated),
- by-product from production of a human food rejected for food safety reasons, or
- by-product that is itself rejected for food safety reasons.

For a more complete discussion of human food by-products for use of animal food and the CGMP requirements found in 21 CFR 117.95 and 507.28, please see the Draft Guidance for Industry #239 entitled "Human Food By-Products for Use as Animal Food."<sup>7</sup>

#### **D. Facilities covered by other animal food CGMPs (21 CFR 507.1(c))**

If an animal food facility is covered by specific CGMPs, it also must comply with the requirements of those regulations in addition to the CGMPs in 21 CFR part 507 (21 CFR 507.1(c)). Thus, the CGMPs in 21 CFR part 507 may be considered "umbrella" CGMPs that apply broadly to animal foods, with certain animal foods requiring additional specialized CGMPs.

##### **1. Low Acid Canned Food (21 CFR part 113)**

Some animal food is a thermally processed low-acid food packaged in hermetically sealed containers (commonly called "low acid canned food"). In addition to the CGMPs in 21 CFR part 507, this animal food is subject to 21 CFR 500.23 and part 113, which includes CGMPs specific to low acid canned food.

##### **2. Medicated Feed (21 CFR part 225)**

Some animal food facilities manufacture, process, pack, or hold animal food that must comply with the 21 CFR part 507 CGMPs, as well as medicated feed that must comply with the medicated feed CGMPs for licensed or unlicensed mills in 21 CFR part 225. Facilities that are required to register under section 415 of the FD&C Act and are manufacturing, processing, packing, or holding medicated feed under 21 CFR part 225 are also subject to 21 CFR part 507, subpart B. For example, if a feed mill manufactures both non-medicated feed and medicated feed, its production of non-medicated feed is subject to 21 CFR part 507, subpart B, and its production of medicated feed is subject to 21 CFR part 225 and part 507, subpart B. Farms exempt from 21 CFR part 507 that manufacture medicated feed remain required to comply with 21 CFR part 225.

We recognize that in many instances animal food facilities will be using the same building, grounds, employees, supervisors, management, equipment, and utensils to perform operations under 21 CFR part 507, subpart B, and part 225. In instances where the facility is subject to both 21 CFR parts 225 and 507 and the CGMPs overlap, the facility must follow the more specific requirements found in 21 CFR part 507. However, the CGMPs under 21 CFR part 507, subpart B do not address the use of animal drugs in the manufacturing of medicated animal feed.

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<sup>7</sup> Draft Guidance for Industry #239 entitled "Human Food By-Products for Use as Animal Food" is available at <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf> or <https://www.fda.gov/food/guidanceregulation/fsma/ucm253380.htm>.

## *Contains Nonbinding Recommendations*

Therefore, the facility must also follow the specific requirements in 21 CFR part 225 related to the use of drugs in the manufacture of medicated animal feed, such as provisions for the handling of drugs and medicated mixes and for laboratory controls.

### **V. CGMP Training and Qualification Requirements (21 CFR Part 507, Subpart A) and Recordkeeping (21 CFR Part 507, Subpart F)**

#### **A. Management responsibilities (21 CFR 507.4(a)(1) and 507.4(c))**

The management of an establishment is required to ensure that all individuals who manufacture, process, pack, or hold animal food subject to the CGMPs are qualified to perform their assigned duties (21 CFR 507.4(a)(1)). Some factors that management might consider when ensuring an individual is qualified to perform assigned duties include: training, experience, and competency in carrying out their assigned duties. Training and experience may be previously obtained, or may be gained on the job under supervision until the individual can independently perform assigned duties. In order to ensure individuals are qualified to perform assigned duties, management should observe individuals' performance of their assigned duties with respect to food safety. If an individual is not able to consistently perform assigned duties in a competent manner that protects animal food from contamination or adulteration, management should consider whether additional actions are necessary. Additional actions may include providing additional training to the individual or reassignment of duties.

In addition, management must clearly assign responsibility for ensuring that individuals comply with the requirements of 21 CFR part 507 to supervisory personnel. The supervisory personnel must have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food (21 CFR 507.4(c)). The clear assignment of this responsibility to supervisory personnel might include: identifying these responsibilities as part of a position description, identifying who holds these responsibilities on an organizational chart, discussing these responsibilities with supervisory personnel, or including assigned responsibilities in a document such as a facility's standard operating procedures. There are many ways to clearly assign responsibility, but regardless of the method it is important that the individuals assigned the responsibility know and understand their responsibility.

#### **B. Qualifications and training of individuals who manufacture, process, pack or hold animal food (21 CFR 507.4(b))**

Individuals who supervise or perform manufacturing, processing, packing, or holding activities for animal food must: (1) be a qualified individual and (2) receive training in the principles of animal food hygiene and animal food safety. These requirements must be met even if the individual only works on a temporary or seasonal basis (21 CFR 507.4(b)).

A qualified individual is 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 (21 CFR 507.3). A current employee may be a qualified individual as a result of the training and experience they have received while working at the

## ***Contains Nonbinding Recommendations***

facility. A new employee may have previous experience related to their assigned duties, or they may need training to understand how to perform their assigned duties so that animal food is safely manufactured, processed, packed, or held. For example, a facility may provide training by reviewing with the new employee the facility's practices relevant to the employee's assigned duties that ensure the safety of the animal food.

Training in the principles of animal food hygiene and animal food safety must include information on the importance of employee health and personal hygiene, but the appropriate scope of the training depends on the animal food, facility and assigned duties (21 CFR 507.4(b)(2)). As we discuss throughout this guidance, the CGMP requirements may be applied differently for different types of animal food. The facility should consider these differences when determining what is appropriate information for training on animal food hygiene and animal food safety. When developing or selecting training, in addition to considering the animal food, facility, and assigned duties, management may also want to consider the individuals' prior experience and education. Training does not need to be specific to each person's assigned duties, but rather should take into account the range of duties to decide the scope of training(s) and whether a single training would be appropriate for all individuals, or separate audience-specific trainings would be more appropriate. The training may be provided by facility personnel, an external source, or a combination of both. Training may be provided by any reasonable means, for example, on the job, in a classroom setting, or online.

Training in the principles of animal food hygiene and animal food safety does not have to be performed at a specific frequency; however, individuals should receive training prior to independently performing their assigned duties. In addition, most facilities should also provide some form of refresher training.

### **C. Training recordkeeping (21 CFR 507.4(d))**

Facilities are required to keep records that document the training on the principles of animal food hygiene and animal food safety for those who supervise or perform manufacturing, processing, packing, or holding activities for animal food (21 CFR 507.4(d)). The records also must include the items listed in 21 CFR 507.202(b), as explained in section V.D.2. The establishment can generate training records in a format that is convenient, for example: (1) training check-list for new employees (e.g., that includes a description of on the job training activities); (2) sign in sheets for specific trainings; or (3) computerized training records. Facilities may use training documentation systems already in use to document other training (e.g., Occupational Safety and Health Administration (OSHA) training).

The record(s) for training in the principles of animal food hygiene and animal food safety must be kept in compliance with the recordkeeping requirements in 21 CFR part 507, subpart F as discussed next in section V.D. Recordkeeping requirements (21 CFR Part 507, Subpart F).

## *Contains Nonbinding Recommendations*

### **D. Recordkeeping requirements (21 CFR Part 507, Subpart F)**

#### **1. CGMP Records subject to the requirements of 21 CFR part 507, subpart F (21 CFR 507.200)**

Records required by 21 CFR part 507 are subject to the recordkeeping requirements of 21 CFR part 507, subpart F (21 CFR 507.200(a)). The only record requirements associated with the 21 CFR part 507 CGMPs are those that document training on the principles of animal food hygiene and animal food safety as required in 21 CFR 507.4(d) ("required training records").

The required training records 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 (21 CFR 507.200(c)). An example of a duly authorized representative of the Secretary of Health and Human Services is a state investigator holding an FDA commission. Failure to provide access to the required training records during an inspection could be considered a violation.

If required training records are obtained by FDA (for example, during an inspection or investigation), they are subject to the records disclosure requirements of 21 CFR part 20 (21 CFR 507.200(b)). This means FDA may release them in response to a Freedom of Information Act request, subject to the requirements and exemptions of part 20. Some exemptions that might apply to records subject to this rule protect: trade secrets and confidential commercial or financial information, and information that would constitute a clearly unwarranted invasion of personal privacy of the individuals involved (for example, home addresses and telephone numbers, personal email addresses). FDA may redact or withhold records from a requestor if a record meets these, or other exemptions. For more information about Freedom of Information at FDA, see <https://www.fda.gov/RegulatoryInformation/FOI/ucm390370.htm>.

#### **2. General requirements applying to records (21 CFR 507.202)**

The required training records must 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. The records must be accurate, indelible, and legible. The records must be created concurrently with performance of the documented activity (21 CFR 507.202(a)). Records that are not easily erased or changed (for example, records written in ink instead of pencil) are considered indelible. Records that are created concurrently with an activity are created at the same time as the activity.

Required records must include: (1) information adequate to identify the plant or facility; (2) the date and, when appropriate, the time of the activity documented; and (3) the signature or initials of the person performing the activity (21 CFR 507.202(b)). We consider the person performing the activity to be the trainee. We recommend that a supervisor responsible for ensuring compliance under 21 CFR 507.4(c) also sign the record.

### *Contains Nonbinding Recommendations*

If you are using electronic records (as defined in 21 CFR 11.3(b)(6)) to meet the recordkeeping requirements for 21 CFR part 507 (including the CGMPs), those electronic records are exempt from the requirements in 21 CFR part 11. If the electronic record is also intended to meet a recordkeeping requirement in a part other than 21 CFR part 507, that electronic record remains subject to 21 CFR part 11 (21 CFR 507.202(c)).

#### **3. Requirements for record retention (21 CFR 507.208) and the use of existing records (21 CFR 507.212)**

Required records must be retained at the plant or facility for at least 2 years after the date they were prepared (21 CFR 507.208(a)). This includes the required training records (documenting the training in principles of animal food hygiene and animal food safety). For example, if a facility offers initial and periodic training in the principles of animal food hygiene and animal food safety, it would retain at least the most recent two years of training records for each individual required to have the training. Even if a facility does not provide periodic training, it must maintain the individual's initial training records for at least two years. The records can be stored offsite if they can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location (21 CFR 507.208(c)).

If you already keep the required training records to comply with other regulations, or for any other reason, you can use those records to meet these recordkeeping requirements as long as they contain all of the required information and satisfy the other relevant requirements of 21 CFR part 507, subpart F. If they do not contain all of the required information, you can supplement them with additional records as necessary to include all of the required information and satisfy the requirements of 21 CFR part 507, subpart F (21 CFR 507.212(a)). The required training records do not need to be kept in one set of records. If existing records contain some of the required information, any additional information required may be either kept separately or combined with the existing records (21 CFR 507.212(b)). If you use multiple records to meet the requirements of 21 CFR part 507, subpart F, the records should reflect how they are associated with each other.

#### **VI. Current Good Manufacturing Practice for Animal Food (21 CFR Part 507, Subpart B)**

##### **A. Personnel (21 CFR 507.14)**

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 as necessary to protect against the contamination of animal food (21 CFR 507.14(a)). Persons working in direct contact with animal food may include employees, contractors, and visitors. Methods for conforming to hygienic practices and maintaining cleanliness include: 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 could fall into animal food, equipment, or containers; storing clothing and personal belongings in

### *Contains Nonbinding Recommendations*

areas other than where animal food is exposed or where equipment or utensils are cleaned; and taking any other precautions necessary to protect against contamination of animal food, animal food contact surfaces, or animal food-packaging materials (21 CFR 507.14(b)).

To the extent necessary to protect against the contamination of animal food, management of the establishment must ensure that personnel maintain adequate personal cleanliness (21 CFR 507.14(b)(1)). Management of the establishment should set expectations for personal cleanliness based on the plant, the individual's role at the plant, and the type of animal food. For example, management expectations for personnel working in a livestock animal food plant might allow clothes that are dusty when working in the plant, but might not allow clothes covered with oil, grease, excessive dirt, or other foreign materials that may contaminate the animal food. In contrast, a pet food plant concerned about microorganism contamination might require that personnel use protective clothing and dedicated plant footwear while working in the plant.

Management of the establishment must ensure that personnel wash hands thoroughly using an adequate hand-washing facility as necessary and appropriate to protect against contamination (21 CFR 507.14(b)(2)). Expectations for employee hand washing might also vary depending on the type of plant, the animal food being produced, and an employee's duties at the plant. Personnel should wash their hands as necessary and appropriate to protect against contamination of animal food from foreign materials (such as grease or dirt). In certain facilities where contamination by undesirable microorganisms is a concern for the type of animal food, hand-washing should occur when individuals enter the food production area. Hand-washing should also occur after the individual handles or touches anything other than food or food contact surfaces, such as the floor, door handles, or hoses, and before they handle any finished animal food that has been processed to reduce or destroy microorganisms. Additional information about adequate hand-washing facilities is discussed in this guidance, see section VI.D.5. Hand-washing facilities (21 CFR 507.20(e)).

To the extent necessary to protect against the contamination of animal food, management of the establishment must ensure that personnel remove or secure jewelry and other objects that might fall into animal food, equipment, or containers (21 CFR 507.14(b)(3)). Examples of objects that could fall into the animal food, equipment, or containers include: pens, sunglasses, gloves, tools, keys, pocket knives, or cell phones. Personnel should consider whether items stored in outside pockets (such as shirt pockets) might be able to fall out during operations, and if so, remove these items or place them in a more secure pocket.

To the extent necessary to protect against the contamination of animal food, management of the establishment must also ensure that personnel store clothing and other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned (21 CFR 507.14(b)(4)). Management should designate an area to store these items where they cannot fall into or be accidentally incorporated into the animal food, equipment or utensils. Some facilities have separate areas to store these items, such as break rooms or lockers. Other facilities may not have a separate area, but may instruct personnel to store items within the plant in a specific location that is away from exposed animal food and equipment or utensil cleaning activities. For example, a facility may instruct personnel to store jackets adjacent to a cold storage area on wall hooks that are located away from exposed animal food.

## ***Contains Nonbinding Recommendations***

In addition to these specific hygienic practices, to the extent necessary to protect against the contamination of animal food, management of the establishment must take any additional precautions that are necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials (21 CFR 507.14(b)(5)). For example, in some plants it may be appropriate for employees to wear hair and beard nets to protect against the contamination of animal food.

### **B. Plant and grounds (21 CFR 507.17)**

#### **1. Maintaining the grounds around an animal food plant (21 CFR 507.17(a))**

Grounds around a plant under control of the management of the establishment must be kept in a way that will protect against the contamination of the animal food (21 CFR 507.17(a)). The grounds are considered to be under the control of management when the property/land is owned or leased by the facility or used with permission. The grounds are close enough to be "around" the plant when they could impact plant operations. Public right of ways or neighboring properties under different ownership would not be considered under the control of the management.

The grounds must be maintained by properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may attract, harbor, or serve as a breeding place for pests (21 CFR 507.17(a)(1)). Facilities should perform these ground maintenance activities at a regular frequency so that the grounds conditions are not an attraction or harborage for pests.

Driveways, yards and parking areas must be maintained so they are not a source of contamination for exposed animal food (21 CFR 507.17(a)(2)). For example, these areas should be well-drained and free of debris to reduce the introduction of foreign material into the animal food. While a few puddles from a recent rain may not be a source of contamination for animal food, low-lying areas that pool water for significant periods of time may cause contamination, especially if they are located near areas where exposed animal food is stored outdoors.

The plant grounds must have adequate drainage of areas that may contribute to contamination of animal food (21 CFR 507.17(a)(3)). Drainage should remove water away from the plant, or animal food storage areas. Driveways and entrances should be drained to minimize standing water, mud, dirt or waterborne debris that may contribute to contamination of animal food. Adequate drainage also reduces the potential for standing water, which may attract pests.

Waste must be treated and disposed of in a way that it will not be a source of contamination where animal food is exposed (21 CFR 507.17(a)(4)). Waste could include sewage, other liquid waste, or processing waste. Portable restrooms should be placed away from animal food so if a leak occurs it does not contaminate animal food. Processing waste should be held in appropriate receptacles and removed from the site regularly. If toxic materials are used to treat waste, they must be stored away from animal food in compliance with 21 CFR 507.19(d) as explained in this guidance, see section VI.C.2. Use of toxic materials in animal food facilities (21 CFR 507.19(d)).

## *Contains Nonbinding Recommendations*

### **2. Plant size, construction, and design (21 CFR 507.17(b))**

A 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 (21 CFR 507.17(b)). We do not expect existing plants to be redesigned and reconstructed to meet the requirements in 21 CFR 507.17(b). Maintenance, repair, retrofitting, or other changes to the existing facility, equipment, or plant procedures may be used to meet the requirements.

There must be adequate space between equipment, walls, and stored materials to allow for cleaning and maintenance of equipment and other employee duties (21 CFR 507.17(b)(1)). Other employee duties may include equipment inspection and pest control. The space between walls and equipment in the manufacturing areas should be cleaned and maintained to prevent harborage of pests or contamination from dirt or accumulated product.

The plant must be constructed in a way that drip or condensate from fixtures, ducts, and pipes are not a source of contamination (21 CFR 507.17(b)(2)). This should include planning for dripping from leakage. When possible, fixtures, ducts, and pipes should not be located over areas where animal food or animal food-contact surfaces are located. Condensation can be controlled by using drip pans to divert water away from animal food, or pipe insulation to prevent sweating. Furthermore, these items should be maintained in good physical repair to prevent paint chips or pieces of insulation from being a source of contamination. See section VI.C.1. Cleaning and maintenance (21 CFR 507.19(a)-(c)).

Adequate ventilation must be provided where necessary and appropriate to minimize vapors and fumes in areas where they may contaminate animal food. When ventilation is used to remove vapors and fumes in the animal food plant, it must be done in a way that minimizes the potential for contamination of animal food (21 CFR 507.17(b)(3)). Similarly, ventilation used to remove dust or lower heat in high heat situations should be done in a way that minimizes possible contamination. Ventilation may be mechanical, such as using fans or venting systems, or may be natural, such as opening doors and windows to allow air movement. When ventilation systems are used, they must be cleaned and maintained so that they do not contaminate the animal food with dust or other contaminants (see 21 CFR 507.19(a)). When windows, doors, or vents are open to the exterior for ventilation, measures (e.g., screens) should be in place to minimize pests entering the plant.

The plant must have 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 (21 CFR 507.17(b)(4)). Lighting should be bright enough so that employees can effectively perform their assigned duties in these areas.

Light bulbs, fixtures, skylights, or other glass items suspended over exposed animal food in any step of preparation must be shatter-resistant to protect against the contamination of animal food from glass breakage (21 CFR 507.17(b)(5)).

## *Contains Nonbinding Recommendations*

### **3. Plant protection of bulk animal food stored outdoors (21 CFR 507.17(c))**

If an animal food plant stores bulk animal food or ingredients outside, it must protect the animal food from contamination by any effective means (21 CFR 507.17(c)). Protective coverings must be used where necessary and appropriate to protect against contamination (21 CFR 507.17(c)(1)). For example, it may be necessary and appropriate to cover animal food with a tarp or other similar material to protect against contamination from outdoor elements (e.g., rain, wind-blown debris) or pests (e.g., bird or rodent droppings, nesting materials). On the other hand, it may not be necessary to cover commodities that are stored outdoors during dry weather, or stored outdoors for time periods where the weather is not likely to contaminate the animal food (e.g., for short time periods or time periods when the regional weather is typically dry). Also, it may not be necessary to cover commodities that will not be adversely impacted by weather.

The area around and above the animal food stored outdoors must be controlled in a manner to eliminate pest harborage (21 CFR 507.17(c)(2)). This could include controlling vegetation (e.g., mowing), providing drainage to prevent standing water, and removing trash, old or decomposing animal food, or unused or broken equipment (e.g., junk pile). In addition, the plant personnel may need to store bulk food away from the eaves of buildings, or remove bird and other pest nests from the eaves of buildings so that they do not serve as a source of contamination to the animal food.

The plant must also check on a regular basis for pests and pest infestation. In addition, the condition of the animal food stored outdoors in bulk must be checked on a regular basis for product condition related to safety of the animal food (21 CFR 507.17(c)(3)). Product condition related to food safety includes spoilage or contamination. A pest control plan should be used that specifies monitoring locations and frequency. Bait stations, or pest proof coverings or other means can be used to control pests. Bait stations or toxic materials must not serve as a potential source of contamination for the animal food (21 CFR 507.19(d)(2)). Toxic materials must be stored in accordance with 21 CFR 507.19(d). See VI.C.2. Use of toxic materials in animal food facilities (21 CFR 507.19(d)).

### **C. Sanitation (21 CFR 507.19)**

#### **1. Cleaning and maintenance (21 CFR 507.19(a)-(c))**

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)). For example, roofs should be maintained so that they do not leak.

All surfaces (food-contact and non-contact) of utensils and equipment must be cleaned and maintained to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials (21 CFR 507.19(b)). Utensils may include items such as buckets, shovels, or scoops. Utensil and equipment maintenance should ensure that parts or pieces will not break or fall off and contaminate the animal food. The cleaning procedures

## ***Contains Nonbinding Recommendations***

necessary to prevent animal food adulteration may vary depending on the type of product being manufactured.

For example, in pet food facilities sanitation is critical for pathogen control in finished pet food, which will be handled by pet owners. Typically, wet cleaning and sanitizing is used in these types of facilities to reduce pathogens. If animal food contact surfaces are wet cleaned, the surfaces must be thoroughly dried before subsequent use, when necessary (21 CFR 507.19(b)(1)). In wet processing, it may be necessary to clean and sanitize to protect against the introduction of undesirable microorganisms into the animal food. If so, 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 (21 CFR 507.19(b)(2)).

In contrast, livestock animal food operations generally avoid the use of water and liquid cleaning compounds because they need to maintain dry surfaces to move grains, oilseeds, and other predominantly dry ingredients through mixing operations for dry finished products. Instead, livestock animal food operations may use dry cleaning methods such as scraping, sweeping, vacuuming, flushing, or sequencing.

When necessary, equipment must be disassembled for thorough cleaning (21 CFR 507.19(b)). Equipment should be disassembled for cleaning at a frequency directed by the manufacturer's instructions, or when the equipment cannot be adequately cleaned without disassembly and could contaminate the animal food (e.g., due to build-up or residue).

Regardless of the type of animal food plant, cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use (21 CFR 507.19(c)). We recommend reading the label of any cleaning compounds or sanitizing agents to determine their proper use (e.g., acceptable for animal food-contact surfaces). Cleaning compounds and sanitizing agents should be used according to their labeled directions.

Finally, utensils and equipment must be stored as necessary to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials (21 CFR 507.19(b)). This may include storing utensils and equipment in a dry area, away from raw materials or ingredients, under protective covering, inverted, or in another way that protects against contamination.

### **2. Use of toxic materials in animal food facilities (21 CFR 507.19(d))**

The only toxic materials that may be used or stored in the area of the plant where animal food is manufactured, processed, or exposed are those that are needed for cleaning and sanitizing, plant and equipment maintenance and operation, laboratory testing procedures, and use in the plant's operations (21 CFR 507.19(d)(1)).

These toxic materials (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 (21 CFR 507.19(d)(2)). We recommend leaving toxic materials in their original containers with the labeling intact when

### ***Contains Nonbinding Recommendations***

possible. If toxic materials are transferred to another container, the container should identify the contents, and instructions for proper use should be readily available for employees (e.g., labeling, safety data sheets (SDS)). Toxic materials should be stored as recommended by the manufacturer (e.g., recommendations for temperature, light sensitivity).

Other toxic materials such as fertilizers and pesticides not meeting the description in 21 CFR 507.19(d)(1) must be stored only in areas of the plant where animal food is not manufactured, processed, or exposed (21 CFR 507.19(d)(3)). These toxic materials should be separated from animal food in the plant by either sufficient space or a sufficient physical barrier so they are not able to contaminate the animal food. When determining how much space or what type of physical barrier is sufficient the plant should consider the possible ways the toxic materials may contaminate the animal food, such as leakage or spillage.

In some isolated situations one substance is manufactured for both animal food use and soil nutrient or fertilizer use. In these instances, so long as the substance is handled according to the CGMP and other relevant animal food safety requirements, the substance could be manufactured, processed, packed, or held in the same plant, on the same equipment.

#### **3. Excluding pests (507.19(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 (21 CFR 507.19(e)). The management of the establishment should develop a comprehensive pest control plan that includes regular monitoring for the presence of pests and measures to exclude pests, such as: blocking possible pest entry points (e.g., using screens, keeping doors and windows secured, caulking holes), using pest trapping devices, and cleaning to remove pest harborage or attractants. Using cats or other animals as a method of pest exclusion is not acceptable because their presence can also lead to the contamination of animal food.

Pesticides may be used in the plant 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)). When using pesticides, we recommend reading and following instructions on the labeling. For more information on the proper use of pesticides in the plant see section VI.C.2. Use of toxic materials in animal food facilities (21 CFR 507.19(d)).

#### **4. Trash (21 CFR 507.19(f))**

Trash must be conveyed, stored, and disposed of in such a way that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies and ground surfaces, and minimizes the potential for trash to attract or harbor pests or serve as a breeding place for pests (21 CFR 507.19(f)).

## *Contains Nonbinding Recommendations*

### **D. Water supply and plumbing (21 CFR 507.20)**

#### **1. Adequate water supply and water source (21 CFR 507.20(a))**

Water used by the plant must be adequate for the operations and derived from an adequate source (21 CFR 507.20(a)(1)). "Adequate" means that the water supply must be sufficient for its intended purpose, in keeping with good public health practice (see 21 CFR 507.3). The term "adequate" provides flexibility for an animal food facility to comply with this requirement in a way that is most suitable for its facility. For example, a water source may be adequate for some plant uses (e.g., for use in a boiler or other non-food-contact equipment) but not for others (e.g., animal food ingredient). The water supply should provide sufficient water volume to support the plant operations (e.g., manufacturing, processing, and cleaning). Water treatment methods may be used to improve the water quality or to remove contaminants.

Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where it is 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 (21 CFR 507.20(a)(2)). Temperature and pressure requirements will vary for the type of manufacturing, processing, packing or cleaning operations that are being performed, and the plant should have suitable water temperature and pressure to adequately perform the activity without creating the potential to contaminate animal food. Some equipment may require certain temperatures or pressure and the equipment manufacturer's instructions should be followed by the plant. Water pressure should be sufficient to easily rinse debris and soap from hands, equipment, utensils, and food-packaging materials.

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)). Considering the intended use, plant management may set water standards, including deciding the water should be free of certain chemical (including radiological), or biological contaminants. The source should not introduce contaminants that could adulterate the animal food. The management of the establishment should monitor the water for relevant contamination and if necessary use water treatment or switch to an alternate water source if the water contains a contaminant that is relevant to the safety of the animal food. The water source should be in compliance with any other applicable water regulations (e.g., local, state, or Environmental Protection Agency). 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)).

#### **2. Plumbing design, installation, and maintenance (21 CFR 507.20(b))**

Plumbing must be designed, installed, and maintained to carry adequate quantities of water to required locations throughout the plant and to properly convey sewage and liquid disposable waste from the plant (21 CFR 507.20(b)(1) and (2)). The plumbing should be of sufficient size to carry water throughout the plant while maintaining sufficient water pressure. Plumbing should convey sewage and liquid disposable waste from the plant without blockages or other issues that may lead to the contamination of the animal food.

### ***Contains Nonbinding Recommendations***

Plumbing must be designed, installed, and maintained to avoid being a source of contamination to the animal food, water supplies, equipment, or utensils and to avoid creating an unsanitary condition (21 CFR 507.20(b)(3)). For example, sewage plumbing should not be installed above animal food or animal food-contact surfaces. If existing plumbing is installed over areas where it could contribute to animal food contamination, design features such as drip pans may be necessary to avoid contamination of the animal food. Plumbing should be properly installed and maintained so it does not drip or condense onto animal food or animal food-contact surfaces. See also section VI.B.2. Plant size, construction, and design (21 CFR 507.17(b)).

Plumbing must be designed, installed, and maintained in a way that provides adequate floor drainage in all areas where flooding-type cleaning is used on floors, or where normal operations release or discharge water or other liquid waste on the floor (21 CFR 507.20(b)(4)). Drainage should be designed, installed, and maintained to immediately remove the standing water so that standing water cannot contaminate the animal food or animal food contact surfaces. Vacuuming standing water is acceptable in areas where flooding-type cleaning is not used on floors and normal operations do not release or discharge water or other liquid waste on floors.

Plumbing must be designed, installed, and maintained so that there is no backflow and there is no cross-connection between discharge pipes and pipes that carry water for animal food or animal food manufacturing (21 CFR 507.20(b)(5)).

#### **3. Disposal of sewage and liquid waste (21 CFR 507.20(c))**

Sewage and liquid waste must be disposed of through an adequate sewage system or through other adequate means (21 CFR 507.20(c)). Sewage systems also should be in compliance with other applicable regulations. The sewage system should have sufficient capacity to handle the amount of sewage and liquid waste generated by the animal food plant. Some waste, such as fats and oils, may not be suitable for disposal in sewage systems. Liquid waste not suitable for sewage systems should be disposed of through appropriate means (e.g., fat and oil rendering, industrial oil disposal).

#### **4. Toilet facilities (21 CFR 507.20(d))**

Each plant must provide employees with adequate, readily accessible toilet facilities (21 CFR 507.20(d)). In many cases, the animal food plant will have toilet facilities in the building. In some instances, the animal food plant may need to arrange to share common toilet facilities in a shared building, or with a nearby building. For seasonal operations or operations without a building, arrangements for access to toilet facilities may need to be made with a nearby building or for the use of portable 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)).

#### **5. Hand-washing facilities (21 CFR 507.20(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

## *Contains Nonbinding Recommendations*

food-packaging materials (21 CFR 507.20(e)). Hand-washing facilities should be provided as part of the toilet facilities. Additional hand-washing facilities may be needed throughout the plant, especially if microbiological contamination is a food safety concern for the type of animal food being produced. If this is the case, hand-washing facilities should be conveniently located near operations where employees may be switching between non-food-contact surfaces and food-contact surfaces, or switching between handling raw materials or ingredients and finished animal food. For seasonal operations or operations without a building, arrangements may need to be made for access to gravity fed hand-washing facilities. Hand-washing facilities should include running water, soap, and a method to dry hands after washing. We recognize that there may be some situations where hand-washing with water is not necessary for the production of safe animal food. The use of waterless hand cleaners (including hand sanitizers) may be adequate under these circumstances.

### **E. Equipment and utensils (21 CFR 507.22)**

#### **1. Requirements for equipment and utensils used to manufacture, process, pack, and hold animal food (21 CFR 507.22(a))**

All plant equipment and utensils must be designed, and constructed of material and workmanship to be adequately cleanable. In addition, these equipment and utensils must be properly maintained. These requirements apply to all equipment and utensils that are used in manufacturing, processing, packing, and holding animal food, including those that do not come into contact with animal food (21 CFR 507.22(a)(1)). All equipment and utensils should be constructed of materials able to withstand the plant's regular cleaning procedures and should be replaced or repaired when they can no longer be easily cleaned. Disposable utensils should be disposed of after one use or according to the manufacturer's recommendations.

Equipment and utensils used in manufacturing, processing, packing, and holding animal food must be designed, constructed, and used so that they do not adulterate the animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants (21 CFR 507.22(a)(2)). Food-grade lubricants must be used when the lubricant will become part of the animal food. We recommend that food-grade lubricants be used as a precaution when the lubricant unintentionally could come into contact with the animal food or an animal food-contact surface, for example, when lubricant is used near a food-contact surface.

When it is unlikely that a lubricant can come into contact with animal food or an animal food-contact surface, non-food grade lubricants can be used but the lubricated equipment and utensils must be designed, constructed, and used to avoid adulteration of animal food with the non-food grade lubricant.

Metal should not be corroded or produce shavings or have pieces that can easily break off that could introduce a physical hazard into the animal food. We recommend that equipment and utensils be constructed of materials that will not easily deteriorate under the conditions of use. For example, equipment or utensils constructed of wood or plastic should not easily splinter or break because this could introduce a physical hazard into the animal food.

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When equipment used in manufacturing, processing, packing, and holding animal food is placed in the plant, it must be installed to facilitate cleaning and maintenance of the equipment and adjacent spaces (21 CFR 507.22(a)(3)). There should be enough space to allow for cleaning, maintenance, and pest control around each piece of equipment.

Animal food-contact surfaces must be made of materials that withstand the environment of their use, the action of animal food, and, if applicable, the action of cleaning compounds and procedures and sanitizing agents (21 CFR 507.22(a)(4)(i)). The material should not crack, peel, break, or otherwise cause contamination of the animal food.

Animal food-contact surfaces must be made of materials that are nontoxic (21 CFR 507.22(a)(4)(ii)). They should be safe for use with the animal food manufactured, processed, packed, or held at the plant. The use of the material should not be hazardous to the animals' health.

Animal food-contact surfaces must be maintained to protect animal food from contamination (21 CFR 507.22(a)(4)(iii)). Animal food-contact surfaces should be kept in working order, repaired, and replaced when necessary so that the animal food does not become contaminated.

### **2. Design, construction, and maintenance of holding, conveying, manufacturing, and processing systems (21 CFR 507.22(b))**

Holding, conveying, manufacturing, and processing systems must be designed, constructed, and maintained in a way to protect against the contamination of animal food. These types of systems include gravimetric, pneumatic, closed, and automated systems (21 CFR 507.22(b)). Systems may be composed of several different pieces of equipment used together to manufacture, process, pack, or hold the animal food. When a piece of equipment becomes part of a system, its use in the system must be in a manner that protects against contamination of the animal food.

### **3. Freezers and cold storage compartments (21 CFR 507.22(c))**

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)). A temperature-measuring device for each compartment is necessary because the temperature may be different in each compartment. The plant does not have to use a continuous monitoring device or temperature-recording device; however the thermometer or other temperature-measuring device must be accurate.

### **4. Instruments and controls (21 CFR 507.22(d))**

If the plant uses instruments or controls to measure, regulate, or record temperatures, pH, water activity ( $a_w$ ), or other conditions that control or prevent the growth of undesirable microorganisms in animal food, these instruments or controls must be accurate, precise, adequately maintained, and adequate in number for their designated uses (21 CFR 507.22(d)). Instruments or controls selected should be sensitive enough to provide the level of precision needed by the plant. The instruments or controls should be used, calibrated, and maintained

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according to the manufacturer's instructions. The plant should have enough devices for routine operations. For example, if a plant has two production lines that need to reach certain temperatures to control the growth of undesirable microorganisms, the plant should have a temperature-measuring device for each production line.

### **5. Compressed air or other gases (21 CFR 507.22(e))**

When compressed air or other gases mechanically introduced are used in animal food, or used to clean animal food-contact surfaces or equipment, it must be used in a way that protects against the contamination of animal food (21 CFR 507.22(e)). For example, compressed air may be used to clean the animal food plant, equipment, or conveyance system, or to operate bulk holding bin doors or gates. The compressed air must not be used in a way that blows dirt, debris, or other contaminants into the animal food or onto animal food-contact surfaces.

## **F. Plant operations (21 CFR 507.25)**

### **1. Management oversight of plant operations (21 CFR 507.25(a))**

The successful implementation of food safety initiatives in a plant, including these CGMPs, depends on management's commitment to providing direction and oversight over plant operations. Animal food safety is best achieved by developing and implementing a system of procedures, practices, and checkpoints that are designed to produce safe animal food. The role of management in developing, implementing, and enforcing the use of these procedures and practices will be critical to the success of the plant's animal food safety system. The CGMPs include requirements that set the expectation for management's oversight of plant operations.

Management of the establishment must ensure that the CGMP requirements of 21 CFR part 507, subpart B are followed for all animal food manufacturing, processing, packing, and holding operations (including receiving, inspecting, transporting, and segregating) (21 CFR 507.25(a)(1)). Ultimately, compliance with the CGMPs is the responsibility of the management of the establishment. We recommend that management of the establishment develop and implement a system of oversight and checks (e.g., standard operating procedures) that ensures that the physical facilities meet the CGMPs and the individuals working at the plant comply with the CGMPs as they perform their duties.

In addition, management of the establishment must ensure that animal food is accurately identified (21 CFR 507.25(a)(2)). This includes any raw materials, other ingredients, rework, and finished animal food. 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. Plant personnel should be able to accurately identify animal food, including raw materials, other ingredients, rework, or finished animal food within the plant so that animal food is not commingled, substituted, or incorrectly formulated in a manner that results in adulterated animal food.

Management of the establishment must ensure animal food-packaging materials are safe and suitable (21 CFR 507.25(a)(3)). Animal food-packaging should be appropriate for the type of

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animal food and should not contaminate the animal food. The packaging should protect the animal food by preventing contamination from the environment and minimizing deterioration.

Management of the establishment must ensure that the overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for the function (21 CFR 507.25(a)(4)). A more specific description of the training and education requirements for supervisors can be found in section V.A. Management responsibilities, where we discuss the requirements of 21 CFR 507.4(c).

Management of the establishment must ensure adequate 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 (21 CFR 507.25(a)(5)). There are many ways to implement this requirement. Management could conduct regular checks to ensure policies and procedures are followed and effective. In addition, management could direct employees to verify that equipment and automated systems are performing correctly. For example, employees might be required to routinely verify the accuracy of scales, or other measuring devices. In addition, they may be required to perform a visual check when the computer system says a bin is empty to ensure it is in fact empty before refilling.

Management of the establishment must ensure that chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination (21 CFR 507.25(a)(6)). Management should review their operations to determine if and when testing procedures are necessary to identify sanitation failures or possible animal food contamination. Management should choose appropriate testing procedures that will accurately identify a sanitation failure, or possible animal food contamination. Management should also ensure that the testing procedures are carried out correctly so that they will produce accurate results. Generally, we anticipate facilities will use these testing procedures as necessary to confirm adherence to CGMPs. For example, a facility may test to confirm adequate cleaning of a line. Or a facility may test food for a sanitation failure when one is suspected. In addition, if a piece of equipment malfunctions and metal fragments are a possible source of animal food contamination, management should use a method such as magnets, metal detectors, or x-ray machines on the finished product to detect this possible animal food adulteration.

When animal food has become adulterated, management of the establishment must ensure that it is rejected, disposed of, or if appropriate it is treated or processed to eliminate the adulteration. Disposal must be done in a way that protects against the contamination of other animal food (21 CFR 507.25(a)(7)). Management should refer to FDA's Compliance Policy Guide Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use<sup>8</sup> to determine whether it is appropriate to treat or process the animal food to eliminate the adulteration. Disposal methods should also comply with other applicable regulatory requirements.

Finally, management of the establishment must ensure that all 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 in order to protect against

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<sup>8</sup> Compliance Policy Guide Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use, <https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074694.htm>.

## ***Contains Nonbinding Recommendations***

the contamination of the animal food (21 CFR 507.25(a)(8)). 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 (21 CFR 507.3). Pathogens are microorganisms of public (human or animal) health significance (21 CFR 507.3). Microorganisms that are pathogens for some animal species may not be pathogens for other animal species. We recommend the facility considers temperature, pH levels, moisture, and other conditions or parameters that will minimize the potential for the growth of undesirable microorganisms in the animal food. The necessary conditions or parameters may vary depending on the types of animal food and their intended use. For example, a plant that manufactures livestock animal food may need to ensure the ingredients are not exposed to excessive moisture that might lead to decomposition. Whereas, a plant that is manufacturing, processing, packing, holding, or distributing certain animal food that will not receive a heat treatment (for example, raw pet food) should keep the animal food at a temperature low enough to control the growth of undesirable microorganisms.

