

Chapter 2

CURRENT GOOD MANUFACTURING PRACTICE



This chapter describes the required components of 21 CFR 507 Subpart B: Current Good Manufacturing Practice or CGMP. CGMP requirements apply to those registered food facilities involved in the manufacturing, processing, packing, and/or holding of animal food, with the exceptions of:

- Establishments solely engaged in the holding and/or transportation of raw agricultural commodities (e.g. grain and oilseeds.)
- Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and
- Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed)

CGMP Objectives

- Describe the purpose of CGMP and its importance in an animal food safety system
- Where to find information on other programs related to CGMP
- Explain the basic requirements of CGMP



This chapter will address the following objectives:

- Describe the purpose of CGMP requirements and their importance in an animal food safety system
- Where to find information on other programs related to CGMP
- Explain the basic requirements of CGMP

Purpose of CGMP

- Considered by FDA to be “...necessary to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health” (Preamble, II: Legal Authority).
- Establishes baseline standards for the production of safe animal food and the creation of a successful Food Safety Plan.



FDA describes the purpose of CGMP requirements in the preamble to the final rule. CGMP requirements are considered by FDA as being “*necessary to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.*” The CGMP requirements in subpart B are intended to serve as baseline standards for producing safe animal food across all types of animal food facilities, including pet food facilities.

The CGMPs include 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. The flexibility in these provisions is indicated by phrases such as “when necessary,” or “as appropriate.”

Other Programs Related to CGMP Regulations

- Other Animal Food Regulations with CGMP Regulations
 - 21 CFR Part 225 – Current Good Manufacturing Practice for Medicated Feeds
- Facility-Specific Prerequisite Programs
 - Employee Training
 - Facility Operations
 - Preventive Maintenance
 - Cleaning/Sanitation
 - Standard Operating Procedures
 - Quality Assurance
 - Animal Food Safety
 - HACCP
 - ISO
 - PAS 222



There are a number of other programs that are related to, and have similar provisions as the CGMP requirements found in 21 CFR part 507, subpart B. As an example, FDA implemented CGMP requirements for the manufacture of medicated feeds (21 CFR Part 225) in the 1970's. The specific requirements of the medicated feed CGMP, including the control of drug components, laboratory assays or controls, and the requirement to maintain a complaint file remain in effect. The medicated feed CGMP establish requirements beyond those and for different purposes than the CGMP discussed in this chapter. However, there are notably comparable sections, such as the design and maintenance of buildings, plant and grounds, and equipment to manufacture safe animal food.

In addition to the medicated feed CGMP requirements, there are other programs that animal food manufacturing facilities may already voluntarily utilize as best practices or as prerequisite programs. Many facilities have employee training programs in place to meet the requirements of non-food safety regulations. Facilities may also have preventive maintenance programs, cleaning or sanitation schedules and programs, Standard Operating Procedures (SOPs), and quality assurance programs. These types of programs are typically directed to maximize product quality, personnel safety, and facility efficiency, but the standards they set forth may very well meet the requirements of the CGMP required by part 507.

Furthermore, some facilities have in place proactive programs already addressing animal food safety. Some common programs used in the animal food industry include HACCP, ISO 22000, and PAS 222. Under these programs, facilities may meet the requirements for CGMP. Each facility is different, and the *Preventive Controls for Animal Food* rule is very flexible, so there are many ways that these programs can be used to meet the requirements of the rule. The ultimate goal is that all requirements are met and safe animal food is produced.

Part 507, Subpart B – Current Good Manufacturing Practice

- 21 CFR 507.14 - *Personnel*
- 21 CFR 507.17 - *Plant and grounds*
- 21 CFR 507.19 - *Sanitation*
- 21 CFR 507.20 - *Water supply and plumbing*
- 21 CFR 507.22 - *Equipment and utensils*
- 21 CFR 507.25 - *Plant operations*
- 21 CFR 507.27 - *Holding and distribution*
- 21 CFR 507.28 - *Holding and distribution of human food by-products for use as animal food.*

The main purpose of this chapter is to familiarize participants with the contents of 21 CFR part 507, subpart B. The CGMP requirements in subpart B have 8 different sections, including *Personnel*, *Plant and grounds*, *Sanitation*, *Water supply and plumbing*, *Equipment and utensils*, *Plant operations*, *Holding and distribution*, and *Holding and distribution of human food by-products for use as animal food*.

