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Guidance for Industry

Current Good Manufacturing Practice Requirements for Food for Animals

DRAFT GUIDANCE

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Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place,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

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Current Good Manufacturing Practice Requirements for Food for Animals

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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, subpart A (subpart A).

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

II. 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. At the same time, we established Current Good Manufacturing Practice requirements (CGMPs) for the manufacturing, processing, packing, and holding of animal food.

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 required 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 the effective implementation of preventive controls. 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 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

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.

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 as the preventive control a procedure that it is already performing. This procedure would then be subject to all of the requirements for a preventive control, including monitoring, corrective actions, verification, and validation (21 CFR 507.39). We intend to issue a guidance providing more detail on how to conduct a hazard analysis and implement preventive controls.

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. This guidance provides additional explanation and examples for facilities to implement these CGMPs based on their unique facility and type of animal food.

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)). Full compliance with the CGMP provisions should reduce the likelihood that the animal food will be adulterated because it was manufactured/processed, packed, or held under insanitary conditions whereby it may have become contaminated or rendered injurious to health or is otherwise unfit for food (sections 402(a)(3) and (4) of the FD&C Act). 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.[1]

The FD&C Act prohibits introducing or delivering for introduction into interstate commerce adulterated animal food, and 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

[1] 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."

food is held by a facility for sale (sections 301(a) and (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.

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)). 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. Examples of establishments that are not required 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); and (5) foreign facilities if the food undergoes further manufacturing/processing by another facility outside the United States (21 CFR 1.226 and

1.227).[2] "Farm" has a specific definition in § 1.227. This definition was amended on September 17, 2015 (80 FR 55908 at 56141).

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

Facilities solely engaged in the following activities are not subject to the CGMP requirements in 21 CFR 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.)

To assist in determining whether a facility meets the criteria described above, we note that the plain meaning of "solely" is only, completely, entirely; without another or others; singly; alone. 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....

This means that 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. In this example, the facility is not "solely" engaged in the holding and/or transportation of one or more raw agricultural commodities and this exemption would not apply.

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;

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

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.
- Human food such as potato chips, cookies, bread, pastry products, and pasta that is not adulterated and is safe for use as animal food, but is not acceptable as human food for quality reasons such as the wrong size, shape, color, or texture.

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

(1) subject to and in compliance with 21 CFR part 117, subpart B and in compliance with all other applicable human food safety requirements of the FD&C Act and implementing regulations, or

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

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

If the facility meets those two conditions, then once the by-product for use as animal food is separated from the human food, the facility must follow the limited requirements found in both 21 CFR 117.95 and 507.28[3] 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:

[3] Sections 117.95 and 507.28 are identical and appear in both places for the convenience of the facilities to which the provisions apply.

- 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 by-products, please see the Draft Guidance for Industry #239 entitled "Human Food By-Products for Use as Animal Food."[4]

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 animal food 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. Therefore, the facility must also follow the specific requirements in 21 CFR part 225 related to

[4] Draft Guidance for Industry #239 entitled "Human Food By-Products for Use as Animal Food" is available at http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance.

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 may 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 monitor and review individuals' performance of assigned duties. If an individual is not able to consistently perform assigned duties in a competent manner, 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, or discussing these responsibilities with supervisory personnel.

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).

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)). 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, we expect that individuals will receive training prior to independently performing their assigned duties. In addition, we expect that most facilities will 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 establishment can generate training records in a format that is convenient, for example: (1) training check-list for new employees; (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 training record(s) must be kept in compliance with the recordkeeping requirements in 21 CFR part 507, subpart F as discussed next in section *V.D.1. Recordkeeping Requirements (21 CFR part 507 subpart F)*.

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"). Facilities are not required to submit the required training records to FDA.

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)). Duly authorized representatives include state investigators commissioned by FDA. 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 http://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)). We consider indelible records to be those that are not easily erased or changed. 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)). The required training records should provide sufficient information to document the training. Examples of additional information that may be included in such a record are: (1) a list of the person(s) trained; (2) a description of the content of the training; and (3) the name and qualifications of the trainer.

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)). The required training records (documenting the training in principles of animal food hygiene and animal food safety) should be kept for 2 years after the individual who was trained stops working for the facility. 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 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 from working in the plant, but might not allow clothes covered with oil, grease, excessive dirt, or other foreign materials. 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 at a minimum when: individuals enter the food production area; after they handle or touch 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.