### **2. Requirements for raw material and other ingredients (21 CFR 507.25(b))**

Raw materials and other ingredients must be examined to ensure they are suitable for manufacturing and processing into animal food. These raw materials and other ingredients must be handled under conditions that will protect against contamination and minimize deterioration (21 CFR 507.25(b)(1)). An examination of raw materials or other ingredients may include: (1) reviewing specifications, guarantees, or other associated information received by the facility; (2) performing a visual check of the animal food or its packaging; (3) performing relevant sampling and testing; (4) getting information from the transporter about shipping conditions (e.g., transport time, weather); and/or (5) checking incoming temperatures for refrigerated or frozen ingredients.

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 (21 CFR 507.25(b)(1)(i)). An examination of shipping containers may include basic activities such as a simple sensory examination of the containers (e.g., looking for broken bags or signs of inappropriate moisture, smelling for off-odors). Receiving personnel should be aware of the condition of the shipping container or vehicle, and consider whether its condition could have contaminated the animal food or indicates potential contamination (for example, signs of rodent chewing). This examination should focus on contamination or deterioration that will not or cannot be addressed by the receiving facility's normal processing steps (e.g., heat treatment, use of magnets). In addition, a facility receiving raw materials and other ingredients must comply with applicable requirements for a receiver in 21 CFR part 1, subpart O, "Sanitary Transportation of Human and Animal Food."

Raw materials must be cleaned as necessary to minimize contamination (21 CFR 507.25(b)(1)(ii)). For example, a plant manufacturing a pet food from vegetables such as sweet potatoes may need to clean them in order to minimize contamination from soil. In other instances it may not be necessary to clean raw materials to minimize contamination. For example, corn used in livestock animal food may contain corn dust that would not require removal to minimize contamination.

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Raw materials, rework, and other ingredients must be stored in containers designed and constructed to protect against contamination and deterioration. In addition, they must be 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 (21 CFR 507.25(b)(1)(iii)). How these requirements are implemented may vary based on the type of animal food and plant. For example, some types of animal food may need containers with lids in order to protect against contamination, but for others that may not be important. In addition, some animal food may not easily support the growth of undesirable microorganisms, but other types of animal food may need to have temperature or moisture tightly controlled.

If raw materials and other ingredients are susceptible to contamination with mycotoxins or other natural toxins, they must be evaluated and used in a way that does not result in an animal food that can cause injury or illness to animals or humans (21 CFR 507.25(b)(2)). Natural toxins include aflatoxin, vomitoxin, fumonisin, and alkaloids. The evaluation of the ingredient should consider its geographic source, seasonal growing conditions the ingredient was exposed to, test results, whether the ingredient meets specification upon receipt, and other factors that may help a facility decide how to use the ingredient to produce safe animal food. Evaluation does not mean that every load of grain received must be tested. The facility may 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. There are several resources that identify maximum recommended levels for the presence of natural toxins.<sup>9</sup>

When an incoming raw material or other ingredient is received frozen, it must be kept frozen or thawed in a way that minimizes the potential for the growth of undesirable microorganisms (21 CFR 507.25(b)(3)).

### **3. Requirements for manufacturing, processing, packing, and holding operations (21 CFR 507.25(c))**

During manufacturing, processing, packing, and holding operations, the animal food must be maintained under conditions that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated (21 CFR 507.25(c)(1)). Undesirable microorganisms include 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 (21 CFR 507.3). For example, depending on

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<sup>9</sup> Guidance for maximum levels of fumonisin can be found in Attachment C of the Compliance Program Guidance Manual 7371.003 Feed Contaminants Program, <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113409.pdf>.

Action levels for aflatoxin can be found in the Compliance Policy Guide Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds, <https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074703.htm>.

Guidance on advisory levels for vomitoxin can be found in the Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed, <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120184.htm>.

### *Contains Nonbinding Recommendations*

the type of animal food it may be necessary to perform these operations under appropriate temperatures or relative humidity to minimize the potential for the growth of undesirable microorganisms.

When a plant is using measures such as heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling  $a_w$  to significantly minimize or prevent the growth of undesirable microorganisms during manufacturing, processing, packing, and holding, those measures must be adequate to prevent the adulteration of animal food (21 CFR 507.25(c)(2)). The methods used should be appropriate for the type of animal food and generally known to significantly minimize or prevent the growth of undesirable microorganism(s) in that animal food. For example, the plant may follow methods from a published scientific paper, or a process authority.

Work-in-process and rework must be handled in a way that protects against contamination and the growth of undesirable microorganisms (21 CFR 507.25(c)(3)). For example, if an animal food is heat treated to control the growth of undesirable microorganisms and it needs to be reworked because it did not meet time and temperature requirements, it should not be commingled with finished animal food. In addition, depending on the type of animal food and processing, it may be necessary to handle the work-in-process or rework under appropriate temperatures or relative humidity to minimize the potential for the growth of undesirable microorganisms.

Manufacturing and processing steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling must be done in a way that protects against the contamination of the animal food (21 CFR 507.25(c)(4)).

Filling, assembling, packaging, and other operations must be done in a way that protects against the contamination of animal food and the growth of undesirable microorganisms (21 CFR 507.24(c)(5)).

Animal food that relies principally on the control of  $a_w$  to prevent the growth of undesirable microorganisms must be processed to and maintained at a safe  $a_w$  level (21 CFR 507.25(c)(6)). The plant should use procedures that consistently achieve a safe  $a_w$  level.

Animal food that relies principally on the control of pH to prevent the growth of undesirable microorganisms must be monitored and the appropriate pH level must be maintained (21 CFR 507.25(c)(7)).

Any ice that is used in contact with animal food must be made from water that is safe and has been manufactured in accordance with the 21 CFR part 507 CGMPs (21 CFR 507.25(c)(8)). For further information on when water is considered safe for its intended use see section VI.D.1. Adequate water supply and water source (21 CFR 507.20(a)).

## *Contains Nonbinding Recommendations*

### **G. Holding and distribution (21 CFR 507.27)**

#### **1. Holding conditions for animal food held for distribution (21 CFR 507.27(a))**

When animal food is held for distribution, it must be held under conditions that will protect it from contamination and minimize deterioration (21 CFR 507.27(a)). Contamination may be physical, chemical, or biological. Deterioration of animal food includes the loss of palatability or intended nutritive value, which could possibly be a safety concern because animals are often fed the same food for prolonged periods of time. As a result, food refusal from loss of palatability or consumption of animal food with less nutritive value may result in poor animal productivity or health issues. In addition, deterioration can indicate the animal food has been held under conditions that would also support the growth of undesirable microorganisms.

If containers are used to hold animal food before distribution, they must be designed and constructed of appropriate material, cleaned as necessary, and maintained in a way that protects against the contamination of animal food (21 CFR 507.27(a)(1)). Facilities may use different container cleaning methods and frequency of cleaning, repair, or replacement depending on the animal food held and the plant's holding practices. Facilities should consider the type of containers, the amount and type of animal food, how often the containers are reused, whether the containers are transferred to other sites (other facilities or farms), as well as other factors in deciding what practices will be sufficient to protect the animal food from contamination and deterioration.

Furthermore, the animal food held for distribution must be held in a way that protects against contamination from sources such as trash (21 CFR 507.27(a)(2)). Factors to consider when developing practices to protect against contamination from sources such as trash may include the identification of the animal food so that it is not mistaken for trash, the animal food's proximity to potential sources of contamination such as trash and containers of waste and animal food awaiting rework, whether clearly marked receptacles for trash and waste are readily accessible to employees, and other factors unique to the plant and the animal food.

#### **2. Labeling for animal food ready for distribution (21 CFR 507.27(b))**

The labeling for animal food ready for distribution must contain, when applicable, information and instructions for safely using the product for the intended animal species (21 CFR 507.27(b)). FDA's animal food general labeling requirements are found in 21 CFR part 501. In addition to meeting Federal labeling requirements, animal food also is subject to individual State laws, which often require that labeling includes information about directions for use and warning or caution statements. Some animal food may present a food safety concern for some species for which the food is not intended, or for an intended species if not used properly. If not already required, safety information should be included on the animal food labeling when ordinary feeding practices would not be sufficient for the product to be safely used. For example, the manufacturer of a mineral mix containing copper 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.

## *Contains Nonbinding Recommendations*

### **3. Shipping containers and bulk vehicles used for animal food distribution (21 CFR 507.27(c))**

This section discusses the requirements for shipping containers and bulk vehicles for compliance with the CGMP requirements in 21 CFR part 507. Facilities may need to implement additional practices in order to comply with other applicable regulations, such as the Sanitary Transportation of Human and Animal Food final rule published by FDA on April 6, 2016 (81 FR 20092). That rule establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport (see 21 CFR part 1, subpart O). Animal food facilities engaging in transportation operations for animal food must comply with applicable requirements in that rule. Small businesses (as defined in the sanitary transportation rule) must comply by April 6, 2018 and other businesses by April 6, 2017.

Under the CGMP requirements, when a facility is responsible for transporting the animal food itself or arranges with a third-party to transport the animal food, the 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 (21 CFR 507.27(c)).

When the facility itself loads and moves the animal food in commerce, facility personnel involved in the process of loading the product into the shipping container or bulk vehicle should be aware of the condition of the shipping container or vehicle, and consider what steps may be required to protect against contamination of the animal food. Depending on the circumstances, examination of shipping containers and bulk vehicles may include: (1) visually looking at the container or bulk vehicle for any residues that may contaminate the animal food; (2) checking when the most recent clean-out of the container or bulk vehicle occurred; or (3) ascertaining the contents of the previous load to determine if it may contaminate the animal food. Depending on the results of the examination, the facility may determine clean-out is necessary prior to use to protect against contamination of the animal food. This does not mean that the shipping container or bulk vehicle must be cleaned prior to each use in all situations.

The CGMP requirements do not require the facility to examine the shipping container or bulk vehicle when the customer arranges for the transportation of the animal food, including when the customer arranges for a third-party carrier to pick up the animal food. If facility personnel are onsite and available, it would be good practice for the facility to examine the shipping container or bulk vehicle to confirm that its condition will not lead to the contamination of the animal food. And as a reminder, the facility may have additional responsibilities under the Sanitary Transportation of Human and Animal Food rule.

### **4. Requirements for animal food returned from distribution (21 CFR 507.27(d))**

Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition (21 CFR 507.27(d)). Management of the establishment or a designated employee may consider many factors in their assessment, including: (1) the type of animal food;

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(2) the reason the animal food was returned; and (3) whether integrity of the animal food was maintained after it left the plant (e.g., is the packaging intact and in good condition). Based on this assessment the management should determine whether the animal food should be discarded, reworked, or redistributed.

Returned animal food must be identified as such and segregated until assessed (21 CFR 507.27(d)). The primary purpose of identifying returned animal food is so that employees easily recognize it as returned animal food that has not yet been assessed. We recommend that the facility use a designated bin or location for returned animal food so that it is not confused with other animal food, including ingredients.

### **5. Requirements for unpackaged or bulk animal food held for distribution (21 CFR 507.27(e))**

Unpackaged or bulk animal food must be held for distribution in a way that does not result in unsafe cross contamination with other animal food (21 CFR 507.27(e)). The management of the establishment may consider factors such as the types of animal food, how the animal food is identified, the holding location, and the practices used for loading and unloading the animal food to implement practices that would prevent unsafe cross contamination.

### **H. Holding and distribution of human food by-products for use as animal food (21 CFR 507.28 and 117.95)**

For a discussion of the limited holding and distribution CGMP requirements for human food by-products for use as animal food found in 21 CFR 117.95 and 507.28, please see the Draft Guidance for Industry #239 entitled "Human Food By-Products for Use as Animal Food."<sup>10</sup>

## **VII. Compliance Dates**

We recognize that animal food facilities may need time to comply with these CGMP requirements. In addition, smaller businesses may need more time than larger businesses to comply with the CGMP requirements because they generally have less income and fewer available resources than larger businesses. Therefore, the compliance dates issued in the final rule were staggered based on business size. Table 1 gives the staggered dates for a business to comply with the CGMP requirements in 21 CFR part 507, subpart B and the related requirements, based on the size of a business.

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<sup>10</sup> Draft Guidance for Industry #239 entitled "Human Food By-Products for Use as Animal Food" is available at <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf> or <https://www.fda.gov/food/guidanceregulation/fsma/ucm253380.htm>.

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**Table 1. Dates for businesses to comply with 21 CFR part 507, subpart B and related requirements.**

<b>Size of Business</b>	<b>Definition</b>	<b>Required date to comply with 21 CFR part 507, subpart B (CGMPs) and related requirements</b>
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) (21 CFR 507.3).	September 17, 2018
Small business	A business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees (21 CFR 507.3).	September 18, 2017
All other businesses	A business that does not meet the definition of a small business, or a very small business.	September 19, 2016

## *Contains Nonbinding Recommendations*

### **Appendix A: Definitions for terms used in the CGMPs (21 CFR 507.3)**

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

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

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

*Facility* means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

- (1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.
- (2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

(21 CFR 1.227)

Farm means *Farm* as defined in 21 CFR 1.227.

*Farm* means:

- (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)(I) 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

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- (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
  - (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.  
(21 CFR 1.227)

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients.

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.  
(section 201(f) of the FD&C Act)

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

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

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

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(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.<sup>11</sup> Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks.

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.

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.

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<sup>11</sup> The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling (section 201(gg) of the FD&C Act).

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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.

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.

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 21 CFR part 507, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Very small business means, for purposes of 21 CFR part 507, 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.

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**Appendix B: Part 507 CGMP Self-Assessment Tool**

This tool groups and describes the CGMP requirements in a way that may be useful when conducting a walk-through review of your facility. The blank "notes" boxes could be used to take notes about your facility's implementation of the CGMP requirements and track CGMP implementation over time. Your facility is not required to use this tool and it is not subject to FDA requirements for: recordkeeping, submission to FDA, or disclosure to third parties or the public. For exact CGMP requirements, consult the sections of title 21 of the Code of Federal Regulations cited in the tables.

**Table 1 Personnel Qualification, Training, Responsibility Requirements**

<b>Personnel Qualification, Training, Responsibility Requirements</b>	<b>Notes</b>
<p>The management of an establishment is required to:</p> <ul style="list-style-type: none"><li>• ensure that all individuals who manufacture, process, pack, or hold animal food subject to the CGMPs are qualified to perform their assigned duties (507.4(a)(1)).</li><li>• ensure that the CGMP requirements of 21 CFR part 507, subpart B are followed for all animal food manufacturing, processing, packing, and holding operations (including receiving, inspecting, transporting, and segregating) (507.25(a)(1)).</li><li>• ensure that the overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for the function (507.25(a)(4)).</li></ul> <p>In addition, responsibility for ensuring compliance by individuals with the requirements of 21 CFR part 507 must be clearly assigned to supervisory personnel who have the education, training, or experience (or combination thereof) necessary to supervise the production of safe animal food (507.4(c)).</p>	

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<b>Personnel Qualification, Training, Responsibility Requirements</b>	<b>Notes</b>
<p>Individuals who supervise or perform manufacturing, processing, packing, or holding activities for animal food must:</p> <ul style="list-style-type: none"><li>• be a qualified individual (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) (507.4(b)(1); and</li><li>• receive training in the principles of animal food hygiene and animal food safety. (507.4(b)(2))</li></ul> <p>These requirements must be met even if the individual only works on a temporary or seasonal basis (507.4(b)).</p> <p>Training in the principles of animal food hygiene and animal food safety must include information on the importance of employee health and personal hygiene, but the appropriate scope of the training depends on the animal food, facility and assigned duties (507.4(b)(2)). Facilities are required to keep records that document this training (507.4(d)).</p>	

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**Table 2 Personnel Hygienic Practice Requirements**

<b>Personnel Hygienic Practice Requirements</b>	<b>Notes</b>
<p>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 as necessary to protect against the contamination of animal food (507.14(a)). Methods include:</p> <ul style="list-style-type: none"><li>• Maintaining adequate personal cleanliness (507.14(b)(1))</li><li>• Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination (507.14(b)(2))</li><li>• Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers (507.14(b)(3))</li><li>• Storing clothing and personal belongings in areas other than where animal food is exposed or where equipment and utensils are cleaned (507.14(b)(4))</li><li>• Taking any other necessary precautions to protect against the contamination of animal food, animal food contact surfaces, or animal food-packaging materials (507.14(b)(5))</li></ul>	

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**Table 3 Ingredient Receiving Requirements**

<b>Ingredient Receiving Requirements</b>	<b>Notes</b>
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 (507.25(b)(1)(i)).	
Raw materials and other ingredients must be examined to ensure they are suitable for manufacturing and processing into animal food. These raw materials and other ingredients must be handled under conditions that will protect against contamination and minimize deterioration (507.25(b)(1)). <ul style="list-style-type: none"><li>• Raw materials must be cleaned as necessary to minimize contamination (507.25(b)(1)(ii)).</li><li>• If raw materials and other ingredients are susceptible to contamination with mycotoxins or other natural toxins, they must be evaluated and used in a way that does not result in an animal food that can cause injury or illness to animals or humans (507.25(b)(2)).</li><li>• When an incoming raw material or other ingredient is received frozen, it must be kept frozen or thawed in a way that minimizes the potential for the growth of undesirable microorganisms (507.25(b)(3)).</li></ul>	

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**Table 4 Manufacturing and Processing Requirements**

<b>Manufacturing and Processing Requirements</b>	<b>Notes</b>
<p>Management must ensure that adequate 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 (507.25(a)(5)).</p> <ul style="list-style-type: none"><li>• Raw materials, rework, and other ingredients must be stored in containers designed and constructed to protect against contamination and deterioration and held under conditions that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated (507.25(b)(1)(iii)).</li><li>• Manufacturing and processing steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling must be done in a way that protects against the contamination of the animal food (507.25(c)(4))</li><li>• Filling, assembling, packaging, and other operations must be done in a way that protects against the contamination of animal food and the growth of undesirable microorganisms (507.25(c)(5)).</li></ul> <p>Management must ensure that chemical, microbial, or extraneous-material testing procedures are used where necessary to identify possible animal food contamination (507.25(a)(6)).</p>	

*Contains Nonbinding Recommendations*

<b>Manufacturing and Processing Requirements</b>	<b>Notes</b>
<p>Management must ensure that all 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 in order to protect against the contamination of the animal food (507.25(a)(8)).</p> <ul style="list-style-type: none"> <li>• During manufacturing, processing, packing, and holding operations, the animal food must be maintained under conditions that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated (507.25(c)(1)).</li> <li>• Work-in-process and rework must be handled in a way that protects against contamination and the growth of undesirable microorganisms (507.25(c)(3)).</li> <li>• When a plant is using measures such as heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling <math>a_w</math> to significantly minimize or prevent the growth of undesirable microorganisms during manufacturing, processing, packing, and holding, those measures must be adequate to prevent the adulteration of animal food (507.25(c)(2)).</li> <li>• When water activity (<math>a_w</math>) is used to prevent the growth of undesirable microorganisms, the animal food must be processed to and maintained at a safe <math>a_w</math> level (507.25(c)(6)).</li> <li>• When pH is used to prevent the growth of undesirable microorganisms, pH must be monitored and the appropriate pH level must be maintained in the animal food (507.25(c)(7)).</li> </ul>	
<p>Management of the establishment must ensure that animal food is accurately identified (507.25(a)(2)).</p>	
<p>When animal food has become adulterated, management of the establishment must ensure that it is rejected, disposed of, or if appropriate it is treated or processed to eliminate the adulteration. Disposal must be done in a way that protects against the contamination of other animal food (507.25(a)(7)).</p>	

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**Table 5 Equipment and Utensil Requirements**

<b>Equipment and Utensil Requirements</b>	<b>Notes</b>
All plant equipment and utensils that are used in manufacturing, processing, packing, and holding animal food (including those that do not come into contact with animal food) must be designed and constructed of material and workmanship to be adequately cleanable and must be properly maintained (507.22(a)(1)).	
Equipment and utensils used in manufacturing, processing, packing, and holding animal food must be designed, constructed, and used so that they do not adulterate the animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants (507.22(a)(2)).	
Equipment must be installed to facilitate cleaning and maintenance of the equipment and adjacent spaces (507.22(a)(3)).	
<p>Animal food-contact surfaces must be:</p> <ul style="list-style-type: none"> <li>• made of materials that withstand the environment of their use, the action of animal food, and, if applicable, the action of cleaning compounds and procedures and sanitizing agents (507.22(a)(4)(i)).</li> <li>• made of nontoxic materials (507.22(a)(4)(ii)); and</li> <li>• maintained to protect animal food from contamination (507.22(a)(4)(iii)).</li> </ul>	
Holding, conveying, manufacturing, and processing systems must be designed, constructed, and maintained in a way to protect against the contamination of animal food. These types of systems include gravimetric, pneumatic, closed, and automated systems (507.22(b)).	
Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device (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 (507.22(d)).	

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**Table 6 Sanitation Requirements**

<b>Sanitation Requirements</b>	<b>Notes</b>
<p>All surfaces (food-contact and non-contact) of utensils and equipment must be cleaned and maintained and utensils and equipment stored to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning (507.19(b)).</p> <ul style="list-style-type: none"><li>• If animal food contact surfaces are wet cleaned, the surfaces must be thoroughly dried before subsequent use, when necessary (507.19(b)(1)).</li><li>• In wet processing, it may be necessary to clean and sanitize to protect against the introduction of undesirable microorganisms into the animal food. If so, 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 (507.19(b)(2)).</li><li>• When compressed air or other gases mechanically introduced are used in animal food, or used to clean animal food-contact surfaces or equipment, it must be used in a way that protects against the contamination of animal food (507.22(e)).</li></ul>	
<p>Management of the establishment must ensure that chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures (507.25(a)(6)).</p>	

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<b>Sanitation Requirements</b>	<b>Notes</b>
<p>Regardless of the type of animal food plant, cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use (507.19(c)). The only toxic materials that may be used or stored in the area of the plant where animal food is manufactured, processed, or exposed are those that are needed for cleaning and sanitizing, plant and equipment maintenance and operation, laboratory testing procedures, and use in the plant's operations (507.19(d)(1)). These toxic materials 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 (507.19(d)(2)).</p> <ul style="list-style-type: none"> <li>• Other toxic materials such as fertilizers and pesticides not needed for cleaning and sanitizing, plant and equipment maintenance and operation, laboratory testing procedures, or use in the plant's operations must be stored only in areas of the plant where animal food is not manufactured, processed, or exposed (507.19(d)(3)).</li> </ul>	
<p>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. Pesticides may be used in the plant only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials (507.19(e)).</p>	
<p>Trash must be conveyed, stored, and disposed of in such a way that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies and ground surfaces, and minimizes the potential for trash to attract or harbor pests or serve as a breeding place for pests (507.19(f)).</p>	

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**Table 7 Packing, Holding, and Distribution Requirements**

<b>Packaging, Holding, and Distribution Requirements</b>	<b>Notes</b>
Management of the establishment must ensure animal food-packaging materials are safe and suitable (507.25(a)(3)).	
<p>When animal food is held for distribution, it must be held under conditions that will protect it from contamination and minimize deterioration (507.27(a)). Including:</p> <ul style="list-style-type: none"> <li>• If containers are used to hold animal food before distribution, they must be designed and constructed of appropriate material, cleaned as necessary, and maintained in a way that protects against the contamination of animal food (507.27(a)(1)).</li> <li>• Animal food must be held in a way that protects against contamination from sources such as trash (507.27(a)(2)).</li> </ul>	
The labeling for the animal food product ready for distribution must contain, when applicable, information and instructions for safely using the product for the intended animal species (507.27(b)).	
When the facility is responsible for transporting the animal food itself or arranges with a third-party to transport the animal food, the 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 (507.27(c)).	
Unpackaged or bulk animal food must be held for distribution in a way that does not result in unsafe cross contamination with other animal food (507.27(e)).	
Returned animal food must be identified as such and segregated until assessed for animal food safety to determine the appropriate disposition (507.27(d)).	

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**Table 8 Plant Construction, Design and Maintenance Requirements**

<b>Plant Construction, Design and Maintenance Requirements</b>	<b>Notes</b>
A 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 (507.17(b)).	
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 (507.19(a)).	
There must be adequate space between equipment, walls, and stored materials to allow for cleaning and maintenance of equipment and other employee duties (507.17(b)(1)).	
The plant must be constructed in a way that drip or condensate from fixtures, ducts, and pipes are not a source of contamination (507.17(b)(2)).	
Adequate ventilation must be provided where necessary and appropriate to minimize vapors and fumes in areas where they may contaminate animal food. When ventilation is used to remove vapors and fumes in the animal food plant, it must be done in a way that minimizes the potential for contamination of animal food (507.17(b)(3)).	
The plant must have 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 (507.17(b)(4)). Light bulbs, fixtures, skylights, or other glass items suspended over exposed animal food must be shatter-resistant to protect against the contamination of animal food from glass breakage (507.17(b)(5)).	

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**Table 9 Water Supply and Plumbing Requirements**

<b>Water Supply and Plumbing Requirements</b>	<b>Notes</b>
<p>Water used by the plant must be adequate for the operations and derived from an adequate source (507.20(a)(1)). Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use (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 (507.20(a)(4)). Any ice that is used in contact with animal food must be made from water that is safe and has been manufactured in accordance with the 21 CFR part 507 CGMPs (507.25(c)(8)).</p>	
<p>Running water at a suitable temperature and under suitable pressure as needed must be provided in all areas where it is 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 (507.20(a)(2)).</p>	
<p>Plumbing must be designed, installed, and maintained to carry adequate quantities of water to required locations throughout the plant (507.20(b)(1)) and properly convey sewage and liquid disposable waste from the plant (507.20(b)(2)).</p>	
<p>Plumbing must be designed, installed, and maintained to avoid being a source of contamination to the animal food, water supplies, equipment, or utensils and to avoid creating an unsanitary condition (507.20(b)(3)).</p>	
<p>Plumbing must be designed, installed, and maintained so that there is no backflow and there is no cross-connection between discharge pipes and pipes that carry water for animal food or animal food manufacturing (507.20(b)(5)).</p>	
<p>Plumbing must be designed, installed, and maintained in a way that provides adequate floor drainage in all areas where flooding-type cleaning is used on floors, or where normal operations release or discharge water or other liquid waste on the floor (507.20(b)(4)).</p>	
<p>Sewage and liquid waste must be disposed of through an adequate sewage system or through other adequate means (507.20(c)).</p>	

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<b>Water Supply and Plumbing Requirements</b>	<b>Notes</b>
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 (507.20(d)).	
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 (507.20(e)).	

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**Table 10 Grounds and Outdoor Animal Food Storage Requirements**

<b>Grounds and Outdoor Animal Food Storage Requirements</b>	<b>Notes</b>
<p>Grounds around a plant under control of the management of the establishment must be kept in a way that will protect against the contamination of the animal food (507.17(a)). Maintenance of grounds must include:</p> <ul style="list-style-type: none"> <li>• Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may attract, harbor, or serve as a breeding place for pests (507.17(a)(1)).</li> <li>• Maintaining driveways, yards, and parking areas so they are not a source of contamination for exposed animal food (507.17(a)(2)).</li> <li>• Adequately draining areas that may contribute to contamination of animal food (507.17(a)(3)).</li> <li>• Treating and disposing of waste so that it does not become a source of contamination in areas where animal food is exposed. (507.17(a)(4))</li> </ul>	
<p>If an animal food plant stores bulk animal food or ingredients outside, it must protect the animal food from contamination by any effective means, including:</p> <ul style="list-style-type: none"> <li>• Using protective coverings where necessary and appropriate (507.17(c)(1))</li> <li>• Controlling areas over and around the bulk animal food to eliminate harborages for pests (507.17(c)(2))</li> <li>• Checking on a regular basis for pests, pest infestation, and product condition related to the safety of the animal food (507.17(c)(3)).</li> </ul>	

#245

# Hazard Analysis and Risk-Based Preventive Controls for Food for Animals Guidance for Industry

## DRAFT GUIDANCE

**This guidance document is being distributed for comment purposes only.**

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

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

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

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**Table of Contents**

<b>INTRODUCTION</b> .....	6
<b>PURPOSE</b> .....	8
<b>CHAPTER 1 – THE FOOD SAFETY PLAN</b> .....	<b>10</b>
1.1 Purpose of this Chapter .....	10
1.2 What is a Food Safety Plan? .....	10
1.3 Who Prepares the Food Safety Plan for a Facility? .....	11
1.4 Who Signs the Food Safety Plan for a Facility? .....	11
1.5 Is the Food Safety Plan the Same as a HACCP Plan? .....	11
1.6 What if a Facility Already has a HACCP Plan? .....	12
1.7 Is there a Required Format for a Food Safety Plan? .....	12
1.8 What Circumstances Require Review (Reanalysis) of My Food Safety Plan? ...	12
1.9 References for Chapter 1 .....	13
<b>CHAPTER 2 – CONDUCTING A HAZARD ANALYSIS</b> .....	<b>14</b>
2.1 Purpose of this Chapter .....	14
2.2 Overview of a Hazard Analysis .....	14
2.3 Recommended Activities in Conducting Your Hazard Analysis .....	15
2.3.1 Conduct Preliminary Steps .....	15
2.3.2 Hazard Analysis Worksheet.....	16
2.4 Conducting a Hazard Analysis.....	18
2.4.1 Identify Known or Reasonably Foreseeable Hazards (Hazard Identification)	
.....	18
2.4.2 Evaluate Known or Reasonably Foreseeable Hazards (Hazard Evaluation)	
.....	19
Assessing severity of the illness or injury.....	20
Assessing probability the hazard will occur .....	20
2.4.3 Assessing the Combination of Severity and Probability.....	24
2.4.4 Evaluating Environmental Pathogens When Animal Food is Exposed to the	
Environment.....	25
2.4.5 Evaluation of Other Factors .....	25
2.5 Use of Your Written Evaluation as Explanation/Justification Whether a Hazard	
Requires a Preventive Control .....	27
2.6 Identifying Preventive Controls .....	28
2.7 Is the Preventive Control Applied at this Step? .....	29
2.8 References for Chapter 2.....	29
<b>CHAPTER 3 – HAZARDS ASSOCIATED WITH THE MANUFACTURING,</b>	
<b>PROCESSING, PACKING, AND HOLDING OF ANIMAL FOOD</b> .....	<b>31</b>
3.1 Purpose of this Chapter .....	31
3.2 Known or Reasonably Foreseeable Hazards.....	31
3.3 Biological Hazards .....	33
3.3.1 Foodborne Pathogens Associated with Animal Food .....	34
Bacterial pathogens .....	34
Other pathogens .....	37

## Contains Nonbinding Recommendations

*Draft—Not for Implementation*

3.3.2	Ingredient-Related Biological Hazards .....	38
3.3.3	Process-Related Biological Hazards .....	38
	Bacterial pathogens that survive process controls .....	38
	Bacterial pathogens that grow .....	39
	Bacterial pathogens in ingredients added after applying process controls .....	41
	Bacterial pathogens introduced after packaging due to lack of container integrity .....	41
3.3.4	Facility-Related Biological Hazards .....	41
	Sources of facility-related biological hazards .....	42
	Transient and resident facility-related environmental pathogens .....	43
	Facility-related environmental pathogens associated with wet and dry processing environments .....	44
	Wet processing environments .....	45
	Dry processing environments .....	46
3.4	Chemical Hazards .....	47
3.4.1	Ingredient-Related Chemical Hazards .....	49
	Pesticides .....	49
	Heavy metals .....	49
	Natural toxins .....	50
	Animal drugs .....	52
	Unapproved color and food additives .....	54
	Chemical hazards that may be intentionally introduced for purposes of economic gain .....	54
	Radiological hazards .....	55
	Environmental chemical contaminants .....	55
3.4.2	Process-Related Chemical Hazards .....	56
	Animal drug carryover in animal food .....	56
	Nutrient deficiencies or toxicities as chemical hazards .....	57
3.4.3	Facility-Related Chemical Hazards .....	58
3.5	Physical Hazards .....	58
3.6	References for Chapter 3 .....	59
<b>CHAPTER 4 – PREVENTIVE CONTROLS .....</b>		<b>69</b>
4.1	Purpose of this Chapter .....	69
4.2	Overview of Preventive Controls .....	69
4.3	Preventive Control Considerations .....	69
4.4	Process Controls .....	70
4.4.1	Use of Parameter Values and Operating Limits in Process Controls .....	71
4.5	Process Controls for Biological Hazards .....	72
4.5.1	Use of Lethality Treatments as Process Controls .....	73
	Heat treatment (thermal processing) .....	73
	High pressure processing (HPP) .....	78
	Irradiation .....	79
4.5.2	Use of Time and Low Temperature as Process Controls .....	81
	Refrigeration .....	82
	Freezing .....	83
4.5.3	Use of Product Formulation as Process Controls .....	84

**Contains Nonbinding Recommendations**

*Draft—Not for Implementation*

Water activity ( $a_w$ ) .....	84
Acidity (pH) .....	86
Preservatives .....	87
4.5.4 Use of Dehydration/Drying as Process Controls .....	88
4.6 Preventive Controls for Chemical Hazards.....	88
4.6.1 Preventive Controls for Nutrient Deficiencies and Toxicities .....	88
4.6.2 Drying and Storage Conditions as Preventive Controls for Mycotoxins....	90
4.6.3 Sequencing and Flushing as Preventive Controls for Drug Carryover .....	90
4.7 Preventive Controls for Physical Hazards .....	91
4.7.1 Preventive Controls for Metal Hazards.....	91
4.7.2 Preventive Controls for Glass Hazards .....	92
4.7.3 Preventive Controls for Hard Plastic Hazards .....	92
4.7.4 Preventive Controls for Conditions of Animal Food That Can be Hazards	92
4.8 Sanitation Controls.....	93
4.8.1 Cleaning Strategies and Sanitation Controls.....	94
4.8.2 Use of Sanitation Controls to Prevent Cross-Contamination .....	97
4.9 Supply-Chain Controls.....	98
4.10 Recall Plan .....	98
4.11 References for Chapter 4.....	99
<b>CHAPTER 5 – OVERVIEW OF PREVENTIVE CONTROL MANAGEMENT</b>	
<b>COMPONENTS .....</b>	<b>103</b>
5.1 Purpose of this Chapter.....	103
5.2 Overview of Preventive Control Management Components .....	103
5.3 Who is Responsible for Conducting Preventive Control Management Component	
Activities? .....	103
5.4 Recordkeeping Requirements for Preventive Control Management Components	
.....	104
5.5 Preventive Control Management Components Examples .....	104
5.6 Monitoring .....	105
5.6.1 What Will Be Monitored?.....	106
5.6.2 How Will Monitoring Be Done?.....	106
5.6.3 How Often Will Monitoring Be Done (Frequency)? .....	106
5.6.4 Who Will Do the Monitoring?.....	107
5.6.5 What Records Do I Need to Document Monitoring? .....	107
5.7 Corrective Actions and Corrections .....	108
5.7.1 Corrective Actions .....	108
5.7.2 Corrections .....	110
5.7.3 Corrective Action and Correction Records .....	110
5.8 Verification Activities.....	112
5.8.1 Verification .....	112
5.8.2 Validation.....	113
5.8.3 Verification of Monitoring.....	115
5.8.4 Verification of Decisions about Corrective Actions .....	116
5.8.5 Verification of Implementation and Effectiveness .....	117
Calibration.....	117
Product testing.....	119

**Contains Nonbinding Recommendations**

*Draft—Not for Implementation*

Environmental monitoring .....	120
Record review .....	121
5.8.6 Reanalysis .....	123
5.9 References for Chapter 5.....	125
<b>APPENDIX A – Glossary of Terms .....</b>	<b>126</b>
<b>APPENDIX B – Table of Abbreviations and Acronyms Used in this Guidance ....</b>	<b>131</b>
<b>APPENDIX C – Flowchart – Hazard Analysis .....</b>	<b>134</b>
<b>APPENDIX D – Example Hazard Analysis Worksheet.....</b>	<b>136</b>
<b>APPENDIX E – Aid to Identifying Animal Food Hazards .....</b>	<b>138</b>
References for Appendix E.....	155

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**Hazard Analysis and  
Risk-Based Preventive Controls for  
Food for Animals**

**Draft Guidance For Industry**

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

**INTRODUCTION**

In Title 21 of the Code of Federal Regulations (21 CFR) part 507 (part 507), we have established our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals”. We published the final rule establishing part 507 in the *Federal Register* of September 17, 2015 (80 FR 56170). Part 507 establishes requirements for current good manufacturing practice for animal food (CGMPs), for hazard analysis and risk-based preventive controls for animal food (PCAF), and related requirements as shown in Table 1.

**Table 1. Subparts Established in 21 CFR Part 507**

<b>SUBPART</b>	<b>TITLE</b>
A	General Provisions
B	Current Good Manufacturing Practice
C	Hazard Analysis and Risk-Based Preventive Controls
D	Withdrawal of a Qualified Facility Exemption
E	Supply-Chain Program
F	Requirements Applying to Records That Must be Established and Maintained

Part 507, subparts A, C, D, E, and F contain the complete animal food preventive controls requirements (the PCAF requirements). This guidance document focuses on subpart C, the primary preventive controls requirements, and also discusses relevant recordkeeping requirements of subpart F. Although subpart E, the supply-chain program, is a type of preventive control, we intend to address subpart E in future guidance.

The PCAF requirements implement certain provisions of the FDA Food Safety Modernization Act (FSMA) established in section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g). Part 507 includes several complete or partial exemptions from the PCAF requirements. See 21 CFR 507.5 for these exemptions.

In part 507, “you” means the owner, operator, or agent in charge of a facility (see 21 CFR 507.3). However, for the purposes of this guidance document, where appropriate, “you” also

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may refer to the preventive controls qualified individual (PCQI) in addition to the owner, operator, or agent in charge of a facility.

Establishing risk-based preventive controls designed to protect your animal food and the consumer (humans purchasing the animal food and animals consuming the food) from biological, chemical (including radiological), and physical hazards, enables you to apply a proactive and systematic approach to your food safety program. Risk-based preventive controls will not give you a zero-risk system for manufacturing, processing, packing, and holding animal food; rather, risk-based preventive controls are designed to minimize the risk of known or reasonably foreseeable animal food hazards that may cause illness or injury to humans or animals if they are present in the animal food you produce.

This guidance document covers facilities that manufacture, process, pack, or hold food intended for all animal species including food-producing animals (e.g., livestock, poultry, and aquaculture species), companion animals (e.g., dogs, cats, horses, and guinea pigs), laboratory animals, and animals maintained in zoological parks. “Animal food” means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients (see 21 CFR 507.3).

This guidance document is intended to help you comply with the PCAF requirements in subparts C and F of part 507:

- a written food safety plan
- hazard analysis
- preventive controls
- monitoring
- corrective actions and corrections
- verification (including validation)
- recall plan
- associated records

You only need to apply preventive controls if, after conducting a hazard analysis of each type of animal food manufactured, processed, packed, or held at your facility, you determine there are known or reasonably foreseeable biological, chemical, or physical hazards that require a preventive control. We do not expect that all known or reasonably foreseeable hazards for an animal food require a preventive control in all facilities.

It is important for you to be aware of the known or reasonably foreseeable hazards that may be associated with your animal food, processes, and facility. When you understand the known or reasonably foreseeable hazards, it is easier to design and implement an effective food safety plan.

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This guidance is not directed to persons who are exempt from the preventive controls requirements of part 507. However, such persons may find some of the principles and recommendations in this guidance helpful in manufacturing, processing, packing, and holding animal food.

In general, FDA's guidance documents, including this guidance, 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's guidances means that something is suggested or recommended, but not required.