21 CFR 507.14 - Personnel

- (a) *The management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food.*
- (b) *The methods for conforming to hygienic practices and maintaining cleanliness include:*
 - (1) *Maintaining adequate personal cleanliness;*
 - (2) *Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;*
 - (3) *Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;*
 - (4) *Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and*
 - (5) *Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal-food packaging materials.*



In the discussion of 21 CFR part 507, subpart A in Chapter 1, some requirements regarding personnel were introduced. Specifically, all individuals engaged in manufacturing, processing, packing, or holding animal food subject to the *Preventive Controls for Animal Food* rule must meet the definition of a *Qualified Individual*, and receive documented training (CFR 21 507.4). The CGMP requirements further describe the specific expectations for those *Qualified Individuals* who manufacture, process, pack, or hold animal food.

The personnel section states that the management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food. For example, management expectations for personnel working in a livestock animal food manufacturing facility might allow clothes that are dusty when working in the facility, but might not allow clothes covered with oil, grease, excessive dirt, or other foreign materials.

The methods for conforming to hygienic practices and maintaining cleanliness include:

- Maintaining adequate personal cleanliness
- Washing hands thoroughly in an adequate hand-washing facility

- Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers
- Storing clothing or other personal belongings away from animal food or equipment cleaning areas
- Taking any other precautions considered to be necessary to protect against contamination of animal food, contact surfaces, or packaging materials

Example - Personnel

- Provide necessary facilities:
 - Lockers to store personal effects
 - Handwashing facilities as appropriate
 - Post appropriate signage to reinforce new practices
- Develop a personnel cleanliness protocol with training that specifies expectations regarding:
 - Handwashing
 - Wearing of jewelry
 - Carrying of cellular phones, tools



Regarding personal belongings, an employer may provide lockers or other storage areas for personnel to store clothing or other personal items in areas away from where animal food is exposed or where equipment is cleaned.

To conform to the personnel requirements, establishments need to ensure that adequate hand-washing facilities are available and that hygienic and cleanliness practices are in place to protect against the contamination of animal food to the extent necessary.

A personnel training program could be implemented to emphasize the importance of hand- washing, the potential hazards associated with wearing different types of jewelry, and the chosen policy on the carrying and use of cell phones and tools within the facility.

Ultimately, there are different ways that an employer can comply with these requirements. How management meets the requirements can vary, so long as the requirements of 21 CFR 507.14 are met.

21 CFR 507.17 – Plant and Grounds

- *(a) The grounds around an animal food plant under the control of the management of the establishment must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:*
 - *(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;*
 - *(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;*
 - *(3) Adequately draining areas that may contribute to contamination of animal food; and*
 - *(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.*



The next three slides focus on the requirements of 21 CFR 507.17 – Plant and Grounds. Each slide is dedicated to a specific set of requirements.

The first set of provisions relate to the condition of grounds around the establishment. The primary requirement is that the condition of the grounds protect against the potential contamination of the animal food. As such, maintaining the grounds must include:

- Properly storing equipment, removing litter and waste, and cutting weeds or grass that may attract or harbor pests
- Maintaining driveways, yards, and parking areas such that they will not contribute to contamination of exposed animal food
- Adequately draining areas that may contribute to contamination of animal food
- Treating and disposing of waste so that it will not contaminate exposed animal food

21 CFR 507.17 – Plant and Grounds

- *(b) The plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, including that the plant must:*
 - *(1) Provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;*
 - *(2) Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;*
 - *(3) Provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors (e.g. steam) and fumes in areas where they may contaminate animal food and in a manner that minimizes the potential for contaminating animal food;*
 - *(4) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned; and*
 - *(5) Provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation to protect against the contamination of animal food in case of glass breakage.*



The second set of requirements relates to the design and construction of the facility. Specifically, the plant must be feasible to clean, perform maintenance activities, and control pests in order to reduce the potential for contamination of animal food, contact surfaces, and packaging materials.

The facility must:

- Provide adequate space throughout the facility for employees to perform their duties related to cleaning and maintenance of equipment
- Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination
 - When possible, ducts, fixtures, and pipes should not be located over animal food or animal food-contact surfaces. Condensation can be controlled by using drip pans to divert water away from animal food, or pipe insulation to prevent sweating. (source GFI #235)
- Provide adequate ventilation where appropriate to minimize vapors and fumes that may contaminate animal food
- Provide adequate lighting in hand-washing areas and bathrooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned
- Provide shatter-resistant light bulbs, fixtures, skylights, or other glass items when they are suspended over exposed animal food in any step of the process

Example – Plant and Grounds

- Existing facilities likely do not need to be redesigned or reconstructed, but compliance with requirements is necessary.
- Example: Provide acceptable lighting with shatter-resistant glass above storage or production areas.



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It is important to note that the preamble of the *Preventive Controls for Animal Food* rule states that existing facilities likely do not need to be redesigned or reconstructed to meet the CGMP requirements. Maintenance, repair, retrofitting, or other changes to the existing facility, equipment, or facility procedures may be used to meet the requirements.

