

**National Grain
and Feed Association**

Current Good Manufacturing Practices (CGMPs)

Food Safety Modernization Act Informational Seminar

March 10, 2016



**CALIFORNIA
GRAIN
& FEED
ASSOCIATION**

Disclaimer

- Some regulatory text from the final rule is included in this presentation, but not all text is provided! Also, in many instances the text provided is abridged to make it more brief and emphasize major concepts.
- Bottom line – this is a complicated rule and this presentation does not cover all aspects or all requirements!



CGMPs: Some History

- Medicated Feed CGMPs (21 CFR Part 225) were developed by FDA in 1976
- CGMPs published by the Association of American Feed Control Officials (AAFCO)
 - Development began in 1999, published in 2010 – only adopted by two states
 - Modeled after medicated feed CGMPs



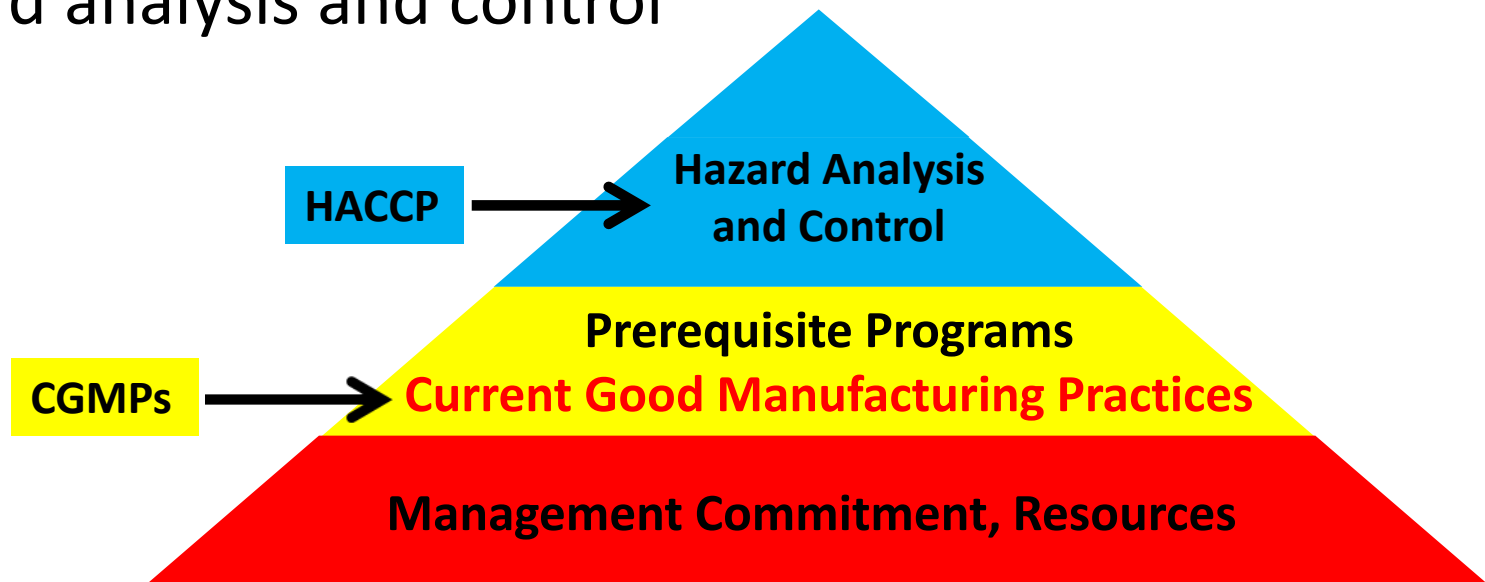
CGMPs: Some History

- FDA during its CGMPs rulemaking process referenced:
 - AAFCO CGMPs – found in AAFCO Official Publication
 - Codex Animal Production and Health Manual of Good Practices – available for download from Food and Animal Organization
 - British Standards Institute PAS 222: Prerequisite Programs for Food Safety in the Manufacturing of Food and Feed for Animals – available for download at BSI



CGMPs – What Are They All About?

- Key Elements of Effective Food Safety Plans
 - Management responsibility and commitment
 - **CGMPs**
 - Prerequisite programs
 - Hazard analysis and control



CGMPs – What Are They All About?