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 not contribute to 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)).

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.

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. Toxic materials used to treat waste 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)).*

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 possible 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 (21 CFR 507.19(a)). When windows, doors, or vents are open to the exterior, 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)).

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).

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. Utensils and equipment should be maintained so that parts or pieces do not break or fall off and contaminate the animal food. The cleaning procedures 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 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, material safety data sheets (MSDS)). 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.

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)).

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 (21 CFR 507.3). 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)). Depending on the intended use, water may need to meet certain standards, or 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. 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.

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 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.

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. 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 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 facilities are 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 should be used when they can come into contact with the animal food or an animal food-contact surface. Equipment and utensils should be designed so that they do not leak lubricants, fuel, contaminated water, or other liquids into the animal food or onto an animal food-contact surface. 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.

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. The system should be designed, constructed, and maintained so that as the animal food moves through the system it does not become contaminated.

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 according to the manufacturer's instructions. The plant must have enough instruments for the designated uses (21 CFR 507.22(d)). 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 under mechanical pressure 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 ensure 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 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 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 expect facilities to 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 Compliance Policy Guide Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use[5] 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 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

[5] FDA, Compliance Policy Guide Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use, http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074694.htm.

(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 expect the facility to consider 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; and/or (4) 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)). 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).

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.

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 it 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. There are several resources that identify maximum recommended levels for the presence of natural toxins.[6]
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 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 water activity (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 be held so that it

[6] Guidance for maximum levels of fumonisin can be found in Appendix C of the Compliance Program Manual 7371.003 Feed Contaminants Program, http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113409.pdf.
Action levels for aflatoxin can be found in the Compliance Policy Guide Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds, http://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, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120184.htm.

can be easily identified as rework and not commingled with finished animal food. In addition, depending on the type of animal food, it may be necessary to handle the 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 water activity (a_w) to prevent the growth of undesirable microorganisms must be processed to and maintained at a safe water activity (a_w) level (21 CFR 507.25(c)(6)). The plant should use procedures that consistently achieve a safe water activity (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)).*

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 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))

When applicable, animal food ready for distribution must have labeling that contains information and instructions for safely using the product for the intended animal species (21 CFR 507.27(b)). FDA's animal food labeling requirements generally 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 label 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.

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

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 (21 CFR 507.27(c)).

When the facility is the shipper, we expect facility personnel involved in the process of loading the product into the shipping container or vehicle to be aware of the condition of the shipping container or vehicle, and consider whether its condition would contaminate the animal food. Depending on the circumstances, this examination could include looking at the shipping container or vehicle to observe whether there are any residues in it that may contaminate the animal food. When a visual examination is not practical, we would expect the facility to know what the shipping container or vehicle had previously been used for and because of that, whether the container needed to be cleaned prior to use to protect the animal food from contamination. This does not mean that the shipping container must be cleaned prior to each use in all situations.

The regulations 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 to pick up the animal food. However, if facility personnel are onsite and available, it would be good practice for the facility to examine the customer's shipping container or bulk vehicle to confirm that the shipping container or bulk vehicle will not lead to the contamination of the animal food.

We note that as part of FDA's implementation of FSMA, FDA issued a final rule on the Sanitary Transportation of Human and Animal Food 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. Animal food facilities engaging in transportation operations for animal food must be in compliance with applicable requirements in that rule. Small businesses (as defined in the sanitary transportation rule) will have two years after the date the rule published to comply with the rule and other businesses will have one year to comply.

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; (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 dedicated 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(a))

The requirements in this section only apply to human food by-products for use as animal food that are held at and distributed by a human food facility covered by 21 CFR 507.12. 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). See section *IV.C.2 Certain by-products of human food for use as animal food (21 CFR 507.12 and 507.28)).*

The holding and distribution requirements in 21 CFR 507.27 apply to all other products subject to the 21 CFR part 507 CGMPs. For a more complete discussion of by-products, please see the Draft Guidance for Industry #239: Human Food By-Products for Use as Animal Food.

1. Holding and identification requirements for human food by-products held for distribution as animal food (21 CFR 507.28(a) and 117.95(a))

When human food by-products for use as animal food are held for distribution, they must be held under conditions that will protect them from contamination (21 CFR 507.28(a)). Contamination may be caused by physical, chemical, or microbiological contaminants.

Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained in a way that protects against the contamination of human food by-products for use as animal food (21 CFR 507.28(a)(1)). Containers and equipment that are commonly used include bulk tanks, bins, totes, drums, tubs, augers, conveyors, or holding vehicles. Methods and frequency of cleaning, repair, or replacement of containers or equipment will depend on what type of product is being held or conveyed and how the containers or equipment are being used. For some types of by-products it may not be necessary to clean the container after each use. The facility should consider the amount and type of by-products, the containers or equipment used, the frequency with which containers or equipment are used, as well as other factors when deciding what cleaning practices and cleaning frequency will protect the by-products from contamination.

In addition, the human food by-products for use as animal food must be held in a way that protects against contamination from sources such as trash (21 CFR 507.28(a)(2)). Good practices to consider include: making it easy to distinguish animal food from trash; locating the by-products away from trash or waste containers; and providing readily accessible, clearly marked, separate receptacles for trash and waste.

Furthermore, human food by-products for use as animal food must be accurately identified during holding (21 CFR 507.28(a)(3)). We recognize that a variety of systems may be used by human food establishments to identify human food by-products for use as animal food within the plant, including labeling, computer systems, paper records, chalkboards, and other methods. Plant personnel should be able to accurately identify the human food by-products for use as animal food so that it is not contaminated, commingled, substituted, or incorrectly distributed in a manner that adulterates the animal food.

2. Labeling of human food by-products held for distribution as animal food (21 CFR 507.28(b))

When the human food by-products for use as animal food are distributed, labeling that identifies the product by the common or usual name must be affixed to or accompany it (21 CFR 507.28(b)). Labeling could be included on the invoice or bill of lading, for example. Our Compliance Policy Guide Sec. 665.100 discusses common or usual names for animal food ingredients, including the use of the ingredient definitions in the AAFCO Official Publication.[7] There are also industry and other regulatory resources that may assist facilities in determining the common or usual name of the animal food, such as the foods listed in the USDA National Nutrient Database for Standard Reference. [8]

3. Shipping containers and bulk vehicles used to distribute human food by-products for use as animal food (21 CFR 507.28(c))

When the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third-party to transport the animal food, the shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute the animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle (21 CFR 507.28(c)).

When the facility is the shipper, we expect facility personnel involved in the process of loading the product into the shipping container or vehicle to be aware of the condition of the shipping container or vehicle, and consider whether its condition would contaminate the human food by-products for use as animal food. Depending on the circumstances, this examination could include looking at the shipping container or vehicle to observe whether there are any residues in it that may contaminate the human food by-product for use as animal food. When a visual examination is not practical, we would expect the facility to know what the shipping container or vehicle had previously been used for and because of that, whether the container needed to be

[7] FDA, Compliance Policy Guide 665.100 Common or Usual Names for Animal Feed Ingredients, http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074687.htm.
[8] USDA, National Nutrient Database for Standard Reference, http://ndb.nal.usda.gov/

cleaned prior to use to protect the human food by-product for use as animal food from contamination. This does not mean that the shipping container must be cleaned prior to each use in all situations.

The regulations 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 to pick up the animal food. However, if facility personnel are onsite and available, it would be good practice for the facility to examine the customer's shipping container or bulk vehicle to confirm that the shipping container or bulk vehicle will not lead to the contamination of the human food by-products for use as animal food.

We note that as part of FDA's implementation of FSMA, FDA issued final a rule on the Sanitary Transportation of Human and Animal Food 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. Human food facilities engaging in transportation operations for human food by-products for use as animal food must be in compliance with applicable requirements in that rule. If human food by-products for use as animal food have not been further processed and are not being transported to another business for further processing (e.g., are being moved from the human food manufacturer to a farm to be fed directly to livestock), then the transportation of the human food by-products for use as animal food is not covered by the rule. Small businesses (as defined in the sanitary transportation rule) will have two years after the date the rule published to comply with the rule and other businesses will have one year to comply.

VIII. 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.

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

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.

Farm means *Farm* as defined in 21 CFR 1.227. This definition was amended on September 17, 2015 (80 FR 55908 at 56141).

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.

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

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.

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.