At a given facility, complying with the CGMP requirements might mean implementing an outdoor maintenance program that provides specific policies related to the proper conditions of the grounds. Inside the facility, it may be that space and ventilation are already addressed because of their impact on facility operations. To address the potential for glass breakage, a facility may need to evaluate its lighting and other glass fixtures that are in place over exposed animal food to ensure the use of shatter-resistant glass or other adequate protection. In areas where the lighting is not adequate for employees to perform their duties, additional lighting should be added.

21 CFR 507.17 – Plant and Grounds

- *(c) The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including:*
 - *(1) Using protective coverings where necessary and appropriate;*
 - *(2) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and*
 - *(3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.*



The third set of requirements relates to protecting any animal food stored outdoors in bulk. The facility may use any effective means to protect against contamination, including:

- Using protective coverings
- Controlling areas over and around the bulk animal food to eliminate harborages for pests
- Checking the animal food on a regular basis for pest activity and any signs of poor product conditions that could be related to the safety of the animal food

Example – Plant and Grounds

- Must protect animal food stored outdoors in bulk by any effective means when necessary or appropriate



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In some parts of the country, during harvest time, large quantities of grain may be stored in piles until the grain can be moved to a more permanent storage location. Depending upon the length of storage and other conditions, the outdoor pile may need to be protected by various means when necessary or appropriate. 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, such as rain or wind-blown debris, or pests; for example, by bird or rodent droppings or nesting materials.
- Control the area around the animal food to eliminate pest harborage, perhaps by mowing vegetation, removing trash and junk piles, and preventing standing water.
- Keep bulk piles away from the eaves of buildings where birds or other pests could roost and serve as a source of contamination.
- Check bulk animal food on a regular basis for product condition and have a pest control plan, specifying monitoring locations and frequency.

Management would ultimately be responsible for determining the necessary and appropriate precautions needed to address potential contamination from the environment and/or pests.

21 CFR 507.19 – Sanitation

- *(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated.*
- *(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:*
 - *(1) When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use; and*
 - *(2) In wet processing of animal food, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.*



21 CFR 507.19 addresses the CGMP requirements related to sanitation. The primary goal of the CGMP requirements in this section is to describe the activities necessary to ensure that the physical facilities of the plant are kept clean and in good repair to prevent animal food from becoming adulterated.

Both contact and non-contact surfaces of utensils and equipment must be cleaned and maintained as necessary. Also, utensils and equipment must be properly stored to protect against the contamination of animal food, contact surfaces, or packaging materials. When necessary, equipment must be disassembled for thorough cleaning.

In situations where wet-cleaning is appropriate, surfaces must, when necessary, be thoroughly dried before subsequent use. When cleaning and sanitizing is necessary to protect against contamination by undesirable microorganisms, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

Example – Sanitation

- Minimize potential sources of environmental contamination by adequate cleaning and, when necessary, sanitizing procedures.
 - Notably, appropriate sanitation practices vary within different industry segments.



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For many facilities, sanitation compliance will be tied to basic housekeeping practices. Take, for example, the level of acceptable cleanliness in the pictures in the slide. The picture on the left shows a hammermill in use. The picture on the right shows a brand-new hammermill before it has ever been used. Even with a dust collection system, hammermills generate dust during use. While there is dust on the equipment and in the grinding room pictured on the left, it is clear that housekeeping is used to minimize buildup over a long period of time. There is no evidence of pests or buildup causing a potential hazard.

It is important to note that the level of acceptable sanitation may differ between animal food manufacturing facilities based on the type of food they produce and any associated hazards. For example, in some animal food facilities where wet cleaning is performed, equipment may be disassembled and sanitized as necessary.

As with other CGMP sections, the management of the establishment is responsible to ensure the measures taken to comply with the sanitation requirements will protect against the contamination of the animal food.

21 CFR 507.19 – Sanitation

- *(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.*
- *(d) The following applies to toxic materials:*
 - *(1) Only the following toxic materials may be used or stored in the plant area where animal food is manufactured, processed, or exposed*
 - *(i) Those required to maintain clean and sanitary conditions;*
 - *(ii) Those necessary for use in laboratory testing procedures;*
 - *(iii) Those necessary for plant and equipment maintenance and operation; and*
 - *(iv) Those necessary for use in the plant's operations.*
 - *(2) Toxic materials described in paragraph (d)(1) of this section must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials; and*
 - *(3) other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.*



All cleaning compounds and sanitizing agents must be safe and adequate for their intended use. Only certain toxic materials may be used or stored in areas of the facility where animal food is manufactured, processed, or exposed. These include:

- Those required to maintain clean and sanitary conditions (e.g. cleaning compounds)
- Those used in laboratory testing procedures (e.g. reagent chemicals)
- Those necessary for facility and equipment maintenance and operation (e.g. greases and oils)
- Those necessary for use in facility operations (e.g. sweeping compounds)

Any such toxic materials must be identified, used, and stored in a manner that protects against the contamination of animal food, contact surfaces, or packaging materials. All other toxic materials not specifically addressed must be stored away from any areas where animal food is manufactured, processed, or exposed.

