National Grain and Feed Association

Overview of CGMPs and Preventive Controls

Food Safety Modernization Act Informational Seminar

March 10, 2016

SAFE ANIMAL FEED EDUCATION

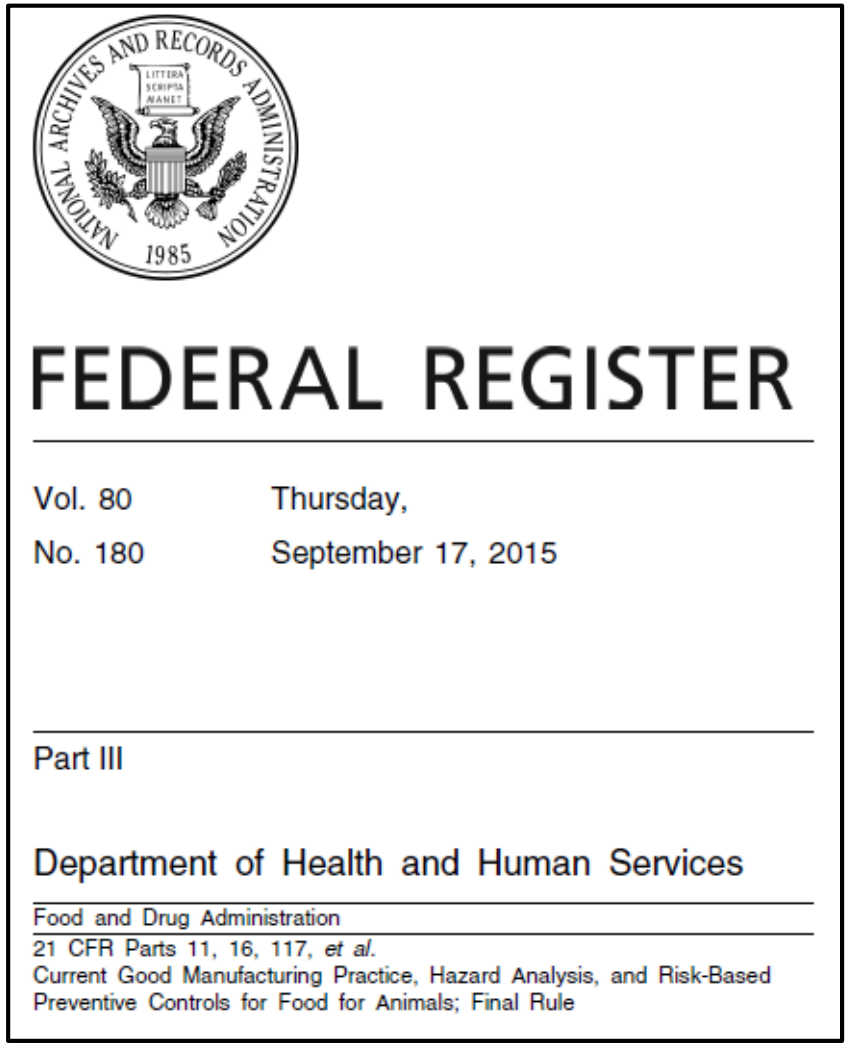
CALIFORNIA GRAIN & FEED ASSOCIATION

Presentation Outline

- Overview of CGMP and Preventive Control Rule
- Review of Exemptions and Modified Requirements
- Qualified Individual Requirements

CGMPs and Preventive Controls 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**



NATIONAL ARCHIVES AND RECORDS ADMINISTRATION 1985

FEDERAL REGISTER

Vol. 80 Thursday,
No. 180 September 17, 2015

Part III

Department of Health and Human Services

Food and Drug Administration

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

CGMPs Requirements

- CGMPs establish ***new*** requirements for animal feed/pet food facilities
  - All other applicable regulations still apply
    - BSE-Prevention requirements
    - 21 CFR Part 225 CGMPs
    - Others …

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C--DRUGS: GENERAL
PART 225 CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

CGMPs Requirements

- **CGMPs** – Required conditions and practices to ensure that animal feed/pet food will not become adulterated
- **FDA and CGMPs**
  - No recordkeeping requirements for CGMPs
  - *Generally*, CGMPs that are required under the final rule are things that can be observed
  - For the purposes of consistent terminology, FDA has suggested that a requirement that has need of documentation similar to what is in Part 225 (medicated feed) and the BSE rule and that keeps a hazard from entering the process or occurring in the process, be thought of as a **prerequisite program** and not **CGMPs**

Exempt from CGMPs

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)

Solely Engaged in Holding

- The definition of "holding" expressly "includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity))"
- Examples of activities cited by FDA as being incidental to "holding" of grain include:
  - Drying grain
  - Fumigating grain
  - Cleaning grain
  - Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation
  - Using modified atmosphere treatments to control pests
  - Using biological controls for pests
  - Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds
  - Weighing grain
  - Blending grain
  - Sampling and grading grain Aerating grain to control temperature

Preventive Control Requirements

- Preventive control requirements mandate that animal food facilities identify and evaluate ***"known and reasonably foreseeable 'hazards'"*** associated with the facility and its animal food and implement one or more "***preventive controls"*** and components to manage such controls (monitoring, verification, corrections and corrective actions, records, and recall plans) for ***"hazards requiring a preventive control"***
- A **written food safety plan** must be developed

§ 507.3 – Definitions

- ***Hazard*** means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals
- ***Known or reasonably foreseeable hazard*** means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food

§ 507.3 – Definitions

- ***Preventive controls*** means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to **significantly minimize or prevent** the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis

§ 507.3 – Definitions

- ***Hazard requiring a preventive control*** means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system

Exempt from Preventive Controls

- Farms
- Facilities **solely engaged in the holding** of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, e.g., grain elevators
- Facilities **solely** engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens

Subject to Modified PC Requirements

- ***Very Small Business***: A business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).

Subject to Modified PC Requirements

- A ***Very Small Business*** is subject to modified requirements:
  - Attest the facility is a ***very small business***; **and**
  - Attest that the facility has identified hazards and that preventive controls have been implemented and are being monitored; **or**
  - Attest that the facility is in compliance with an applicable non-federal feed safety law.
  - All required attestations are to be submitted to FDA

Qualified Individual Requirements

- Individuals who manufacture, process, pack, or hold animal food subject to the rule are to be qualified to perform their assigned duties
  - Each individual (including temporary, seasonal and contract personnel) must:
    1. Have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties; and
    2. Receive training in the principle of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, and the facility

Qualified Individual Requirements

- Rule does not specify the frequency of training, but FDA expects training to occur before working in production operations and periodic refresher training thereafter
- Rule requires that training records are to be maintained for at least two years
- Rule does not prescribe the content of training records
- FDA expects much of the training will be provided in-house by knowledgeable employees; no requirement for outside trainers
- FDA expects the training materials being developed by the Food Safety Preventive Controls Alliance (FSPCA) to be useful for training purposes; FSPCA materials will be available online, and available for free download

Overview of CGMPs and Preventive Controls

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