### **PURPOSE**

The purpose of this guidance is to help you develop a food safety plan that complies with FDA's PCAF requirements.

Specifically, this document provides guidance on:

- the biological, chemical (including radiological), and physical agents that are known or reasonably foreseeable hazards in manufacturing, processing, packing, and holding of animal food
- the components of a food safety plan and the importance of each component
- how to conduct a hazard analysis and develop a food safety plan for the animal food that you produce
- identifying preventive controls for biological, chemical, and physical hazards associated with animal food and how to apply those preventive controls
- preventive control management components (i.e., monitoring, corrective actions and corrections, and verification (including validation))
- the recordkeeping requirements associated with the food safety plan and implementation of the food safety plan

We recommend that you consider how this guidance relates to your operations and tailor your food safety plan to the specific circumstances for the animal food you produce. We do not provide all the details you might need for all components of your food safety plan and the type of animal food you manufacture, process, pack, or hold. You have the flexibility to identify and implement preventive controls and associated preventive control management components from among all procedures, practices, and processes that provide assurances that the hazard requiring a preventive control is controlled (i.e., significantly minimized or prevented).

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Terms we use that are defined in the regulation, or that we define for purposes of this guidance, are in quotations. For a list of definitions used in this guidance, see Appendix A. For a list of abbreviations and acronyms used in this guidance, see Appendix B.

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### **CHAPTER 1 – THE FOOD SAFETY PLAN**

#### **1.1 Purpose of this Chapter**

The guidance provided in this chapter is intended to help facilities that are subject to the preventive controls requirements of the Preventive Controls for Animal Food (PCAF) regulation understand what a food safety plan is. A facility subject to the preventive controls requirements must prepare, or have prepared, and implement a written food safety plan. See 21 CFR 507.31(a).

#### **1.2 What is a Food Safety Plan?**

A food safety plan is a written plan prepared by (or whose preparation is overseen by) a preventive controls qualified individual, which must include the elements listed in 21 CFR 507.31(c).

Below, we describe the written documents required in the food safety plan. See 21 CFR 507.31(c).

- Hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of animal food at your animal food facility to determine whether there are hazards requiring a preventive control (see 21 CFR 507.33(a)(1)). Some facilities may not identify any known or reasonably foreseeable hazards associated with animal food at their facilities, or after evaluation may determine there are no known or reasonably foreseeable hazards requiring a preventive control. This hazard analysis must be written regardless of whether there are any hazards requiring a preventive control. See 21 CFR 507.33(a)(2).
- When the hazard analysis determines there are known or reasonably foreseeable hazards requiring a preventive control, the food safety plan also includes the following written documents:
  - Preventive controls (see 21 CFR 507.34), as appropriate to the facility and the animal food, that may include:
    - process controls
    - sanitation controls
    - supply-chain controls
    - recall plan
    - other preventive controls
  - Procedures for monitoring the implementation of the preventive controls, as appropriate to the nature of the preventive control and its role in the facility's animal food safety system. See 21 CFR 507.40(a)(1).

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- Corrective action procedures, as appropriate to the nature of the hazard and the nature of the preventive control. See 21 CFR 507.42(a)(1).
- Verification procedures, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's animal food safety system. See 21 CFR 507.49(b).
- Recall plan. See 21 CFR 507.38(a)(1).

This written food safety plan is a record that you must maintain. See 21 CFR 507.31(d); and, 21 CFR part 507 subpart F, particularly 21 CFR 507.208. In addition, you must maintain records documenting implementation of the food safety plan. See 21 CFR 507.55 for a list of records that must be maintained to document implementation of the food safety plan.

### **1.3 Who Prepares the Food Safety Plan for a Facility?**

A “preventive controls qualified individual” (PCQI) must prepare (or oversee the preparation of) the food safety plan. See 21 CFR 507.31(b).

A PCQI is 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 (see 21 CFR 507.3). A standardized curriculum recognized as adequate by FDA includes, for example, the animal food training course developed by the Food Safety Preventive Controls Alliance (FSPCA) (Ref. 1). The PCQI does not need to be an employee of the facility but should be familiar with the facility and the facility's operations.

### **1.4 Who Signs the Food Safety Plan for a Facility?**

The food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility when the food safety plan is first completed and whenever the plan is modified. See 21 CFR 507.206.

### **1.5 Is the Food Safety Plan the Same as a HACCP Plan?**

Although a food safety plan and Hazard Analysis and Critical Control Point (HACCP) plan are similar, they are not identical. A HACCP plan is a written document based upon the principles of HACCP and which delineates the procedures to be followed. HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards. HACCP systems, which are the result of the implementation of a HACCP plan, have been mandated by U.S. Federal regulations issued by the FDA for processing seafood and juice and by the United States Department of Agriculture Food Safety and Inspection Service (USDA/FSIS) for processing meat and poultry. No HACCP system has been mandated by FDA for any animal food. HACCP principles have been voluntarily adopted however by some segments of the animal food industry, such as some rendering facilities.

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### **1.6 What if a Facility Already has a HACCP Plan?**

If you have an existing HACCP plan, you should determine if your HACCP plan satisfies all the requirements for the food safety plan in the PCAF regulation. You can use existing programs, procedures, and records and supplement those with any additional information required. If you are using or planning to use a HACCP plan at your animal food facility, you may find helpful a complete discussion of the differences between a food safety plan and a HACCP plan in the draft guidance document issued on August 24, 2016, titled “Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food”, Chapter 1 (Ref. 2).

### **1.7 Is there a Required Format for a Food Safety Plan?**

There is no standardized or required way to organize a food safety plan. The food safety plan may be in electronic or hardcopy format. The food safety plan is a record subject to the requirements in 21 CFR part 507, subpart F (see 21 CFR 507.31(d)).

You have flexibility in your approach to documenting your hazard analysis and in your approach to documenting preventive controls established for those hazards requiring a preventive control. The formats shown in this guidance are for illustrative purposes and may not be complete. You can use whatever format works best for your facility, provided that the food safety plan includes all the required information. The FSPCA training materials also provide example food safety plans for animal food that may be helpful (Ref. 1).

One approach for organizing the food safety plan to allow for signing and dating is to collect in a single location (e.g., a binder or folder) all the required documents with a cover page for the owner, operator, or agent in charge of the facility to sign and date. See 21 CFR 507.206. However, because the food safety plan also could be various documents kept in different locations within the facility, another approach is for the owner, operator, or agent in charge of the facility to sign and date a list of the required documents (e.g., as in a table of contents).

### **1.8 What Circumstances Require Review (Reanalysis) of My Food Safety Plan?**

The food safety plan is a dynamic document that reflects your current hazard analysis, preventive controls, and other required elements (see 21 CFR 507.31). The food safety plan as a whole must be reanalyzed at least once every 3 years (21 CFR 507.50(a)). However, reanalysis of the plan as a whole or the applicable portion of the plan is required whenever 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; you become aware of new information about potential hazards associated with the animal food; when appropriate after an unanticipated animal food safety problem that requires a corrective action; or, you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective. See 21 CFR 507.50(b). You also 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. See 21 CFR 507.50(f).

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### **1.9 References for Chapter 1**

1. Food Safety Preventive Controls Alliance. 2017. “Food Safety Preventive Controls Alliance Home Page”. Accessed December 4, 2017.  
<https://www.ifsh.iit.edu/fspca>.
2. Food and Drug Administration. 2016. “Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry: Draft Guidance”. Accessed December 4, 2017.  
<https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm517610.pdf>.

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**CHAPTER 2 – CONDUCTING A HAZARD ANALYSIS**

**2.1 Purpose of this Chapter**

The guidance provided in this chapter is intended to help you conduct a hazard analysis in accordance with the PCAF requirements. The hazard analysis must be written regardless of the outcome or results of the analysis, and must include two elements: (1) a hazard identification, and (2) a hazard evaluation to determine whether there are any hazards requiring a preventive control. See 21 CFR 507.33.

**2.2 Overview of a Hazard Analysis**

The term “hazard analysis” is not defined in part 507. See Box 2-1 for a definition of “hazard analysis”.

**Box 2-1. Definition of Hazard Analysis**

**Hazard Analysis**

The process of identifying and evaluating known or reasonably foreseeable hazards to determine whether there are any hazards requiring a preventive control.

This chapter guides you through the steps we recommend in conducting your hazard analysis. You are not required to use a certain format for conducting your hazard analysis. However, you may find it useful to use the Flow Chart in Appendix C and the Hazard Analysis and Preventive Controls Worksheet in Appendix D (also see Box 2-3 in this chapter). You may use other formats (including the use of a written narrative) as long as your hazard analysis contains the elements of hazard identification and hazard evaluation and a determination of whether any of the hazards require a preventive control.

Use your completed hazard analysis to determine what hazards require preventive controls. Your completed hazard analysis will be useful in determining the appropriate preventive control(s) to use in your facility. The hazard identification and evaluation in your hazard analysis should help provide justification for your decisions.

You may group animal food products together for your hazard analysis if the animal food safety hazards and controls are essentially the same for all animal food products in the group, but you should clearly identify any product or process differences. We suggest you refer to your written hazard analysis when you reanalyze or modify your food safety plan. Your written hazard analysis can be a resource for you if inspectors, investigators, auditors, or your customers ask you to explain how you determined that a preventive control is not required for a known or reasonably foreseeable hazard.

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Your food safety plan will not be effective in protecting consumers and preventing food safety issues if you do not conduct the hazard analysis correctly and do not identify hazards that require a preventive control. A proper analysis of biological, chemical (including radiological), and physical hazards associated with your animal food and your facility calls for good judgment, detailed knowledge of the properties of the raw materials and other ingredients, detailed knowledge of your manufacturing, processing, packing, and holding processes, and access to relevant scientific expertise.

### **2.3 Recommended Activities in Conducting Your Hazard Analysis**

We recommend that you conduct certain preliminary steps, and set up a Hazard Analysis Worksheet, as a useful framework for organizing and documenting your hazard analysis.

#### **2.3.1 Conduct Preliminary Steps**

#### **Box 2-2. Preliminary Steps**

1. Select the preventive controls qualified individual (you may also assemble a food safety team)
2. Describe the animal food, its distribution, intended use, and the intended animal species, life stage, or production class
3. Develop a process flow diagram and verify this diagram onsite
4. Describe the process

You must have a preventive controls qualified individual (PCQI) prepare, or oversee the preparation of, your food safety plan. See 21 CFR 507.31(b). The food safety plan includes your written hazard analysis. See 21 CFR 507.31(c)(1). We recommend that a food safety team of individuals with expertise in the day-to-day operations of your facility help you conduct your hazard analysis under the oversight of a PCQI. Team individuals may include personnel from different areas, such as production, quality control, sanitation, or maintenance. Using individuals from different functions within the facility can help provide a complete understanding of your process and the things that could result in hazards in your animal food.

You can supplement the expertise of the food safety team by competent technical experts from other off-site functions within the firm (where applicable), such as research and development, technical applications groups, and quality management. You also may find it helpful to bring in technical experts from outside of the firm such as experts from universities, cooperative extension services, trade associations, private consulting firms, or other sources.

The effectiveness of your food safety team is impacted by the quality and completeness of the information you provide to them about your facility and animal food to be assessed. Therefore, for this team to conduct the hazard analysis for the food safety plan, we recommend that you define and document the following details about your facility:

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- animal food type (including identification of the animal species, life stage or production class, and intended use) and its distribution
- process flow diagram
- detailed process description to supplement the process flow diagram

A description of the animal food and how the animal food will be distributed and used helps the PCQI understand elements of, or handling of, the animal food that may impact animal food safety such as proper storage conditions and any required labeling information (e.g., “Do not feed to cattle or other ruminants”). The description should include the full name of the finished animal food, species and life stage or production class, the packaging type and material, and storage and distribution details. Finished animal food 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 the food is suitable for feeding to animals.

Understanding how the animal food will be fed to the animal (e.g., fed in fields, troughs, or in a pet owner’s home) and knowing the intended animal being fed (e.g., dairy cow or dog) helps to determine which hazards require a preventive control. For example, a facility manufacturing pet food should consider that the animal food will be directly handled by humans and fed in the home as opposed to livestock animal food that is added to a trough usually without direct contact by humans. Therefore, handling of pet food by humans in the home is an important factor to consider when conducting your hazard analysis (see 21 CFR 507.33(d)(8)).

The purpose of a process flow diagram is to provide a clear, simple description of the steps involved in the processing of your animal food and its associated ingredients as they flow through your facility from receipt to distribution. The process flow diagram should cover all steps in the process that the facility performs, including receiving and storage steps for each raw material or other ingredient, preparation, processing, packaging, storage, and distribution of the product. Additionally, the process flow diagram should identify the equipment (e.g., bins, legs, mixers, extruders, and pellet mills) used in the operations. An accurate process flow diagram serves as a useful organization format by identifying each of the process steps that you need to assess for the hazard analysis. You should verify the process flow diagram onsite in order to ensure no steps have been overlooked.

The purpose of a detailed process description is to explain what happens at each of the process steps. Information such as where and when micro ingredients are added to an animal food mix, whether an ingredient is handled manually, or whether rework is incorporated into an animal food can be important for an accurate hazard analysis.

### **2.3.2 Hazard Analysis Worksheet**

Once your PCQI (and food safety team if applicable) gathers the information you will use to conduct your hazard analysis, we recommend that you set up a method to organize your hazard analysis. The Hazard Analysis Worksheet (HA worksheet) we provide in this guidance can be a useful tool to organize your written hazard analysis, although, as stated in section 2.2, you may

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use any method that results in a written hazard analysis. In this section, we discuss how to set up the HA worksheet (see Box 2-3, which contains a form adapted from the FSPCA model food safety plan (Ref. 1).

The HA worksheet is organized by column. The information needed for the first four columns is explained in this chapter and Chapter 3. Chapter 4 describes more thoroughly the information needed for columns five and six.

**Column 1 – Ingredient and Processing Step:** List: (1) the receipt of ingredients used in your process as a way of identifying hazards associated with an ingredient (you may group similar ingredients such as grains); and (2) the processing steps. A process flow diagram and detailed process description (see Box 2-2) can help you identify the processing steps included in your hazard analysis.

**Column 2 – Known or Reasonably Foreseeable Hazard:** List the results of your identification of the known or reasonably foreseeable hazards from your hazard analysis. Include biological, chemical, or physical hazards that could be introduced or increased from ingredients, your process, or the environment. See section 2.4.1.

**Column 3 – Does the Known or Reasonably Foreseeable Hazard Require a Preventive Control:** For each known or reasonably foreseeable hazard identified in column 2, record the conclusions of your hazard analysis – i.e., the determinations you make whether each known or reasonably foreseeable hazard requires a preventive control (“Yes” or “No”). See section 2.4.2.

**Column 4 – Explanation/Justification:** You should justify, or explain, your “Yes” or “No” conclusion for column 3 based on your evaluation of the hazard. Record the key factors or a summary of the evaluation that led to the determination for each hazard of whether a preventive control is required. Explaining your reasons for a “No” conclusion can be just as important as explaining your reasons for a “Yes” conclusion. See section 2.5.

**Column 5 – Preventive Control(s) Applied:** Identify the preventive control(s) you will apply to significantly minimize or prevent the hazard requiring a preventive control (indicated by “Yes” in column 3). You might list, for example, the type of preventive control (e.g., process, sanitation, or supply-chain-applied controls), or list the specific preventive control you select (e.g., irradiation, time and temperature, or water activity). See section 2.6, and Chapter 4.

If the identified hazard does not require a preventive control, (indicated by “No” in column 3), you can leave the corresponding cell blank or put in “N/A” for not applicable.

**Column 6 – Is the Preventive Control Applied at this Step:** The HA worksheet allows you to break your production process into multiple steps (such as receiving or processing), and you may apply your preventive control at a step in the process other than the step where you list the hazard. Specify whether the preventive control will be applied at the specific processing step (i.e., “Yes” or “No”). See section 2.7.

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**Box 2-3. Example Hazard Analysis Worksheet (see Appendix D)**

(Column 1)  Ingredient and Processing Step	(Column 2)  Known or Reasonably Foreseeable Hazard	(Column 3)  Does the Known or Reasonably Foreseeable Hazard Require a Preventive Control?  “Yes” or “No”	(Column 4)  Explanation/ Justification	(Column 5)  Preventive Control(s) Applied	(Column 6)  Is the Preventive Control Applied at this Step?  “Yes” or “No”

**2.4 Conducting a Hazard Analysis**

**2.4.1 Identify Known or Reasonably Foreseeable Hazards (Hazard Identification)**

You must identify known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed or held at your facility (see 21 CFR 507.33(a)). The hazard identification must consider known or reasonably foreseeable hazards that include biological, chemical (including radiological), and physical hazards that may be present in the animal food for any of the following reasons: (1) the hazard occurs naturally, (2) the hazard may be unintentionally introduced, or (3) the hazard may be intentionally introduced for purposes of economic gain. See 21 CFR 507.33(b)(1) and (2).

We recommend that you start with an exercise such as a brainstorming session to identify hazards that are known to be, or have the potential to be, associated with your facility or animal food (the known or reasonably foreseeable hazards). A brainstorming session can help you generate a list of biological, chemical, and physical hazards. Things you could consider as you work through this procedure include:

- Information about the animal food type (including identification of the animal species, life stage or production class, and intended use) and its distribution.
- Raw materials and ingredients used in the animal food. Hazards, such as pathogens known to be associated with specific types of animal food, may be introduced during product manufacturing. For example, various ingredients may contain pathogenic bacteria that need to be significantly minimized or prevented to produce a safe pet food.

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- In-plant experience regarding what hazards may be associated with the finished animal food. This may include product testing results, consumer complaints, or knowledge of facility personnel about the condition, function, and design of the facility relevant to contamination.
- Activities conducted at each step in the manufacturing process. Some activities may unintentionally introduce hazards into the animal food (e.g., chopping with a metal blade may introduce metal fragments; conveying with a broken plastic leg cup may introduce plastic fragments; or, an improper bin clean-out may result in nutrient toxicities or deficiencies in animal food).
- Equipment used to make the animal food. Some types of equipment are more difficult to clean than others or are more prone to damage, which may increase the risk of hazards being introduced into the animal food.
- Sanitation practices. You should consider the sanitary conditions within the facility (e.g., cleanliness of equipment and processing environment) and employee hygiene. Hard-to-clean equipment may result in pathogen harborage sites. Producing medicated and nonmedicated animal food on the same line may result in an unsafe drug in a nonmedicated animal food, which may result in animal illness or death.
- External information. Sources may include scientific papers, epidemiological studies (e.g., data from previous foodborne illness incidents associated with ingredients or processes relevant to an animal food), information from applicable government or industry food safety documents, and historical data for similar animal food, if available.

After reviewing all relevant information, the PCQI (with the food safety team if applicable) can develop a list of known or reasonably foreseeable hazards that may be introduced or increased (e.g., due to pathogen growth) at each step described on the flow diagram.

We recommend that you consult Chapter 3 and Appendix E of this guidance to help you identify known or reasonably foreseeable hazards for your animal food. Chapter 3 provides a review of biological, chemical, and physical hazards and Appendix E provides tables describing ingredient-related and process-related hazards. The hazards described in Chapter 3 and Appendix E do not represent all possible hazards. You are responsible for identifying known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility, even if they are not listed in Chapter 3.

#### **2.4.2 Evaluate Known or Reasonably Foreseeable Hazards (Hazard Evaluation)**

Each known or reasonably foreseeable animal food hazard must be evaluated to assess the following (see 21 CFR 507.33(c)(1)):

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- Severity of the illness or injury to humans or animals if the hazard were to occur.
- The probability of occurrence of the hazard in the absence of a preventive control.

Your written hazard analysis also 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 (see 21 CFR 507.33(c)(2)).
- Consider the effect of certain factors on the safety of the finished animal food for the intended animal such as design of the facility and storage and distribution (see 21 CFR 507.33(d)).

### ***Assessing severity of the illness or injury***

To assess the severity of the illness or injury if the hazard were to occur, you should consider certain factors, including:

- Susceptibility of the animal to the illness or injury (e.g., dogs are more susceptible to aflatoxin than most other species).
- Susceptibility of humans to the illness or injury (e.g., infants, children, and immunocompromised individuals may be more susceptible to certain foodborne illnesses from handling pathogen contaminated pet food, or through consuming products derived from animals that had consumed contaminated food).
- The potential magnitude and duration of the illness or injury (e.g., how long an animal may be sick, whether the illness requires veterinary care and hospitalization, and production loss such as a decline in milk or egg production).
- The possible impact of secondary problems (e.g., chronic sequelae such as kidney damage or neurological disease).

If your facility does not have the expertise to assess the severity of an illness or injury that could result from a known or reasonably foreseeable hazard, you (and your PCQI) should consult with outside experts.

### ***Assessing probability the hazard will occur***

The probability (i.e., likelihood) of occurrence of a particular hazard in the absence of a preventive control can be influenced by:

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- frequency of association of the hazard with the animal food or facility
- effectiveness of facility programs such as current good manufacturing practices (CGMPs)
- method of manufacture in the facility
- conditions during transportation
- expected storage conditions during holding at the facility or after distribution
- intended use of the animal food

Knowing your animal food, ingredients, processes, packaging, transportation, distribution, and the use of the animal food is helpful in estimating the likely occurrence of known or reasonably foreseeable hazards. Hazards likely to occur in one operation or facility may not be likely to occur in another operation or facility producing the same or similar animal food because different equipment and processes may be used, the ingredients and their source may be different, or different transportation services are used. For example, one facility manufactures with only local grains while another facility receives most of its grains from out of state where growing and harvesting conditions may differ. You should consider each facility location individually when estimating the likelihood of occurrence of an animal food safety hazard.

You also could consider your facility's implementation of prerequisite programs when evaluating the probability that a hazard will occur in the absence of a preventive control. Proper implementation of an adequate prerequisite program may decrease the probability the hazard will occur. This probability may decrease to such a level that you determine the hazard does not require a preventive control. If you rely on a prerequisite program in your evaluation of probability of occurrence of a hazard, adequate information about the prerequisite program, such as a copy of your standard operating procedures (SOPs), must be included in your hazard analysis as part of your evaluation. During an inspection, FDA could determine that your prerequisite program does not adequately reduce the probability of the hazard occurrence and that a preventive control and associated preventive control management components may be necessary for the hazard.

Examples of prerequisite programs include CGMPs (21 CFR part 507, subpart B), compliance with requirements on the use of animal proteins in ruminant feed (21 CFR 589.2000 and 589.2001, the bovine spongiform encephalopathy (BSE) regulations), and a facility's standard operating procedures. For example, the BSE agent is a hazard that may cause severe illness in cattle and humans. A facility that handles protein derived from mammalian tissues or cattle material prohibited in animal food may consider compliance with FDA's BSE regulations as a prerequisite program. If the facility is properly implementing the requirements in the regulation, the facility may conclude that their prerequisite program adequately reduces the probability that the BSE agent will occur in the absence of a preventive control. This conclusion may lead the facility to determine that the hazard does not require a preventive control. We recommend that

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you provide an explanation for your decision, based on your evaluation, in the explanation/justification section (column 4) of your hazard analysis worksheet.

When estimating likelihood of occurrence, you should consider information from available sources, which may include the following:

- data from foodborne illness incidents
- data from recalls
- data from the Reportable Food Registry
- information in the scientific literature
- facility's historical information

#### Data from foodborne illness incidents

You should consider foodborne illness incidents associated with the same or similar animal food types. The Centers for Disease Control and Prevention (CDC) and FDA provide some information on outbreaks in humans from exposure to animal food. See Box 2-4 for sources. See references in section 2.8 for links to access this information.

#### **Box 2-4. Sources of Data about Outbreaks**

##### **Food and Drug Administration (FDA)**

- Outbreak investigations – reports for FDA regulated foods (Ref. 2)

##### **Centers for Disease Control and Prevention (CDC)**

- Foodborne Outbreak Online Database – searchable by pathogen for U.S. outbreaks related to animal food (Ref. 3)

#### Data from recalls

Recalls provide useful information for understanding the types of hazards found in animal food. We classify recalls as specified in 21 CFR 7.3(m).

Recall classification means the numerical designation (i.e., I, II, or III) FDA assigns to a particular product recall indicating the relative degree of health hazard presented by the recalled product.

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- Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1))
- Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote (21 CFR 7.3(m)(2))
- Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences (21 CFR 7.3(m)(3))

Federal and State Web sites post information on food recalls. See Box 2-5. Also see references in section 2.8 for links to access this information.

**Box 2-5. Sources of Data about Recalls**

- **FDA Recalls, Market Withdrawals, and Safety Alerts** (Ref. 4)
- **U.S. Department of Agriculture, Food Safety and Inspection Service Recall Archive** (Ref. 5)

Data from the Reportable Food Registry

The Reportable Food Registry (RFR) is an electronic portal for industry to report when there is reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death. The RFR helps FDA better protect public health by tracking patterns and targeting inspections. The responsible party at a registered food facility is required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. (See section 417 of the FD&C Act). We release an annual RFR report that provides a synopsis of a one-year reporting period (Ref. 6). When conducting your hazard analysis, the RFR reports can be helpful to understand the types of hazards that have previously been associated with animal food and to identify new and emerging animal food hazards.

Information in the scientific literature

Peer-reviewed scientific journals and other sources of technical literature (e.g., Codex Alimentarius Commission (Codex), the Food and Agriculture Organization, and the World Health Organization) provide considerable information on foodborne hazards, their occurrence, potential for growth in food, and their control (Refs. 7, 8 and 9). Codex maintains internationally recognized codes of practice that are based on scientific literature and are available in several languages. USDA provides a microbial modeling program that is available online and can be used to evaluate potential growth of pathogens under a variety of conditions (Ref. 10). Keep in

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mind that modeling programs may not reflect exactly what will occur in a particular animal food, but they can provide an estimate of relative risk of different scenarios.

We provide guidance documents about animal food safety. These guidance documents, which represent FDA's current thinking on a topic, are organized by topic and typically by a guidance number (a higher number corresponds to a more recent date). Trade associations also provide animal food safety recommendations for specific types of animal foods and industry needs. Another useful resource is the Google Scholar search engine.

### Facility's historical information

You may already have considerable information on your products from various laboratory tests on finished animal food, ingredients, in-process materials, or environmental monitoring. In addition, you may have experienced a contamination problem in the past that suggests a hazard is known or reasonably foreseeable, or received consumer complaints about certain hazards, such as physical hazards. You should consider your facility's historical data when conducting your hazard evaluation.

### **2.4.3 Assessing the Combination of Severity and Probability**

You can separately assess: (1) the severity of illness and injury if the hazard were to occur, and (2) the probability of the hazard's occurrence in the absence of a preventive control. However, you also can consider the combination of severity and probability when evaluating the known or reasonably foreseeable hazard to determine if the hazard requires a preventive control.

For example, an illness or injury may have a moderate severity (e.g., may require medical or veterinary intervention in most cases), but the probability that the hazard will occur in the absence of a preventive control is low (e.g., rarely occurs in your type of animal food). If you look at the severity of the illness/injury and the probability that the hazard that causes the illness/injury will occur in the absence of a preventive control independently, the determination of whether the hazard requires a preventive control may be difficult in situations when the severity is moderate but probability is low (or the reverse). Looking at the severity and probability in combination may be helpful in making the determination of whether the hazard requires a preventive control.

Evaluating the combination of severity and probability can be done in different ways. See the FSPCA animal food curriculum for an example of a system to evaluate severity and probability in combination (Ref. 1). If you evaluate the combination of severity and probability for the hazard using a specific system, we would consider that system part of your hazard analysis, which must be written (see 21 CFR 507.33(a)(2)).

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#### **2.4.4 Evaluating Environmental Pathogens When Animal Food is Exposed to the Environment**

If the animal food you make is exposed to the environment in your facility before packaging, the animal food could be contaminated with environmental pathogens such as *Listeria monocytogenes* (*L. monocytogenes*) or *Salmonella*. You must then include an evaluation of environmental pathogens in your hazard evaluation if the animal food you make is exposed to the environment before packaging and does not receive a treatment or include a control measure that would significantly minimize the pathogen. See 21 CFR 507.33(c)(2).

#### **2.4.5 Evaluation of Other Factors**

When evaluating hazards, you must consider the effect of the following on the safety of the finished animal food for the intended animal (21 CFR 507.33(d)):

- The formulation of the animal food: The addition of certain ingredients such as acids and preservatives may be critical to the safety of the finished animal food, because they may inhibit growth of, or even kill, microorganisms of public health (human or animal) significance. This could impact the evaluation at steps during production and storage with respect to pathogen growth. A multicomponent animal food may have individual ingredients that do not support growth of undesirable microorganisms (e.g., because of pH or water activity ( $a_w$ )), but when put together there may be an interface where the pH and  $a_w$  changes.
- The condition, function, and design of the facility and equipment: The condition, function, or design of a facility or its equipment could potentially result in hazards in finished animal food. For example, older equipment in a pet food facility (e.g., older extruders, dryers, and conveying equipment) may be more difficult to clean (e.g., because of close fitting components or hollow parts) and thus provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments. Equipment designed with metal-to-metal contact may generate metal fragments (a physical hazard). A facility that manufactures, processes, packs, or holds animal food such as raw pet food may have cold, moist conditions that are conducive to the development of a niche where the pathogen *L. monocytogenes* can become established and contaminate animal food-contact surfaces and finished animal food.
- Raw materials and other ingredients: A finished animal food can become contaminated through the use of contaminated animal food ingredients. For example, corn can be contaminated with aflatoxin, a chemical hazard. Machinery-harvested ingredients may be contaminated with physical hazards because the machinery may pick up foreign material from the field or not adequately separate foreign material from the harvested crop.

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- **Transportation practices:** The safety of a finished animal food may be affected by transportation practices for incoming raw materials and ingredients or for the outgoing finished animal food. For example, you could consider whether an ingredient may require time and temperature control to ensure safety, or a bulk ingredient may need protective covering to prevent physical hazards. You also should be aware of applicable requirements of the Sanitary Transportation of Human and Animal Food regulation in 21 CFR part 1, subpart O, which helps ensure that motor vehicle and rail vehicle transportation practices do not create food safety risks.
- **Manufacturing/processing procedures:** Hazards may arise from manufacturing/processing procedures such as mixing of micronutrients that could result in nutrient deficiencies or toxicities (e.g., excessive vitamin D in dog food, excessive copper in food for sheep, or inadequate thiamine in thermally processed cat food) in the finished animal food. In the production of nonmedicated animal food in a medicated feed facility, the manufacturing/processing procedures may result in unsafe drug carryover to the nonmedicated animal food due to inadequate clean-out procedures or improper sequencing of different animal food (e.g., the use of monensin, which is safe for use for cattle but toxic to horses, could result in an unsafe drug carryover). Physical hazards may occur from metal fragments generated during the manufacture of animal food on equipment (e.g., screens or hammer blades) used to reduce product size.
- **Packaging activities and labeling activities:** The packaging of an animal food can vary (e.g., reusable totes, single use poly bags, cans, or pouches). Improper packaging could introduce a hazard into the animal food. You should ensure the finished animal food will be labeled appropriately. Some animal food may need labeling information to ensure safe use of the finished animal food. For example, the manufacturer of a copper supplement might include the use levels for animal food for different species or a labeling statement specifying the maximum safe level of copper in an animal food intended for sheep.
- **Storage and distribution:** Some finished animal food is stored and distributed under certain conditions to maintain safety (e.g., raw pet food is frozen). There may be an increased probability that a hazard will occur in the absence of a preventive control for such animal food.
- **Intended or reasonably foreseeable use:** Animal food is often manufactured to meet the specific nutrient requirements of the intended species. For example, a diet manufactured for beef cattle may contain higher levels of copper compared to a diet intended for sheep due to the differences in nutrient requirements. The intended or reasonably foreseeable use is that the diet will be fed to beef cattle and not to sheep because a high copper diet would be toxic to sheep. Some animal food, e.g., pet food, is expected to be fed in the home, where humans might be exposed to biological hazards from handling the pet food.

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- Sanitation, including employee hygiene: Sanitation measures and practices can impact the likelihood of a hazard being introduced into animal food. For example, the frequency with which a production line is shut down for a complete cleaning can impact the potential for animal food residues to transfer pathogens from equipment to the animal food (e.g., pathogens present on raw meat that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene such as hand-washing can reduce the potential for transfer of pathogens such as *Salmonella*.
- Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins): Hazards such as aflatoxin are subject to a weather-dependent effect in that aflatoxin levels in some raw agricultural commodities are more of a problem in some years than in others.

### **2.5 Use of Your Written Evaluation as Explanation/Justification Whether a Hazard Requires a Preventive Control**

You must include in your food safety plan your written hazard evaluation, which is part of your written hazard analysis (see 21 CFR 507.31(c)(1)). Your evaluation should provide justification for determining that a known or reasonably foreseeable hazard does or does not require a preventive control.

If you use the HA worksheet shown in Box 2-3 and Appendix D, your determination about whether a hazard requires a preventive control is shown by a “Yes” or “No” answer in column 3. You base this determination on your written evaluation of the severity of the illness or injury if the hazard occurs and the probability the hazard will occur in the absence of a preventive control, as well as any other relevant evaluation factors you consider (see 21 CFR 507.33(c) and (d)).

In column 4 of the HA worksheet, you would explain or justify your column 3 “Yes” or “No” answer. Depending on the length of your written hazard evaluation, the justification may be the entirety of your evaluation, could be a shortened summary of your evaluation, or could be a reference to a separate document.

For example, your facility identifies metal fragments as a known or reasonably foreseeable hazard. You have implemented a system of prerequisite programs with SOPs for the use of screens and magnets that include daily observation and cleaning as needed of the screens and magnets. You evaluate this hazard by assessing the severity of the injury a metal fragment could cause. Based on your written evaluation, you determine that the metal hazard would result in minimal or no illness or injury to the animals consuming your animal food. You also determine there would be no illness or injury to humans consuming products derived from food-producing animals that ate your animal food contaminated with metal fragments or through handling the animal food. You then assess the probability the metal hazard will occur in the absence of a preventive control. Based on your written evaluation, you determine that the probability of occurrence of the metal hazard in the absence of a preventive control is low, in part because of the implementation of your system of prerequisite programs.

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If you use the HA worksheet in Box 2-3 and Appendix D, your column 4 justification could be a short statement referencing your SOPs for the use of screens and magnets. Because you rely in part on your system of prerequisite programs in your evaluation of a hazard, adequate information about your system (e.g., a copy of the SOP) must be included in your hazard analysis.

If your HA worksheet is the only place that you document your written evaluation, you must include your HA worksheet in your food safety plan and your worksheet must include your assessment of the severity of illness or injury and the probability of occurrence of the hazard in the absence of a preventive control (see 21 CFR 507.33(c)(1)). Therefore, you may want to include additional columns to the HA worksheet to record your severity and probability assessments. See the FSPCA curriculum for animal food for an alternate example of a hazard analysis worksheet (Ref. 1).

### **2.6 Identifying Preventive Controls**

#### **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. (21 CFR 507.3)

For each hazard that you identified in column 2 as known or reasonably foreseeable and then indicated in column 3 as requiring a preventive control, you must identify and implement at least one preventive control to significantly minimize or prevent the hazard (see 21 CFR 507.34(a)(1)). See Chapter 4 for a detailed description of preventive controls.

If a preventive control can be applied at a point or step in the animal food production process and is essential at that point to prevent or eliminate the hazard requiring a preventive control, or reduce it to an acceptable level, you should classify the point or step as a critical control point (CCP). There are several preventive control approaches, which may or may not include CCPs, that you can consider depending on the known or reasonably foreseeable hazard and where in the process flow you determine the control measure should be applied. These include:

- process controls (21 CFR 507.34(c)(1))
- sanitation controls (21 CFR 507.34(c)(2))
- supply-chain controls (21 CFR 507.34(c)(3))
- other preventive controls (21 CFR 507.34(c)(5))

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Process controls are applied at specific processing steps where parameters such as time and temperature must be controlled to significantly minimize or prevent a hazard. Sanitation controls may be important to prevent contamination with microbial pathogens. Supply-chain controls involve use of the supply-chain program for a hazard that the receiving facility has identified in raw materials or ingredients and that will be controlled by the supplier (see 21 CFR part 507, subpart E). Other preventive controls, that are not identified as process controls, sanitation controls, or supply-chain controls, include any other procedures, practices, and processes necessary to significantly minimize or prevent a hazard. Examples of other controls include hygiene training and other current good manufacturing practices.

For every hazard you determine requires a preventive control, you must identify and implement at least one preventive control. See 21 CFR 507.34(a)(1). Importantly, remember that more than one hazard may be addressed by a preventive control. For example, several vegetative pathogens, such as *Salmonella*, *L. monocytogenes*, and pathogenic *E. coli*, are killed by sufficient heating. If you use the HA worksheet in Box 2-3, record the preventive controls that you choose in column 5 of the HA worksheet for each “Yes” answer in column 3. If the hazard does not require a preventive control, you would not complete columns 5 and 6.

### **2.7 Is the Preventive Control Applied at this Step?**

When evaluating the known or reasonably foreseeable hazards, you should identify the step or steps in your production of animal food where the hazard may occur (such as receiving, processing, packaging, or storage). Once you determine that a hazard requires a preventive control, you then identify a preventive control that will significantly minimize or prevent the hazard and determine where in your production process to apply the preventive control. Determining that a hazard occurs at a particular processing step does not mean that the hazard must be controlled at that processing step.

For example, you may identify *Salmonella* as a hazard in raw meat ingredients at the receiving step of your production process. You determine that the hazard does not need to be controlled at receiving because the raw meat is going to undergo a preventive control during processing that will significantly minimize the *Salmonella* hazard. If you use the HA worksheet in Box 2-3, record in column 6 that the hazard would not be controlled at the receiving step and would instead be controlled during the processing step (i.e., “Yes” or “No”).

### **2.8 References for Chapter 2**

1. Food Safety Preventive Controls Alliance. 2016. “Preventive Controls for Animal Food Participant Manual”. First Edition v.1.0.
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**CHAPTER 3 – HAZARDS ASSOCIATED WITH THE MANUFACTURING,  
PROCESSING, PACKING, AND HOLDING OF ANIMAL FOOD**

**3.1 Purpose of this Chapter**

The guidance provided in this chapter is intended to help you consider the biological, chemical, and physical hazards that may be known or reasonably foreseeable hazards in animal food facilities and that may be applicable to your facility and animal food. It is important for you to understand the hazards that may be associated with your products using the raw materials and other ingredients, processes, and equipment specific for those products, as well as the environment of your specific facility. This chapter does not provide an exhaustive compilation of hazards or details about each hazard. Where possible, we cite scientific literature, regulations, or guidance that may provide useful detailed discussion or analysis of hazards.

Although this chapter sometimes describes the types of preventive controls that may be appropriate for you to implement to control specific hazards, see Chapter 4 – Preventive Controls, of this guidance for more detailed discussion of preventive controls.

**3.2 Known or Reasonably Foreseeable Hazards**

Animal food can become contaminated with biological, chemical (including radiological), or physical hazards. Table 3-1 contains some examples of biological, chemical, and physical hazards in animal food. For additional examples of hazards in animal food by food category see Appendix E – Aid to Identifying Animal Food Hazards.