Example – Sanitation

- Examples of toxic materials: fertilizers, cleaning compounds, treated seeds, and pesticides
- Toxic materials must be stored separately from materials intended for animal food and where animal food is manufactured, processed, packed, or stored.



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There are many animal food manufacturing facilities that store and sell toxic materials such as fertilizers, cleaning compounds, treated seeds, and pesticides. While this is an acceptable activity, those materials must be stored in an area of the facility where animal food is not manufactured, processed, or exposed.

In the preamble of the rule, FDA states that it expects this requirement to result in these toxic materials being separated from animal food either by sufficient space or a sufficient physical barrier such that they are not able to contaminate the animal food. As a good practice, these toxic materials should be stored separately from materials that are intended for animal food, such as ingredients, finished animal food, or packaging materials.

21 CFR 507.19 – Sanitation

- *(e) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of pesticides in the plant is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.*
- *(f) Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests.*



Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas of the facility. While pesticides may be used within the facility, according to these requirements, precautions must be taken to protect against the contamination of animal food, contact surfaces, and packaging materials.

Trash must be conveyed, stored, and disposed of in a way that will not contaminate animal food, contact surfaces, packaging materials, water supplies, or ground surfaces. Further, trash must be handled in such a way that minimizes the potential for it attract or harbor pests.

21 CFR 507.20 – Water supply and plumbing

- (a) *The following apply to the water supply:*
 - (1) *Water must be adequate for the operations and must be derived from an adequate source;*
 - (2) *Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities;*
 - (3) *Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use; and*
 - (4) *Water may be reused for washing, rinsing or conveying animal food if it does not increase the level of contamination of the animal food.*



21 CFR 507.20 describes the requirements for water supply and plumbing. Requirements relate specifically to the water supply, plumbing, waste disposal, and toilet and hand-washing facilities. It is important to note that not all animal food facilities may use water for manufacturing, and therefore some of the requirements related to water used for these operations may not be applicable.

The following requirements apply to the water supply:

- Water must be adequate for the operations and come from an adequate source
- Running water at a suitable temperature and pressure must be provided as 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
- Water that contacts animal food, contact surfaces, or packaging materials must be safe for its intended use
- Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination

Adequate Water

- Water must be:
 - Adequate for operation, from adequate source
 - Provides sufficient temperature and water volume to support facility operations
 - Safe for intended use if it contacts animal food, animal food contact surfaces, or animal food packaging material
 - Should be free of contaminants that could adulterate the animal food
 - Reused water is acceptable if it does not increase the contamination of the animal food



Water used by the facility must be adequate for the operations and derived from an adequate source. Adequate is defined in 21 CFR 507.3, and in this sense, the water supply must be sufficient for its intended purpose, in keeping with good public health practice. The water supply must provide sufficient water volume to support the facility operations (e.g., manufacturing, processing, and cleaning). Water treatment methods may be used to improve the water quality or to remove contaminants.

The most impactful of the water supply and plumbing requirements are likely to be those related to the use of water in the manufacturing of an animal food. Water may be added to foods during processing, such as during the steam conditioning process prior to pelleting or extrusion. Also, many facilities may utilize water to clean utensils, such as scoops. In these cases, facilities could maintain records of water safety, either from a water treatment department or, in the case of facilities utilizing well water, through periodic testing of water quality. However, the type or frequency of water testing is not specified in the regulations.

Depending on the intended use, water may need to meet certain standards, or be free of certain chemical (including radiological) or biological contaminants. The water source cannot introduce contaminants that could adulterate the animal food. The water source should be in compliance with any other applicable regulations.

The CGMPs do not require testing for water safety; however, testing may be one way to determine whether the water source is adequate and safe for its intended use. Test reports may be one way to demonstrate that the facility determined the water source is adequate and safe for its intended use.

