

#235

Current Good Manufacturing Practice Requirements for Food for Animals

Guidance for Industry

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For questions regarding this document, contact 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/>.

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

I. Introduction

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.¹

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.

¹ 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.² 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.³

² 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."

³ 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).⁴ "Farm" has a specific definition in 21 CFR 1.227.

⁴ 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/food-defense-tools/food-defense-plan-builder>

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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 requirements⁵.

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;

⁵ 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 507.28⁶ 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:

⁶ 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."⁷

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.

⁷ 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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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

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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).

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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.

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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

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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.

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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)).

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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)).

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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

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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

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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)).

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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.

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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

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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 Use⁸ 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

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

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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.⁹

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

⁹ Guidance for maximum levels of fumonisin can be found in Attachment C of the Compliance Program Guidance Manual 7371.003 Feed Contaminants Program,

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>.

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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)).

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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.

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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."¹⁰

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.

¹⁰ 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.

Size of Business	Definition	Required date to comply with 21 CFR part 507, subpart B (CGMPs) and related requirements
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

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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.¹¹ 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.

¹¹ 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

Personnel Qualification, Training, Responsibility Requirements	Notes
<p>The management of an establishment is required to:</p> <ul style="list-style-type: none">• 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)).• 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)).• 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)). <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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Personnel Qualification, Training, Responsibility Requirements	Notes
<p>Individuals who supervise or perform manufacturing, processing, packing, or holding activities for animal food must:</p> <ul style="list-style-type: none">• 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• receive training in the principles of animal food hygiene and animal food safety. (507.4(b)(2)) <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>	

Contains Nonbinding Recommendations

Table 2 Personnel Hygienic Practice Requirements

Personnel Hygienic Practice Requirements	Notes
<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">• Maintaining adequate personal cleanliness (507.14(b)(1))• Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination (507.14(b)(2))• Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers (507.14(b)(3))• 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))• 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))	

Contains Nonbinding Recommendations

Table 3 Ingredient Receiving Requirements

Ingredient Receiving Requirements	Notes
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">• Raw materials must be cleaned as necessary to minimize contamination (507.25(b)(1)(ii)).• 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)).• 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)).	

Contains Nonbinding Recommendations

Table 4 Manufacturing and Processing Requirements

Manufacturing and Processing Requirements	Notes
<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">• 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)).• 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))• 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)). <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

Manufacturing and Processing Requirements	Notes
<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"> • 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)). • 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)). • 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 (507.25(c)(2)). • When water activity (a_w) is used to prevent the growth of undesirable microorganisms, the animal food must be processed to and maintained at a safe a_w level (507.25(c)(6)). • 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)). 	
<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>	

Contains Nonbinding Recommendations

Table 5 Equipment and Utensil Requirements

Equipment and Utensil Requirements	Notes
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"> • 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)). • made of nontoxic materials (507.22(a)(4)(ii)); and • maintained to protect animal food from contamination (507.22(a)(4)(iii)). 	
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)).	

Contains Nonbinding Recommendations

Table 6 Sanitation Requirements

Sanitation Requirements	Notes
<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">• If animal food contact surfaces are wet cleaned, the surfaces must be thoroughly dried before subsequent use, when necessary (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 (507.19(b)(2)).• 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)).	
<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>	

Contains Nonbinding Recommendations

Sanitation Requirements	Notes
<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"> • 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)). 	
<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>	

Contains Nonbinding Recommendations

Table 7 Packing, Holding, and Distribution Requirements

Packaging, Holding, and Distribution Requirements	Notes
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"> • 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)). • Animal food must be held in a way that protects against contamination from sources such as trash (507.27(a)(2)). 	
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)).	

Contains Nonbinding Recommendations

Table 8 Plant Construction, Design and Maintenance Requirements

Plant Construction, Design and Maintenance Requirements	Notes
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)).	

Contains Nonbinding Recommendations

Table 9 Water Supply and Plumbing Requirements

Water Supply and Plumbing Requirements	Notes
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)).	
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)).	
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)).	
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)).	
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)).	
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)).	
Sewage and liquid waste must be disposed of through an adequate sewage system or through other adequate means (507.20(c)).	

Contains Nonbinding Recommendations

Water Supply and Plumbing Requirements	Notes
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)).	

Contains Nonbinding Recommendations

Table 10 Grounds and Outdoor Animal Food Storage Requirements

Grounds and Outdoor Animal Food Storage Requirements	Notes
<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"> • 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)). • Maintaining driveways, yards, and parking areas so they are not a source of contamination for exposed animal food (507.17(a)(2)). • Adequately draining areas that may contribute to contamination of animal food (507.17(a)(3)). • 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)) 	
<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"> • Using protective coverings where necessary and appropriate (507.17(c)(1)) • Controlling areas over and around the bulk animal food to eliminate harborages for pests (507.17(c)(2)) • Checking on a regular basis for pests, pest infestation, and product condition related to the safety of the animal food (507.17(c)(3)). 	