**Table 3-1. Examples of Known or Reasonably Foreseeable Hazards**

<b>Hazard Category</b>	<b>Hazard Sub-Category</b>	<b>Examples</b>
Biological	Bacteria	<i>Salmonella</i> spp. <i>Listeria monocytogenes</i> ( <i>L. monocytogenes</i> ) Pathogenic <i>Escherichia coli</i> ( <i>E. coli</i> )
Biological	Parasites	<i>Toxoplasma gondii</i> <i>Cryptosporidium</i>
Biological	Prions	Prion causing Bovine Spongiform Encephalopathy (BSE)
Chemical	Pesticide residues	Organochlorines Organophosphates Carbamates

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<b>Hazard Category</b>	<b>Hazard Sub-Category</b>	<b>Examples</b>
Chemical	Heavy metals	Lead Cadmium Mercury
Chemical	Natural Toxins	Aflatoxin Fumonisin Ochratoxin Plant toxins (glucosinolates) Tissue toxins
Chemical	Drug residues Drug carryover	Animal drugs (e.g., penicillin, pentobarbital) Carryover of ionophores (e.g., monensin) into horse feed
Chemical	Unapproved color and food additives	D&C Red No. 6 Propylene glycol (specifically in cat food) Ethylene glycol Melamine
Chemical	Intentionally introduced for the purpose of economic gain	Triazines (melamine, cyanuric acid)
Chemical	Radionuclides	Radium 226 and 228
Chemical	Environmental	Dioxins Polychlorinated Biphenyls (PCBs) Polyaromatic Hydrocarbons (PAH)
Chemical	Nutrient deficiencies or toxicities	Minerals (e.g., inadequate calcium or salt (sodium chloride); excess calcium, selenium, or salt) Vitamins (e.g., inadequate thiamine (cat food); excess vitamin D)
Chemical	Industrial chemicals	Cleaning chemicals Non-food-grade lubricants

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Hazard Category	Hazard Sub-Category	Examples
Physical	Physical	Metal Glass Hard plastic

In your hazard analysis, you must identify and evaluate the known or reasonably foreseeable biological, chemical, and physical hazards related to your animal food (which includes raw materials and other ingredients (ingredient-related hazards)), processes (process-related hazards), and your animal food-production environment (facility-related hazards). See 21 CFR 507.33. Throughout this chapter, we discuss biological, chemical, and physical hazards from the perspective of ingredient-related hazards, process-related hazards, and facility-related hazards.

### 3.3 Biological Hazards

The biological hazards that are the focus of this guidance are bacterial pathogens (e.g., *Salmonella* spp., *L. monocytogenes*, and pathogenic *E. coli*), and certain parasites (e.g., *Toxoplasma gondii*) that may be associated with animal food or animal food processing operations and that can cause illness or disease in humans or animals. The other biological hazards mentioned in Table 3-1 include other parasites (e.g., *Cryptosporidium* spp.) and prions (e.g., prions causing BSE in cattle).

Animal food can become contaminated with bacterial pathogens. These pathogens can be:

- ingredient-related hazards – i.e., introduced from raw materials and other ingredients
- process-related hazards – e.g., if the pathogens:
  - survive the manufacturing process
  - increase in number due to lack of time/temperature control or due to the animal food’s formulation
  - are introduced into a finished animal food due to loss of container integrity
- facility-related hazards – e.g., if the pathogens are introduced from:
  - insanitary animal food processing equipment
  - cross-contamination between raw and cooked products
  - contaminated air
  - sewage or contaminated water

Table 3-2 is a Quick Reference Guide to help you identify bacteria and parasites and potential sources or entry points in your facility. The hazards listed in Table 3-2 will not apply to all animal food at all facilities. For additional examples of hazards in animal food by food category see Appendix E – Aid to Identifying Animal Food Hazards.

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**Table 3-2. Quick Reference Guide for Common Sources of Bacteria and Parasites in Animal Food**

Primary Source	Bacteria and Parasites (and Some Example Sources)
Ingredient-related	<p><i>Salmonella</i> spp. (raw meat and poultry, raw eggs or egg product, animal protein product (such as meat and bone meal and fish meal), plant protein products (such as canola meal, soybean meal), fruits and vegetables, and flavor agents)</p> <p><i>L. monocytogenes</i> (raw agricultural commodities)</p> <p>Pathogenic <i>E. coli</i> (raw meat, fruits and vegetables, plant protein product)</p> <p><i>Clostridium</i> spp.</p> <p><i>Toxoplasma gondii</i> (raw meat)</p> <p><i>Cryptosporidium</i> spp. (contaminated water used as an ingredient)</p>
Process-related	<p><i>Salmonella</i> spp.</p> <p><i>L. monocytogenes</i></p> <p>Pathogenic <i>E. coli</i></p> <p><i>Clostridium</i> spp.</p>
Facility-related	<p><i>Salmonella</i> spp. (pests, dust, floors, cold wet areas, equipment, drains, condensate, coolers, and soil)</p> <p><i>L. monocytogenes</i> (floors, cold wet areas, equipment, drains, condensate, coolers, and soil)</p>

**3.3.1 Foodborne Pathogens Associated with Animal Food**

***Bacterial pathogens***

Bacterial pathogens can be classified based on whether they form spores (sporeformers) or whether they exist as vegetative cells and do not form spores (non-sporeformers). Spores are not hazardous as long as they remain in the spore state. Spores are very resistant to heat, chemicals, and other treatments that would normally kill vegetative cells of both sporeformers and non-sporeformers.

When spores survive a processing step designed to kill vegetative bacteria, they may become a hazard in the animal food if they are exposed to conditions that allow germination and growth as vegetative cells. This can be particularly serious when a processing step has removed most of

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their competition. Thus, other controls such as reduced pH or water activity ( $a_w$ ) or temperature control (refrigeration or freezing) may be needed to control sporeformers that remain after a kill step. As a result, when spores are a concern, the process steps used to kill them are often much more stringent than those necessary to kill vegetative cells.

*Salmonella* spp. is the bacterium responsible for salmonellosis in humans and animals. For animals, different animal species typically develop disease in response to different *Salmonella* serotypes. *Salmonella* serotypes that cause disease in a particular species are referred to as pathogenic for that animal species. For livestock and poultry food, the following are some examples of the food and the pathogenic *Salmonella* serotypes that have been associated with disease in the particular animal species consuming the animal food:

- food for poultry with *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis
- food for swine with *Salmonella* Choleraesuis
- food for sheep with *Salmonella* Abortusovis
- food for horse with *Salmonella* Abortusequi
- food for cattle with *Salmonella* Newport or *Salmonella* Dublin

We consider animal food for livestock and poultry to be adulterated when contaminated with a *Salmonella* serotype that is considered pathogenic to the animal intended to consume that animal food and the animal food will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella* (Ref. 1). The *Salmonella* serotypes listed above are not commonly found in animal food at manufacturing facilities and as indicated above, some *Salmonella* serotypes are pathogenic only for certain species. Therefore, you may determine that *Salmonella* is not a known or reasonably foreseeable hazard for your animal food, or is not a hazard requiring a preventive control, if you manufacture livestock or poultry food.

We consider all pet food contaminated with any *Salmonella* serotype to be adulterated when the pet food will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella* (Ref. 1). Infected dogs and cats can either be asymptomatic or exhibit clinical signs of gastroenteritis. In severe cases, clinical signs can also include fever, dehydration, rapid heart rate, rapid breathing, shock, and death. Infected dogs and cats can shed the bacteria in their feces for up to 6 weeks, whether they are exhibiting clinical signs or are asymptomatic (Ref. 2).

Pet food contaminated with *Salmonella* also poses a significant risk to humans who handle pet food. In addition, pet owners can become infected when handling *Salmonella*-contaminated pet food dishes. This association between human outbreaks of salmonellosis and *Salmonella*-contaminated pet food is well documented. For example, the CDC reported that from January 1, 2006 to October 31, 2008, 70 human cases of salmonellosis were linked to *Salmonella* Schwarzengrund in dry dog food manufactured by a facility in the U.S. (Ref. 3). In 2012, 49 individuals were infected with *Salmonella* Infantis, which was linked to dry dog food manufactured by a different facility in the U.S. (Ref. 4). There also are published reports of transmission of *Salmonella* to humans via contact with *Salmonella*-infected pets or exposure to fecal-contaminated environments (Refs. 5, 6 and 7).

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***Listeria monocytogenes* (*L. monocytogenes*)** is the bacterium responsible for listeriosis in humans and animals. Clinical signs of listeriosis in dogs and cats can range from the non-specific such as vomiting, diarrhea, and fever to the more specific such as neurological (imbalance or circling), or abortion in a pregnant animal. If the animal becomes septicemic (an infection throughout its body), the clinical signs can range from high fever and lethargy to shock or death.

There have been recalls of *L. monocytogenes* contaminated pet food (mostly raw dog and cat food) due to the potential to cause listeriosis in humans or pets (Refs. 8, 9 and 10). We are not aware of any confirmed cases of humans becoming ill after handling *L. monocytogenes* contaminated pet food or from contact with infected dogs and cats. However, transmission of *L. monocytogenes* from contaminated pet food to humans or pets could be similar to transmission of *Salmonella*.

**Pathogenic Strains of *Escherichia coli* (*E. coli*)** are bacteria associated with foodborne illness in humans and animals. Dogs and cats with foodborne illness caused by pathogenic *E. coli* can be asymptomatic or have symptoms ranging from mild gastroenteritis to hemorrhagic diarrhea. A study conducted to evaluate the prevalence of microbial organisms in various types of pet food found strains of non-O157:H7 Shiga toxin-producing *E. coli* in some raw pet food and jerky type treats (Ref. 11). We are not aware of any confirmed cases of humans becoming ill after handling pathogenic *E. coli* contaminated pet food. However, transmission of pathogenic *E. coli* from contaminated pet food to humans could be similar to transmission of *Salmonella*.

***Clostridium spp.*** are spore-forming bacteria that grow best in low oxygen conditions and can produce toxins (e.g., neurotoxins or enterotoxins). The bacteria form spores that can survive in a dormant state until exposed to conditions that support their germination and growth (e.g., low oxygen conditions). *Clostridium botulinum* is one example. There are seven types of *C. botulinum* designated by letters A through G. Type C is most important in most animal species, but types D, B, and occasionally A and E can be a cause of disease (Ref. 12). Most domestic animals are susceptible to intoxication by *C. botulinum* toxin, but some species are more susceptible (e.g., mink, horses and cattle) and some species are fairly resistant (e.g., dogs and cats) (Ref. 13). *C. botulinum* is often found in the intestinal tracts of poultry, cattle, and swine (Ref. 14). Poultry carcasses (and some slaughter by-products) that are manufactured into animal food (such as food for mink) can be a source of botulinum toxin if the animal food is not properly treated (e.g., not heat treated, acidified, refrigerated, or frozen) and a low oxygen condition occurs during production. *C. botulinum* toxin could also occur in inadequately processed low-acid canned food (LACF). However, with respect to microbiological hazards, activities subject to 21 CFR part 113 (which covers LACF) are not subject to the requirements in 21 CFR part 507, subparts C and E, provided the facility is in compliance with 21 CFR part 113. See 21 CFR 507.5(b).

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### ***Other pathogens***

***Toxoplasma gondii* (*T. gondii*)** is a parasite that causes toxoplasmosis in humans and many animals (Ref. 15). A common route of transmission in humans is through ingestion of contaminated and undercooked meat. Inadvertent ingestion can also occur through handling contaminated utensils or eating food contaminated by those utensils. Humans also can become infected through indirect ingestion after handling cat feces containing oocysts (a fertilized egg) or from handling anything contaminated with cat feces containing oocysts (e.g., dirt while gardening, eating unwashed fruits and vegetables, or drinking contaminated water). Pregnant women who become infected can pass the infection to their fetus. Immunocompromised people and pregnant women are at the highest risk for toxoplasmosis. Young or immunocompromised animals can also develop clinical infections, causing a variety of diseases depending on the tissues infected (e.g., pneumonia, encephalitis, liver necrosis).

A recent meta-analysis was conducted to look at the prevalence of *T. gondii* in food-producing animals used for meat in the U.S. (Ref. 16). The study found *T. gondii* infection is more widespread in lamb, goats, non-confinement-raised chickens, and non-confinement-raised pigs. The consumption of raw meat significantly increases the seroprevalence (i.e., the overall occurrence of a disease in a given population at one time, as measured by blood tests) of *T. gondii* in cats (Ref. 17). This includes cats that are outdoors and hunting prey, but also includes cats fed raw meat based diets (Ref. 17). A pet food manufacturer, especially one making raw pet food for cats, might consider this parasite as a known or reasonably foreseeable biological hazard in meat from the species of animals in which *T. gondii* is more likely to be found.

**Transmissible Spongiform Encephalopathy Agents** – Transmissible spongiform encephalopathies, or prion diseases, are diseases caused by abnormal, misfolded forms of the prion protein. The prion protein occurs normally in vertebrate animals and is found at highest levels in central nervous system tissues.

Prion diseases of animals in the United States are bovine spongiform encephalopathy (BSE) in cattle, scrapie in sheep and goats, and chronic wasting disease (CWD) in deer and elk. Of the prion diseases, only BSE is transmitted primarily through animal food. BSE transmission can occur when tissues from infected cattle are rendered and the meat and bone meal (MBM) is recycled as an additive in cattle food, and then eaten by non-infected cattle. This type of tissue recycling was banned in the United States in 1997 by FDA's BSE regulation (21 CFR 589.2000), which prohibits the use of mammalian protein, with certain exceptions, in food for ruminants. Though scrapie and CWD are not considered foodborne diseases, the BSE regulation protects against the potential for transmission by this route because it prohibits the use of mammalian protein in food for all ruminant animals, including food for sheep, goats, deer, antelopes, buffalo, and elk.

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Measures that exclude mammalian-derived tissue, such as bovine derived MBM, from ruminant feed (including measures that prevent bovine derived MBM entering ruminant feed via cross-contamination during manufacturing and distribution), which are required under 21 CFR 589.2000 and 21 CFR 589.2001, are considered by FDA to be effective against the transmission of the BSE agent. See Chapter 2 of this guidance for additional information.

### **3.3.2 Ingredient-Related Biological Hazards**

See Table 3-2 in this chapter of this guidance for information that can help you identify ingredient-related biological hazards that may be associated with specific animal food. See Chapter 4 – Preventive Controls for recommendations on control of some specific ingredient-related biological hazards.

### **3.3.3 Process-Related Biological Hazards**

This section helps you identify process-related biological hazards for the animal food that you produce. Some process-related biological hazards can occur if something goes wrong with a process control. For example, pathogens that you intend to control by heat treatment could survive if your animal food is not subjected to an adequate time-temperature combination during application of the heat treatment. Also, pathogens that you intend to control by refrigeration could multiply or multiply and produce toxin if there is a lack of proper refrigeration during animal food holding.

Other process-related biological hazards are not related to something going wrong with a process control. For example, if you use a process control that significantly minimizes pathogens in a pet food and then add flavoring after the control, pathogens in the flavoring could be introduced into the pet food after the process control step. Also, pathogens could be introduced into animal food after packaging if there is a lack of container integrity.

In the following sections on process-related biological hazards, we describe examples of these kinds of process-related biological hazards. See Chapter 4, section 4.5, for recommendations on control of some specific process-related biological hazards.

#### ***Bacterial pathogens that survive process controls***

If a process control that you designed to kill bacterial pathogens does not work as intended, the bacterial pathogens, spores, or both that you intended to control can be present in your animal food. See Chapter 4 for an overview of recognized and established processing conditions to control pathogens and for factors to consider when designing your process to prevent problems. For example:

- Some animal food doesn't heat consistently throughout. If the minimum process for lethality is not achieved at the coldest spot of the animal food, pathogens may survive the heat treatment.

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- Certain characteristics of animal food make it either easier or harder to destroy bacterial pathogens, if present. For example, it is more difficult to kill pathogens in animal food with high oil content; oils tend to shield pathogens from the effects of heat. The presence of moisture, both in and surrounding the animal food, makes destruction easier. If these characteristics have not been considered in designing the process, pathogens may survive the treatment.
- Different bacterial pathogens have different heat resistances and spores of bacterial pathogens are more heat tolerant than vegetative cells. If the process is not designed to control the most resistant pathogen of concern in the animal food, pathogens may survive the treatment.

### ***Bacterial pathogens that grow***

#### Due to time and temperature abuse

Bacterial pathogens introduced from contaminated ingredients into an animal food that does not undergo a lethality process, or pathogens that survive a lethality process as a result of a problem with a process control, can multiply (grow) and, depending on the pathogen, produce toxin as a result of time and temperature abuse of the animal food. Time and temperature abuse occurs when animal food is allowed to remain at temperatures favorable to bacterial pathogen growth for sufficient time resulting in unsafe levels of the pathogens or their toxins in the animal food. Animal food that is subjected to time and temperature abuse can support growth of pathogens such as *Salmonella*. For example, holding raw materials and ingredients that require refrigeration at room-temperature for several hours prior to processing can lead to pathogen growth. Time and temperature abuse can cause pathogenic bacteria to grow to such levels that the process control normally used may not be adequate to eliminate the hazard.

In evaluating the potential of bacterial pathogens to grow in your animal food, you should consider the following factors:

- the types of pathogenic bacteria that are known or reasonably foreseeable
- whether those pathogens can grow in the animal food
- the expected initial level of the pathogenic bacteria in the animal food

See Chapter 4 for an overview of processing conditions to minimize pathogen growth by controlling temperatures to prevent pathogen growth and controlling time of exposure to temperatures at which growth can occur.

#### Due to poor formulation control

Animal food types most susceptible to biological hazards due to problems with formulation (e.g., pH,  $a_w$ , and preservatives) are those that do not receive a kill step during their processing and that may require refrigeration or freezing for safety during their manufacture and shelf life (e.g., some raw or minimally cooked pet food). For these animal food types, product formulation can play an important role in significantly minimizing or preventing hazards. Well-controlled

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formulation parameters such as pH,  $a_w$ , and use of preservatives can work in concert to establish an ecosystem designed to inhibit the growth of the pathogens that may be present.

To determine the potential for a process-related hazard due to poor formulation control, we recommend that you know the formulations or ingredient lists of your incoming ingredients, as well as the equilibrated pH, titratable acidity,  $a_w$ , percent moisture and percent sodium, as appropriate, of the finished animal food. Much of the animal food susceptible to biological hazards due to problems with formulation is made up of multiple ingredients, each with its own specific set of formulation parameters. In determining the potential for a process-related biological hazard due to poor formulation control, we also recommend that you consider the interactions that may occur among the various raw materials and other ingredients when combined. See Chapter 4, section 4.5.3, for an overview of formulation-based controls.

#### Due to reduced oxygen packaging

From a food safety standpoint, packaging serves two functions: (1) it prevents contamination of the animal food; and (2) it makes possible, or extends the effectiveness of, food preservation methods. For example, packaging can maintain the atmosphere in a controlled or modified atmosphere package or a vacuum package, or it can prevent rehydration of a dried animal food. Modified atmosphere packaging and vacuum packaging methods are grouped into a category that we call reduced oxygen packaging (ROP). ROP is used to prevent the growth of spoilage organisms, thereby extending the shelf life of the product. There are some other product quality benefits as well, such as reductions in rancidity, shrinkage, and color loss.

However, ROP does not control the growth of all bacterial pathogens and can create a process-related biological hazard. The extended shelf life provides more time for toxin production or pathogen growth if pathogens are present and temperatures are suitable for growth. Lower oxygen levels favor pathogens that can grow in the absence of oxygen over the aerobic spoilage organisms that require oxygen for growth. For this reason, you may get toxin production before you get spoilage.

The primary concern with ROP is *C. botulinum*, although there also may be concerns with other pathogens such as *L. monocytogenes*, particularly in refrigerated animal food (e.g., pet food). If you have identified *C. botulinum* as a known or reasonably foreseeable hazard in your animal food, you should not use ROP unless barriers for *C. botulinum* are present. These barriers could include  $a_w$ , pH, salt, thermal processing in the final container, and freezing with frozen storage and distribution. Each of these barriers by itself can be effective in the control of *C. botulinum* growth. Refrigeration below 38°F (3.33°C) can prevent growth of all strains of *C. botulinum*, but because temperatures above this are commonly employed for refrigeration, temperature should not be relied on as the only control. Combinations of barriers that individually would not control growth of *C. botulinum* can work together to prevent growth.

For a further discussion on the potential for ROP to create a process-related biological hazard as it relates to human food, see Annex 6 of the 2013 Food Code (Ref. 18).

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### ***Bacterial pathogens in ingredients added after applying process controls***

The manufacture of certain animal food involves, by design, the addition of ingredients after application of process controls. For example, flavorings and fats may be added after extrusion (i.e., the process control) but prior to packaging in the production of some pet food. A facility that produces animal food containing ingredients added after a process control should consider the potential for the added components to be a source of a process-related biological hazard as part of its hazard analysis.

### ***Bacterial pathogens introduced after packaging due to lack of container integrity***

Animal food manufactured and processed (e.g., heat treated) in a container and/or clean-filled after treatment can become contaminated if its container loses seal integrity, thereby exposing the processed animal food to biological hazards. Poorly formed or defective container closures can increase the risk of microbial pathogens entering the container through container handling that occurs after the product has been filled and the container has been sealed.

### **3.3.4 Facility-Related Biological Hazards**

Facility-related biological hazards in animal food could occur from exposure or contact with contaminated equipment during procedures such as conveying, mixing, cooling, or packaging. In addition, animal food that is subjected to a preventive control (e.g., heat treatment, high pressure processing) to significantly minimize pathogens identified as hazards requiring a preventive control, may be recontaminated through exposure to a facility environment that contains these pathogens (Ref. 19). As discussed in the following sections on facility-related biological hazards, there are challenges to preventing recontamination.

The PCAF requirements specify that your hazard evaluation 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. See 21 CFR 507.33(c)(2). In the following sections, we provide information on potential sources of facility-related environmental pathogens in different types of animal food facilities.

Effectively designed and implemented CGMPs are key to keeping biological hazards out of your animal food. However, the application of CGMPs cannot guarantee that a processed animal food will not become contaminated from the environment. This is one reason why the PCAF requirements specify that 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 (see 21 CFR 507.34(c)(2)). The PCAF requirements specify that (as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's animal food safety system) you must conduct activities that include environmental monitoring for an environmental pathogen, or for an appropriate indicator organism, if contamination of an animal food with an environmental

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pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples. See 21 CFR 507.49(a)(3).

### *Sources of facility-related biological hazards*

The likelihood of product contamination with a facility-related environmental pathogen increases as the prevalence of the environmental pathogens in the processing environment increases. The prevalence of the environmental pathogens in the processing environment can be influenced by the raw materials used in the process, the type of process, and the hygienic practices applied to keep the processing area clean and, as necessary, sanitized. Table 3-3 is a guide to help you identify some of the sources of facility-related biological hazards that can contaminate the animal food processing environment; Table 3-3 does not provide an exhaustive list of such sources.

**Table 3-3. Sources and Modes of Contamination of Facility-Related Biological Hazards**

Source	Modes of Contamination
Raw agricultural commodities and other ingredients (e.g., raw milk, raw offal, oil seeds, fruits and vegetables, meat and bone meal)	Transfer of biological hazards from the ingredient to equipment and utensils Transfer of biological hazards from the ingredient to personnel handling the ingredient Inadequate cleaning of containers used to store ingredients containing hazards
Food handlers and maintenance personnel	Transfer of biological hazards from one point to another on their person (e.g., shoes and other clothing) Improper hand washing Transfer of biological hazards to animal food through improper handling or maintenance practices (e.g., insufficient cleaning and sanitizing animal food-contact surfaces after equipment maintenance)
Air and water	Lack of appropriate air filtration for cooling, drying, air conveying Improper air flow from raw materials and other ingredients areas to finished animal food areas Aerosols from improper cleaning practices

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Source	Modes of Contamination
Insects and pests (e.g., flies, cockroaches, rodents)	Transfer of biological hazards from outside the facility or from one point to another in the facility as pests travel  Contact with finished animal food
Transport equipment (e.g., forklifts, racks, carts, conveyor belts)	Transfer of biological hazards throughout the facility via wheels on equipment  Cross-contamination from using the same equipment for ingredients and finished animal food

***Transient and resident facility-related environmental pathogens***

Once bacterial pathogens have been introduced into the processing environment, experience has shown that pathogens may be present as transient contamination or as resident contamination within a facility.

Transient contamination

Bacterial pathogens, including environmental pathogens, are typically introduced into the processing facility through incoming raw materials and other ingredients, personnel, or pests. It is important to ensure that these microorganisms remain transient and do not become established in the environment where they can grow and multiply. Transient contaminants can, however, result in a diversity of pathogens in the processing environment that can show up in the processing lines and finished animal food. This phenomenon could occur in animal food operations using a wide variety of raw materials and other ingredients (e.g., raw meat, meat and bone meal, canola meal) because these materials can contain very diverse microflora. In general, routine cleaning and sanitizing in accordance with CGMPs is adequate to protect against contamination by transient bacteria in the processing facility.

Resident contamination

Bacterial pathogens causing resident contamination can also be introduced into the processing facility, where the pathogens then become established in a harborage site, multiply, and persist for extended periods of time, even years. A harborage site, or niche, is a site in the environment or on equipment (e.g., junctions, cracks, holes, and dead-end areas) that enables the accumulation of residues (e.g., animal food debris, dust, and water) and permits the growth of microorganisms such as *Salmonella* and *L. monocytogenes*. These sites may be difficult to inspect or access and therefore can help protect environmental pathogens during routine cleaning and sanitizing. While routine cleaning and sanitation practices are adequate to protect against the presence of transient contaminants, such practices do not control the presence of resident contaminants once they have become established. Sanitation controls, including proper

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personnel practices, and good equipment and facility design are important in preventing transient bacterial pathogens from becoming resident strains.

Once an environmental pathogen has become established as a resident contaminant, there is a persistent contamination risk for animal food processed in that facility. Intensified sanitation procedures will be needed to eliminate the contamination. *Salmonella* and *L. monocytogenes* are the pathogens most likely to set up residence in animal food processing facilities. Also, the potential exists for other pathogens (e.g., pathogenic *E. coli*) to become established as resident contaminants.

Key determinants for the pathogens to become established in an animal food processing environment are: (1) the temperature at which the animal food processing environment is maintained; (2) the available moisture in the animal food processing environment; and (3) the availability of nutrients for growth. For processed animal food, this typically translates into two primary categories of animal food processing environments:

- frozen/refrigerated and wet
- warm/ambient and dry

In both cases, proper cleaning is needed to minimize nutrient availability for growth of environmental pathogens. The pathogen most often associated with cold and wet processing environments is *L. monocytogenes*, and the pathogen most often associated with warm and dry processing environments is *Salmonella* (Refs. 20 and 21 ).

#### ***Facility-related environmental pathogens associated with wet and dry processing environments***

Animal food processing operations can generally be classified into one of two simple categories – wet processing environments or dry processing environments (Table 3-4). This very simple distinction has significant implications for the best strategies for controlling animal food contamination from environmental pathogens.

**Table 3-4. Some Examples of Animal Food Processed in Wet and Dry Processing Environments**

<b>Processing Environment Conditions</b>	<b>Examples of Animal Food</b>
Wet	Frozen raw pet food Refrigerated pet food Freeze-dried raw pet food

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Processing Environment Conditions	Examples of Animal Food
Dry	Milk powders Extruded animal food Rawhide pet chews/treats Jerky treats Dehydrated animal food Meat and bone meal

***Wet processing environments***

The most effective strategy to prevent the contamination of finished animal food with *L. monocytogenes* is to maintain an environment as dry as possible. Wet environments have some obvious characteristics that can lead to contamination by *L. monocytogenes*, such as:

- wet floors due to constant wet cleaning will facilitate the transfer of *L. monocytogenes* from an environmental source to animal food-contact surfaces
- wet floors can create harborage sites if they are not well maintained and have broken or cracked grout or tiles. These structures may provide protected harborage to environmental pathogens even when the floors are cleaned and sanitized
- condensation on overhead structures as a result of air temperature and humidity control issues and from use of water in heating and cooling operations creates a means of transfer of *L. monocytogenes* from non-animal food-contact surfaces to exposed animal food and animal food-contact surfaces
- frost formation due to condensation at freezer entry and exit points provides an opportunity for moisture accumulation and a constant source of water in which *L. monocytogenes* can multiply

Wet floors can serve as potential vectors for *L. monocytogenes* via the movement of people and equipment and material handling items such as totes and pallets. For example, wet floors can serve as a potential vector for pathogen transfer when personnel walk through standing water on poorly designed floors and drains and during cleaning. *L. monocytogenes* is not usually airborne; however, in wet environments, aerosols from high pressure water hoses used during cleaning operations help spread *L. monocytogenes* throughout the environment and from one surface (e.g., floors) to another surface (e.g., animal food-contact surfaces such as conveyors, tables, and animal food containers). In many facilities, certain processing operations are inherently wet such as raw material preparation and mixing and formulation of liquid components. In these cases, we recommend that you use personnel, equipment traffic, and cleaning practices that minimize

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water accumulation and aerosol formation to prevent in-process and finished animal food recontamination.

We recommend that wet processing areas be dried out as much as possible. This could be a challenge for some segments of the animal food industry that depend on the unlimited use of water for equipment and facility cleaning practices.

#### ***Dry processing environments***

Environmental moisture control is critically important in preventing *Salmonella* contamination in low-moisture products (Ref. 21). Water in the dry processing environment is one of the most significant risk factors (perhaps the single most important factor) for *Salmonella* contamination because water allows for pathogen growth, significantly increasing the risk for animal food contamination. Water, present even in very small amounts for short, sporadic time periods, may allow *Salmonella* to grow in the environment. Moisture may be obvious from sources such as water droplets or puddles from wet cleaning, but not so obvious from sources such as high relative humidity or moisture accumulating inside equipment.

*Salmonella* can, to varying degrees, be introduced into low-moisture animal food manufacturing facilities and become established in those environments. Harborage sites may develop and become a source of product contamination unless the sites are identified and eliminated (Refs. 22 and 23).

Growth of *Salmonella* is only possible in the presence of water. Because animal food particles and dust are normally expected to be present in processing areas, adequate nutrients are always available to microorganisms. Growth cannot occur, however, if the plant environment is sufficiently dry. The potential *Salmonella* harborage sites become more important when water is present for a sufficient period of time. The presence of water in the dry processing environment can result from improper use of water during cleaning, which has been linked to the occurrence and spread of *Salmonella* (Ref. 24). Other sources resulting in the presence of water in a dry area include condensate formation, leaking water or steam valves, infiltration of water following heavy rains (e.g., leaky roofs), and the use of water during fire emergencies. We recommend that you remove water immediately from the primary *Salmonella*-controlled hygiene areas (areas where animal food that will not undergo a lethality process is exposed to the environment) following such events to keep the plant environment as dry as possible.

You should maintain dry conditions at all times in primary *Salmonella*-controlled hygiene areas, except for the occasions when you have determined that controlled wet cleaning is necessary. Potential problems arise when there is visible water present in the dry areas or when there are areas in which standing water has dried. *Salmonella* may be found both in wet spots and in spots where standing water has dried (Ref. 25). The latter situation may present an additional risk of spread via the generation of airborne contaminated dust (Ref. 19).

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### **3.4 Chemical Hazards**

The chemical hazards that are the subject of this guidance include chemical hazards that are natural components of ingredients (e.g., glucosinolates) or natural toxins (e.g., mycotoxins), contaminants of raw materials and other ingredients (e.g., pesticides and drug residues), and chemical hazards as a result of manufacturing errors (e.g., nutrient deficiencies or toxicities). Animal food can become contaminated with chemical hazards that can be:

- ingredient-related hazards – that is, introduced from raw materials and other ingredients such as natural toxins or contaminants on or in ingredients
- process-related hazards – e.g., from manufacturing errors, or cross-contamination
- facility-related hazards – e.g., from chemicals used on animal food processing equipment or utensils, or chemicals stored in the facility

Some chemical hazards may cause immediate effects (e.g., gastrointestinal symptoms, shock, or death), such as those caused by industrial chemicals (e.g., caustic cleaning compounds). Other chemical hazards may cause more chronic effects after long-term exposure to the chemical (e.g., weight loss, depression, liver failure, neurological disease, or cancer) such as those caused by lead or some mycotoxins.

An example of a range of acute to chronic toxic effects can be seen in sheep fed animal food with excess levels of copper (Refs. 26 and 27) . Acute toxic effects in sheep include sudden onset of abdominal pain, diarrhea, loss of appetite, shock, or death. Chronic toxic effects of copper in sheep include similar symptoms to acute exposure, but present over a longer period of time. Chronic toxic effects in sheep also include difficulty breathing, jaundice, and death.

FDA has set action levels and tolerances for some chemical contaminants in animal food (Ref. 28). These levels represent limits at or above which FDA may take legal action to remove products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal quantifiable (or in some cases detectable) level of the contaminant. Action levels and tolerances are established based on the unavailability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. FDA has established temporary tolerances for polychlorinated biphenyls (PCBs) in animal food and food packaging material (see 21 CFR 509.30).

Under the FD&C Act, certain substances, such as food additives, color additives, and new animal drugs, require premarket approval before they may be legally used. Approval for food additives, color additives, and new animal drugs can have limitations so that the substance can only be used legally on or in animal food for specific purposes, specific species, or for a specific life stage or production class.

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Chemical substances in an animal food are not always considered hazards and their occurrence may be unavoidable. The particular chemical, and its level in the animal food, determines if the chemical is a hazard. The preventive controls that you identify and implement for controlling specific chemical hazards should be based on the characteristics of the chemical and how the chemical is introduced into your animal food. For examples of chemical hazards in animal food, see Appendix E.

For additional information on the control of chemical hazards, see Chapter 4, section 4.6.

In the remainder of this section on chemical hazards, we briefly describe characteristics of some chemical hazards that can be present in animal food and processing environments, including ways they can be introduced into animal food. Effectively designed and implemented CGMPs can be key to keeping many process-related chemical hazards and facility-related chemical hazards out of your animal food.

Table 3-5 is a guide to help you identify some of the most common sources of chemical hazards; however, this is not an exhaustive list.

**Table 3-5. Guide for Common Sources of Chemical Hazards**

Source	Examples
Ingredient-related chemical hazards	Pesticide residues and mycotoxins on raw agricultural commodities and grains Heavy metals in or on raw agricultural commodities or in mineral ingredients or pre-mixes Natural toxins (e.g., glucosinolates in the Brassicaceae family) Animal drug residues Unapproved food or color additives Radiological hazards Dioxins
Process-related chemical hazards	Nutrient deficiencies or toxicities due to manufacturing error Radiological hazards from use of contaminated water supply Animal drug carryover from medicated to non-medicated animal food Food or color additives not approved for certain species due to incomplete cleanout of equipment

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Source	Examples
Facility-related chemical hazards	Contamination with industrial chemicals such as cleaners or sanitizers  Chemicals not used in processing animal food but stored in the facility such as fertilizers  Heavy metals due to leaching from containers or utensils

### 3.4.1 Ingredient-Related Chemical Hazards

#### *Pesticides*

Pesticide chemical residues may be of concern in food crops and in foods of animal origin. The term pesticide chemical is used for any substance (with certain exceptions) that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (see FD&C Act, § 201(q)). Pesticides (e.g., insecticides, fungicides, rodenticides, insect repellants, herbicides, and some antimicrobials) are designed to prevent, destroy, repel, or reduce pests (Ref. 29).

All pesticide chemicals sold or distributed in the United States must be registered by the Environmental Protection Agency (EPA). See 40 CFR part 180. The EPA also establishes tolerances (maximum amounts) for pesticide chemical residues in or on food. Pesticide chemical residues in or on food render the food adulterated under section 402(a)(2)(B) of the FD&C Act unless EPA has set a tolerance for that residue in or on that food and the residue quantity is within that tolerance limit or there is an exemption from the tolerance requirement for that residue (see FD&C Act, § 408(a)(2)(B)). FDA and the USDA enforce tolerances in food under their jurisdiction, using a memorandum of understanding to coordinate activities among FDA, USDA, and EPA (Ref. 30). A detailed description of how FDA enforces tolerances for pesticide chemical residues in animal food is available in FDA's Compliance Policy Guide Sec. 575.100 (Ref. 31).

The most common reasons for adulteration of animal food products with a pesticide chemical residue are the improper treatment of a raw agricultural commodity with a registered pesticide or the raw agricultural commodity being exposed to non-registered pesticides (Ref. 31).

#### *Heavy metals*

Heavy metals are naturally occurring elements such as lead, arsenic, cadmium, and mercury. Increased levels of heavy metals in the environment are often a result of industrial and agricultural practices (e.g., use of pesticides containing heavy metals, use of manure as a fertilizer, or release of industrial waste) (Ref. 32). Mercury is known to accumulate in certain fish species. One study of food found mercury concentrations in tested cat and dog food that ranged from 1 to 604 nanograms per gram (ng/g) (Ref. 33). Though not environmental, another potential source of contamination of animal food during manufacturing is the leaching of heavy metals from containers or utensils that come in contact with the animal food.

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Mineral supplements and premixes for animal food have been found to be a common source of high levels of heavy metals (Refs. 34 and 35). Raw minerals are typically mined or recycled. Mineral ore deposits are often a mixture of several different inorganic forms of the mineral and may include several other minerals as well as contaminants. For example, in some regions, lead is a natural contaminant of calcium carbonate (limestone) (Ref. 36).

Consumption of animal food contaminated with heavy metals can cause adverse health consequences to the animal. For example, lead exposure in birds can cause anorexia, loss of condition, wing and leg weakness, and anemia. In dogs, lead exposure presents predominantly as gastrointestinal abnormalities; however, anxiety, hysterical barking, jaw champing, salivation, blindness, ataxia, muscle spasms, and convulsions may develop (Ref. 37). Whether an animal develops an injury or illness as a result of exposure to minerals (including heavy metals) depends upon the species, level of the mineral in the animal food, and frequency of exposure (Ref. 26).

Information on heavy metals in animal food is available (Refs. 38 and 26).

### ***Natural toxins***

#### Mycotoxins

Natural toxins (i.e., naturally occurring toxins), such as mycotoxins, are recognized as hazards in raw or processed agricultural commodities. The term mycotoxins is used for a group of natural toxins which include, among others, aflatoxins, fumonisins, deoxynivalenol (vomitoxin), zearalenone, ochratoxin, and ergot alkaloids, that are recognized as hazards in raw or processed agricultural commodities. Mycotoxins are toxic secondary metabolites produced by certain fungi (i.e., molds) that can infect raw agricultural commodities (e.g., grains, fruits, and nuts) and proliferate in the field and during storage.

The occurrence of mycotoxins in raw agricultural commodities is not entirely avoidable. Occurrence of these toxins on commodities susceptible to mold infestation is influenced by environmental factors such as temperature, humidity, and extent of rainfall during the pre-harvesting, harvesting, and post-harvesting periods. The molds that produce mycotoxins typically grow and become established in the raw agricultural commodity during stressful growing conditions (e.g., when there is insect damage to the crop or a drought) and holding conditions (e.g., wet storage from condensation).

Mycotoxins may produce various toxicological effects. Some mycotoxins are teratogenic, immunotoxic, mutagenic, or carcinogenic in susceptible animal species and are associated with various diseases in pet animals, livestock, poultry, aquaculture species, and humans in many parts of the world. The FDA has set species specific recommended maximum levels for aflatoxins, fumonisins, and deoxynivalenol in some animal food (Table 3-6). FDA has not established levels for other mycotoxins such as ochratoxin and zearalenone. When these mycotoxins are found in animal food the FDA reviews each finding on a case-by-case basis.

Hazardous levels of mycotoxins have been found in individual ingredients as well as finished animal food. When mycotoxins are found in individual ingredients, FDA guidance (included in

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Table 3-6 below) may be used to identify if the ingredient may safely be used in different species. For example, corn containing 20 parts per billion (ppb) or more aflatoxin should not be used in animal food for dairy animals since it could result in unsafe residues of aflatoxin in milk (greater than 0.5 ppb). Aflatoxin levels at or below 300 ppb in corn can be used in animal food for finishing beef cattle because the level does not pose a health concern for the beef cattle or to humans consuming food derived from the beef cattle.