21 CFR 507.20 – Water supply and plumbing

- *(b) Plumbing must be designed, installed, and maintained to:*
 - *(1) Carry adequate quantities of water to required locations throughout the plant;*
 - *(2) Properly convey sewage and liquid disposable waste from the plant;*
 - *(3) Avoid being a source of contamination to animal food, water supplies, equipment, or utensils, or creating an unsanitary condition;*
 - *(4) Provide adequate floor drainage in all areas where floor are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and*
 - *(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.*



Facility plumbing must be designed, installed, and maintained to:

- Carry adequate quantities of water to required locations throughout the facility
- Properly convey sewage and liquid waste
- Avoid being a source of contamination or creating an unsanitary condition
- Provide adequate floor drainage for cleaning or where normal operations release or discharge water or other liquid waste
- Ensure that there is no potential for cross contamination between waste water or sewage and water used in animal food manufacturing

21 CFR 507.20 – Water supply and plumbing

- *(c) Sewage and liquid disposal waste must be disposed of through an adequate system or through other adequate means.*
- *(d) Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal-food packaging materials.*
- *(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.*



Sewage and liquid waste must be adequately disposed of.

Each facility must provide employees with adequate and readily accessible toilet facilities. Some facilities may not have toilet facilities physically located in the facility, which is acceptable as long as there are toilet facilities nearby and readily accessible. In some instances, the facility 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 arrangements may be needed for the use of portable toilet facilities. These facilities must be kept clean so as not to become a potential source of contamination. Similarly, a facility must also provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination.

Example – Water supply and plumbing

- If water temperature must reach a specific parameter for sanitation purposes, it should be measured.
- Adequate restroom facilities are required, and sewage/waste water must be conveyed so as to not cause animal food adulteration.
- Additional handwashing facilities may be necessary depending on the operation.



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In some facilities, hot water is used for sanitation of equipment. In this case, a facility may choose to measure the temperature of the water in accordance with a written policy. Records might be generated if considered important by the facility, but such records would not be required as there is no recordkeeping associated with CGMP requirements.

Hand-washing facilities should be provided as part of the toilet facilities. Additional hand-washing facilities may be needed throughout the facility, 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. According to GFI #235, hand-washing facilities should include running water, soap, and a method to dry hands after washing. 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.

21 CFR 507.22 – Equipment and Utensils

- *(a) The following apply to plant equipment and utensils used in manufacturing, processing, packing, and holding animal food:*
 - *(1) All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;*
 - *(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;*
 - *(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;*



21 CFR 507.22 describes the CGMP requirements for equipment and utensils. All equipment and utensils used in the manufacturing, processing, packing, and holding of animal food must be:

- Designed and constructed to be adequately cleaned (this includes equipment and utensils that do not come into direct contact with animal food)
- Properly maintained
- Designed, constructed, and used in such a way to avoid the adulteration of animal food with any contaminants
- Installed in such a way to allow for cleaning and maintenance of both the equipment and the adjacent spaces.

21 CFR 507.22 – Equipment and Utensils

- (4) *Animal food-contact surfaces must be:*
 - (i) *Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;*
 - (ii) *Made of nontoxic materials; and*
 - (iii) *Maintained to protect animal food from being contaminated.*
- (b) *Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way to protect against the contamination of animal food.*
- (c) *Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-monitoring device.*



Animal food contact surfaces must be:

- Made of materials that can withstand the environment, animal food, and any cleaning compounds and procedures
- Made of nontoxic materials
- Maintained to protect against contamination

All systems, including holding, conveying, and manufacturing/processing systems, must be designed, constructed, and maintained to protect against contamination of animal food. Such systems could include components such as ingredient storage bins, bucket elevators, and thermal processing equipment.

For applicable facilities, each freezer or cold storage holding animal food must have a method to accurately monitor the temperature. The monitoring instrument could be as simple as an individual thermometer, or as sophisticated as an automated system that continuously monitors the temperature and initiates an alarm when an unsafe condition exists.

Example – Equipment and Utensils

- Equipment, storage, conveyors, and utensils, such as brooms, shovels, scoops, must be in good physical condition so they are not a source of contamination themselves.
- Select equipment and utensils made of materials that will withstand the conditions of use in the facility.



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Equipment and utensils should be maintained so that they do not become a source of contamination. This includes keeping items in good physical condition so that broken or corroded pieces do not fall off and contaminate the animal food. It also includes keeping items clean, especially those utensils and pieces of equipment that may be used in multiple areas and/or with multiple types of animal foods. A facility may consider labeling any specific use utensils to reduce cross contamination concerns.

It is important to select equipment and utensils that are constructed of materials that will not easily deteriorate under the conditions of use. For example, equipment or utensils used in a wet environment should be constructed of suitable materials that will not readily corrode or deteriorate under wet conditions.

21 CFR 507.22 – Equipment and Utensils

- *(d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, a_w or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.*
- *(e) Compressed air or other gasses mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food.*



Any instruments used for measuring, regulating, or recording conditions (such as pH or water activity(a_w)) that control or prevent the growth of undesirable microorganisms must be accurate, precise, adequately maintained, and adequate in number for their intended use.