- Required conditions and practices to ensure that animal feed/pet food will not become adulterated
- Serve as a foundation for an effective food safety plan



CGMPs for Animal Food

- **PART 507—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals:**
 - Subpart A: General Provisions
 - **Subpart B: Current Good Manufacturing Practices (CGMPs)**
 - Subpart C: Hazard Analysis and Risk-Based Preventive Controls
 - Subpart D: Withdrawal of a Qualified Facility Exemption
 - Subpart E: Supply-Chain Program
 - Subpart F: Requirements Applying to Records That Must Be Established and Maintained



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21 CFR Parts 11, 16, 117, *et al.*

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Final Rule



Subpart B – CGMPs: Exemptions

1. Farms
2. Establishments **solely engaged in the holding** and/or transportation of one or more raw agricultural commodities other than fruits or vegetables (e.g., grain elevators)
3. Establishments **solely** engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts)
4. Establishments **solely** engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed)



Subpart B – CGMPs

- **Eight sections that establish requirements for follow conditions/practices:**
 - **§ 507.14 Personnel** – cleanliness and training
 - **§ 507.17 Plant and Grounds** – maintenance, design, construction
 - **§ 507.19 Sanitation** – housekeeping, cleaning, pest control
 - **§ 507.20 Water supply and plumbing** – water quality, plumbing design, rubbish control
 - **§ 507.20 Equipment and utensils** – maintenance, design, construction
 - **§ 507.25 Plant operations** – labeling, inspection of raw materials, ingredients, protection against metal/foreign objects
 - **§ 507.27 Holding and distribution** – storage and transportation
 - **§ 507.28 Holding and distribution of human food by-products for use as animal food**



Subpart B – CGMPs

- Approximately **85 provisions** establish a variety of requirements; **but** there's flexibility – not all apply to all facilities....
 - **4 provisions** contain the word “suitable”
 - **11 provisions** contain the word “appropriate”
 - **16 provisions** contain the word “adequate”
 - **14 provisions** use the phrases “as necessary”, “where necessary” and “when necessary”
- Flexibility is necessary so that CGMPs can be applied to the broad range of animal food facilities covered by the rule



§ 507.14 Personnel

- (a) The management ... must take reasonable measures and precautions to ensure that all persons ... 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
 - (5) Taking any other **necessary** precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials



§ 507.14 Personnel

- (b) The methods for conforming to hygienic practices and maintaining cleanliness include:
- (2) Washing hands thoroughly in an **adequate** hand-washing facility **as necessary** and **appropriate** to protect against contamination
 - FDA (from preamble): We [FDA] recognize that there may be some situations where hand washing facilities are not readily available. The use of waterless hand cleaners (including hand sanitizers) may be adequate under these circumstances.



§ 507.14 Personnel

- (b) The methods for conforming to hygienic practices and maintaining cleanliness include:
 - (4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned
- FDA (from preamble): We [FDA] understand that personnel may need layers of clothing in certain plants that are exposed to varying temperatures. However, when clothing is removed, it needs to be stored away from exposed animal food so it does not become a source of contamination.



§ 507.17 Plant and Grounds

- (a) The grounds ... must be kept in a condition that will protect against the contamination of animal food ...
 - e.g., properly store equipment, controlling weeds and maintaining grass; removing litter and waste, eliminating standing water
- (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 ...
 - Providing **adequate** space, **adequate** ventilation **where necessary** and **appropriate, adequate** lighting; shatter-resistant glass in areas where animal food is exposed
 - FDA (from preamble): We (FDA) do not intend that existing plants must be redesigned or reconstructed



§ 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
 - (3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food



§ 507.19 Sanitation

- (a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated
- (b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained ... to protect against the contamination of animal food... **When necessary**, equipment must be disassembled for thorough cleaning
- (c) Cleaning compounds and sanitizing agents must be safe and **adequate** under the conditions of use

§ 507.19 Sanitation

- (d)(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
 - (iv) Those **necessary** for use in the plant's operations
- (d)(2) Toxic materials ... must be identified, used, and stored in a manner that protects against the contamination of animal food



§ 507.19 Sanitation

- (d)(3) Other toxic materials (such as fertilizers and pesticides) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed
- FDA (from preamble): We [FDA] expect that this will result in [other] 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



§ 507.19 Sanitation

- (e) Effective measures must be taken to exclude pests ... to protect against the contamination of animal food ...
- (f) Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food ... and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests

§ 507.20 Water supply and plumbing

- (a)(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 ...
- (3) Water must be safe for its intended use ...



§ 507.20 Water supply and plumbing

- (c) Sewage and liquid disposal waste must be disposed of through an **adequate** sewerage system or through other **adequate** means
- (d) Each plant must provide employees with **adequate**, readily accessible toilet
 - FDA (from preamble): We [FDA] understand that ... toilet facilities [may not be] inside a plant, but we believe it is important that toilet facilities are available near the plant for employee use ...