**Table 3-6. Mycotoxins Associated with Ingredients Used in Animal Food**

<b>Mycotoxins</b>	<b>Ingredients in which the Mycotoxin may be Found</b>	<b>Related Guidance</b>
Aflatoxins	Corn, Cottonseed, Peanuts	Compliance Policy Guide Sec. 683.100 - Action Levels for Aflatoxins in Animal Feeds (Ref. 39)
Fumonisin	Corn	Guidance for Industry #112; Fumonisin Levels in Human Foods and Animal Feeds; Final Guidance (Ref. 40)
Deoxynivalenol (Vomitoxin)	Wheat, Barley	Guidance for Industry and FDA; Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed (Ref. 41)
Ochratoxin	Oats, Wheat, Flax (Linseed), Soybean Meal	Reviewed on a case-by-case basis
Zearalenone	Grains (e.g., wheat, barley, oats)	Reviewed on a case-by-case basis

Mycotoxins are not significantly degraded by food processing and can contaminate finished processed animal food (Ref. 42). In 1998, 2005, 2011, and 2013 aflatoxin contamination of dog and cat food resulted in illness, dog mortalities, and extensive recalls of affected dog and cat food (Refs. 43 and 44).

### Plant toxins

Plants are known to produce a number of toxicants and anti-nutritional factors, such as protease inhibitors, hemolytic agents, and neurotoxins, which often serve the plant as natural defense compounds against pests or pathogens. An anti-nutritional factor, or anti-nutrient, is a naturally-occurring substance found in plant-derived foods that interferes with absorption or proper functioning of nutrients in the body (Ref. 45). For example, most cereal grains contain protease inhibitors, which can diminish the nutritive value of proteins. For the purpose of this guidance,

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anti-nutritional factors are included in plant toxins as they are known or reasonably foreseeable hazards associated with some ingredients.

There are a variety of plant toxins with different health effects. Many legumes contain relatively high levels of lectins and cyanogenic glycosides. Lectins, if not destroyed by cooking or removed by soaking, can cause severe nausea, vomiting, and diarrhea. The levels of cyanogenic glycosides in cassava and some legumes can lead to death or chronic neurological disease if these foods are eaten uncooked (Ref. 46). Plants from the family Brassicaceae contain glucosinolates which may be deleterious to animal health such as impairing thyroid function in many species (Ref. 47).

Some plant based ingredients, including those plant ingredients that may contain natural toxins, are approved as food additives (see discussion below *Unapproved Color and Food Additives*). A food additive regulation may specify a method of manufacture, restrict the intended animal species, restrict the percentage of the food additive in a finished animal food, set a maximum level of the natural toxins, or a combination of these measures. For example, the approval for heat toasted crambe meal specifies, among other things, that glucosinolate calculated as epiprogoitrin cannot be more than 4 percent of the meal by weight. The approval also restricts use to feed for feedlot cattle as a source of protein in an amount not to exceed 4.2 percent of the total ration (see 21 CFR 573.310).

#### Tissue toxins

The presence of thyroid gland tissue in cattle and lamb products has been associated with exogenous thyrotoxicosis (hyperthyroidism) in humans due to bioactive thyroid gland hormones (Ref. 48). For this reason, USDA prohibits the use of thyroid glands and laryngeal muscle tissue for human food (Ref. 49).

Cases of exogenous thyrotoxicosis in dogs have been associated with pet treats that contained detectable thyroid hormones (Ref. 50). In early 2017, FDA received reports of ill dogs that, upon further investigation, resulted in the recall of two different brands of dog food because of elevated levels of thyroid hormone (Refs. 51 and 52). Laryngeal tissue (gullets) obtained from beef and lamb slaughter establishments used in the manufacture of pet treats could be a potential source of thyroid tissue that could result in thyrotoxicosis in pets. Because of this potential hazard, New Zealand restricts the use of tissue from the thyroid gland or surrounding structures (larynx) in pet food (Ref. 53). When identifying known or reasonably foreseeable hazards, pet food and pet treat manufacturers should determine whether laryngeal tissue (gullet) is included in their source material and thus could result in thyrotoxicosis in pets consuming treats derived from this material. Removal of the thyroid gland does not ensure that all thyroid tissue is eliminated.

#### ***Animal drugs***

Animal drugs can be chemical hazards introduced into your animal food such as through an ingredient containing residues (ingredient-related chemical hazard) or through drug carryover or cross contamination during manufacturing (process-related chemical hazard). An example of an

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ingredient-related hazard is drug contamination in an animal food as a result of using a raw material that contains drug residues. A drug contamination that is a result of a process-related hazard typically is the result of cross-contamination of animal food from either incorrect sequencing of medicated feeds or incorrect cleanout of equipment between batches of medicated and non-medicated animal food. See section 3.4.2 for process-related drug contamination.

#### Animal drug residues in ingredients

In the United States, animal drugs require approval by FDA before they can be marketed for administration to animals. For animal drugs used in food-producing animals, FDA establishes a tolerance for the drug residue in human food as part of the approval process. Animal drug residues detected in food derived from food-producing animals (i.e., animal tissues such as meat, milk, and eggs) are considered a hazard for human food if an established animal drug tolerance is exceeded.

Many slaughter products not used in human food (e.g., not fit for human consumption for various reasons) are used in animal food. Animal food derived from meat, organs (e.g., liver, kidney, heart, brain, and thymus), and fat/skin may contain drug residues (Ref. 54). Although the metabolism and elimination of drugs may vary widely within and between species, as a general rule the highest drug concentrations will be found in the liver or kidney (e.g., penicillin in kidneys or sulfa drugs in liver). Depending on the chemical property of the drug, residues of certain drugs may become concentrated during animal food manufacturing and processing. For example, drugs that are highly lipid soluble will often be found at the highest concentration in animal food rich in fats/oils. In 2013, two companies recalled various pet treats after antibiotic residues were found upon testing of the treats by a New York State laboratory (Ref. 55). In 2014, FDA issued an import alert for poultry jerky-type treats due to the presence of antibiotic and/or antiviral residues as a result of positive test results for these residues in jerky treats from certain countries (Ref. 56).

Another example of a drug residue in animal tissues is pentobarbital, which is a component of euthanasia solutions that are used to humanely kill animals. While pentobarbital residues may be found in animal tissues, pentobarbital is not used in the slaughter of animals for human consumption. Pentobarbital residues in animal tissues are most likely the result of euthanasia of horses or other animals not intended for human consumption. Pentobarbital is stable in tissue, aqueous environments, and resists degradation at rendering temperatures (Refs. 57 and 58). There are reports of pentobarbital toxicosis in domestic species, zoological animals, and wildlife (Refs. 59, 60 and 61). In 2015, cases of toxicosis linked to pentobarbital in horsemeat resulted in the death of two animals and illness of a third in a wildlife preservation center in the United States (Ref. 62). In 2017, pentobarbital in dog food resulted in illness in four dogs and the death of a fifth dog (Ref. 63).

Pentobarbital residues should be identified as a known or reasonably foreseeable hazard for facilities that salvage skeletal muscle, organs, or other tissues from animals that died other than by slaughter if the cause of death is unknown, or the animal was known to be euthanized with chemicals. The salvaged skeletal muscle, organs or other tissues are generally used for food for carnivorous animals such as those at zoos, wildlife rehabilitation centers, private wildlife

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preservation centers, alligator farms, mink farms, or in pet food products. We recommend operations that salvage skeletal muscles, organs, or other tissues for processing determine whether animals have been euthanized using pentobarbital and, if so, exclude those animals from use as animal food.

### ***Unapproved color and food additives***

Any substance/ingredient intentionally added to an animal food must be used in accordance with a food additive regulation (see 21 CFR part 573), unless it is generally recognized as safe (GRAS) among qualified experts for its intended use as described in 21 CFR 570.30. Substances that are GRAS for their intended uses in animal food are listed in 21 CFR parts 582 and 584. A substance that is a color additive must be used in accordance with a color additive listing (see 21 CFR parts 73 and 74). If a color additive listed in 21 CFR part 74, subpart A, is used, ensure that the batch has been certified in accordance with 21 CFR part 80. If the batch is not certified, the color additive is considered unapproved for use in food. Under the PCAF regulation, an unapproved food or color additive is a chemical hazard (see 21 CFR 507.33(b)(1)(ii)).

The Association of American Feed Control Officials (AAFCO) Official Publication contains feed (animal food) ingredients and their definitions (Ref. 38). We intend to continue to accept the listing of certain ingredients in the AAFCO Official Publication for their marketing in interstate commerce, provided there are no food safety concerns about the use or composition of the ingredient that would render the food adulterated under section 402 of the FD&C Act.

Some food and color additives are specifically prohibited from use in animal food because the additives pose a potential risk to public health or have not been shown by adequate scientific data to be safe for use in such food or feed (see 21 CFR part 589, and 21 CFR 81.10). Examples of such food and color additives are gentian violet (see 21 CFR 589.1000), propylene glycol in or on cat food (see 21 CFR 589.1001), and FD&C Red No. 4 (see 21 CFR 81.10(d)). We consider a prohibited food additive or color additive to be an unapproved food additive or color additive for the purposes of the PCAF regulation and thus a chemical hazard.

A substance with a use that is GRAS or approved as a food additive for use in human food may not always be suitable for use in animal food. One example is xylitol, which is found in human foods such as chewing gum, sugar-free nut butters, and some baked goods. However, xylitol is toxic to dogs and if ingested can cause severe hypoglycemia, liver disease, or death (Ref. 64).

### ***Chemical hazards that may be intentionally introduced for purposes of economic gain***

The PCAF requirements specify that you must consider, as part of your hazard identification, known or reasonably foreseeable hazards that may be intentionally introduced for purposes of economic gain (21 CFR 507.33(b)(2)(iii)). We recommend that you focus on a pattern of such adulteration in the past, suggesting a potential for intentional adulteration even though the past occurrences may not be associated with your supplier or your exact type of animal food. To determine if a hazard that may be intentionally introduced for purposes of economic gain is a hazard requiring a preventive control, we recommend that your hazard analysis consider the

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country of origin of an ingredient that may contain the hazard and any specific supplier associated with an ingredient containing that hazard.

One historical example of intentional adulteration for the purpose of economic gain in animal food was the addition of melamine and other triazines into plant protein ingredients (e.g., wheat gluten and rice protein concentrate) exported to the United States in 2007 by firms in China (Ref. 65). The adulterated plant protein ingredients were used in the manufacture of pet food. This adulteration resulted in a massive pet food recall and illness and death of many dogs and cats. The melamine adulterated pet food also ended up in food for poultry, swine, and food-producing fish. This raised concerns about the safety of human food products derived from those food-producing animals and resulted in the quarantine of thousands of animals until a risk assessment was completed (Ref. 66). Melamine was also intentionally used by one country in milk products (for human food), though none of the milk products were exported to the United States (Ref. 67).

The repeated use of melamine over the years, in animal and human food, demonstrates that patterns of economically motivated adulteration can emerge and should be considered as part of a hazard analysis. If you identify melamine as an economically motivated chemical hazard in your animal food, you need to determine whether melamine is a hazard requiring a preventive control (see 21 CFR 507.33). In particular, you should consider this economic adulterant when using plant protein ingredients from a country where melamine adulteration has occurred.

Sources for information about economically motivated adulteration include an on-line food fraud database and food fraud mitigation guidance made available by the U.S. Pharmacopeia Convention (Ref. 68), and a report from the Congressional Research Service (Ref. 69).

### ***Radiological hazards***

Radiological hazards can become incorporated into animal food during animal food production through the use of water that contains the radionuclides. This water may be an ingredient in the animal food, or used during the manufacturing process such as for washing ingredients or equipment. There are areas in the United States where high concentrations of some radionuclides, such as radium-226, radium-228, and uranium, can be detected in well water (Refs. 70 and 71). In those regions, radiological hazards should be considered a known or reasonably foreseeable hazard for animal food operations using well water.

Radiological hazards also may result from accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. You should be vigilant regarding accidental releases of radiological hazards and their potential to contaminate your animal food, either directly due to contamination of natural resources near your facility, or as a result of raw materials and other ingredients that you obtain from a region that has experienced an accidental release of radiation.

### ***Environmental chemical contaminants***

Environmental contaminants like dioxins, polychlorinated biphenyls (PCBs), and polyaromatic hydrocarbons (PAHs) are chemical hazards that have the potential to be introduced into your

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animal food either through an ingredient (e.g., clay anti-caking agents), or during manufacturing (e.g., contaminated water source) (Refs. 72 and 73). Some of the dioxin and PCB congeners may be carcinogens at low levels of exposure over extended periods of time. Currently there are no tolerances established by the FDA for dioxins in animal food. However, temporary tolerances for residues of PCBs in animal food can be found in 21 CFR 509.30.

Environmental contaminants such as dioxins can get into water from emissions from waste incineration and other combustion that get deposited into bodies of water; and discharges into water from chemical factories (Ref. 74). Over the past decade, EPA and industry have been working together to dramatically reduce the presence of dioxins in the environment. Dioxins, however, are extremely persistent compounds and break down very slowly; thus, current exposures to dioxins in the United States are due to decades-old releases.

### **3.4.2 Process-Related Chemical Hazards**

Some process-related chemical hazards, such as drug carryover, are unintentionally introduced into animal food through cross-contamination due to incomplete cleanout of equipment. Other process-related chemical hazards are caused by animal food manufacturing errors resulting in nutrient deficiencies or toxicities. As discussed previously, some ingredient-related chemical hazards can also be process-related chemical hazards.

#### ***Animal drug carryover in animal food***

Many feed mills manufacture animal food that contains one or more approved animal drugs. Such animal food is commonly known as medicated feed. These medicated feeds are subject to 21 CFR part 225 – Current Good Manufacturing Practice for Medicated Feeds. Part 225 requires, among other things, that facilities making medicated feed take steps to ensure adequate cleanout of their equipment in order to maintain proper drug levels and to avoid unsafe contamination of animal food with drugs. Flushing of equipment and sequential production of medicated feed are two commonly practiced procedures for preventing unsafe contamination from drug carryover. See 21 CFR 225.65.

Failure to perform proper equipment cleanout procedures or failure to adequately follow the procedures could result in contaminated animal food that may cause illness or death in animals. For example, incomplete clean-out from a previous batch of animal food manufactured with monensin (which is particularly toxic to horses) has been the source of contamination in animal food. In 2014 and 2015, monensin contamination of animal food resulted in the death of horses and layer hens (Refs. 75 and 76).

When conducting your hazard analysis, you should identify whether an animal drug used in your facility is a known or reasonably foreseeable hazard to another species, production class (e.g., layers versus broilers), or life stage (e.g., calf versus adult dairy cow) for which you manufacture animal food. If you identify a carryover drug hazard, you must evaluate it to determine if the carryover drug hazard requires a preventive control (see 21 CFR 507.33). Your preventive control might include sequencing of animal food production and flushing of equipment. You

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should also consider whether further preventive controls are needed to prevent the accidental addition of animal drugs to the wrong animal food that could result in unsafe animal food.

#### ***Nutrient deficiencies or toxicities as chemical hazards***

Nutrient deficiency or toxicity hazards are a concern in animal food because animals often consume one animal food type as their sole source of nutrition. A nutrient deficiency or toxicity hazard can result in serious injury, illness, or even death to animals. A nutrient deficiency hazard can occur when a nutrient in the animal food is below the level needed by the intended animal and could result in illness or death (e.g., low thiamine in cat food that can result in neurological and other symptoms in cats). A nutrient toxicity hazard can occur when an excessive level of a nutrient is in animal food and could result in illness or death of the intended animal (e.g., excess sodium in poultry food that can result in trouble breathing, leg paralysis, and death). Because different animal 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.

A nutrient deficiency or toxicity hazard also can result from diets containing inappropriate proportions of essential nutrients. For example, the ratio of calcium and phosphorus should be considered when formulating an animal food since calcium and phosphorus work together for the animal's muscle and metabolic functions and are the major mineral constituents of bone.

There have been numerous animal food recalls as well as animal illnesses and deaths from nutrient deficiencies or toxicities. FDA has received multiple reports through its reportable food registry (RFR) that were a result of animal food with nutrient deficiencies or toxicities (Ref. 77). Examples of RFR reports and recalls include:

- low levels of thiamine in cat food
- low levels of vitamin D in food for swine
- elevated levels of copper in food for sheep
- elevated levels of vitamin D in dog, guinea pig, and fish food
- elevated levels of calcium and phosphorus in food for broiler chickens and turkeys
- elevated levels of urea in food for cattle

Nutrient deficiency or toxicity hazards can be the result of incorrect levels of nutrients in incoming raw materials or ingredients, incorrect recipe/formulation, errors in manufacturing, or a combination of these. If the raw materials or other ingredients do not contain nutrients at the expected levels, this may result in either a nutrient deficiency or toxicity hazard when the ingredient is incorporated into the animal food based on a preset formulation. For information on control strategies for nutrient deficiency or toxicity hazards, see Chapter 4, section 4.6.1.

Animal food distributed as a sole source of nutrition should be formulated to meet the minimum nutrient requirements established by the National Research Council (NRC) when available for the intended species (including life-stage and production class) (Ref. 78). Information in the peer-reviewed scientific literature, including NRC publications, also may be used to identify the maximum inclusion rate of certain nutrients. The NRC Mineral Tolerances of Animals also may

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be used to identify appropriate levels of minerals in animal food (Ref. 26). Another helpful resource for formulating a nutritionally adequate pet food is the AAFCO dog and cat food nutrient profiles (Ref. 38).

#### 3.4.3 Facility-Related Chemical Hazards

Industrial chemicals or other contaminants from the animal food processing environment can contaminate animal food during production – e.g., if chemicals used to clean a production line are not adequately removed from the production line, if heavy metals are leaching from containers or utensils, or if a non-food-grade lubricant comes in contact with animal food. In this guidance, we do not discuss preventive controls for facility-related chemical hazards such as cleaning chemicals and the leaching of heavy metals from containers or utensils, because such hazards are usually addressed through CGMPs (Ref. 79).

#### 3.5 Physical Hazards

Physical hazards are broadly classified as sharp hazards, choking hazards, and conditions of animal food hazards such as size and hardness. Injuries from physical hazards may include oral cavity damage (e.g., tooth damage or laceration of the mouth or throat), laceration or perforation of the gastrointestinal tract, and choking. In this section, we describe common physical hazards – i.e., metal, glass, hard plastic, and conditions of animal food.

**Metal (Ferrous and Non-Ferrous):** Metal-to-metal contact during processing can introduce metal fragments into products. For example, metal fragments can break off during mechanical cutting and blending operations, and some metal equipment has parts that can break or fall off, such as wire-mesh belts. Metal screens may become worn over time or be torn introducing metal fragments (Ref. 80).

**Glass:** Glass fragments in animal food can cause injury to the animal eating the food. Most animal food facilities do not use glass containers for their animal food.

**Hard Plastic:** Hard plastic can be introduced into animal food when tools and equipment such as scoops, paddles, buckets, or other containers develop fatigue, crack, and break as they wear. Hard plastic also can be introduced into animal food when plastic sieves and screens deteriorate.

**Conditions of Animal Food:** The term conditions of animal food as used in this guidance refers to the physical, mechanical and other characteristics (e.g., particle size, hardness, surface roughness, digestibility, and ability to soften when moistened) of animal food that can cause injuries or illness in animals. Hazards related to the conditions of the animal food can occur when the particle size is too large to eat resulting in starvation (e.g., crumbles too large for small birds). Alternatively, an animal food ground too fine can aerosolize and cause respiratory problems and corneal injuries, which occurred with swine food (Ref. 81). Lack of digestibility can result in an obstructed digestive tract. An animal food could have a combination of characteristics resulting in injury or death (e.g., some dental treats for dogs) (Ref. 82).

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In general, there is overlap between facility-related physical hazards and process-related physical hazards. For example, nuts and bolts used during maintenance procedures could be a facility-related hazard, but production equipment that has nuts and bolts that could fall out during production could be a process-related hazard. Conditions of animal food hazards are typically process-related hazards. Table 3-7 is a Quick Reference Guide to help you recognize common sources of these physical hazards.

**Table 3-7. Quick Reference Guide for Common Sources of Physical Hazards**

Source	Metal	Plastic, Ceramic, and Glass	Conditions of Animal Food	Other
Ingredient-related	Farm field debris Chopped, ground, and pulverized items where metal was not properly controlled by supplier	Farm field debris Packaging materials	Out of specification raw materials (e.g., too finely ground)	Farm field debris (e.g., stones, wooden sticks)
Facility-related and process- related (processing/ production environment and equipment)	Grinders, hammer- mills, shredders Sieves, screens, wire-mesh belts Mixing paddles Metal cans (shavings, lids) Pumps Utensils (knives)	Equipment (inspection belts, small wares) Facility (windows, air flow curtains) Facility glass Scoops Mixing paddles Buckets	Particle size of animal food inappropriate for animal species/life- stage  Lack of digestibility	

### 3.6 References for Chapter 3

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### **CHAPTER 4 – PREVENTIVE CONTROLS**

#### **4.1 Purpose of this Chapter**

The guidance provided in this chapter is intended to help you identify and implement preventive controls. This chapter provides an overview of common preventive controls that you could use to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in animal food and the animal food production environment when the outcome of your hazard analysis is that one or more known or reasonably foreseeable hazards requires a preventive control. The guidance provided in this chapter also is intended to help you determine pertinent parameters to use when monitoring the preventive controls that you identify and implement.

This chapter does not provide all the details needed for identifying and implementing preventive controls. You have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes that are available to you and that would provide assurances that the hazard is controlled (i.e., significantly minimized or prevented).

#### **4.2 Overview of Preventive Controls**

The Preventive Controls for Animal Food (PCAF) regulation defines “preventive controls” as 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 (21 CFR 507.3). Preventive controls include: (1) controls at critical control points (CCPs), if there are any CCPs; and (2) controls, other than those at CCPs, that are also appropriate for animal food safety (21 CFR 507.34(a)(2)(i) and (ii)).

The PCAF regulation requires that preventive controls must be written (21 CFR 507.34(b)). The PCAF regulation also specifies that preventive controls include, as appropriate to the facility and the animal food: (1) process controls; (2) sanitation controls; (3) supply-chain controls; (4) a recall plan; and (5) other preventive controls (see 21 CFR 507.34(c)). The PCAF regulation also requires you to validate that the preventive controls that you identify and implement 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 (see 21 CFR 507.47(a)). For information on validation and other preventive control management components, see Chapter 5.

#### **4.3 Preventive Control Considerations**

When identifying preventive controls for your animal food hazards, you should consider:

- The effect of the control on the targeted known or reasonably foreseeable animal food hazards. For example:

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- Is the preventive control hazard-specific or does it control more than one hazard?
- Does the control effectiveness depend upon other controls?
- Can the preventive control be validated (as necessary)?
- The feasibility of monitoring those controls. For example:
  - Are the minimum or maximum parameter values for the preventive control measurable and practical?
  - Are you relying on parameter values or observations for your monitoring?
  - Can you obtain the results of monitoring quickly (i.e., real-time) to determine if the process is in control?
  - Are you monitoring a batch or continuous process?
  - Are you monitoring continuously or doing spot checks?
  - Can the parameters be monitored in-line or must the animal food be sampled?
  - Will the monitored parameters be indirectly linked to the minimum or maximum values (i.e., belt speed or pump flow rate for time of process)?
- The location of the control with respect to other preventive control measures. For example:
  - Is the application of the control measure at the last point in the process to ensure control of the targeted known or reasonably foreseeable hazard?
  - Will the failure of an upstream control result in the failure of a downstream control(s)?
- The severity of the consequences in case of a failure of a preventive control. For example:
  - Is it reasonably likely that unsafe animal food would be produced as a result of the preventive control failure?
  - Is the hazard that could occur reasonably likely to cause serious adverse health consequences or death to humans or animals?
- Synergistic effects between control measures. For example:
  - Consider whether one control measure can enhance the efficacy of another control measure; e.g., formulation process controls may combine the use of preservatives, acidification, and water activity at levels that individually will not control pathogen growth, but they work together to do so.

## **4.4 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

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facility's food safety system: (1) parameters associated with the control of the hazard; and (2) 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. See 21 CFR 507.34(c)(1). Process controls do not include those procedures, practices, and processes that are not applied to the animal food itself, e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards.

#### **4.4.1 Use of Parameter Values and Operating Limits in Process Controls**

Parameters are those properties that are controlled to ensure the hazard will be significantly minimized or prevented and the parameter value is 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. Examples of processing parameters that can have a minimum or maximum parameter value (or combination of values) include time, temperature, flow rate, line speed, product bed depth, weight, product thickness or size, viscosity, moisture level, water activity, salt concentration, pH and others, depending upon the process. During processing, if a process parameter value does not meet your identified minimum or maximum parameter value (or combination of values) in your written food safety plan, the process is not in control (i.e., a deviation has occurred) and there is a potential for producing a product that presents a human or animal health risk.

Operating limits are criteria that may be more stringent than your minimum or maximum parameter values of your preventive control and are established for reasons other than animal food safety. We recommend that you consider using operating limits to reduce the likelihood of a deviation from the established parameter value. Operating limits may be established to avoid deviations from an allowed parameter value, to account for normal variation, and for quality reasons. A benefit of using an operating limit is that such use may allow you to adjust your process if an operating limit is not met but the process does not deviate from your minimum or maximum parameter value.

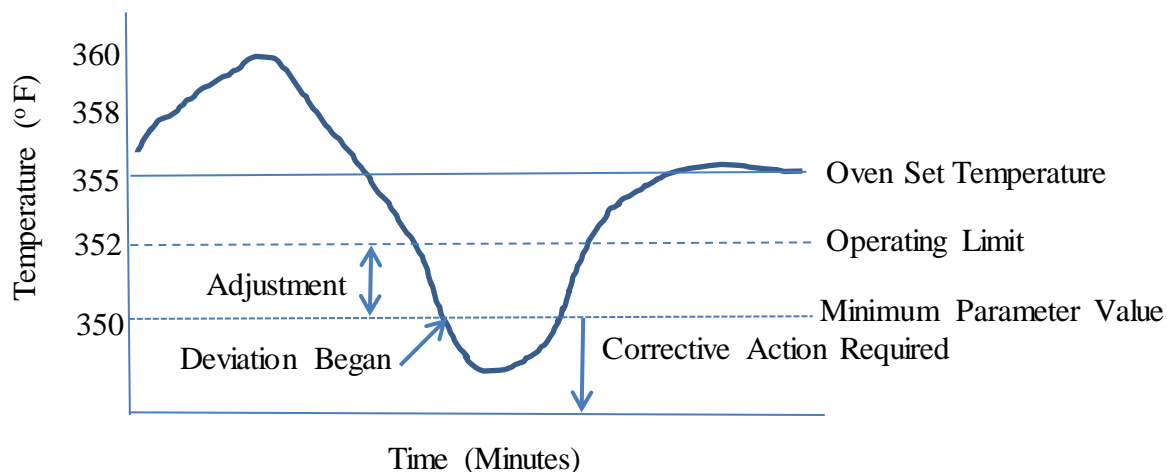
For example, you are baking dog biscuits and your minimum temperature parameter value established for controlling *Salmonella* is 350°F (177°C) and your minimum time parameter value is 15 minutes. In this example, we focus on the temperature parameter only and do not discuss time. Your written procedure would need to include both time and temperature if they are both parameters with values established for control of *Salmonella*. To achieve your desired quality specifications and to ensure safety, you bake the dog biscuits at 355°F (179°C) (i.e., the oven set temperature). If your minimum parameter value is 350°F (177°C) to control *Salmonella*, you may have an operating limit of 352°F (178°C). For example, you may set an alarm on your oven so if your oven temperature drops to 352°F (178°C), the alarm will sound and you can adjust the oven temperature to ensure that the temperature does not drop below the minimum parameter value of 350°F (177°C). However, if you are finding that the alarm is sounding often because your oven temperature drops below your operating limit, we recommend you conduct a correction to address the problem. If the oven temperature drops below the minimum parameter value of 350°F (177°C), the hazard is not under control and a corrective action is required.

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See Figure 4-1 for an illustration on the use of operating limits to avoid a deviation from an established parameter value and Chapter 5 (section 5.7) for a discussion about the difference between corrective actions and corrections. One source of additional information on the use of operating limits is the FSPCA curriculum (Ref. 1).

Figure 4-1: The use of operating limits to avoid a deviation from an established parameter value



### 4.5 Process Controls for Biological Hazards

Many process controls, such as the application of heat to an animal food to adequately reduce pathogens, are applied in the same manner and for the same purpose as control measures established within Hazard Analysis and Critical Control Point (HACCP) plans for human food and applied at CCPs as recommended by the National Advisory Committee on Microbiological Criteria for Foods (Ref. 2) and the Codex Alimentarius Commission (Ref. 3). No HACCP system has been mandated by FDA for any animal food. HACCP principles have been voluntarily adopted by some segments of the animal food industry, such as some in the rendering industry and pet food industry.

In addition to this guidance, a number of sources of scientific and technical information can be useful in establishing process control parameters and parameter values. These sources may use the term critical limit as opposed to parameter value. While these terms have a similar meaning, critical limit is more closely associated with HACCP. Trade associations, process authorities, industry scientists, university and extension scientists, and consultants can provide expertise and direction on establishing process control parameters and parameter values. The Grocery Manufacturers Association has provided advice on control of *Salmonella* in low-moisture foods (Ref. 4), and the American Feed Industry Association has provided advice on control of *Salmonella* in animal food (Ref. 5). Information also can be obtained from peer reviewed scientific literature. For additional resources, see the training materials provided by the Food Safety Preventive Controls Alliance for human food and animal food (Refs. 1 and 6). In addition to information from such resources, you also can conduct scientific studies for specific products in-house, at a contract laboratory, or at a university to establish appropriate process parameters and parameter values.

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Note that there may be differences between the application of processing parameters as discussed in these referenced sources and how you would apply the processing parameters to your specific animal food and manufacturing process. For example, your animal food matrix may have a different particle size or composition than the reference source. The processing parameters and/or minimum or maximum parameter values may need to be adjusted to account for those differences. The preventive control process parameter and parameter value(s) must be validated in accordance with 21 CFR 507.47. For more information on validation see Chapter 5, section 5.8.2.

#### **4.5.1 Use of Lethality Treatments as Process Controls**

The term lethality treatment refers to a treatment that is used to kill or inactivate microorganisms. In general, when discussing bacterial pathogens in this document we use the terms kill or destroy when referring to treatments lethal to vegetative cells and inactivate when discussing treatments lethal to spores. Protozoa may be killed or inactivated by common lethality treatments (Refs. 7, 8 and 9). Common lethality treatments include: (1) heat treatments (e.g., extrusion, cooking, pasteurizing, or baking); (2) high pressure processing (HPP); and (3) irradiation. We discuss each of these in the following sections of this chapter.

##### ***Heat treatment (thermal processing)***

Heat treatment is a common lethality process control. Heat treatments generally fall into the following two categories:

- Heat treatment that leads to commercial sterility: heat processing at high temperatures (> 212°F (100°C)) under pressure with the objective of killing all forms of microorganisms, including the spores of bacteria. The treated products are shelf-stable without refrigeration.
- Heat treatment that reduces microbial pathogens but does not lead to commercial sterility: heat processing at lower temperatures (e.g., 158°F (70°C) to 212°F (100°C)), with the processes designed to kill the vegetative forms of microorganisms with little to no effect on the spores of bacteria. The treated products may or may not be intended to be shelf-stable. Pasteurization is an example of a lethal heat treatment that reduces microbial pathogens but does not lead to a shelf stable product. Pasteurization typically is applied to kill non-sporeformers such as *Salmonella*, *L. monocytogenes*, and pathogenic strains of *E. coli*.

This chapter does not address heat treatments that lead to commercial sterility of low-acid canned foods. Such treatments are subject to the requirements of 21 CFR 500.23 and 21 CFR part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; commonly called Low-Acid Canned Foods (LACF)). Microbiological hazards regulated under part 113 are not subject to the requirements for hazard analysis and risk-based preventive controls. Note that although some hermetically sealed containers (e.g., pouches or trays) used to package thermally processed low-acid foods generally would not be viewed as cans, the term

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low-acid canned foods has been used for decades as a shorthand description for thermally processed low-acid foods packaged in hermetically sealed containers, and we continue to use that term (and its abbreviation, LACF).

#### Thermal destruction of microorganisms

To design a lethal heat treatment for use as a preventive control, you should have a basic understanding of thermobacteriology (i.e., the relationship between bacteria and heat), including two key types of data and information:

1. The kinetics of thermal inactivation or destruction of microorganisms, known as thermal death time data; and,
2. The rate at which heating occurs within the animal food, also known as heat transfer or heat penetration.

Immediately following, we describe basic concepts associated with thermal death time data and heat transfer/heat penetration. A more extensive review of thermobacteriology, including graphical representations of the relationship of  $D$ -values and  $z$ -values to Thermal Death Time, is available (Ref. 10).

Some terms and concepts used to describe the thermal destruction of microorganisms include:

- **$F$ -value or TDT (Thermal Death Time)** is the time required to kill a given population of microorganisms at a specified temperature
- **$D$ -value or the decimal reduction time** is the time required to kill 90% of a population of microorganisms at a constant temperature and under specified conditions
- **$Z$ -value** refers to the temperature increase required to reduce the  $D$ -value by a factor of 10

Food processing experts evaluate treatments intended to kill or inactivate pathogens in food in terms of logs of kill, where the term log is a shorthand expression of the mathematical term logarithm. A logarithm is the exponent to which a base number must be raised to equal a given number. In thermobacteriology, the base number is usually 10. As an example, the number  $100 = 10^2$  where the base number is 10 and the exponent is 2. Because the exponent is 2, a 2-log reduction represents a 100-fold reduction. Likewise, a 3-log reduction represents a 1000-fold reduction,  $10^3$ . The important thing to understand is that each log of kill is capable of causing a ten-fold reduction in the population of microorganisms that the treatment is designed to kill, i.e., the most resistant microorganism of public health significance.

The decimal reduction time ( $D$ ) is used synonymously with log in the context of thermobacteriology. A 1-log or 1- $D$  process would be one that is capable of reducing the population of the most resistant microorganism of concern in the animal food ten-fold, e.g., from 10,000 cells of the microorganism per gram of animal food to 1,000 cells of the microorganism

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per gram of animal food. Importantly, it is not possible for a process to technically achieve a level of reduction equivalent to zero, or no microorganisms in animal food; instead, as a technical matter the probability of finding the organism becomes less likely as the number of log reduction increases. Thus, a 5-log reduction process would be one that is capable of reducing the population by 100,000 fold, e.g., from 10,000 cells of the microorganism per gram of animal food to a probability of 1 cell in 10 grams of animal food, or 100,000 cells of the microorganism per gram of animal food to a probability of 1 cell per gram of animal food. You should use a heat treatment that delivers a sufficient amount of log reduction to ensure the most resistant microorganism of concern is non-detectable when the animal food is tested using a validated method.

Table 4-1 provides examples of the effect of lethal heat treatments on microorganisms in animal food using terms commonly associated with thermobacteriology.

**Table 4-1. The Concept of Log Reductions of Microorganisms in Animal Food**

Initial Number of the Most Resistant Microorganism of Concern Per Gram of Animal Food	Log Reduction (also known as <i>D</i> )	Decrease in Most Resistant Microorganism of Concern Per Gram of Animal Food	Percent of Change	Final Number of Most Resistant Microorganism of Concern Per Gram of Animal Food
10,000 or 4 log <sup>1</sup>	1	10-fold	90%	1,000 or 3 log
10,000 or 4 log	2	10 X 10 = 100-fold	99%	100 or 2 log
10,000 or 4 log	3	10 X 10 X 10 = 1000-fold	99.9%	10 or 1 log
10,000 or 4 log	4	10 X 10 X 10 X 10 = 10,000-fold	99.99%	1 or 0 log
10,000 or 4 log	5	10 X 10 X 10 X 10 X 10 = 100,000-fold	99.999%	0.1 or -1 log <sup>2</sup>
10,000 or 4 log	6	10 X 10 X 10 X 10 X 10 = 1,000,000-fold	99.9999%	0.01 or -2 log

<sup>1</sup> Additional equivalent ways to express 10,000 include 10<sup>4</sup>, 10<sup>^4</sup>, and 10E4.

<sup>2</sup> Additional equivalent ways to express 0.1 include 10<sup>-1</sup> or 1 in 10.

### Relative heat resistance of microorganisms

Some microorganisms are more resistant to heat than other microorganisms and, thus, require more stringent heating conditions to kill or inactivate them. Table 4-2 shows the relative heat resistance of common types of microorganisms.

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**Table 4-2. Relative Heat Resistance of Microbial Forms**

Resistance to Heat	Microbial Form
Highest	Bacterial Spores
Moderate	Some vegetative bacterial cells Cysts of parasites Fungi, including fungal spores
Least	Some vegetative bacterial cells Viruses

As already noted, this chapter addresses heat treatments that reduce pathogens in animal food but do not lead to commercial sterility. These heat treatments are used to significantly minimize the number of vegetative cells of bacterial pathogens such as *Salmonella*, *L. monocytogenes*, and pathogenic *E. coli*.

Factors affecting the heat resistance of microorganisms

In addition to the inherent heat resistance of specific microorganisms (or life stages of microorganisms, such as the spore stage) other factors associated with animal food (such as water activity, fat content, pH, salt content, and protein content) can affect the heat resistance of microorganisms. Table 4-3 lists the most common factors that you should consider when designing a heat treatment as a process control for biological hazards.

**Table 4-3. Factors that Influence the Heat Resistance of Microorganisms in Animal Food**

Factor	Effect on Microbial Heat Resistance
Water	As the water activity, humidity, or moisture goes down, in general the heat resistance increases.
Fat	As the fat content increases, there is a general increase in heat resistance of some microorganisms.
Salts	The effect of salt varies and depends on the kind of salt and its concentration. Some salts that decrease water activity appear to increase heat resistance of microorganisms while other salts that may increase water activity (e.g., calcium and magnesium) appear to decrease heat resistance.
Carbohydrates	The presence of sugars can increase the heat resistance of microorganisms due in part to the decrease in water activity.

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Factor	Effect on Microbial Heat Resistance
pH	Most microorganisms are more heat resistant near their optimum pH for growth. Generally, as the pH increases or decreases relative to this optimum pH, the microorganisms become more sensitive to heat.
Proteins	Proteins have a protective effect and, thus, increase the heat resistance of microorganisms.

Other factors that can influence the heat resistance of microorganisms include the number of microorganisms, the age of the microorganisms, the temperatures at which microbial growth occurs, the presence of inhibitory compounds, and the time-temperature combination used.

### Lethal heat treatments

Lethal heat treatments (heat treatments) such as baking, rendering, roasting, pelleting, extrusion, and other conventional heating methods are used for processing a wide variety of animal food (e.g., cereal-grain products, pet food kibble, jerky treats, and fish food). Heat treatments may be performed for a variety of reasons, such as to make animal food safe by eliminating foodborne pathogens such as *Salmonella* and *L. monocytogenes*, to improve palatability, to increase nutrient bioavailability, and to inactivate anti-nutrient factors. This discussion focuses on the heat treatment methods for biological hazards and animal food safety.