Any compressed air or other gasses employed in the manufacture of an animal food or for cleaning purposes must be used in a way that protects against contamination of animal food.

Example – Equipment and Utensils

- Thermometers used with freezers and cold storage, or other instruments to maintain specific environmental conditions associated with preventing animal food hazards, must be effective.
- Compressed air should be used cautiously when cleaning so as to protect against the contamination of animal food.



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In any situation where a device, such as a thermometer or pH meter, is being used to monitor and maintain conditions related to animal food safety, it is very important that the devices are accurate, precise, and adequately maintained. A poorly functioning device is likely to do more harm than good by providing inaccurate information. It is also important that the facility has enough devices for their designated uses. For example, if a facility has two production lines that need to reach certain temperatures to control the growth of undesirable microorganisms, the facility should have a temperature-measuring device for each production line.

Compressed air can be a popular way to clean large areas, especially when some surfaces are hard to reach. In addition to following safety protocols related to dust-explosion hazards, compressed air must be used in a manner that protects against the contamination of animal food. If contamination cannot be avoided, other methods of cleaning, such as sweeping or vacuuming, must be used.

21 CFR 507.25 – Plant operations

- *(a) Management of the establishment must ensure that:*
 - *(1) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with current good manufacturing practice requirements of this subpart;*
 - *(2) Animal food, including raw materials, other ingredients, or rework is accurately identified;*
 - *(3) Animal food-packaging materials are safe and suitable;*
 - *(4) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;*



21 CFR 507.25 introduces the CGMP requirements related to general facility operations. The first part of the requirements focuses on the responsibilities of management (21 CFR 507.25(a)). These responsibilities include ensuring that:

- All establishment operations are conducted in accordance with CGMP requirements
- All animal food, which includes ingredients and raw materials, is accurately identified
- Packaging materials are safe and suitable for the intended use
- Facility cleanliness is under proper and assigned supervision

21 CFR 507.25 – Plant operations

- (5) Adequate precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food-packaging materials;
- (6) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;
- (7) Animal food that has become adulterated is rejected, disposed of, or if appropriate, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and
- (8) All animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food.



Continuing from the previous slide, management is also responsible for ensuring that:

- Adequate precautions are taken to prevent facility operations from contributing to contamination of animal food, contact surfaces, or packaging materials
- Testing procedures are used as necessary to identify sanitation failures or animal food contamination
- Any adulterated animal food is either disposed of in such a way that does not contaminate other animal food, or is appropriately treated or processed to eliminate the adulteration
- Operations are conducted under conditions and controls deemed necessary to protect against the contamination of animal foods by undesirable microorganisms

21 CFR 507.25 – Plant operations

- *(b) Raw materials and other ingredients:*
 - *(1) Must be examined to ensure that they are suitable for manufacturing and processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration. In addition:*
 - *(i) Shipping containers (e.g. totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be examined upon receipt to determine whether contamination or deterioration of animal food has occurred;*
 - *(ii) Raw materials must be cleaned as necessary to minimize contamination; and*
 - *(iii) Raw materials and other ingredients, including rework, must be stored in containers designed and constructed in a way that protects against contamination and deterioration and held under conditions, e.g. appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated.*



The second part of 21 CFR 507.25 – Plant Operations requirements focuses on raw materials and other ingredients (21 CFR 507.25(b)). All raw materials and other ingredients must be examined to ensure they are suitable for the animal food being manufactured. Materials must also be handled in such a way to protect against contamination and minimize deterioration. In addition:

- All containers and bulk vehicles holding incoming raw materials and ingredients must be examined at receiving to determine if any contamination or deterioration has obviously occurred
- As necessary, raw materials must be cleaned to minimize contamination
- All raw materials and rework must be stored in such a way that protects against contamination, deterioration, and potential adulteration due to the growth of undesirable microorganisms

21 CFR 507.25 – Plant operations

- *(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans; and*
- *(3) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for growth of undesirable microorganisms.*



Any raw materials susceptible to natural toxins, most commonly mycotoxins, must be evaluated and used in such a way that both human and animal health is protected.

For any raw material that is frozen, it must remain frozen until use, at which time any thawing must be done in a way that minimizes the potential for growth of undesirable microorganisms.

Note – Inbound Ingredient Evaluation

- Preamble points:
 - Weather can be considered when evaluating raw materials susceptible to mycotoxin contamination.
 - Not every load of grain needs to be tested as long as evaluation results in the facility using ingredients in a manner that does not result in harm to humans or animals.
 - Visual examination of ingredients or shipping containers is acceptable, with emphasis on observing any unusual residues that may contaminate the animal food.



