

Current Good Manufacturing Practice



Adapted from Chapter 2 of "Preventive Controls for Animal Food" by Food Safety Preventive Controls Alliance, 2016.

OFFICE OF THE TEXAS STATE CHEMIST

TEXAS A&M GRILIFE RESEARCH

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

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

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

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 Byproducts 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.

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





21 CFR 507.17 – Plant and Grounds

- (a) The grounds around an animal food plant under the control of 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.

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 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.

Example – Plant and Grounds

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





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.

Example – Plant and Grounds

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



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.

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.





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.

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.



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.

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.

Adequate Water

Water must be:

- Adequate for operation, from an adequate source
- Provides sufficient temperature and water volume to support facility operations
- Safe for intended use if it contacts animal food, animal foodcontact 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

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 for 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.

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 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.

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 hand-washing facilities may be necessary depending on the operation.

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 equipment and 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.

Example – Equipment and Utensils

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



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.

Example – Equipment and Utensils

Temperature off 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.

- (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 supervision of one or more competent individuals assigned responsibility for this function;

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

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

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

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

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

- (5) Filling, assembling, packaging, and other operations must be performed in such as 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.

Example – Plant Operations

- Where appropriate, 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.



- 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.





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 - 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.

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 – 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 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 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.

Example – Holding and Distribution

For holding and distribution of ingredients, human food byproducts for use in animal food, or animal food, it is required that containers are appropriate to protect against contamination.





Example – Holding and Distribution

For holding and distribution of ingredients, human food byproducts for use in animal food, or animal food, it is required that containers and bulk vehicles must be examined prior to use.





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.



END

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