There are a variety of ways to manage the application of these heat treatments depending upon the type of animal food and the method of heat application (e.g., rendering or extrusion). You may obtain information from peer-review journals and extension white papers to determine appropriate heat treatment parameters for your facility and type of animal food. Alternatively, you could establish the process scientifically and validate it through a scientific study demonstrating that if the minimum/maximum values are met for all the pertinent parameters (e.g., cooking temperature, time, and particle size) all particles will receive an adequate heat treatment. For example, the processing time and temperature to eliminate pathogens in a homogeneous mixture of an ingredient with uniform particle size may be different than an animal food containing different size particles of various ingredients. As another example, an all-dry kibble and a kibble with a semi-moist center would be processed using different time-temperature combinations. Besides time and temperature, other factors may impact process effectiveness.

Normally, a study to validate a heat treatment is performed by a person or group knowledgeable in the design of heat treatments to determine the critical parameters required for the heat process being applied to ensure that it delivers the desired reduction level (logs of kill, as described earlier in this chapter). If you do a study to validate the adequacy of your heat treatment preventive control(s), a preventive controls qualified individual (PCQI) must conduct (or oversee) your study. See CFR 507.47(b)(1). You may choose to seek assistance for your study from entities with special expertise in heat treatments. Thus for such studies, your PCQI will likely oversee, rather than conduct, the study. Once that study has been completed, the person

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conducting the study will provide a time and temperature for the processor to monitor during processing, as well as any other parameters that are critical to delivery of an adequate heat treatment, such as maximum particle size.

#### Emerging technologies based on thermal effects

Microwave, radio frequency, ohmic heating, and inductive heating are heat-based processes that can kill microorganisms by thermal effects. Microwave and radio frequency heating are based on the use of electromagnetic waves of certain frequencies to generate heat in a material through two mechanisms - dielectric and ionic. Ohmic heating is the process of passing electric currents (primarily alternating) through animal food to heat it. The heating occurs in the form of internal energy generation within the material. Ohmic heating is distinguished from other electrical heating methods by the presence of electrodes contacting the animal food (as opposed to microwave heating, where electrodes are absent), and depends on frequency of the current and waveform (typically sinusoidal). Inductive heating is a process of inducing electric currents within the animal food due to oscillating electromagnetic fields generated by electric coils.

For any of these heat-based processes, the cumulative lethality delivered by the process (as represented in a heating curve which measures total time the food is exposed to the rising and falling temperatures) and the location of the cold points will determine the effect on microorganisms. The effectiveness of these processes also depends on water activity and pH of the product. Although the shape of the destruction or inactivation curves is expected to be similar to those in conventional heating, the intricacies of each of the technologies need special attention if you plan to use them for microbial destruction or inactivation. For instance, in microwave heating a number of factors influence the location of the cold points, such as the composition, shape, and size of the food, the microwave frequency, and the applicator design. The location of the coldest-point and time/temperature history can be predicted through simulation software, and we expect that animal food processors may be able to use these emerging technologies in the future.

Additional information about these and other heat treatment technologies is available (Refs. 11, 12 and 13).

#### ***High pressure processing (HPP)***

Microorganisms vary in their sensitivity to high pressure. If you plan to use HPP, you should consider the target pathogen (e.g., *Salmonella*, *L. monocytogenes*, pathogenic *E. coli*, *Clostridium* spp. and *T. gondii*), animal food characteristics, and whether the process is to result in animal food that will be frozen, refrigerated, or shelf-stable. Destruction of the microorganism is primarily caused by changes in the structure and permeability of the cell wall, which causes fluids to be forced into the cell.

Bacterial spores are the most pressure-resistant biological forms known. Spores resist inactivation by high pressure alone and most require the addition of heat or some other mechanism to achieve appropriate levels of destruction. *C. botulinum* is one of the most pressure-resistant microorganisms (Ref. 10). Because of this, if *C. botulinum* is a known or

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reasonably foreseeable hazard in your animal food and the animal food is processed using HPP, you should refrigerate or freeze the animal food to provide control of sporeformers and toxin production.

The unit of measure frequently used for HPP in the food industry is the pascal (Pa) or megapascal (MPa, 1,000,000 Pa). High pressure processing of food requires pressures of 400 to 700 MPa, or 4000-7000 bars (58,000-101,000 pounds per square inch gauge). Most commercial human food industry applications use pressures in the range of 600 to 700 MPa (Ref. 10).

High pressure processing requires very specialized and costly equipment. Currently, the human food industry uses HPP batch systems. For batch processing, the food is packaged in a flexible or semi-flexible package, prior to placing the product in the HPP system, where the product is placed into a chamber and immersed in water or some other pressurizing fluid, then subjected to the high pressure for a time of 1-20 minutes, depending on the temperature and pressure. The chamber is then depressurized and the product removed. Applications and the feasibility for commercialization for other HPP systems such as semi-continuous, continuous, and pulsed HPP have been described elsewhere (Ref. 10).

The pressure-time combination sufficient to inactivate pathogens with the greatest resistance to inactivation by pressure is determined based on the estimated pathogen load (i.e., number of pathogens per gram of food) in the animal food. Detailed reviews of the application and use of HPP as a process control in human food are available (Refs. 10 and 14). Publicly available data on pressure ranges and corresponding retention times required for inactivating pathogens in animal food during HPP treatments are limited at this time. If you rely on HPP to control pathogens in your animal food, you will likely need to conduct studies to validate your pressure-time combinations for inactivating pathogens in that animal food (see 21 CFR 507.47).

### ***Irradiation***

Food is irradiated primarily to inactivate organisms that cause spoilage, quality deterioration, or are an animal food safety concern. The application of ionizing radiation damages DNA and very effectively inhibits DNA synthesis and further cell division in organisms exposed to these forms and levels of energy. The amount of radiation energy used to control organisms varies according to the radiation resistance of the particular organism, which is often specific to the number or load of the organisms present (Ref. 15).

In the United States, a source of radiation used to irradiate food is considered a food additive and, as such, the use of irradiation in producing food (including animal food) requires premarket approval by FDA. See sections 201(s) and 409 of the FD&C Act and 21 CFR part 579, which incorporates part 179 (21 CFR 579.12). The only sources of ionizing radiation approved for use on specific types of animal food are cobalt-60 or cesium-137 generated gamma rays, electron beams not exceeding 10 million electron volts (MeV), and X-rays not exceeding 5 MeV or 7.5 MeV (except as otherwise permitted) depending on the source. See 21 CFR 579.22 and 579.40.

Some common terms used when describing the application of ionizing radiation in the treatment of animal food are:

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- Dose (absorbed) – The amount of energy absorbed per unit mass of irradiated material
- *D*-value – Amount of radiation required to reduce the population of a specific microorganism by 90% (1-log) under the stated conditions
- Gray (Gy) – A unit of absorbed dose of ionizing radiation, equal to 1 joule/kg of irradiated material (e.g., animal food)
- Electron volt (eV) – A unit of energy. One electron volt is the kinetic energy acquired by an electron in passing through a potential difference of one volt in a vacuum

Food treated with ionizing radiation must receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use. See 21 CFR 179.25(b). Table 4-5 summarizes maximum allowed doses of radiation for certain animal foods. Doses below 10 kiloGrays (kGy) have been used to inactivate pathogens such as *Salmonella* in dry cat, dog, and rodent food (Ref. 16). Irradiation of dried chicken-breast meat at 10-25 kGy was studied for use as pet food and the study authors concluded that the irradiated chicken meat was safe for that use (Ref. 17).

Table 4-4 provides a summary of compiled data on the ranges of decimal reduction doses (*D*-values) for some non-sporeforming pathogenic bacteria determined in various human foods under various conditions (Ref. 15). Only the pathogenic bacteria relevant to animal food are listed in the table. If you use irradiation to control bacterial pathogens in your animal food, you should base your irradiation doses on *D*-values determined for pathogens under similar conditions (e.g., composition, physical state, atmospheric environment, and temperature of the animal food).

**Table 4-4. *D*-values (kGy) for Some Foodborne Pathogenic Bacteria**

Bacteria	Non-frozen food	Frozen food
<i>Salmonella</i> spp.	0.18-0.92	0.37-1.28
<i>L. monocytogenes</i>	0.20-1.0	0.52-1.4
<i>E. coli</i> O157:H7	0.24-0.43	0.30-0.98

Bacterial spores are more resistant to irradiation than non-sporeforming bacteria. The spores of *C. botulinum* types A and B are particularly resistant.

For illustrative purposes, Table 4-5 lists the FDA-approved uses of ionizing radiation for animal food as of January 2018. We created the table from the regulatory language in 21 CFR 579.22 and 579.40, which specifies the limitations on the approved uses of ionizing radiation for the

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treatment of animal food. You should refer to 21 CFR part 579 for the most current limitations on the approved uses for the treatment of animal food using ionizing radiation.

**Table 4-5. FDA-Approved Uses for the Ionizing Radiation Treatment of Animal Food**

Animal Food	Use	Dose	Limitations
Bagged complete diets, packaged feeds, feed ingredients, bulk feeds, animal treats and chews	Microbial disinfection, control or elimination	Not to exceed 50 kiloGrays (kGy)	Animal food and animal food ingredients treated by irradiation should be formulated to account for nutritional loss
Poultry feed and poultry feed ingredients	Single treatment for rendering complete poultry diets or poultry feed ingredients <i>Salmonella</i> negative	Minimum dose 2.0 kGy; maximum dose 25 kGy. The absorbed dose of irradiation is to be based on initial concentration of <i>Salmonella</i> using the relationship that 1.0 kGy reduces <i>Salmonella</i> concentration by one log cycle	For poultry feed or feed ingredients that do not contain drugs  Feeds should be formulated to account for nutritional loss

See 21 CFR part 579, subpart B – Radiation and Radiation Sources.

The regulation includes requirements to account for nutritional loss after irradiation. This nutritional loss could result in a nutrient deficiency hazard that you determine requires a preventive control. In dry cat, dog, and rodent food, gamma radiation within the approved dose is known to cause a significant reduction in Vitamin A (Ref. 16). Irradiated cat food has been associated with the development of neurological disease in cats under certain circumstances (Ref. 18).

### 4.5.2 Use of Time and Low Temperature as Process Controls

Temperature is an essential factor that affects the growth of bacteria. Bacterial growth can occur over a wide range of temperatures from about 23°F (-5°C) to 194°F (90° C).

Thermophiles grow at temperatures above 131°F (55°C). Mesophiles (e.g., *Salmonella* spp. and *E. coli*) grow at or near room temperatures. Psychrophiles grow at or near refrigeration temperatures. Psychrotrophs (e.g., *L. monocytogenes*) are capable of growth at refrigeration temperatures, but their optimal growth temperature is in the mesophilic range. Table 4-6 lists four types of bacteria based on their temperature growth ranges.

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**Table 4-6. Temperature Ranges for the Growth of Microorganisms**

Group	Minimum Temperature for Growth °F (°C )	Optimum Temperature for Growth °F (°C )	Maximum Temperature for Growth °F (°C )
Thermophiles	104 - 113 (40 - 45)	131 - 167 (55 - 75)	140 - 194 (60 - 90)
Mesophiles	41 - 59 (5 - 15)	86 - 113 (30 - 45)	95 - 117 (35 - 47)
Psychrophiles	23 - 41 (-5 - +5)	54 - 59 (12 - 15)	59 - 68 (15 - 20)
Psychrotrophs	23 - 41 (-5 - +5)	77 - 86 (25 - 30)	86 - 95 (30 - 35)

Typically, the higher the temperature (within the normal growth range), the more rapid the growth of the microorganism. It is not only the temperature that is of concern; it is the total time of exposure at temperatures that allows growth that needs to be minimized. The most general recommendation is to hold refrigerated food below 41°F (5°C).

***Refrigeration***

Refrigeration works well for controlling the growth of most pathogenic bacteria. However, some pathogens, like *L. monocytogenes* can grow at temperatures close to freezing. Refrigeration has the added advantage of slowing down biological and chemical processes that result in spoilage and oxidative rancidity.

Maintaining cold temperatures during storage can be accomplished in several ways, such as ice, chemical coolant gel packs, and mechanical dry refrigeration (e.g., in a cooler). Maintaining cold temperatures with ice or gel packs can be effective if there is an adequate amount of ice or gel packs. Therefore, you should ensure an adequate amount of ice or gel packs are present on the animal food at all times and monitor the temperature with a thermometer or temperature recording device.

For mechanical dry refrigerated storage in a cooler, if the ambient temperature can be related to the product temperature, monitoring the temperature of the storage area will ensure that the product temperature is maintained. Monitoring of the cooler is ordinarily done using continuous monitoring instruments such as recorder thermometer charts, maximum-indicating thermometers, and high temperature alarms.

Time/Temperature

When food that is intended to be stored under refrigeration is removed from refrigeration, the temperature of the food gradually increases and can reach the temperature associated with the growth range specific to particular pathogens. Bacterial pathogens go through a lag phase, where little or no growth occurs as the microorganisms adjust to their new environment. As the product temperature approaches the growth range, pathogens enter what is called the log phase where

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their numbers increase logarithmically. For animal food intended to be refrigerated, the objective is to prevent the log phase from happening, ideally keeping pathogens in their lag phase. We call the temperature range of concern (41°F (5°C) to 135°F (57°C)) the danger zone (Ref. 19). Different pathogens have different rates of growth at different temperatures, and the rate of growth will be affected by the type of animal food and its inherent properties. Therefore, the actual maximum time that an animal food may be safely held in the danger zone depends on a number of factors, including the type of pathogens that are present and the ability of the animal food to support their growth.

Management of time and temperature during processing may be more complicated than during storage, because it involves information about the time and temperature exposure of the animal food (including raw materials and ingredients) during production. You can manage time and temperature during processing in a variety of ways, such as marking units of animal food and tracking how long they remain at unrefrigerated temperatures; monitoring the temperature in a chilled processing room; or monitoring animal food temperatures during different phases of production.

#### Cooling after cooking

Cooling after cooking can be a critical function influencing the safety of human food (Ref. 19). Cooling after cooking may be important for animal food that is cooked but still requires refrigeration (e.g., pet food that is not shelf-stable). Depending upon the animal food type and raw materials and ingredients, cooked animal food can still have viable pathogenic bacteria present. Pathogens that are particularly heat tolerant (such as *L. monocytogenes* and the spores of *C. botulinum*) can sometimes survive the cooking process; however, this should not be the case if you selected the appropriate target pathogen for control by the applied process and you validated the control.

The spores of sporeforming pathogens (such as *C. botulinum*), if they are present, can survive the cooking process because temperatures that can only be achieved under pressure are usually needed to inactivate spores. These spores will begin to germinate when the product temperature drops to a temperature at which they can grow (usually below 135°F (57°C)). If the animal food is temperature-abused, pathogenic spores could germinate, grow, and the resulting cells can possibly produce toxin due to the fact that most spoilage bacteria (which may otherwise compete for growth) have been eliminated by the cooking process (Ref. 19).

If the cooking process is adequate (i.e., heat and pressure) to inactivate spores, the cooling step will not be critical. However, the animal food can be recontaminated during the cooling process as a result of improper handling, condensate or drip, or contact with other animal food.

#### ***Freezing***

During frozen storage, populations of viable microorganisms in most animal food will decrease; however, some microorganisms remain viable for long periods of time during frozen storage. Most viruses, bacterial spores, and some bacterial cells survive freezing unchanged. Some other microorganisms (e.g., parasitic protozoa such as *T. gondii*), are generally more sensitive than

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viruses and bacteria to the freezing and thawing process (i.e., freezing, frozen storage, or thawing). For this reason, freezing and frozen storage are good methods for inactivating protozoa in various animal food (Ref. 7). This is especially important if animals are likely to eat the animal food raw, after thawing. However, freezing should not be considered a preventive control to significantly minimize pathogens such as *Salmonella* spp., *L. monocytogenes*, and pathogenic *E. coli*.

#### 4.5.3 Use of Product Formulation as Process Controls

In this section of this chapter, we discuss two key factors,  $a_w$  and pH, that are frequently used as a formulation process control. We also discuss the use of preservatives as a formulation process control.

##### *Water activity ( $a_w$ )*

Microorganisms need water to survive as well as to grow. Two measurements relevant to safety of animal food are equilibrium relative humidity (ERH) and  $a_w$ . Water activity refers to the availability of water to the organism. In general, microorganisms survive and grow better when the  $a_w$  is high than when the  $a_w$  is low.

If you have a closed container of pure water, the air above the water becomes saturated with water vapor over time. The ERH of the air at saturation is 100%, which is equivalent to an  $a_w$  of the water of 1.0. Thus, pure water has an  $a_w$  of 1.0 (Ref. 20).

Animal food represents more complex systems than water, and the water can bind to components of the animal food so not all the water in the animal food is available to microorganisms; thus, the  $a_w$  of animal food is less than 1.0.

Water activity is directly related to the vapor pressure of the water in a solution. You can determine  $a_w$  by measuring the ERH of the air over the solution in a closed container. Equilibrium relative humidity, expressed as a percentage, divided by 100 equals the  $a_w$ :

$$a_w = \text{ERH}/100$$

or the partial pressure of water vapor above the animal food ( $p$ ) divided by the partial pressure of water vapor above pure water ( $p_o$ ) at the same temperature: (Ref. 21).

$$a_w = p/p_o$$

Animal food types vary in their  $a_w$  and can be classified into three categories based on  $a_w$ : moist animal food ( $a_w$  above 0.85), intermediate-moisture animal food ( $a_w$  between 0.60 and 0.85), and low-moisture animal food ( $a_w$  below 0.60). Depending on  $a_w$ , animal food may require additional preventive controls to significantly minimize pathogens. Moist animal food would require refrigeration or another control such as heat treatment, acid pH, or preservatives to control the growth of pathogens. Intermediate-moisture animal food would not require refrigeration to control pathogens but may have a limited shelf life because of spoilage, primarily

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by yeast and mold. The microbiological stability of intermediate-moisture animal food may depend on factors other than  $a_w$ , such as reduced pH, chemical preservatives, heat treatments, or combinations of these, even though the reduced  $a_w$  is of major importance. Low-moisture animal food has an extended shelf life, even without refrigeration when stored properly. Table 4-7 classifies animal food into three categories based on  $a_w$  and provides examples of animal food types.

**Table 4-7. Examples of Animal Food Types Based on Water Activity ( $a_w$ )**

Water Activity	Categories	Animal Food Types
Above 0.85	Moist Animal Food	Refrigerated and frozen pet food Fresh meats and fish Fresh fruits and vegetables
Between 0.60 and 0.85	Intermediate-Moisture Animal Food	Soft or semi-moist pet food Dry pet food (e.g., kibble) Dog biscuit treat Dried distillers grains Molasses
Below 0.60	Low-Moisture Animal Food	Corn syrup solids Extruded wheat pellet Whole egg powder

Some of the intermediate and low  $a_w$  animal food types have naturally low  $a_w$  (e.g., molasses). We do not discuss those animal food types because  $a_w$  does not have to be controlled during processing. Other intermediate and low  $a_w$  animal food types, like dry pet food (kibble), pelleted livestock food, and distillers grains start with a high  $a_w$  and, through processing, end up with a reduced  $a_w$ . This section of this chapter focuses on these types of animal food.

### Control of water activity

There are two primary ways of reducing water activity in animal food: (1) product formulation (e.g., by adding humectants such as propylene glycol (except in cat food) and salt); and (2) dehydration (drying). In this section of this chapter, we discuss reducing water activity by product formulation. See section 4.5.4 for more information on dehydration/drying.

Every organism has a minimum, optimum, and maximum  $a_w$  for growth (see Table 4-8 for the minimum  $a_w$  for pathogen growth (Refs. 22 and 23)). Yeasts and molds can grow at low  $a_w$ ; however, 0.85 is generally considered the safe cutoff level for bacterial pathogen growth (Ref. 24).

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**Table 4-8. Minimum Water Activity for Bacterial Pathogen Growth**

Pathogen	Minimum $a_w$ (using salt)
<i>Salmonella</i> spp.	0.95
<i>L. monocytogenes</i>	0.920
Pathogenic <i>E. coli</i>	0.950
<i>C. botulinum</i>	0.935-0.970

There are two basic ways for how you can approach product formulation that uses management of  $a_w$  for animal food safety. One approach is to closely follow a scientifically established process control for animal food that ensures a sufficiently low  $a_w$ . The other approach is to develop your own process control capable of achieving the desired  $a_w$  and to ensure its adequacy by taking finished product samples and testing them for  $a_w$ .

Exposure to a moist environment will impact the ability of  $a_w$  to serve as a preventive control. If you rely on  $a_w$ , consider your storage conditions; specifically, protection from water in the environment. For example, a leaking roof could cause stored plant protein meal to become wet, resulting in a meal with  $a_w$  that could support the growth of pathogens.

**Acidity (pH)**

The term pH refers to a numeric scale used to describe acidity and alkalinity. The pH reflects the concentration of hydrogen ions and is expressed mathematically as the negative logarithm of the hydrogen ion concentration in moles per liter. The pH scale ranges from 0 to 14 with 0-6 being acidic, 7 neutral, and 8-14 basic.

$$\text{pH} = -\log[\text{H}^+]$$

Microorganisms can grow only at certain pH levels. Lowering the pH is a method of inhibiting the growth of bacteria rather than a method of killing bacteria. Although many microorganisms held at low pH for an extended period of time will be killed, some pathogenic bacteria, and in particular pathogenic *E. coli*, can survive acidic conditions for an extended period of time, even if their growth is inhibited. For details on the pH values for limiting growth of bacterial pathogens, see Table 4-9 (Ref. 25).

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**Table 4-9. pH Values for Limiting Pathogen Growth**

<b>Pathogen</b>	<b>pH Less Than</b>	<b>pH Greater Than</b>
<i>Salmonella</i> spp.	3.8	9.5
<i>L. monocytogenes</i>	4.39	9.4
Pathogenic <i>E. coli</i>	4.4	9
<i>C. botulinum</i>	4.6	8.5

Acidification

Because an acid pH can inhibit the growth of many bacteria, acidification of animal food could be used as a formulation process control. Acidification is the direct addition of acid to a low-acid animal food (i.e., food with a pH above 4.6). There are a variety of acids (such as acetic acid, lactic acid, and citric acid) that can be used to acidify animal food.

There are several different methods you might use to add acid to the animal food. One method is called direct acidification, where predetermined amounts of acid and the low-acid animal food are added to individual finished product containers during production. In this method, it is important that the processor control the acid-to-animal food ratio. Another method of acidification is batch acidification. As the name implies, acid and animal food are combined in large batches and allowed to equilibrate. The acidified animal food is then packaged. If you use acidification to significantly minimize pathogenic microorganisms in your animal food, you must validate the process for acidifying that animal food (see 21 CFR 507.47).

Fermentation

During bacterial fermentation of animal food, acid-producing bacteria produce lactic acid, which reduces the pH of the food. Examples of animal food fermented by bacterial fermentation to a pH below 4.6 include haylage and silage. Many of these fermentation activities occur on-farm and operations meeting the “farm” definition in 21 CFR 1.227 are exempt from the PCAF regulation (see 21 CFR 507.5(a)).

***Preservatives***

Preservatives can be used to prevent the growth of microorganisms – e.g., when used in an animal food that is not thermally processed or not thermally processed to an extent that is sufficient to kill the vegetative cells of non-pathogenic microorganisms (such as spoilage microorganisms) that are capable of reproducing in the animal food under the conditions in which the animal food is stored, distributed, retailed, and held by the user. Preservatives work by denaturing protein, inhibiting enzymes, or altering or destroying the cell walls or cell

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membranes of microorganisms. A listing of some substances that are generally recognized as safe (GRAS) for use as chemical preservatives is available in 21 CFR part 582, subpart D.

#### **4.5.4 Use of Dehydration/Drying as Process Controls**

In the United States, there are three primary methods of dehydration as a process control for biological hazards:

- Forced air drying – used for solid animal food like grains and legumes
- Spray drying – used for liquids and semi-liquids like milk, blood, and blood plasma
- Freeze-drying – used for a limited selection of animal food like some raw pet food

Dehydrated/dried animal food is usually considered shelf-stable due to its low  $a_w$  and, therefore, is often stored and distributed unrefrigerated. Examples of shelf-stable dehydrated/dried animal food include freeze-dried raw pet food, milk powders, spray dried animal blood, and dried grains and soybeans.

If you use dehydration/drying as a process control, you should determine if the animal food will require a packaging material that will prevent rehydration of the animal food under the expected conditions of storage and distribution. Additionally, finished animal food packaging and package closures should be free of gross defects that could expose the animal food to moisture during storage and distribution.

Use of the dehydration process can be an effective method for preventing or significantly minimizing deterioration of animal food. Deterioration of animal food includes the loss of palatability or nutritive value typically associated with the animal food. This deterioration could be a safety concern because animals are often fed the same food containing the same ingredients for prolonged periods of time. Food refusal or consumption of animal food containing inadequate amounts of nutrients may result in poor productivity or health issues.

#### **4.6 Preventive Controls for Chemical Hazards**

##### **4.6.1 Preventive Controls for Nutrient Deficiencies and Toxicities**

As discussed in Chapter 3, nutrient deficiencies or toxicities are considered chemical hazards for animal food and FDA has a history of recalls of animal food due to this type of chemical hazard. Depending on your facility, the type of animal food, and the intended species (and life stage) of animals, you may determine that a known or reasonably foreseeable nutrient deficiency or toxicity hazard requires a preventive control.

Many nutrient deficiency or toxicity hazards occur before or during processing, for example, due to a miscalculation in the initial recipe/formulation of an animal food for an intended species or life stage, inadvertent addition of the wrong mineral mix to a batch of animal food, or failure to account for the effects some processing procedures (such as LACF thermal processing or irradiation of animal food) have on certain nutrients. Implementation of process controls would

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be appropriate for many nutrient deficiency or toxicity hazards. Though preventive controls for nutrient deficiencies or toxicities can vary, we describe a few examples.

Essential nutrients in your animal food need to be present at the levels needed by the intended animal species (and life stage) and cannot be present in low or excessive levels if the levels could result in a nutrient deficiency or toxicity hazard. For example, a known or reasonably foreseeable nutrient deficiency or toxicity chemical hazard involves vitamin D. Past recalls of animal food include both those for vitamin D excess and vitamin D deficiencies (see section 3.4.2 in Chapter 3). If you identify vitamin D deficiency or toxicity in your animal food as a hazard requiring a preventive control, your preventive control will depend on your manufacturing procedures and could include several types of controls. Ensuring you have the proper nutrient recipe/formulation for a specific species (and life stage) could be one control. An animal nutritionist or similarly trained individual should prepare the recipe/formulation. Another control could be one to ensure that the animal food manufacturing equipment is capable of producing a homogeneous animal food. For example, a large mixer that is not filled with the minimum volume of ingredients recommended by the manufacturer may not mix a small batch of animal food adequately, which could result in the vitamin D not being uniformly distributed throughout the animal food (i.e., deficient in some parts, excessive in others).

Thiamine deficiency is a known or reasonably foreseeable chemical hazard for cat food that is thermally processed as an LACF product. If you are manufacturing a cat food that will undergo LACF thermal processing, you should identify thiamine deficiency as a chemical hazard requiring a preventive control. One process control could include the addition of extra thiamine to the cat food to account for the loss during processing. Testing thiamine levels of processed cat food, at a frequency deemed necessary and appropriate, could be an additional process control, or a verification activity to ensure the addition of extra thiamine is effective.

Copper excess is a known or reasonably foreseeable chemical hazard for sheep food. If you are manufacturing food for cattle that requires copper at levels that would be toxic to sheep, and you manufacture food for sheep on the same equipment, you would likely identify copper excess as a known or reasonably foreseeable nutrient toxicity hazard requiring a preventive control. A preventive control you could implement is a combination of sequencing of animal food production and proper flushing of equipment after cattle food production. Sequencing would ensure any food for sheep is manufactured prior to any food for cattle. You could implement additional controls so there is not an inadvertent mix up by an employee, to ensure the proper mineral supplement containing copper is added to the appropriate animal food (cattle versus sheep). And, you could add control procedures for labeling of finished animal food to ensure a bag of food for cattle (with higher levels of copper) is not mistakenly labeled as sheep food.

If you are purchasing a micronutrient or mineral pre-mix, and you have identified a nutrient deficiency or toxicity hazard for that pre-mix, you could analyze the pre-mix to ensure it meets your specifications to control the nutrient deficiency or toxicity hazard. Or if you are a receiving facility that will rely on your supplier to control the hazard in the pre-mix, you must establish and implement a risk-based supply-chain program (see 21 CFR 507.105). Your supply-chain program may allow your approved supplier to test a particular lot of pre-mix for the hazard and

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provide you with a Certificate of Analysis or other documentation, which you must review and assess (see 21 CFR 507.115(a)(4)).

You might identify specific CGMPs as your preventive control for certain nutrient deficiencies or toxicities. If you do this, the specific CGMP must be included in your food safety plan as your preventive control (see 21 CFR 507.31) along with the required preventive control management components (see 21 CFR 507.39).

#### **4.6.2 Drying and Storage Conditions as Preventive Controls for Mycotoxins**

Mycotoxins are toxic metabolites produced by certain fungi (e.g., molds) that can infect and proliferate on raw agricultural commodities (e.g., grains such as wheat and corn, peanuts, fruits, and tree nuts) in the field and during storage (see Chapter 3, section 3.4.1). Growth of toxigenic fungi during storage and transportation can be enhanced by improper drying or rewetting of the crop from rain or condensation. Thus, proper drying and maintaining appropriate storage conditions are preventive controls that can significantly minimize or prevent the growth of mold and production of mycotoxins in storage.

By far the most critical environmental factors determining whether a raw agricultural commodity will support mold growth are temperature, moisture content, and time. In storage, each of these parameters can be manipulated to prevent mold growth in a raw agricultural commodity. The control of moisture is the principal preventive control for preventing mold growth. Although low-temperature storage can help inhibit mold growth in some conditions, large-scale storage of raw agricultural commodities generally takes place in structures that do not provide for temperature control. Thus, low-temperature storage generally is not a preventive control for mycotoxins during the storage of raw agricultural commodities.

#### **4.6.3 Sequencing and Flushing as Preventive Controls for Drug Carryover**

If a facility does not have dedicated equipment for manufacturing certain types of animal food then sequencing and flushing are procedures that could be used to prevent or significantly minimize drug carryover.

Sequencing involves scheduling the production of animal food containing certain drugs (e.g., ionophores or other antimicrobials) to occur after the production of nonmedicated animal food to minimize the potential for cross-contamination.

Flushing is a method to help remove drugs or animal food that may be left in or on the equipment after production. Flushing is the process of running an ingredient through the manufacturing equipment and associated handling equipment (e.g., conveyors) after the production of a batch of medicated animal food, for the purpose of removing any drug left in or on the equipment. Abrasive flushing material such as corn, soybean meal, and peanut hulls, is helpful when manufacturing a medicated animal food with high fat content or containing molasses that may stick to equipment. Depending on the facility and the animal food manufactured, flushing may need to be conducted more often than at the end or start of the day.

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You must comply with the validation requirements in 21 CFR 507.47 for your flushing method for use as a preventive control.

In a medicated feed mill, required employee training in the principles of animal food hygiene and animal food safety (see 21 CFR 507.4(b)(2)) should include information about the drugs used by the facility and the potential for illness or injury to animals when those drugs cross-contaminate nonmedicated animal food.

#### **4.7 Preventive Controls for Physical Hazards**

##### **4.7.1 Preventive Controls for Metal Hazards**

Metal-to-metal contact during processing can introduce metal fragments into products. For example, metal fragments can break off during mechanical cutting and blending operations. Some metal equipment has parts that can break or fall off, such as wire-mesh belts. You can control metal hazards by using physical separation techniques (e.g., magnets, sieves, screens), electronic or X-ray metal detection devices, and by regularly inspecting at-risk equipment for signs of damage.

The effectiveness of physical separation techniques depends on the nature of the animal food. For example, these measures are more likely to be effective in liquids, powders, and similar animal food ingredients and finished animal food in which the metal fragment will not become imbedded.

The use of electronic metal detectors is complex, especially with regard to stainless steel, which is difficult to detect. The orientation of the metal object in the animal food affects the ability of the equipment to detect it. For example, if a detector is not properly calibrated and is set to detect a sphere 0.08 inch (2 mm) in diameter, it may fail to detect a stainless steel wire that is smaller in diameter but up to 0.9 inch (24 mm) long, depending on the orientation of the wire as it travels through the detector. Processing conditions, such as ambient humidity or product acidity, may affect the conductivity of the product and create an interference signal that may mask metal inclusion unless the detector is properly calibrated. You should consider these factors when calibrating and using such equipment.

X-ray devices can also be used for metal detection. One advantage of using such a device is that X-rays can detect non-metal foreign objects such as glass fragments.

Also, preventive controls can include scheduled maintenance of equipment and periodic examination of your processing equipment for damage that can cause the introduction of metal fragments into the animal food. You should particularly look at equipment that is prone to breaking, such as saw blades, or equipment that has metal-to-metal contact. The success of this strategy depends in large part on the nature of the equipment inspected and the frequency of the inspection. However, this approach will not necessarily prevent metal fragments from being incorporated into the product in all cases, but may enable you to separate products that may have been exposed to metal fragments. Visually inspecting equipment for damaged or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders,

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and wire-mesh belts. More complex equipment that contains many parts, some of which may not be readily visible, may not be suitable for visual inspection and you should use controls such as metal detection or physical separation techniques.

#### **4.7.2 Preventive Controls for Glass Hazards**

Glass fragments can be introduced into animal food when processing occurs under overhead light fixtures and light bulbs made of glass that can fracture. Animals may ingest these glass fragments which can cause serious injury (e.g., laceration or perforation of the gastrointestinal tract and choking). Light bulbs, fixtures, skylights, or other glass items suspended over exposed animal food in any step of preparation must be shatter-resistant to protect against the contamination of animal food from glass breakage (see 21 CFR 507.17(b)(5)). If you identify glass fragments as a known or reasonably foreseeable physical hazard at your facility, you could address them through the use of prerequisite programs (e.g., CGMPs).

#### **4.7.3 Preventive Controls for Hard Plastic Hazards**

Hard plastic can be introduced into animal food at any time during processing when tools and equipment (e.g., scoops, buckets, paddles, sieves, and screens) wear down. Normal use and processing may wear down these tools or equipment over time resulting in fatigue, cracking, and breaking. As a preventive measure, it is important to regularly examine plastics for cracks throughout your facility. Plastic can also be present in incoming ingredients (e.g., animal identification tags in rendered products, or packaging material from products originally intended for human food used for animal food). Preventive controls that can be used to significantly minimize or prevent hard plastics in animal food at receiving or during manufacturing include visually inspecting animal food and using physical separation techniques (e.g., sieves and screens).

#### **4.7.4 Preventive Controls for Conditions of Animal Food That Can be Hazards**

Conditions of the animal food that can cause illness or injury in animals include physical, mechanical, and other characteristics of animal food (e.g., particle size, hardness, surface roughness, digestibility, and ability to soften when moistened). Preventive controls will vary depending on the type of animal food and the specific condition of the animal food that you have determined requires a preventive control.

If you determine particle size (e.g., too small or too large) is a condition of animal food hazard that requires a preventive control, you could address particle size through process controls. If you are reducing the particle size during manufacturing, your process controls would ensure the process is achieving the desired particle size, for example, through selection of the hammer-mill screen size.

Another condition of animal food hazard you might identify is excessive hardness or poor digestibility. Recipe/formulations and manufacturing processes could impact the hardness and/or digestibility of animal food. For example, starch is used in animal food for nutritive value and as a thickening agent. When starch is gelatinized, the chemical structure of the starch is

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changed, providing digestive enzymes in saliva access to the glycosidic linkages in the starch. The enzymes soften the animal food during chewing and make it easier for the animal to swallow. If you have identified the inability to soften when moistened as a condition of animal food hazard that requires a preventive control for your animal food, you might use a supply-chain program to ensure starch meets your specifications (e.g., iodine value, solubility, and viscosity). You also may rely on your manufacturing process to gelatinize the starch. In this situation, you may determine that you need to implement a process control to ensure acceptable gelatinization of the starch to significantly minimize or prevent indigestible animal food. Your process control would include parameters for the processing (e.g., temperature, time, pressure, and moisture content) necessary to gelatinize the starch in your food.

#### 4.8 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: (1) cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and (2) 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. See 21 CFR 507.34(c)(2).

Recall that the CGMPs include requirements for sanitation of the plant (see 21 CFR 507.19). These requirements are applicable to the cleanliness of equipment, utensils, buildings, structures, and fixtures. To comply with these CGMP requirements, cleaning procedures should take place routinely, often daily, in your facility. To facilitate sanitation, there are requirements for the design and construction of equipment and utensils (see 21 CFR 507.22(a)).

Some of your sanitation procedures, practices, and processes used in your facility for general cleaning and sanitation may be performed to comply with CGMP requirements. Other sanitation procedures, practices, and processes may be sanitation controls if used to significantly minimize or prevent a biological hazard. You determine which hazards require a sanitation control through your hazard analysis. For example, you may determine a sanitation control is needed in addition to the general facility cleaning if there is a biological hazard such as *L. monocytogenes* that you determined requires a preventive control. The sanitation control is the cleaning and sanitizing you conduct on animal food-contact surfaces of utensils and equipment to significantly minimize or prevent *L. monocytogenes*. Because the cleaning and sanitizing are used as a sanitation control, they are subject to the preventive control management components in 21 CFR 507.39.

For your sanitation controls to be effective, you should first assess the cleaning procedures, practices, and processes that you will have in place to comply with the CGMP requirements. Equipment design that ensures that all surfaces can be accessed and cleaned (see 21 CFR 507.22(a)(1)) is essential for the effective application of sanitation controls. Considerations for equipment design include factors such as whether equipment includes hollow bodies or poorly developed welds and seams, as well as whether ease of disassembly allows adequate access to all

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animal food-contact surfaces to ensure thorough cleaning and sanitation. Design considerations also apply to animal food facility structures (e.g., floors, walls, piping, and ceilings) to facilitate cleaning and sanitation practices. Due to this link between your CGMP procedures, practices, and processes and your sanitation controls, your CGMP procedures, practices, and processes are sometimes called prerequisite programs. See our Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals (Ref. 26). Sources of scientific and technical information also can be useful in establishing sanitation controls (Refs. 27, 28 and 29).

### **4.8.1 Cleaning Strategies and Sanitation Controls**

The PCAF regulation does not define the term “cleaning”. In this guidance, we use the term “cleaning” to mean the removal of soil, animal food residue, dirt, grease or other objectionable matter. Cleaning procedures, practices, and processes are generally considered part of a facility’s general sanitation program. The PCAF regulation defines “sanitize” to mean 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 (21 CFR 507.3). Although cleaning operations and sanitizing operations often are conducted separately – and sequentially – some systems (such as steam systems) both clean and sanitize surfaces; we consider that such systems satisfy the definition of “sanitize”.

The cleaning procedures and any sanitation controls you use will vary based on the nature of your facility, such as whether your facility has a dry or wet processing environment.

Table 4-10 describes three types of cleaning strategies that you can use to remove soil, food residue, dirt, grease, or other objectionable matter depending upon the processing environment (wet or dry). Table 4-10 also includes some recommendations when using these cleaning strategies.