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Some specific points raised for inbound ingredient evaluation in the preamble to the *Preventive Controls for Animal Food* rule include:

- When considering the need to evaluate incoming raw materials that are susceptible to mycotoxins, an establishment can take into consideration current weather-related information. For example, if conditions were not favorable for mycotoxins, less frequent observation may be warranted.
- Using mycotoxins as an example, every load of grain is not required to be tested; rather, the requirement is that some method be established to ensure that the facility uses potentially affected ingredients in a manner that protects both human and animal health.
- Visual examination may be a perfectly acceptable method of examining both ingredients and containers, so long as there is an emphasis on looking for unusual characteristics, properties, or residues that may indicate contamination. For example, gnawed packaging may indicate that the ingredient has been potentially contaminated by rodents.

21 CFR 507.25 – Plant operations

- *(c) For the purposes of manufacturing, processing, packing, and holding operations, the following apply:*
 - *(1) Animal food must be maintained under conditions, e.g. appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;*

The last section of 21 CFR 507.25(c) is more general in nature and lists requirements for manufacturing, processing, packing, and holding. During manufacturing, processing, packing, and holding, all animal food must be maintained under conditions that minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated. There are eight sub-bullets under 507.25(c) which will be covered in the next three slides.

21 CFR 507.25 – Plant operations

- (2) Measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (e.g., heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling a_w) must be adequate to prevent adulteration of animal food;
- (3) Work-in-progress and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms;
- (4) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food;



Specific measures may be taken during the manufacturing, processing, packing, and holding of animal food to minimize or prevent the growth of undesirable microorganisms. These measures might include heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling a_w . If any of these methods are used for the specific purpose of addressing the growth of undesirable microorganisms, they must be adequate to prevent adulteration.

During the manufacturing process, any work-in-progress or rework must be handled so as to protect against contamination and the growth of undesirable microorganisms.

All processing steps must be performed in a way that protects against contamination.

21 CFR 507.25 – Plant operations

- (5) *Filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms;*
- (6) *Animal food that relies principally on the control of water activity (a_w) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe a_w level;*
- (7) *Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and*
- (8) *When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.*



All filling and packaging operations must be performed in a way that protects against contamination and the growth of undesirable microorganisms.

Animal food that relies on either a_w and/or pH to prevent the growth of undesirable microorganisms must be processed, monitored, and maintained at safe and appropriate levels.

If ice is to be used in manufacturing, processing, packing, or holding, and it will come into contact with animal food, it must be made from a safe source of water in accordance with CGMP requirements.

Example – Plant operations

- Conduct appropriate evaluations to ensure inbound materials are safe
 - Raw materials must be evaluated for suitability, and shipping containers inspected to verify adulteration has not occurred.
- Hold materials in a safe manner
 - Flushes, rework, and rejected feed must be identified and utilized or disposed of appropriately.
 - Work-in-progress and rework must be protected from contamination and growth of biological hazards.
- Manufacture in a way to ensure safety
 - Reliance on water activity or pH to prevent growth of biological hazards must be monitored.



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In general terms, the CGMP requirements related to facility operations require an establishment to evaluate inbound materials to make sure they are safe. Evaluation may include:

- Reviewing specifications, guarantees, or other associated information received by the facility
- Performing a visual check of the animal food or its packaging
- Performing relevant sampling and testing
- Checking incoming temperatures for refrigerated or frozen ingredients

The CGMP requirements also stipulate that a facility hold all the materials in safe manner. All materials, including those such as flushes, rework, and rejected food must be accurately identified. Identification may include labeling, computer systems, paper records, chalkboards, and other methods. Note that in the preamble to the final rule, FDA states bulk silos and bins are not required to be placarded, because this is impractical and not a common industry practice. Materials in bulk bins and silos may be identified by any effective means, such as being able to identify bulk bin or silo contents using an electronic monitoring system. Facility personnel should be able to accurately identify animal food, including raw materials, other ingredients, rework, or finished animal food within the facility so that animal food is not commingled, substituted, or incorrectly formulated in a manner that results in adulterated animal food.

Finally, the facility must manufacture animal foods using processes that will not lead to contamination or adulteration.

21 CFR 507.27 – Holding and Distribution

- *(a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:*
 - *(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of animal food; and*
 - *(2) Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.*



21 CFR 507.27 provides the CGMP requirements for holding and distribution. All animal food must be held under conditions that will protect against contamination and deterioration. These conditions and practices include containers being designed, appropriately constructed, cleaned as necessary, and maintained to protect against contamination, and holding animal food for distribution so that it does not become contaminated by sources such as trash.