§ 507.20 Water supply and plumbing

- (e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination ...
- FDA (from preamble): We [FDA] understand that there may not be running water in every plant ... [I]n some cases hand-washing facilities might consist of waterless hand cleaners (including hand sanitizers)

§ 507.22 Equipment and utensils

- (a)(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 ... adulteration ... with non-food lubricants, fuel, metal fragments, contaminated water, or any other contaminants

§ 507.22 Equipment and utensils

- (3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces
- (4) Animal food-contact surfaces must be:
 - (i) Made of materials that withstand ... their use and the action of animal food, and, if applicable, ... cleaning compounds, cleaning procedures, and sanitizing agents
 - (ii) Made of nontoxic materials
 - (iii) Maintained to protect animal food from being contaminated



§ 507.22 Equipment and utensils

- (c) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device
 - FDA (from preamble): We [FDA] do not intend the establishment to use a continuous monitoring device or temperature recording device
- (e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food



§ 507.25 Plant operations

- (a)(2) Animal food, including raw materials, other ingredients, or rework is **accurately** identified
- FDA (from preamble): We [FDA] clarify that bulk silos and bins are not required to be placarded, because this is impractical and not industry practice
- (a)(4) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function

§ 507.25 Plant operations

- (a)(6) Chemical, microbial, or extraneous-material testing procedures are used **where necessary** to identify sanitation failures or possible animal food contamination
- FDA (from preamble): Using testing procedures, where necessary, to identify sanitation failures or to identify contaminated animal food may be an important component of manufacturing, processing, packing, or holding animal food. This type of testing may be independent of the requirements of subpart C, hazard analysis and risk based preventive controls, and therefore we have included it in the CGMP regulations.



§ 507.25 Plant operations

- (b)(1) Raw materials and other ingredients 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
- FDA (from preamble): An examination of raw materials and other ingredients may include basic activities such as a simple visual examination of the product (e.g., looking for broken bags), or performing a chemical or microbial analysis



§ 507.25 Plant operations

(b) Raw materials and other ingredients:

(1)(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

- FDA (from preamble): [O]ur [FDA] intent [is] that incoming containers consistently be checked to make sure there is no gross visible contamination or deterioration of animal food



§ 507.25 Plant operations

(b) Raw materials and other ingredients:

(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not ... cause injury or illness to animals or humans

- FDA (from preamble): We [FDA] do not intend that every load of grain received must be tested before it can be used. We intend for “evaluation” to be broad and flexible enough to consider any information that allows the plant to use the raw materials and other ingredients in a manner that does not result in harm to humans or animals. For example, an evaluation could be based on a general review of the weather conditions during the growing season and whether it could result in mycotoxins.



§ 507.25 Plant operations

- (c)(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
- (c)(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

§ 507.27 Holding and distribution

- (a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration
 - (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

§ 507.27 Holding and distribution

- (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
 - FDA (from preamble): This examination could include viewing the shipping container or vehicle to observe whether there are any unusual residues in it that may contaminate the animal food, or it could be simply knowing 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. We [FDA] do not expect a plant or facility to examine the shipping container or bulk vehicle when a customer transports the animal food or arranges for a third-party to pick up the animal food.



§ 507.27 Holding and distribution

- (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.
- FDA (from preamble): This returned animal food could contain hazards resulting in contamination that could result in a food safety concern. If redistributed prior to assessment, depending on the nature and severity of the contamination, it could result in injury (or death) to animals.



§ 507.28 Holding and distribution of human food by-products for use as animal food

- Human food processors do not need to implement additional preventive controls or CGMP regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except to prevent physical and chemical contamination when holding and distributing the by-product.
- However, further processing a by-product for use as animal food (e.g., drying, pelleting, heat-treatment) requires companies to process the by-product in compliance with CGMPs to ensure the animal food's safety and to make sure that the processing does not introduce hazards to the animal food. The company can choose to follow either the human food or animal food CGMPs when further processing the by-product.



§ 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
 - (3) During holding, human food by-products for use as animal food must be accurately identified
- (b) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed

§ 507.28 Holding and distribution of human food by-products for use as animal food

- 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



Compliance Dates for **CGMPs** and PCs

Business Size	CGMPs Compliance Date	Preventive Controls Compliance Date
Business Other than Small and Very Small	1 year – Sept. 19, 2016	2 years – Sept. 18, 2017
Small Business	2 years – Sept. 18, 2017	3 years – Sept. 17, 2018
Very Small Business	3 years – Sept. 17, 2018	4 years – Sept. 17, 2019

- **Small Business:** A business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees. The rule specifies that all employees within the business and all of its subsidiaries and affiliates, regardless of whether an employee is involved in animal food-related activities, is to be counted in this determination.



Current Good Manufacturing Practices

David Fairfield

Senior Vice President, Feed Services

National Grain and Feed Association

Email: dfairfield@ngfa.org

Phone: (712) 243-4035

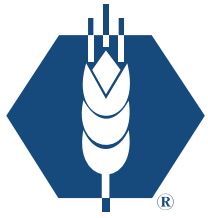
Matt Frederking

Vice President, Regulatory Affairs and Quality

Ralco Animal Nutrition

Email: Matt.Frederking@ralconutrition.com

Phone: (507) 532-5748



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