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**Table 4-10. Types of Cleaning Strategies**

<b>Cleaning Strategy</b>	<b>Description</b>	<b>Recommendations</b>
Wet Cleaning	<p>Uses water-based and/or wet chemical cleaning solutions</p> <p>Typically used for wet processing environments</p>	<p>When feasible, initially dry clean area or equipment</p> <p>Use water on an as needed basis</p> <p>Use water only in required areas</p> <p>When feasible, avoid using water in a manner that could aerosolize (e.g., high pressure)</p> <p>When animal food-contact surfaces are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use (see 21 CFR 507.19(b)(1))</p>
Controlled Wet Cleaning	<p>Uses a limited amount of water</p> <p>Typically used for dry processing environments</p>	<p>When feasible, initially dry clean area or equipment</p> <p>Use only as much water as is necessary</p> <p>Move specific pieces of equipment to a designated area for cleaning and sanitizing and dry them prior to returning them to the dry manufacturing area</p> <p>When animal food-contact surfaces are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use (see 21 CFR 507.19(b)(1)), and complete drying should immediately follow after the controlled wet cleaning</p>

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Cleaning Strategy	Description	Recommendations
Dry Cleaning	<p>The physical removal of residues (e.g., animal food particles and dust) without water</p> <p>Typically used for dry processing environments</p>	<p>Remove animal food residues by actions such as sweeping, brushing, scraping, flushing or vacuuming the residues from equipment surfaces and the facility environment</p> <p>Be careful to not distribute animal food particles to other equipment or areas during removal</p> <p>Compressed air must be used in a way that protects against the contamination of animal food (see 21 CFR 507.22(e)) (e.g., does not blow dirt, debris, or other contaminants into the animal food or onto animal food-contact surfaces)</p>

Moisture control is important in preventing contamination with undesirable microorganisms. For example, water in a dry processing environment is one of the most significant risk factors for *Salmonella* contamination because the presence of water allows for pathogen growth leading to product contamination from the environment or from insanitary food contact surfaces. You should maintain dry conditions at all times when you determine that *Salmonella* in the environment is a hazard requiring a preventive control, except for the occasions when you decide that controlled wet cleaning is necessary. Potential problems arise when there is visible water present in the dry areas or when there are areas in which standing water has dried. *Salmonella* may be found both in wet spots and in spots where standing water has dried. Therefore, dry cleaning or controlled wet cleaning practices should be considered for use as a component of sanitation controls in a dry processing environment.

Wet processing operations are typically cleaned using wet cleaning practices. However, the use of water should be minimized even in facilities that are wet cleaned. Wet floors can serve as potential sources for *L. monocytogenes* via the movement of people and equipment and material handling items such as totes and pallets. Cleaning and sanitizing floors, including drains, could help reduce the potential for *L. monocytogenes* to establish in the environment. *L. monocytogenes* is not usually airborne; however, in wet environments, aerosols from high pressure water hoses used during cleaning operations help spread *L. monocytogenes* throughout the environment and from one surface (e.g., floors) to another surface (e.g., animal food-contact surfaces, such as conveyors, tables, and animal food containers). Cleaning and sanitizing may be an important sanitation control for facilities that have determined they need to control *L. monocytogenes* because they are producing animal food such as raw pet food which may be exposed to the environment prior to packaging.

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If you determine sanitizing is necessary, you should sanitize animal food contact surfaces and other areas as appropriate after the surfaces are cleaned. You should use all sanitizers in accordance with the EPA-registered (or similar registration in other countries) label use instructions, including approval for use in food establishments.

For additional information on the impact of wet and dry processing environments on *L. monocytogenes* and *Salmonella*, see Chapter 3, section 3.3.4.

### 4.8.2 Use of Sanitation Controls to Prevent Cross-Contamination

As noted previously in this section, sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes 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. See 21 CFR 507.34(c)(2)(ii).

Table 4-11 describes practices that you can use to prevent cross-contamination of processed animal food from insanitary objects, personnel, and raw product.

**Table 4-11. Practices to Prevent Cross-Contamination**

Practice	Description
Hygienic Zoning	Hygienic zoning for separation and segregation of process operations such as raw vs. work-in-process vs. finished product; wet vs. dry; personnel and materials traffic flow; air balance
Hygienic Zone Specific Cleaning	Dedicated cleaning and sanitation practices (including sanitizing) within hygiene zones

The objective of hygienic zoning is to reduce the potential for transient pathogens to enter sensitive areas in your facility. You should determine the need for, and scope of, a hygienic zoning program based on the outcome of your hazard analysis and considering your facility and type of animal food. In determining the need for, and scope of, a hygienic zoning program, you should take into account the design of your plant, packaging, personnel and ingredient traffic flows, and any cross over areas. You also should consider potential contaminants from raw materials, air flow, support areas, and other activities taking place in your facility.

Hygienic zoning is more likely to have application in the production of pet food than in facilities producing livestock food. For example, a facility that makes pet food might decide it needs to implement a hygienic zoning program to prevent cross-contamination with *Salmonella* spp. or *L. monocytogenes* since the pet food may be exposed to the environment prior to packaging.

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#### **4.9 Supply-Chain Controls**

A supply-chain control is a type of preventive control (21 CFR 507.34(c)(3)). The requirements for implementing a supply-chain program to control a hazard that must be controlled by a supplier are found in 21 CFR part 507, subpart E.

The requirements for a supply-chain control differ from those for a process control or sanitation control. If a supply-chain program is needed based on the outcome of your hazard analysis, you must be familiar with the requirements of the supply-chain program. The sections in 21 CFR part 507, subpart E are as follows:

- Requirement to establish and implement a supply-chain program (21 CFR 507.105)
- General requirements applicable to a supply-chain program (21 CFR 507.110)
- Responsibilities of the receiving facility (21 CFR 507.115)
- Using approved suppliers (21 CFR 507.120)
- Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) (21 CFR 507.125)
- Conducting supplier verification activities for raw materials and other ingredients (21 CFR 507.130)
- Onsite audit (21 CFR 507.135)
- Records documenting the supply-chain program (21 CFR 507.175)

We intend to address the requirements of the supply-chain program in future guidance.

#### **4.10 Recall Plan**

For animal food with a hazard requiring a preventive control, you must establish a written recall plan for the animal food. The written 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:

- directly notify the direct consignees of the animal food being recalled, including how to return or dispose of the affected animal food (21 CFR 507.38(b)(1))
- notify the public about any hazard presented by the animal food when appropriate to protect human and animal health (21 CFR 507.38(b)(2))
- conduct effectiveness checks to verify that the recall is carried out (21 CFR 507.38(b)(3))
- appropriately dispose of recalled animal food – e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the animal food (21 CFR 507.38(b)(4))

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We recommend that you consult our general guidance on policy, procedures, and industry responsibilities regarding recalls in 21 CFR part 7, subpart C (sections 7.40 through 7.59) and FDA’s Guidance for Industry: Product Recalls, Including Removals and Corrections (Ref. 30).

Careful planning when developing a recall plan can increase recall efficiency. You must assign responsibility for performing all procedures in your recall plan (21 CFR 507.38(a)(2)). You may consider assigning responsibilities to a position rather than specifying an individual by name. Assigning responsibilities to a position would not require you to update the recall section of your food safety plan if you have a change in personnel. For facilities that have multiple shifts, this may allow you to initiate a recall faster since you would not have to wait for an individual who may work on a different shift. However, we also recommended you ensure each person in that position, to which the responsibility is assigned, understands the steps to be taken during a recall.

A recall can be disruptive to your operation and business, but there are steps you can take in advance to minimize this disruptive effect:

- Adequately code animal food to make possible positive lot identification and to facilitate effective recall of all violative lots.
- Maintain such animal food distribution records as are necessary to facilitate location of products that are being recalled. You may wish to maintain such records for a period of time that exceeds the shelf life and expected use of the product as a matter of business practice.

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### **CHAPTER 5 – OVERVIEW OF PREVENTIVE CONTROL MANAGEMENT COMPONENTS**

#### **5.1 Purpose of this Chapter**

The guidance provided in this chapter is intended to help you implement the preventive control management components (PC management components) that are part of your food safety plan. See 21 CFR 507.39. Note that if you determine through your hazard analysis that there are no hazards requiring preventive controls, you must still document that determination in your written hazard analysis (21 CFR 507.33(a)(2)). However, you would not need to establish preventive controls and associated PC management components.

#### **5.2 Overview of Preventive Control Management Components**

The PC management components include monitoring, corrective actions and corrections, verification activities (including validation and verification of implementation and effectiveness), and their associated records. You must apply appropriate PC management components to ensure the effectiveness of your preventive control(s) identified in your food safety plan, taking into account the nature of the preventive control and its role in your facility's animal food safety system. See 21 CFR 507.39. This chapter will focus on PC management components associated with process controls, sanitation controls, and other preventive controls. We intend to address in future guidance the supply-chain program and PC management components that relate to the supply-chain program.

#### **5.3 Who is Responsible for Conducting Preventive Control Management Component Activities?**

In this Chapter we discuss two types of individuals who are responsible for conducting PC management components, a "preventive controls qualified individual" (PCQI) and a "qualified individual" (QI) (see Box 5-1). As discussed in Chapter 1, your PCQI is a qualified individual who successfully completed 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 PCQI must prepare (or oversee the preparation of) your food safety plan. Specifically for PC management components, PCQIs must conduct or oversee validation of preventive controls and some verification of implementation and effectiveness activities (see 21 CFR 507.53(a)). The PCQI may designate another individual to conduct some of these activities provided the individual is a QI and the PCQI maintains oversight.

#### **Box 5-1. Definition of Qualified Individual**

##### **Qualified Individual (QI)**

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. (21 CFR 507.3)

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In many cases, a QI may be assigned the responsibility for conducting the PC management component activities. As discussed in detail below, the individual(s) who conducts and generates records for monitoring, corrective actions and corrections, some verification activities, and some verification of implementation and effectiveness activities must be qualified to perform these assigned duties. See 21 CFR 507.4(b)(1). For a discussion of training required for a QI, see FDA's Guidance for Industry #235, Current Good Manufacturing Practice Requirements for Food for Animals (Ref. 1).

### **5.4 Recordkeeping Requirements for Preventive Control Management Components**

The specific records required for each PC management component are found in their respective sections of the PCAF regulation:

- 21 CFR 507.40 – Monitoring
- 21 CFR 507.42 – Corrective actions and corrections
- 21 CFR 507.45 – Verification (including validation and verification of implementation and effectiveness)

These records are subject to the recordkeeping requirements in 21 CFR part 507, subpart F – Requirements Applying to Records That Must Be Established and Maintained. The records must meet the various requirements in 21 CFR 507.202. For example, the records must contain the actual values and observations obtained during monitoring and as appropriate during verification; be created concurrently with the activity documented including the date and if necessary the time; and, be signed or initialed by the individual performing the activity (see 21 CFR 507.202(a) and (b)).

In general, records must be retained for at least two years (see 21 CFR 507.208(a)(1)). Some records are required to be retained longer, such as those related to the general adequacy of the equipment or processes being used at the facility (see 21 CFR 507.208(b)). Results of scientific studies and evaluations (i.e., used for validation) must be retained for at least two years after their use is discontinued (e.g., discontinued because you have updated the records documenting validation). See 21 CFR 507.208(b). The recordkeeping requirements are discussed further in each PC management component section of this chapter.

### **5.5 Preventive Control Management Components Examples**

We use two animal food scenarios throughout this chapter to help illustrate the requirements we describe in this chapter. The scenarios are simplified for purposes of this guidance, and focus on a single hazard and preventive control for each facility. We use different employee position titles in the examples, but all individuals are QIs. See Boxes 5-3a and b through 5-12a and b for the two example scenarios.

Boxes 5-2a and 5-2b provide an introduction to the two scenarios.

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### Box 5-2a. PC Management Components Example – Introduction

**Salmonella in dog biscuit treats:** At your facility, you bake dog biscuits containing chicken by-products. Based on your hazard analysis, *Salmonella* is a known or reasonably foreseeable biological hazard requiring a preventive control. The preventive control you identify is thermal processing (time and temperature preventive control) implemented by baking the biscuits in an oven to significantly minimize *Salmonella*. You set the minimum parameter value for temperature at 350°F (177°C) and the minimum parameter value for baking time at 15 minutes. In order to ensure the safety of the dog biscuits, you bake them at a temperature of 355°F (179°C). The preventive control is validated by your PCQI before you begin initial production (see Box 5-5a). These procedures (i.e., your preventive control) are written in your food safety plan. Your facility runs 3 shifts daily, 8 hours each, and every seventh day shuts down during the last shift for cleaning. Immediately after exiting the baking chamber, the biscuits are gently cooled down to ambient temperature on an enclosed cooling conveyor that delivers the biscuits to the bagging/packaging machine where they are packaged 20 biscuits per sealed poly bag.

### Box 5-2b. PC Management Components Example – Introduction

**Monensin in horse food:** At your feed mill, you manufacture food for cattle containing the animal drug monensin. You also manufacture horse food using the same equipment. Based on your hazard analysis, you identify monensin in horse food as a known or reasonably foreseeable chemical hazard and determine that this hazard requires a preventive control. You identify and implement as your preventive control daily sequencing and flushing procedures. Your sequencing procedure specifies that horse food must be manufactured prior to animal food containing monensin (e.g., food for beef cattle). Your flushing procedure specifies the amount and type of flush material to use and that flushing must be performed at the end of each day. The preventive control is validated by your PCQI before you begin initial production of horse food (see Box 5-5b). These procedures (i.e., your preventive control) are written in your food safety plan.

## 5.6 Monitoring

“Monitor” means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended (21 CFR 507.3). You must establish and implement written procedures for monitoring preventive controls, including the frequency with which they are to be performed (as appropriate to the nature of the preventive control and its role in your animal food safety system). See 21 CFR 507.40.

Your monitoring procedures should answer five questions:

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1. What will be monitored?
2. How will monitoring be done?
3. How often will monitoring be done (frequency)?
4. Who will do the monitoring?
5. What records do I need to document monitoring?

### **5.6.1 What Will Be Monitored?**

What you monitor should be directly related to control of the hazard. For example, for a process control you monitor parameters to ensure the maximum or minimum parameter values, or a combination of parameter values used to control the hazard, are met.

For preventive controls other than process controls, what you monitor depends on the type of preventive control. For example, for sanitation controls, you may monitor that the sanitizer is prepared and applied according to your written procedures.

### **5.6.2 How Will Monitoring Be Done?**

The type of monitoring method you choose will depend on the preventive control you are implementing. You may monitor by using a variety of instruments, laboratory analyses, or visual checks.

Instrumentation may be appropriate for a preventive control that has a parameter that can be measured during processing. For example, you would use instruments to monitor parameters such as pH,  $a_w$ , temperature, or pressure.

Laboratory analysis may be conducted using an onsite rapid testing method or conducted off-site by an outside laboratory. For example, if you are controlling the level of aflatoxin in your raw corn, you may use a rapid test to monitor for the presence of aflatoxin.

Visual checks also may be an appropriate monitoring activity, such as observing package integrity to ensure a finished pet food will not be exposed to contaminants from the environment (e.g., looking for broken bags or containers).

### **5.6.3 How Often Will Monitoring Be Done (Frequency)?**

You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed (21 CFR 507.40(b)). The frequency of monitoring depends upon the hazard you identify, your preventive control, and the animal food. You may determine that some preventive controls require continuous monitoring while others can be adequately monitored on a less frequent basis.

Continuous monitoring is typically performed by an instrument that produces a continuous record, for example a temperature-chart recorder on an oven. Continuous monitoring is desirable and in some cases you may decide it is necessary. Even with continuous monitoring, you should

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check the paper or electronic record of the continuous monitoring instrument (device) with adequate frequency to provide assurance that the preventive control is being consistently performed, for example, by determining if there are deviations from the control parameter values.

In some situations, you may decide that continuous monitoring is not necessary. Non-continuous monitoring might include temperature checks at designated points in the production process or samples taken for pH analysis at designated time points during the day. When determining the frequency for non-continuous monitoring, you should consider the variation during normal processing, how close your operating limits are to your parameter values (if appropriate), and how much animal food could be impacted if a deviation occurs. See Chapter 4, section 4.4.1, for more information about operating limits.

You should monitor often enough: (1) to determine the normal variability in what you are measuring or observing, and (2) to detect a deviation. Generally, the greater the time span between measurements, or between checks that procedures are being followed, the more animal food you put at risk. If a measurement or observation shows that a deviation occurred, you should assume that the preventive control was not effective or not implemented correctly following the most recent acceptable measurement or observation.

#### **5.6.4 Who Will Do the Monitoring?**

The person conducting the monitoring must be a QI for their assigned duties. See 21 CFR 507.4(b)(1).

#### **5.6.5 What Records Do I Need to Document Monitoring?**

You must document your monitoring of preventive controls in records that are subject to verification and records review by a PCQI (see 21 CFR 507.40(c)(1) and 507.49(a)(4)(i)). Records include the documents that are generated during continuous or periodic monitoring.

Records for monitoring refrigeration temperature may be affirmative or exception records. Affirmative monitoring records demonstrate that refrigeration temperature (your preventive control) is under control. See 21 CFR 507.40(c)(2)(i). For example, an affirmative record is the record on which your QI records your refrigerator temperature demonstrating the temperature is controlled or the chart recorder record from the continuous monitoring system.

A continuous monitoring system of refrigeration temperature may generate an exception record if there is a loss of temperature control. Exception records may be adequate in circumstances other than monitoring of refrigeration temperature. See 21 CFR 507.40(c)(2)(ii). When using exception records, a record is generated only when a deviation occurs. For example, if your freezer temperature rises above your parameter value, your computer system generates an exception record demonstrating the rise of temperature and time of deviation. If you use an exception record, you must have evidence that your system is working as intended (see 21 CFR 507.49), such as a record that the system has been challenged by increasing the temperature to a point at which an exception record is generated.

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Boxes 5-3a and 5-3b provide examples of monitoring.

**Box 5-3a. PC Management Component Example – Monitoring**

**Salmonella in dog biscuit treats:** According to your time and temperature preventive control, you bake your biscuits in a conveyor oven set at a speed to give a 15-minute baking time at 355°F (179°C) to ensure you stay above your minimum parameter value of 350°F (177°C). Your conveyor oven is equipped with a thermocouple probe, a temperature chart recorder, and alarm system that continuously measures oven temperature.

Per your written preventive control procedures, the designated operator does a visual check of the chart recorder every hour to ensure the oven temperature remains at 355°F (179°C) (your 1<sup>st</sup> monitoring procedure) and documents this in the monitoring record. In addition, the operator uses a stopwatch to check conveyor speed every 2 hours to ensure a 15-minute baking time (your 2<sup>nd</sup> monitoring procedure) and records the results in the monitoring record.

**Box 5-3b. PC Management Component Example – Monitoring**

**Monensin in horse food:** To monitor your sequencing and flushing preventive control, your written procedures state that the designated operator(s) must record the order of each batch of animal food produced that day to document horse food is produced prior to any animal food containing monensin, and to document the flushing of equipment at the end of the day. To accomplish this, the designated operator completes a real-time sequencing production record (your 1<sup>st</sup> monitoring record) for each batch of animal food produced and a flushing record (your 2<sup>nd</sup> monitoring record) at the end of the day. Per your written procedures, your sequencing production record contains: the date, the type of animal food produced, the order in which the animal food is to be produced, the time the batch was produced, the name of any drugs used in the batch, the quantity produced, and the batch lot number. Per your written procedures, your flushing record contains: the date, the time the flushing occurred, and the type and amount of material used for flushing.

**5.7 Corrective Actions and Corrections**

When your preventive control is not properly implemented, you must conduct a corrective action or correction. See 21 CFR 507.42. The purpose of corrective actions is to prevent adulterated animal food from entering commerce. When minor, isolated problems occur that do not directly impact animal food safety, corrections may be appropriate instead of corrective actions.

**5.7.1 Corrective Actions**

As appropriate to the nature of the hazard and the nature of the preventive control, you must establish and implement written corrective action procedures you must take if preventive controls are not properly implemented (21 CFR 507.42(a)(1)). As appropriate, your written

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corrective action procedures also must include procedures to address the presence of a pathogen or appropriate indicator organism in an animal food detected as a result of your product testing (see 21 CFR 507.42(a)(1)(i)), and the presence of an environmental pathogen or appropriate indicator organism detected through your environmental monitoring (21 CFR 507.42(a)(1)(ii)).

Specifically, the corrective action procedures must describe the steps to be taken to ensure that:

- appropriate action is taken to identify and correct the problem that has occurred with the implementation of a preventive control (21 CFR 507.42(a)(2)(i))
- appropriate action is taken when necessary to reduce the likelihood that the problem will recur (21 CFR 507.42(a)(2)(ii))
- all affected animal food is evaluated for safety (21 CFR 507.42(a)(2)(iii))
- all affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated (21 CFR 507.42(a)(2)(iv))

A predetermined corrective action procedure has advantages. For example, the written procedure provides detailed instructions for an employee to follow in the event of a deviation in applying a preventive control, and is prepared at a time when an emergency situation is not calling for an immediate decision.

You may not be able to anticipate all the problems that could happen and include them in your written corrective action procedures; however, you still must take corrective actions when an unanticipated problem occurs. You must take appropriate corrective actions if:

- you do not properly implement a preventive control and you have not established a written corrective action procedure (see 21 CFR 507.42(b)(1)(i));
- your preventive control (or combination of controls) or your food safety plan as a whole is ineffective (see 21 CFR 507.42(b)(1)(ii)); or
- a review of your records (as required in 21 CFR 507.49(a)(4)) finds that your records are not complete, the activities you conducted did not follow your food safety plan, or you did not make appropriate decisions about corrective actions (see 21 CFR 507.42(b)(1)(iii)).

The corrective actions for the problems in the bulleted list immediately above include standard corrective action procedures (i.e., identify and correct the problem, take steps to reduce the likelihood the problem will recur, evaluate all affected animal food for safety, and prevent adulterated animal food from entering commerce). See 21 CFR 507.42(b)(2)(i)-(iv). In addition, when appropriate, you must reanalyze your food safety plan (or the applicable portion of your food safety plan) to determine whether you need to modify your plan. See 21 CFR 507.42(b)(2)(v).

Finally, all corrective actions taken must be documented. See 21 CFR 507.42(d).

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### **5.7.2 Corrections**

Corrections may be appropriate instead of corrective actions when minor, isolated problems occur that do not directly impact animal food safety. A “correction” is 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). See 21 CFR 507.3. The term “correction” focuses on the first step in a corrective action procedure (i.e., identify and correct the problem).

For example, the following scenario illustrates when a correction may be appropriate instead of a corrective action. At production start-up, you observe pet food residue on “clean” equipment. Before using the equipment, you correct the pet food residue problem by re-cleaning and sanitizing the equipment. Because you correct the pet food residue problem before production, no pet food is affected and no corrective actions are needed. You are not required to document this particular correction (see 21 CFR 507.42(d)).

If the correction was not made prior to production start-up, then you would need to follow your corrective action procedures because the sanitation preventive control was not properly implemented (see 21 CFR 507.42(a)(1)). In addition, if the problem is not isolated, such as you repeatedly find pet food residue on “clean” equipment, you would need to take corrective action to reduce the likelihood the problem will recur (see 21 CFR 507.42(b)(2)).

### **5.7.3 Corrective Action and Correction Records**

You must document all corrective actions taken (and, when appropriate, corrections) in records that are subject to verification and records review. See 21 CFR 507.42(d). One way to comply with this requirement is to document the corrective action steps you have taken:

1. Document the actions taken to identify and correct the problem with implementation of the preventive control. For example, explain how you identified what went wrong with a process control and how you restored the process control.
2. Document what you did to reduce the likelihood that the problem will recur. Evaluation of historical corrective action records can help you identify recurring problems. When a deviation from a preventive control procedure recurs frequently and you find that the preventive control is ineffective, you must reanalyze the food safety plan (see 21 CFR 507.50(b)(4)).
3. Document how you evaluated the safety of all affected animal food. Depending on the nature of the deviation, you may need someone with specific technical expertise to conduct the evaluation.

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4. Document what you did with any affected animal food, including identifying the specific animal food involved (e.g., lot numbers or batches, if applicable), the amount of animal food involved, and the disposition of the affected animal food (e.g., destroyed, reprocessed, or diverted to another use).

You are only required to document corrections in records when appropriate. See 21 CFR 507.42(d). However, we recommend documenting some corrections because they provide a record of both the problem and the steps you took to correct the problem. If the problem recurs on a frequent basis, such documentation also can be helpful in determining if a corrective action is needed (e.g., repairing or replacing equipment).

Boxes 5-4a and 5-4b provide examples of corrective actions.

#### **Box 5-4a. PC Management Component Example – Corrective Actions**

**Salmonella in dog biscuit treats:** If your oven temperature drops below 352°F (178°C) (your operating limit), an alarm sounds. If the alarm sounds, the designated operator checks the oven to determine the problem, and does a correction if the problem is minor. If the temperature drops below 350°F (177°C) (i.e., deviates from your established minimum parameter value), the conveyor stops and the designated operator immediately initiates a corrective action per your written corrective action procedures.

During production, an oven alarm sounds indicating that the oven temperature fell below 352°F (178°C). The designated operator conducts an initial inspection of the oven to see whether a minor adjustment will correct the temperature. While he is examining the oven, the temperature drops below 350°F (177°C) (the established minimum parameter value for temperature) and the conveyor stops running. Per your written corrective action procedures, the designated operator promptly informs the shift manager, who oversees corrective actions. The shift manager then contacts the maintenance department. The maintenance individual determines the oven air recirculation fan was not operating properly and installs a new fan. The shift manager documents this repair in the corrective action records, along with her signature and date.

The shift manager also documents the lot number for the batch of biscuits that was in the oven when the oven temperature was below 350°F (177°C). All biscuits in this batch are separated from other ingredients and products and set aside for destruction. To destroy the batch, an employee puts the batch of biscuits in trash bags, adds a denaturing agent, and places the batch in the dumpster. The shift manager observes and documents the destruction along with the lot number of the batch in the corrective action records.

Once the replacement parts are installed, the designated operator confirms that the oven temperature is at 355°F (179°C) prior to resuming production. To reduce the likelihood of a future preventive control failure, the maintenance department schedules more frequent checks to ensure that all parts of the oven are functioning properly.

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**Box 5-4b. PC Management Component Example – Corrective Actions**

**Monensin in horse food:** Per your verification of monitoring procedures (see Box 5-5b), the plant manager conducts a review of sequencing and flushing records at the end of each day. One day he finds that a batch of horse food was manufactured directly after a batch of beef cattle food containing monensin. The plant manager is the individual assigned responsibility for identifying the cause of the improper implementation of the sequencing and flushing preventive control. The plant manager determines that failure to follow the established sequencing procedures is due to human error.

The plant manager records the lot code of the affected horse food and labels the container to identify that the batch must be kept from entering commerce until the affected horse food can be evaluated for safety. According to your corrective action procedures, when your sequencing plan is not properly executed you may either rework the batch of affected food for beef cattle, or destroy the batch to ensure the food is not fed to susceptible animals (i.e., horses).

When you determine that the affected horse food is safe to be reworked for food for beef cattle, you reformulate the batch to be nutritionally adequate for beef cattle. You generate a rework record to document your corrective action that the affected horse food is being reworked and reformulated for beef cattle, and that the reworked horse food is safe for beef cattle.

To reduce the likelihood of a recurrence of the human error problem, all designated operators are immediately retrained on the sequencing and flushing preventive control procedures and their importance. This retraining is part of your corrective action and is documented in a record in your facility files.

## **5.8 Verification Activities**

### **5.8.1 Verification**

“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 (21 CFR 507.3). Verification answers the question: “Can I affirm that the preventive controls in my food safety plan are effective and being properly implemented to control the hazard(s)?”

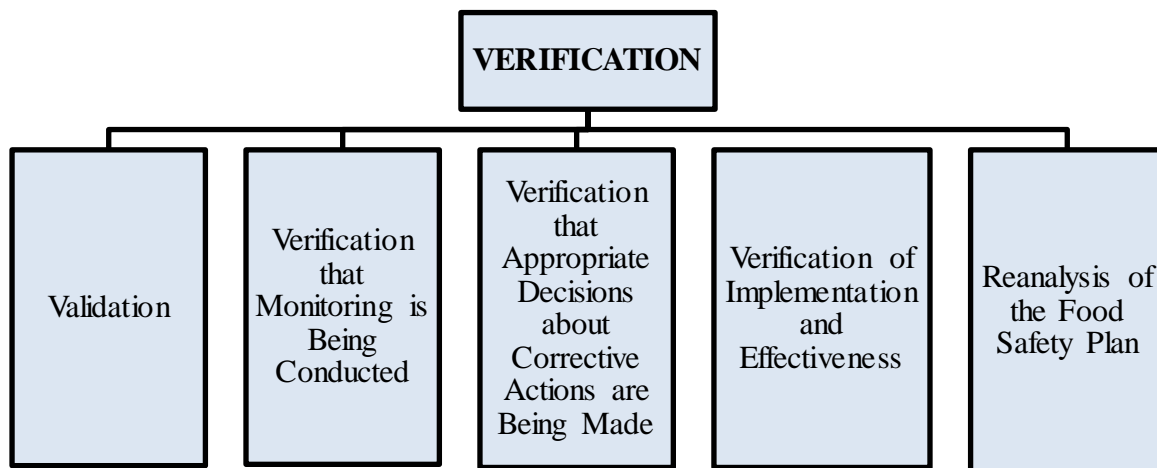
To implement your preventive control, you are required to conduct several verification activities as appropriate to the nature of the preventive control and its role in your facility’s food safety system. Your verification activities must be documented in records. See 21 CFR 507.45(b). A complete list of the verification activities is in 21 CFR 507.45, and summarized below and in Figure 5.1:

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- validation in accordance with 21 CFR 507.47 – Validation
- verification that monitoring is being conducted in accordance with 21 CFR 507.40 – Monitoring
- verification that appropriate decisions about corrective actions are being made in accordance with 21 CFR 507.42 – Corrective Actions and Corrections
- verification of implementation and effectiveness of your preventive controls in accordance with 21 CFR 507.49 – Verification of Implementation and Effectiveness
- reanalysis of your food safety plan in accordance with 21 CFR 507.50 – Reanalysis

**Figure 5-1. Verification Activities**



### 5.8.2 Validation

“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 (21 CFR 507.3). You must validate that the preventive controls you identify and implement are adequate to control the hazard as appropriate to the nature of the preventive control and the role of the preventive control in your facility’s food safety system. See 21 CFR 507.47(a). In general, validation answers the question: “Can I provide scientific, technical, or study data evidence that my preventive control(s) can adequately control the hazard(s)?”

Validation is a verification activity that has its own requirements in 21 CFR 507.47. Validation must be performed or overseen by a PCQI (21 CFR 507.47(b)(1)).

Your PCQI must use or oversee the use of scientific and technical evidence to determine that the preventive controls you are implementing are adequate to control the biological, chemical, or physical hazards. See 21 CFR 507.47(b)(2). This evidence may come from various sources, such as peer-reviewed scientific articles, university extension whitepapers, government

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documents, predictive mathematical models and other risk-based models, and technical information from equipment manufacturers and trade associations. When using these resources as evidence to validate your preventive controls, you should ensure that the evidence is applicable to your animal food and facility (e.g., processing equipment, manufacturing procedures, or storage conditions).

Sometimes, evidence may not exist; existing evidence is not applicable to your animal food and facility; or, the evidence is not sufficient to validate your preventive control. In these circumstances, you must conduct studies to determine that your preventive control, when properly implemented, is adequate to control the hazards. See 21 CFR 507.47(b)(2). We recommend that you consult with a food safety expert with knowledge of developing and conducting studies. The study must be conducted or overseen by a PCQI (21 CFR 507.47(b)(1)).

Validation must be documented in your records. See 21 CFR 507.45(b). You must retain records that document validation of your food safety plan for at least 2 years after their use is discontinued. See 21 CFR 507.208(b).

Validation must be completed within specific timeframes:

- prior to implementation of the food safety plan  
(see 21 CFR 507.47(b)(1)(i)(A))
- when necessary to demonstrate the preventive control can be implemented as designed:
  - within 90 calendar days after production of the applicable animal food first begins (21 CFR 507.47(b)(1)(i)(B)(1)), or
  - within a reasonable timeframe, provided that the PCQI 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 (21 CFR 507.47(b)(1)(i)(B)(2))
- whenever a change to a preventive control or combination of preventive controls could impact whether the preventive control or combination of preventive controls, when properly implemented, will effectively control the hazards  
(21 CFR 507.47(b)(1)(ii))
- whenever a reanalysis of the food safety plan reveals the need to do so  
(21 CFR 507.47(b)(1)(iii))

Although validation is appropriate for a variety of preventive controls, validation is not required for sanitation controls, your recall plan, the supply-chain program (in 21 CFR part 507, subpart E), and other preventive controls if a PCQI prepares a written justification that validation is not applicable (see 21 CFR 507.47(c)).

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Boxes 5-5a and 5-5b provide examples of validation.

**Box 5-5a. PC Management Component Example – Validation**

**Salmonella in dog biscuit treats:** Before you begin initial production of your dog biscuit treats, your PCQI searches peer-reviewed journals and extension white papers to find scientific literature on the time and temperature needed to significantly minimize *Salmonella* in dog biscuits. After evaluating the types of biscuits (including size, ingredients, and shape), processing equipment, and the manufacturing processes found in the literature review, your PCQI determines the time and temperature found in the literature (a minimum of 15 minutes at 350°F (177°C) or higher) are effective as a preventive control for *Salmonella* in your biscuits baked at your facility. In order to ensure the safety of the dog biscuits, you bake your dog biscuits at 355°F (179°C). You maintain the scientific literature (i.e., evidence) your PCQI uses to validate the preventive control, and her determination that the preventive control is adequate to control the *Salmonella* hazard, as part of your facility's records.

**Box 5-5b. PC Management Component Example – Validation**

**Monensin in horse food:** Your PCQI obtains scientific literature and extension white papers to document the historical use by the animal food industry of sequencing and flushing procedures to prevent the occurrence of unsafe monensin levels in food for horses. Your PCQI evaluates the information and determines that the sequencing and flushing procedures described in the published literature and commonly practiced by the animal food industry can be appropriately implemented at your facility and will adequately control the hazard. You maintain as part of your facility's records the scientific literature (i.e., evidence) your PCQI uses to validate the preventive control and his determination that the preventive control is adequate.

### 5.8.3 Verification of Monitoring

You are required to verify that monitoring is being conducted in accordance with 21 CFR 507.40 (see 21 CFR 507.45(a)(2)). Verification relies, in part, on review of monitoring records to ensure that the preventive controls you have established are being implemented according to your food safety plan. Verification that monitoring is being conducted as required must be done in a way that is appropriate to the nature of the preventive control and its role in your facility's food safety system (see 21 CFR 507.45(a)(2)). You could determine, based on your preventive controls, that verification of monitoring can be accomplished by reviewing monitoring records, e.g., a review by a manager at the end of the operating day, or just the review by the PCQI required under 21 CFR 507.49(a)(4)(i). In addition, you may choose to actually observe the monitoring, e.g., a manager can periodically observe the equipment operator as the operator conducts the monitoring. Verification of monitoring must be documented in your records (see 21 CFR 507.45(b)).

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Boxes 5-6a and 5-6b provide examples of verification of monitoring.

### Box 5-6a. PC Management Component Example – Verification of Monitoring

**Salmonella in dog biscuit treats:** Once during each shift, the shift manager checks the monitoring record for the oven temperature (the chart recorder printout and the record of the operator's check of the printout) and conveyor belt speed (the record of the operator's stopwatch timing results) to ensure the designated operator is monitoring at your specified frequency. At the end of each shift, the shift manager reviews the monitoring record and verifies that monitoring is being conducted according to your written procedures. The shift manager documents her verification of monitoring, including verification that there were no deviations from set parameter values, by initialing and dating a logbook kept with the oven monitoring records.

### Box 5-6b. PC Management Component Example – Verification of Monitoring

**Monensin in horse food:** At the end of each day, the plant manager confirms that the sequencing production record for each batch of animal food (the 1<sup>st</sup> monitoring record) and the flushing record (the 2<sup>nd</sup> monitoring record) are generated and complete. He then compares the sequencing production records and flushing records to the written sequencing and flushing procedures. The plant manager signs and dates the monitoring records to show that he verified that the monitoring took place according to the sequencing and flushing procedures.

#### 5.8.4 Verification of Decisions about Corrective Actions

You are required to verify that appropriate decisions about corrective actions are being made in accordance with 21 CFR 507.42 (see 21 CFR 507.45(a)(3)). The regulation allows flexibility for you to determine the activities you can use to verify that appropriate decisions were made about your corrective actions. You could determine, based on your preventive controls, that verification of decisions regarding corrective actions can be accomplished by reviewing corrective action records, e.g., a review by a manager after a corrective action, or just the review by the PCQI required under 21 CFR 507.49(a)(4)(i). In addition, you may choose to actually observe the corrective actions, e.g., a manager can observe the QI as he conducts the corrective action.

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Boxes 5-7a and 5-7b provide examples of verification of decisions about corrective actions.

### **Box 5-7a. PC Management Component Example – Verification of Decisions about Corrective Actions**

**Salmonella in dog biscuit treats:** The shift manager verifies that appropriate decisions were made about corrective actions, confirming that the steps taken are consistent with your written corrective action procedures in your food safety plan. (See Box 5-11a for PCQI verification of corrective actions).

### **Box 5-7b. PC Management Component Example – Verification of Decisions about Corrective Actions**

**Monensin in horse food:** The plant manager verifies that appropriate decisions were made about corrective actions, confirming that the steps taken are consistent with your written corrective action procedures in your food safety plan. (See Box 5-11b for PCQI verification of corrective actions).

## **5.8.5 Verification of Implementation and Effectiveness**

You are required to verify that you are consistently implementing your preventive controls, and that your preventive controls are effective in significantly minimizing or preventing the hazard. See 21 CFR 507.49(a).

Various activities are required, as appropriate, to verify implementation and effectiveness of your preventive controls. Those activities must include, as appropriate to your facility, animal food, and the nature of the preventive control and its role in your facility's food safety system, calibration of instruments, product testing, environmental monitoring, and review of records. There may be additional activities you include based on your facility, animal food, and the nature of the preventive control and its role in your facility's food safety system. If you determine in your food safety plan that calibration of instruments, product testing, or environmental monitoring are appropriate for your facility, animal food, the nature of your preventive control, and the role of your preventive control in your facility's food safety system, then you must conduct these verification activities. See 21 CFR 507.49(a).

### ***Calibration***

You are required to calibrate, or check for accuracy, your instruments used for process monitoring and verification. See 21 CFR 507.49(a)(1). You must establish and implement written procedures for the method and frequency of the calibration (or accuracy check). See 21 CFR 507.49 (b)(1).

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By calibrate we mean compare to a standard, with adjustment to correct error as necessary. By accuracy check we mean simply comparison to a standard. An example of an accuracy check is using test weights to compare the weights shown on a small weight scale with the known weights of the test weights. Calibration as recommended by the instrument's manufacturer is important to ensure that the preventive control dependent on the instrument can be accurately monitored and verified. You may perform checks for accuracy on a more frequent basis than what is recommended by the instrument's manufacturer. If the outcome of the accuracy check shows your instrument is not accurate, we expect you to calibrate or replace the instrument.

When calibration or an accuracy check of a process monitoring or verification instrument shows that the instrument is not accurate, you should evaluate the monitoring records since the last instrument calibration or accuracy check to determine whether the inaccuracy would have contributed to a deviation. This deviation could indicate a failure of your preventive control, meaning a corrective action is needed, including evaluation of the affected animal food. Food safety plans with infrequent calibration or accuracy checks can place more products at risk than those with more frequent checks if a problem with instrument accuracy occurs.

Boxes 5-8a and 5-8b provide examples of calibration, a component of verification of implementation and effectiveness.

### **Box 5-8a. PC Management Component Example – Verification of Implementation and Effectiveness, Calibration**

**Salmonella in dog biscuit treats:** Based on the recommendation of your PCQI, you use calibration of the thermocouple and conveyor speed as activities for verification of implementation and effectiveness of the time and temperature preventive control. The oven thermocouple is calibrated every six months based on the recommended maintenance schedule provided by the oven manufacturer. Thermocouple accuracy checks are conducted daily by comparing the readings to a separate temperature-indicating device. The separate temperature-indicating device is calibrated yearly. The conveyor speed also is calibrated every six months to coincide with the thermocouple calibration to ensure the retention time of the biscuit treats in the oven is accurate. You document in records all accuracy checks and calibrations for review by your PCQI. You have included written procedures for the method and frequency of calibration and accuracy checks in your written food safety plan.