According to the GFI #235, some factors to consider when developing practices to protect animal food against contamination during holding can include:

- Identification of animal food so it is not mistaken as trash
- Proximity of the animal food to potential sources of contamination, such as trash, waste, and rework
- Accessibility of clearly marked trash receptacles

21 CFR 507.27 – Holding and Distribution

- *(b) The labeling for the animal food ready for distribution must contain, when applicable, information and instructions for safely using the animal food for the intended animal species.*
- *(c) Shipping containers (e.g. totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food.*
- *(d) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.*
- *(e) Unpackaged or bulk animal food must be held in a manner that does not result in unsafe cross contamination with other animal food.*



When an animal food is ready for distribution, animal food labeling must contain, when applicable, information and instructions related to the safe use of the animal food for the intended animal species.

All shipping containers and bulk vehicles must be examined prior to use when the facility is responsible for transport or arranges transport with a third party.

Any animal food returned from distribution must be identified, segregated, and evaluated for safety to determine the appropriate disposition.

Any unpackaged or bulk animal food must be held in such a way that does not result in any unsafe cross contamination with other animal foods.

21 CFR 507.28 – Holding and Distribution of Human Food By-Products for Use as Animal Food

- *(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:*
 - *(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;*
 - *(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and*
 - *(3) During holding, human food by-products for use as animal food must be accurately identified.*



21 CFR 507.28 provides requirements for holding and distribution of human food by-products for use as animal food.

Examples of human food by-products that are used as animal food from GFI #235, include:

- Wheat middlings generated in processing wheat for flour
- Grain products (e.g. hulls, bran, and germ) from other grain processing operations
- Peels, rinds, pumace, 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.

This provision only applies to human food facilities that meet the conditions in 21 CFR 507.12. These facilities only have to follow these holding and distribution requirements for their human food by-products for use as animal food. These requirements are very similar to the previous holding and distribution requirements for all other animal food facilities outlined in 21 CFR 507.27. In this slide, only the last bullet is a significant addition from the requirements in 21 CFR 507.27, and states that during holding, human food by-products for use as animal food must be

accurately identified. Regardless of how the human food by-product for use as animal food is labeled, the intent is to distinguish animal food from trash or material for other uses.

21 CFR 507.28 – Holding and Distribution of Human Food By-Products for Use as Animal Food

- *(b) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.*
- *(c) Shipping containers (e.g. totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.*



In this slide, the only difference of significance from the holding and distribution requirements in 21 CFR 507.27 is that the labeling for human food by-products is required to identify the product by the common or usual name when the by-product is distributed.

Example – Holding and Distribution

- For holding and distribution of ingredients, human food by-products for use in animal food, or animal food, it is required that:
 - Containers are appropriate to protect against contamination.



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The general CGMP requirements for the holding and distribution of ingredients, human food by-products, and animal food are that:

- Containers and bulk vehicles are appropriate to protect against contamination of the animal food, such as by microbial growth or physical contaminants. They must be designed, constructed of appropriate material, cleaned as necessary, and properly maintained.
- Facilities may use different container cleaning methods and frequency of cleaning, repair, or replacement depending on the animal food held and the facility'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.

Example – Holding and Distribution

- For holding and distribution of ingredients, human food by-products for use in animal food, or animal food, it is required that:
 - Containers and bulk vehicles must be examined prior to use.



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Containers and bulk vehicles must be examined prior to use when the facility is the shipper. This examination could include looking at the shipping container or vehicle to observe whether there are any residues in it that may contaminate the ingredients, human food by-product for use as animal food, or animal food. When a visual examination is not practical, the facility should know what the shipping container or vehicle had previously been used for and because of that, whether the container needs 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.

When the facility is the shipper they are responsible for examining containers prior to use. However, when the customer arranges the shipping, examination is not required by the facility. However, the *Sanitary Transportation of Human and Animal Food* rule requires facilities that load animal food to determine that transportation equipment, such as trucks or railcars, is in appropriate sanitary condition, regardless if the loading facility arranged for the conveyance or not.

CGMP Regulations Summary

- CGMP regulations provide the foundation necessary for production of safe animal food.
- CGMP regulations are required, and most are managed outside the Food Safety Plan.
- It is important to understand the specific requirements, and train as necessary in order that all individuals involved understand and effectively implement CGMP regulations.



In summary, the CGMP requirements provide the foundation necessary for the production of safe animal food. While CGMP requirements must be implemented in accordance with the *Preventive Control for Animal Food* rule, they are managed outside of the Food Safety Plan and do not require documentation. However, because the CGMP covers all areas of animal food manufacturing, including personnel, facilities, and operations, it is vitally important that the specifics are understood, and that all individuals involved in the manufacturing, processing, packing, and holding of animal food are trained as necessary in order to effectively carry out their assigned duties in a manner that satisfies the requirements.