### **Box 5-8b. PC Management Component Example – Verification of Implementation and Effectiveness, Calibration**

**Monensin in horse food:** Based on the recommendation of your PCQI, you use calibration of the weighing system to ensure an accurate amount of flushing material is added to the system as the activity for the verification of implementation and effectiveness of flushing as a preventive control in your facility. Your PCQI determines that an annual calibration is a sufficient frequency. You have included a written procedure for the method and frequency of calibration in your written food safety plan.

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***Product testing***

In your facility, you may use product testing as a verification of implementation and effectiveness of your preventive controls. Product testing is often considered an effective way to verify the control of a biological hazard. Also, you may use product testing to verify the control of other hazards, such as nutrient deficiencies or toxicities. Product testing is not required for all facilities that identify pathogens or other hazards requiring a preventive control.

If you use product testing to verify that your preventive control is consistently implemented and effective, you must establish and implement written procedures for the product testing. See 21 CFR 407.49(b). The following requirements in 21 CFR 507.49(b)(2) apply to the procedures for product testing. The procedures must:

- be scientifically valid
- identify the test microorganisms or other analytes
- specify the procedures for identifying samples, including their relationship to specific lots of product
- include the procedures for sampling, including the number of samples and sampling frequency
- identify the tests conducted including the analytical methods used
- identify the laboratory conducting the testing
- include the corrective action procedures required by 21 CFR 507.42(a)(1)

Boxes 5-9a and 5-9b provide examples of product testing, a component of verification of implementation and effectiveness of preventive controls.

**Box 5-9a. PC Management Component Example – Verification of Implementation and Effectiveness, Product Testing**

***Salmonella* in dog biscuit treats:** Your PCQI determines that product testing for *Salmonella* is an appropriate activity for verification of implementation and effectiveness of your time and temperature preventive control. Your written procedures specify that once a week, a sample will be randomly collected from each batch during the selected shift (which alternates each week). Each sample of biscuits collected consists of 10 sub-samples with each sub-sample weighing about 200 grams and labeled with the corresponding batch number(s). The samples are analyzed in-house using a validated method from the most recent edition of the *Bacteriological Analytical Manual*, chapter 5. If a laboratory sample is found to contain *Salmonella*, your shift manager follows corrective action procedures found in your food safety plan to address the presence of a pathogen detected upon product testing.

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### Box 5-9b. PC Management Component Example – Verification of Implementation and Effectiveness, Product Testing

**Monensin in horse food:** The PCQI did not identify product testing as an activity for verification of implementation and effectiveness for your sequencing and flushing preventive control.

#### *Environmental monitoring*

Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, may be used when your hazard analysis determines that contamination of animal food with an environmental pathogen (or appropriate indicator organism) is a hazard requiring a preventive control. You determine (based on your facility, your animal food, and the nature of the preventive control and its role in your facility's food safety system) if environmental monitoring is appropriate to verify the adequacy of your preventive control. For example, you could decide that environmental monitoring is necessary to verify that your sanitation controls are implemented properly and working effectively to control *Salmonella* in the environment.

The presence of an indicator organism indicates conditions may be suitable for the presence and growth of an environmental pathogen. FDA's current thinking is that *Listeria* spp. may be an appropriate indicator organism for *L. monocytogenes*, because tests for *Listeria* spp. will detect multiple species of *Listeria*, including *L. monocytogenes*. Though data are available to support the use of Enterobacteriaceae for environmental monitoring, we are not aware of any data or information supporting the use of an indicator organism by itself for the purpose of environmental monitoring for *Salmonella* spp. (Ref. 2).

If you use environmental monitoring to verify that your preventive controls are consistently implemented and effective, you must establish and implement written procedures for the environmental monitoring. See 21 CFR 507.49(b). The following requirements in 21 CFR 507.49(b)(3) apply to the procedures for environmental monitoring. The procedures must:

- be scientifically valid
- identify the test microorganisms
- 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)
- 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)
- identify the tests conducted, including the analytical methods used
- identify the laboratory conducting the testing
- include the corrective action procedures required by 21 CFR 507.42(a)(1)(ii)

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Environmental monitoring involves collecting samples for environmental pathogen analysis from areas in your facility where animal food is manufactured, processed, packed or held. You determine where and how often environmental samples are taken in your facility and include this in your written procedures. An effective environmental monitoring program diligently tries to find the pathogen. To be effective, the sampling is conducted with sufficient frequency and samples are taken in places in the facility where the pathogen is likely found, such as areas that may have been contaminated with raw animal food ingredients, or areas that are frequently wet. For additional information on environmental monitoring see (Ref. 2).

Boxes 5-10a and 5-10b provide examples of decisions about environmental monitoring, a component of verification of implementation and effectiveness of preventive controls.

### **Box 5-10a. PC Management Component Example – Verification of Implementation and Effectiveness, Environmental Monitoring**

**Salmonella in dog biscuit treats:** The PCQI did not identify environmental monitoring as a verification of implementation and effectiveness activity for your time and temperature preventive control since the dog biscuits are not exposed to the environment prior to packaging.

### **Box 5-10b. PC Management Component Example – Verification of Implementation and Effectiveness, Environmental Monitoring**

**Monensin in horse food:** The PCQI did not identify environmental monitoring as a verification of implementation and effectiveness activity for your sequencing and flushing preventive control.

### ***Record review***

Verification of implementation and effectiveness includes the review of certain records within specified timeframes. This review must be conducted by, or under the oversight of, a PCQI (see 21 CFR 507.49(a)(4)). Monitoring and corrective action records must be reviewed within seven working days after the records are created or within a reasonable timeframe, provided the PCQI prepares (or oversees the preparation of) a written justification for a timeframe that exceeds seven working days. See 21 CFR 507.49(a)(4)(i). Records of calibration, product testing, environmental monitoring, supplier and supply-chain verification activities, and other verification activities must be reviewed within a reasonable timeframe after they are created. See 21 CFR 507.49(a)(4)(ii).

Record review by, or under the oversight of, a PCQI must ensure the following:

- records are complete
- activities reflected in the records occurred in accordance with the food safety plan
- preventive controls are effective
- appropriate decisions were made about corrective actions

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See 21 CFR 507.49(a)(4).

Record review conducted in accordance with 21 CFR 507.49 must be documented in records (see 21 CFR 507.45(b)).

Boxes 5-11a and 5-11b provide examples of record review, a component of verification of implementation and effectiveness.

### **Box 5-11a. PC Management Component Example – Verification of Implementation and Effectiveness, Record Review**

**Salmonella in dog biscuit treats:** You determine that the monitoring records (your temperature chart recorder printout and record of the operator's check of the printout and conveyor speed record) will be verified at the end of each shift by the shift manager (see Box 5-6a). Your plant manager will conduct a review of the monitoring records every Monday. Since the shift manager is reviewing monitoring records at the end of each shift, and the plant manager is reviewing weekly, your PCQI writes a justification that she only needs to review the monitoring records once a month. During her monthly review, your PCQI signs that she verified the monitoring records.

Within one week after the calibration is performed (see Box 5-8a), your PCQI reviews the calibration records of the oven thermocouple, temperature indicating device, and conveyor speed to complete record review for verification of implementation and effectiveness of the time and temperature preventive control. The PCQI reviews the daily thermocouple accuracy check during her monthly review of the monitoring records. She documents her review of the calibration and accuracy check records at the time she performs these verification activities.

When a corrective action is taken, your corrective action procedures require the PCQI to review associated records within five working days. Your PCQI reviews the corrective action records generated after the failure of your time and temperature preventive control (see Boxes 5-4a). The corrective action records she reviews are:

1. the temperature chart recorder record that identified the problem
2. documentation of the lot number of the affected biscuits
3. affected biscuit destruction record
4. oven repair record
5. maintenance schedule update

Through the corrective action record review, she also ensures that the outcome of the safety evaluation, destruction of the biscuits, and increase in the oven maintenance schedule were appropriate decisions for this corrective action.

Once the corrective action records are reviewed and the PCQI determines that appropriate decisions were made about the corrective action, your PCQI signs the records and places them in the corrective action file.

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### Box 5-11b. PC Management Component Example – Verification of Implementation and Effectiveness, Record Review

**Monensin in horse food:** Your facility determines that the two monitoring records (sequencing production record and flushing record) will be verified daily by the plant manager (see Boxes 5-3b and 5-6b), and reviewed weekly by the PCQI. Your PCQI reviews and signs the two monitoring records.

Your PCQI reviews the annual calibration record of the weighing system within one week after the weighing system is calibrated (see Box 5-8b).

When a corrective action is taken, your facility's procedures require your PCQI to review associated records within seven working days. During the weekly record review, your PCQI reviews the corrective action records generated after the failure of your sequencing and flushing preventive control (see Box 5-4b). He ensures the following records are complete and consistent with your corrective action procedures for the sequencing and flushing preventive control:

1. the sequencing and flushing records that identified the problem
2. documentation of the lot number of the affected horse food
3. rework record
4. employee retraining record

Through the corrective action record review, he also ensures that the outcome of the safety evaluation, rework of the horse food for beef cattle food, and retraining of the designated operators are appropriate decisions for this corrective action.

Once the corrective action records are reviewed and the PCQI determines appropriate decisions were made about the corrective action, your PCQI signs the records and places them in the corrective action file.

#### 5.8.6 Reanalysis

You must conduct a reanalysis of your food safety plan (see 21 CFR 507.50). Reanalysis is a verification activity and must be documented (see 21 CFR 507.45(b)). Your required reanalysis must be conducted by, or overseen by, your PCQI (see 21 CFR 507.50(e)).

At least once every three years, you must conduct a reanalysis of your food safety plan as a whole. See 21 CFR 507.50(a). A reanalysis of the plan or the applicable portion of the plan is also required 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 (see 21 CFR 507.50(b)(1))

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- you become aware of new information about potential hazards associated with the animal food (see 21 CFR 507.50(b)(2))
- appropriate after an unanticipated animal food safety problem (see 21 CFR 507.50(b)(3))
- you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective (see 21 CFR 507.50(b)(4))
- FDA determines a reanalysis is necessary to respond to new hazards and developments in scientific understanding (see 21 CFR 507.50(f))

You must complete reanalysis of your food safety plan and validate any additional preventive controls: (1) before any change in activity is in effect; or, (2) when necessary to demonstrate the control measure can be implemented as designed, within 90 calendar days after production of animal food begins, or within a reasonable timeframe that exceeds 90 days as outlined in a written justification from your PCQI. See 21 CFR 507.50(c).

If 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, you must revise your written food safety plan or document the basis for your conclusion that no revisions are needed. See 21 CFR 507.50(d).

The documentation of reanalysis must include the date the reanalysis was conducted and the signature or initials of the individual conducting the reanalysis. See 21 CFR 507.202(b)(2) and (3).

Boxes 5-12a and 5-12b provide examples of reanalysis.

#### **Box 5-12a. PC Management Component Example – Reanalysis**

**Salmonella in dog biscuit treats:** Your PCQI determines that a reanalysis of the food safety plan for the preventive control of *Salmonella* in your dog biscuit treats is not necessary. The oven fan was replaced and confirmed to be operating properly by the designated operator.

You decide to install a production line to make miniature size dog biscuit treats. This is a significant change in your production that creates a significant increase in the *Salmonella* hazard, which requires a reanalysis of your food safety plan. Prior to beginning production of the miniature biscuits, your PCQI validates the time and temperature preventive control required to significantly minimize *Salmonella* in the smaller size biscuit. The new preventive control, procedures for monitoring the preventive control, and corrective action procedures are added to your revised food safety plan.

#### **Box 5-12b. PC Management Component Example – Reanalysis**

**Monensin in horse food:** Your PCQI determines that a reanalysis of the food safety plan is appropriate because it has been three years since the last reanalysis. Your PCQI conducts the reanalysis and concludes that no changes are needed for the sequencing and flushing preventive control.

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**5.9 References for Chapter 5**

1. Food and Drug Administration. 2017. “Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals”. Accessed December 5, 2017.  
<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-av-gen/documents/document/ucm499200.pdf>.
2. Food and Drug Administration. 2014. “FDA Memorandum Environmental Monitoring”.

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**APPENDIX A – Glossary of Terms**

**Definitions Established in 21 CFR 507.3:**

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

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

*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 21 CFR part 1, subpart H.

*Farm* means farm as defined in 21 CFR 1.227.

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

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

*Hazard requiring a preventive control* means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or

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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.

*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

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(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 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 [part 507] 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.

*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/

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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.

*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.

*You* means, for purposes of 21 CFR part 507, the owner, operator, or agent in charge of a facility.

### **Other Terms Used in this Guidance:**

**Clean in place (CIP):** A system used to clean process piping, bins, tanks, mixing equipment, or larger pieces of equipment without disassembly, where interior product zones are fully exposed and soil can be readily washed away by the flow of the cleaning solution.

**Cleaning:** The removal of soil, animal food residue, dirt, grease or other objectionable matter.

**Corrective action:** An action to identify and correct specific problems, including failure to properly implement a preventive control, that occur during the production of animal food.

A corrective action must include certain elements, such as identification and correction of the problem, reducing the likelihood of recurrence, evaluating the animal food for safety, and preventing adulterated animal food from entering commerce. The requirements for corrective actions are found in 21 CFR 507.42(a) and (b).

**Deviation:** Failure to meet a parameter value (e.g., by being above or below the parameter value).

**Environmental sample:** A sample that is collected from a surface or area of the plant for the purpose of testing the surface or area for the presence of an environmental pathogen or appropriate indicator organism.

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**HACCP (Hazard Analysis and Critical Control Point):** A systematic approach to the identification, evaluation, and control of food safety hazards.

**Hazard analysis:** The process of identifying and evaluating known or reasonably foreseeable hazards to determine whether there are any hazards requiring a preventive control.

**Operating limits:** Criteria that may be more stringent than the minimum or maximum parameter values and are established for reasons other than animal food safety.

**Parameter value:** 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.

**PCAF regulation:** Part 507 of title 21 of the Code of Federal Regulations, established by the final rule entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals”.

**PCAF requirements:** The requirements of subparts A, C, D, E, and F of part 507 of Title 21 of the Code of Federal Regulations.

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**APPENDIX B – Table of Abbreviations and Acronyms Used in this Guidance**

ABBREVIATION OR ACRONYM	WHAT IT MEANS
AAFCO	Association of American Feed Control Officials
$a_w$	water activity
BSE	Bovine Spongiform Encephalopathy
<i>C. botulinum</i>	<i>Clostridium botulinum</i>
CCP	critical control point
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CGMP	current good manufacturing practice
CGMP requirements	current good manufacturing practice requirements in 21 CFR part 507, subparts A, B, and F
CIP	clean in place
Codex	Codex Alimentarius Commission
CWD	Chronic Wasting Disease
D-value	decimal reduction time
DNA	deoxyribonucleic acid
<i>E. coli</i>	<i>Escherichia coli</i>
EPA	U.S. Environmental Protection Agency
ERH	equilibrium relative humidity
eV	electron volt
FDA	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act

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ABBREVIATION OR ACRONYM	WHAT IT MEANS
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture
FSMA	FDA Food Safety Modernization Act
FSPCA	Food Safety Preventive Controls Alliance
GRAS	generally recognized as safe
Gy	Gray (a unit of absorbed dose of ionizing radiation, equal to 1 joule/kg of irradiated material)
HACCP	Hazard Analysis and Critical Control Point
HA worksheet	Hazard Analysis worksheet
HPP	high pressure processing
kGy	kiloGray
Kg	kilogram
LACF	low-acid canned food
<i>L. monocytogenes</i>	<i>Listeria monocytogenes</i>
MBM	meat and bone meal
MeV	million electron volts
mm	millimeter
MPa	megapascal
ng	nanogram
NRC	National Research Council
Pa	pascal
PAH	polyaromatic hydrocarbon

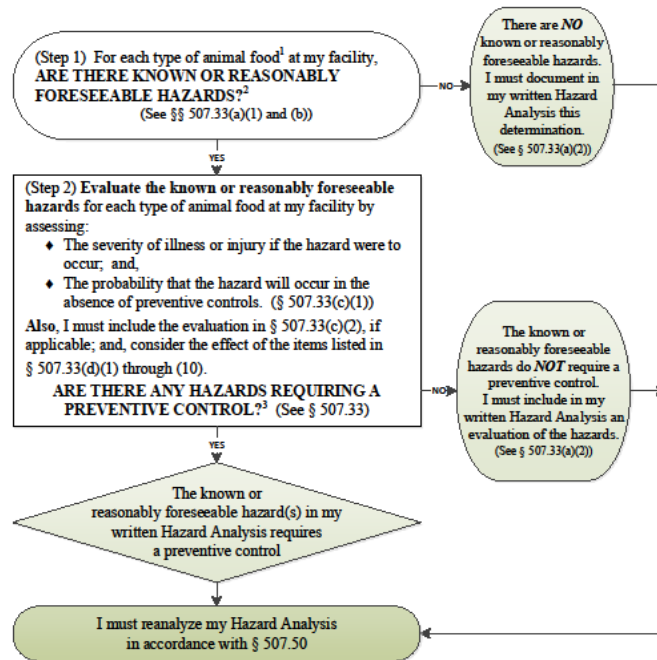
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ABBREVIATION OR ACRONYM	WHAT IT MEANS
PCAF regulation	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals regulation in 21 CFR part 507
PCB	polychlorinated biphenyl
PC management components	preventive control management components
PCQI	preventive controls qualified individual
PC requirements	Preventive control requirements in 21 CFR part 507, subparts A, C, D, E, and F
pH	refers to a numeric scale used to describe acidity and alkalinity
ppb	parts per billion
QI	qualified individual
RFR	Reportable Food Registry
ROP	reduced oxygen packaging
SOP	standard operating procedure
TDT	thermal death time
<i>T. gondii</i>	<i>Toxoplasma gondii</i>
USDA	U.S. Department of Agriculture
z-value	refers to the temperature increase required to reduce the D-value by a factor of 10

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**APPENDIX C – Flowchart – Hazard Analysis**  
**(21 CFR 507.33)**

My facility is subject to the hazard analysis and preventive controls requirements. My required **written** Food Safety Plan must be prepared by a preventive controls qualified individual and include a **written** Hazard Analysis.



1. *Animal food* means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients (21 CFR 507.3).

2. *Hazard* means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals (21 CFR 507.3).

*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 (21 CFR 507.3).

3. *Hazard requiring a preventive control* means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system (21 CFR 507.3).

To view, click on the image.

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### **APPENDIX C – Hazard Analysis (21 CFR 507.33)**

My facility is subject to the hazard analysis and preventive controls requirements. My required written Food Safety Plan must be prepared by, or under the oversight of, a preventive controls qualified individual and include a written Hazard Analysis.

**Step 1 – FOR EACH TYPE OF ANIMAL FOOD AT MY FACILITY, ARE THERE KNOWN OR REASONABLY FORESEEABLE HAZARDS?** See 21 CFR 507.33(a)(1) and (b).

**NO** – There are NO known or reasonably foreseeable hazards. I must document in my written Hazard Analysis this determination. See 21 CFR 507.33(a)(2). I must reanalyze my Hazard Analysis in accordance with 21 CFR 507.50.

**YES – Step 2** – Evaluate the known or reasonably foreseeable hazards for each type of animal food at my facility by assessing:

- The severity of illness or injury if the hazard were to occur; and,
- The probability that the hazard will occur in the absence of preventive controls.  
(21 CFR 507.33(c)(1))

Also, I must include the evaluation in 21 CFR 507.33(c)(2), if applicable; and, consider the effect of the items listed in 21 CFR 507.33(d)(1) through (10) on the safety of the finished animal food for the intended animal.

**ARE THERE ANY HAZARDS REQUIRING A PREVENTIVE CONTROL?**

See 21 CFR 507.33.

**NO** – The known or reasonably foreseeable hazards do NOT require a preventive control. I must include in my written Hazard Analysis an evaluation of the hazards. See 21 CFR 507.33(a)(2). I must reanalyze my Hazard Analysis in accordance with 21 CFR 507.50.

**YES** – The known or reasonably foreseeable hazard(s) in my written Hazard Analysis requires a preventive control. I must reanalyze my Hazard Analysis in accordance with 21 CFR 507.50. (I must also identify and implement preventive controls and appropriate preventive control management components in accordance with 21 CFR 507.34 and 507.39).

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**APPENDIX D – Example Hazard Analysis Worksheet**

The example Hazard Analysis worksheet is organized by column. Chapters 2 and 3 provide information that can be used to complete columns one through four. Chapter 4 provides information that can be used to complete columns five and six.

Note: A typical worksheet may include multiple pages. Also, you may need to attach additional information or documentation, such as when you determine that a hazard does not require a preventive control.

<b>PLANT NAME:</b> _____
<b>ADDRESS:</b> _____
<b>ANIMAL FOOD:</b> _____
<b>INTENDED SPECIES:</b> _____
<b>LIFE STAGE/PRODUCTION CLASS:</b> _____
<b>DATE (MM/DD/YY):</b> _____

(Column 1)	(Column 2)	(Column 3)	(Column 4)	(Column 5)	(Column 6)
Ingredient and Processing Step	Known or Reasonably Foreseeable Hazard	Does the Known or Reasonably Foreseeable Hazard Require a Preventive Control? “Yes” or “No”	Explanation/Justification	Preventive Control(s) Applied	Is the Preventive Control Applied at this Step?  “Yes” or “No”

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### APPENDIX D

#### How to Use the Hazard Analysis Worksheet

**Column 1 – Ingredient and Processing Step:** List: (1) the receipt of ingredients used in your process as a way of identifying hazards associated with an ingredient (you may group similar ingredients such as grains); and (2) the processing steps. A process flow diagram and detailed process description (see **Chapter 2, Box 2-2**) can help you identify the processing steps included in your hazard analysis.

**Column 2 – Known or Reasonably Foreseeable Hazard:** List the results of your identification of the known or reasonably foreseeable hazards from your hazard analysis. Include biological, chemical, or physical hazards that could be introduced or increased from ingredients, your process, or the environment. See **Chapter 2, section 2.4.1**.

**Column 3 – Does the Known or Reasonably Foreseeable Hazard Require a Preventive Control:** For each known or reasonably foreseeable hazard identified in column 2, record the conclusions of your hazard analysis – i.e., the determinations you make whether each known or reasonably foreseeable hazard requires a preventive control (“Yes” or “No”). See **Chapter 2, section 2.4.2**.

**Column 4 – Explanation/Justification:** You should justify, or explain, your “Yes” or “No” conclusion for column 3 based on your evaluation of the hazard. Record the key factors or a summary of the evaluation that led to the determination for each hazard of whether a preventive control is required. Explaining your reasons for a “No” conclusion can be just as important as explaining your reasons for a “Yes” conclusion. See **Chapter 2, section 2.5**.

**Column 5 – Preventive Control(s) Applied:** Identify the preventive control(s) you will apply to significantly minimize or prevent the hazard requiring a preventive control (indicated by “Yes” in column 3). You might list, for example, the type of preventive control (e.g., process, sanitation, or supply-chain-applied controls), or list the specific preventive control you select (e.g., irradiation, time and temperature, or water activity). See **Chapter 2, section 2.6, and Chapter 4**.

If the identified hazard does not require a preventive control (indicated by “No” in column 3), you can leave the corresponding cell blank or put in N/A for “not applicable”.

**Column 6 – Is the Preventive Control Applied at this Step:** The Hazard Analysis worksheet allows you to break your production process into multiple steps (such as receiving or processing), and you may apply your preventive control at a step in the process other than the step where you list the hazard. Specify whether the preventive control will be applied at the specific processing step (i.e., “Yes” or “No”). See **Chapter 2, section 2.7**.

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### APPENDIX E – Aid to Identifying Animal Food Hazards

#### INTRODUCTION

A hazard is a biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals. See 21 CFR 507.3. There is a universe of hazards associated with animal food. However, not all hazards are likely to be known or reasonably foreseeable hazards in your animal food (including raw materials, ingredients, and mixed ingredient products). In the Aid to Identifying Animal Food Hazards tables, CVM narrowed the list of hazards to those that have been reported in animal food at levels that are known to be violative, unsafe, of concern, or that have caused illness or injury. To compile this list, CVM used publicly-available sources, such as:

1. FDA publicly available information – FDA’s recalls & withdrawals database, Reportable Food Registry reports, FDA guidance documents, FDA sampling reports, FDA regulatory tolerances; and
2. Public data – EPA regulatory tolerances, published scientific and trade articles, and university extension service publications.

These hazards can be associated with raw materials or ingredients brought into your facility. In addition, these hazards can be introduced, concentrated, or produced during processing or post-processing at your facility.

These tables of hazards are intended to provide a starting point for an individual facility’s identification of known or reasonably foreseeable hazards in various categories of animal food. The tables do not list all possible animal foods or hazards. The Appendix E tables are numbered and titled as follows:

<b>TABLE NUMBER</b>	<b>TITLE</b>
<a href="#"><u>1</u></a>	Animal Protein Products
<a href="#"><u>2</u></a>	Forage Products
<a href="#"><u>3</u></a>	Grain Products
<a href="#"><u>4</u></a>	Plant Protein Products
<a href="#"><u>5</u></a>	Processed Grain By-Products
<a href="#"><u>6</u></a>	Roughage Products
<a href="#"><u>7</u></a>	Technical Additives and Other Substances Used for Manufacturing
<a href="#"><u>8</u></a>	Fat and Oil
<a href="#"><u>9</u></a>	Other Nutritional Products
<a href="#"><u>10</u></a>	Mixed Ingredient Products

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**APPENDIX E**

Cells with identified hazards are marked with “Ref.” and a reference number. The listed reference may be specific for one or more example products; however, the hazard identified in the reference may not be applicable to every example product in the animal food sub-category. References are listed numerically at the end of this Appendix. A dash (“-”) is inserted when we did not identify the hazard in the animal food at the time of issuance of this guidance document.

See Chapter 3 for additional information on hazards associated with animal food.

**TABLE 1. ANIMAL PROTEIN PRODUCTS**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Blood and Serum	Animal Serum; Serum Albumin; Serum Globulin; Blood Protein; Spray Dried Animal Blood; Spray Dried Animal Blood Cells	Ref. 1	■	■	■	■	■	■	■	■	■	■

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<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Non-Ruminant Hydrolyzed	Hydrolyzed Poultry By-Products Aggregate; Hydrolyzed Whole Swine	Refs. 2, 3	■	■	■	■	■	■	■	■	■	■
Ruminant Hydrolyzed	Hydrolyzed Hair; Hydrolyzed Leather Meal; Fleshing Hydrolysate	Ref. 3	Ref. 4	■	■	■	■	■	■	■	■	■
Non-Ruminant Meal	Poultry Meal; Poultry By-Product Meal	Refs. 3, 5, 6	■	■	■	■	■	■	■	■	■	■

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<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Ruminant Meal	Meat and Bone Meal (45% & 50%); Meat Meal; Meat Meal Tankage; Hydrolyzed Leather Meal; Blood Meal	Refs. 3, 6	Ref. 4	■	■	■	■	■	■	■	■	■
Meat and Meat By-Products	Muscle; Organs	Refs. 3,7, 8	Ref. 4	Refs. 9, 10, 11	Refs. 12, 13, 14	■	■	■	■	■	■	■
Poultry By-Product	Hatchery By-Product; Poultry By-Products; Egg Products	Refs. 3, 5	■	■	■	■	■	■	■	■	■	■

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SUB-CATEGORY	EXAMPLE PRODUCTS	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Game Meat	Deer; Wild Boar; Rabbit; Birds	Ref. 15	Ref. 4	Refs. 9, 11, 16	■	■	■	■	■	■	■	■
Marine Products	Fish Meal; Crab Meal; Shrimp Meal	Refs. 6, 17	■	■	■	■	■	■	■	■	■	■
Milk Products	Skim Milk, Dried; Milk, Whole, Dried, Feed Grade; Casein, Dried; Buttermilk, Dried; Whey, Low Lactose, Dried; Whey, Dried	Refs. 18, 19	■	■	■	■	■	■	■	■	■	■

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SUB-CATEGORY	EXAMPLE PRODUCTS	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Insects	Crickets	Ref. 20	■	■	■	■	■	■	■	■	■	■

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**TABLE 2. FORAGE PRODUCTS**

SUB-CATEGORY	EXAMPLE PRODUCTS	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Hay	Alfalfa; Timothy, Orchard Grass; Lespedeza	■	■	■	■	■	Ref. 21	■	Refs. 22-29	■	■	Ref. 30
Processed Forage	Alfalfa Pellets; Lespedeza Meal; Ground Soybean Hay	■	■	■	■	■	■	■	Refs. 24, 25, 26	■	■	■

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**TABLE 3. GRAIN PRODUCTS**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Whole Grain	Barley; Pearl Millet; Oats; Rice; Triticale; Wheat; Corn; Sorghum (milo)	■	■	■	■	■	■	■	Refs. 31-38	■	Ref. 39	■
Grain Flour	Barley Flour; Corn Flour; Rye Flour	■	■	■	■	■	■	■	Refs. 31-38	■	■	■
Grain Meal	Wheat Germ; Corn Meal; Corn Germ	■	■	■	■	■	■	■	Refs. 31-38	■	■	■

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**TABLE 4. PLANT PROTEIN PRODUCTS**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Dried Plant Protein	Kelp Meal; Torula Dried Yeast; Soy Protein Concentrate	■	■	■	■	■	■	■	■	■	■	■
Plant Protein Meal	Camelina Meal; Canola Meal; Coconut Meal; Cottonseed Meal; Linseed Meal; Peanut Meal; Safflower Meal; Soybean Meal	Refs. 40-43	■	■	■	Ref. 44	■	■	Refs. 45-52	■	Ref. 53	■

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**TABLE 5. PROCESSED GRAIN BY-PRODUCTS**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Processed Grain Hulls, Bran, Screenings, and Mill By-Product	Rice Hulls; Wheat Refuse Screenings; Corn Cobs; Hominy Feed; Wheat Middlings	■	■	■	■	■	■	■	Refs. 54-58	■	Refs. 39, 53	Ref. 59
Brewers Grain By-Products	Brewers Dried Grains w/Solubles (Beverage); Malt Sprouts; Malt Cleanings	■	■	■	■	■	■	■	Refs. 60, 61	■	■	■
Distillers By-Products (from Fuel Ethanol and Alcoholic Beverage Production)	Distillers Dried Grains; Corn; Distillers Dried Grain with Solubles; Distillers Dried Solubles; Distillers Wet Grains	■	■	■	Refs. 62, 63	■	■	■	Refs. 64-69	■	■	■

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**TABLE 6. ROUGHAGE PRODUCTS**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Pulp and Pomace	Citrus Pulp; Tomato Pomace; Apple Pomace; Beet Pulp	■	■	■	■	■	■	■	Refs. 70, 71	■	Refs. 39, 53	■
Hulls	Cottonseed Hulls; Almond Hulls; Sunflower Hulls	■	■	■	■	■	■	■	Refs. 72- 75	■	■	■
Other Plant Parts	Wheat straw; Corn Stover; Bagasse	■	■	■	■	■	■	■	Refs. 31, 76, 77	■	■	■

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**TABLE 7. TECHNICAL ADDITIVES AND OTHER SUBSTANCES USED FOR MANUFACTURING**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Color Additives	Caramel; Paprika Oleoresin; Canthaxanthin; Tagetes Meal; FD&C Blue No. 1; FD&C Red No. 3	■	■	■	■	■	■	■	■	■	■	■
Enzymes	Cellulases; Lipases; Proteases; Phytases	■	■	■	■	■	■	■	■	■	■	■
Natural and Artificial Flavoring Agents	Tarragon; Garlic Essential Oil; Peppermint Oil; Citral; Ethyl Vanillin	■	■	■	■	■	■	■	■	■	■	■
Preservatives	Ascorbic Acid; Calcium Sorbate; Ethoxyquin; Propionic Acid	■	■	■	■	■	■	■	■	■	■	■
Stabilizers, Thickeners, and Emulsifiers	Apple Pectin; Carrageenan; Gum Arabic; Guar Gum; Xanthan Gum	■	■	■	■	■	■	■	■	■	■	■

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**TABLE 8. FAT AND OIL**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Animal Fat	Fat, Mammalian; Fat, Poultry	■	Ref. 4	■	■	■	Refs. 78, 79	■	■	■	■	■
Vegetable Fats and Oils	Cotton Seed Oil; Canola Oil; Soybean Oil; Corn Oil	■	■	■	■	■	Refs. 78, 79	■	■	■	Ref. 39	■
Hydrogenated or Hydrolyzed Fat, or Oil	Hydrogenated Glycerides; Hydrolyzed Sucrose Polyesters; Hydrolyzed Fat, or Oil, Feed Grade	■	■	■	■	■	■	■	■	■	■	■

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**TABLE 9. OTHER NUTRITIONAL PRODUCTS**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Non-Protein Nitrogen	Urea; Feed Grade Biuret; Fermented Ammoniated Condensed Whey	■	■	■	■	■	■	■	■	■	■	■
Amino Acids and Related Products	DL-Methionine, Glycine, Taurine	■	■	■	■	■	■	■	■	■	■	■
Protein Concentrate	Barley Protein Concentrate; Corn Gluten Feed; Corn Gluten Meal (wet or dry milled); Grain Sorghum Gluten Meal	■	■	■	■	Ref. 80	■	■	Ref. 81	■	■	■

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<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Minerals	Copper Sulfate; Calcite; Ferric Chloride; Limestone; Oyster Shell Flour; Soft Rock Phosphate	■	■	■	■	■	Refs. 82, 83	Refs. 15 84, 85	■	■	■	■
Vitamins	Riboflavin; Vitamin D <sub>3</sub> ; Niacin	■	■	■	■	■	■	■	■	■	■	■
Fermentation Products	Presscake; Direct-Fed Microorganisms	■	■	■	■	■	■	■	■	■	■	■
Molasses and Molasses Solubles	Molasses sourced from Beet, Cane, Citrus, Starch	■	■	■	■	■	■	■	■	■	■	■

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<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g., metal, glass, plastic)
Fruits and Vegetables	Carrots; Peas; Apples; Tomatoes	Ref. 86	■	■	■	■	■	■	■	■	Ref. 39	■
Waste	Poultry Manure (dried, cage or dried, floor); Dried Poultry Litter; Dried Ruminant Waste; Processed Animal Waste Derivative	Refs. 15, 87	■	Refs. 15, 87	Refs. 15, 87	■	■	Refs. 15, 87	Refs. 15, 87	Refs. 15, 87	Refs. 15, 87	■

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**TABLE 10. MIXED INGREDIENT PRODUCTS**

<b>SUB-CATEGORY</b>	<b>EXAMPLE PRODUCTS</b>	<b>Biological Hazards:</b> Pathogenic Bacteria (e.g., <i>Salmonella</i> ; <i>L. monocytogenes</i> )	<b>Biological Hazards:</b> Prions (e.g., BSE)	<b>Biological Hazards:</b> Viruses or Parasites	<b>Chemical Hazards:</b> Animal Drug residue and carryover	<b>Chemical Hazards:</b> Economic Adulterants (e.g., melamine; urea)	<b>Chemical Hazards:</b> Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	<b>Chemical Hazards:</b> Heavy Metals	<b>Chemical Hazards:</b> Natural Toxins (e.g., mycotoxins)	<b>Chemical Hazards:</b> Nutrient Deficiency or Toxicity	<b>Chemical Hazards:</b> Pesticides	<b>Physical Hazards:</b> Physical (e.g. metal, glass, plastic)
Hermetically Sealed Can or Pouch	Dog Food; Cat Food	*	-	-	Ref. 12	Refs. 88, 89	-	-	-	Refs. 90-95	-	-
Mixed Diets	Kibble; Pellet; Flakes; Sticks; Crumbles; Creep Feed; Grower Finisher Diet; Milk Replacer	Refs. 1, 7, 96-100	Ref. 4	-	Refs. 101-104	Refs. 105, 106	-	-	Refs. 67, 107-119	Refs. 95, 108, 120-127	Refs. 39, 53	Ref. 128
Other Pet Food	Frozen Raw Pet Food; Frozen Feeder Rodents, Refrigerated Pet Food	Refs. 129-138	-	Refs. 10, 11, 132, 135, 137	Refs. 13, 14	-	-	-	-	Ref. 139	Refs. 39, 53	Ref. 140
Pet Treats	Chews; Jerky	Refs. 96, 141, 142	-	-	Ref. 143	-	-	-	Ref. 144	-	Ref. 39	Ref. 145
Protein, Vitamins, and Minerals	Blocks; Liquid Supplements; Vitamin Premixes; Mineral Premixes	-	-	-	-	-	Refs. 15, 83	Refs. 84, 85	-	-	-	-

\* See 21 CFR 507.5 – Exemptions. 21 CFR part 507, subparts C and E do not apply with respect to activities subject to 21 CFR part 113 (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 with respect to those activities (21 CFR 507.5(b)(1)).

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# Title 21

## **PART 507 - CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS**

**Authority:** 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

**Source:** 80 FR 56337, Sept. 17, 2015, unless otherwise noted.

### **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 an audited entity'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, 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 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.

*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 (including any subsidiaries and affiliates) 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.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

## **§ 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).

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

### **§ 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), 5001 Campus Dr., College Park, MD 20740; 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), 5001 Campus Dr., College Park, MD 20740. 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.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016; 81 FR 49897, July 29, 2016]

### **§ 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 are 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.

*[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]*

## **§ 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 ready for distribution must contain, when applicable, information and instructions for safely using the animal food 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.

*[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]*

## **§ 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);
  - (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.

*[80 FR 56337, Sept. 17, 2015, as amended at 84 FR 12491, Apr. 2, 2019]*

### **§ 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 to humans or animals 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).

*[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]*

### **§ 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 this subpart 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 this subpart 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 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 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.

*[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]*

### **§ 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; or
        - (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.

*[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3718, Jan. 22, 2016]*

**§ 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; and
  - (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 Division Director in whose division 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.

*[80 FR 56337, Sept. 17, 2015, as amended at 85 FR 16554, Mar. 24, 2020]*

## **§ 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, fax number, and name of the FDA Division Director in whose division 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 Division Director in whose division 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 fax number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and
  - (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 Division 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 Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

*[85 FR 16555, Mar. 24, 2020]*

### **§ 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 Division Director in whose division 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 Division Director

in whose division 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 or her 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 Division Director in whose division 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.

*[80 FR 56337, Sept. 17, 2015, as amended at 85 FR 16555, Mar. 24, 2020]*

## **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.

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**EFFECTIVE DATE NOTE**

At 80 FR 56337, Sept. 17, 2015, part 507 was added, effective Nov. 16, 2015, with the exception of paragraph (a)(2) in § 507.105, which is not yet effective.

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**§ 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 countries.
- (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.

*[80 FR 56337, Sept. 17, 2015, as amended at 84 FR 12491, Apr. 2, 2019]*

### **§ 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.

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#### **EFFECTIVE DATE NOTE**

At 80 FR 56337, Sept. 17, 2015, part 507 was added, effective Nov. 16, 2015, with the exception of paragraph (d) in § 507.135, which is not yet effective.

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#### **§ 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.

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**EFFECTIVE DATE NOTE**

At 80 FR 56337, Sept. 17, 2015, part 507 was added, effective Nov. 16, 2015, with the exception of paragraph (c)(2) in § 507.175, which is not yet effective.

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## **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.



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