What you need to know about FSMA

FDA’s Final Rule for CGMPs and Preventive Controls for Animal Feed and Pet Food

NGFA and Grain Journal Journal Webinar

Oct. 5, 2015
Presentation Outline

1. Status of Major FSMA Rulemakings
2. General Applicability of Rules
3. FDA’s revised Farm Definition
4. Current Good Manufacturing Requirements for Animal Feed and Pet Food
5. Risk-Based Preventive Control Requirements for Animal Feed and Pet Food
6. Supply-Chain Program Requirements for Animal Feed and Pet Food
7. Compliance Dates for Requirements
8. Guidance and Training Resources
<table>
<thead>
<tr>
<th>Subject of Rule</th>
<th>Date for Issuing Final Rule</th>
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<tbody>
<tr>
<td>Current Good Manufacturing Practice (CGMPs) and Preventive Controls - Animal Feed</td>
<td>Aug. 30, 2015 (Sept. 17, 2015)</td>
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<td>Foreign Supplier Verification Programs</td>
<td>Oct. 31, 2015</td>
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<td>Sanitary Transportation of Food/Feed</td>
<td>March 31, 2016</td>
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Coverage of FSMA Rules

• Applicability of Proposed Rules – Top Tier:
  • CGMPs/Preventive Controls: Generally applies to facilities required to register as a “food facility” with FDA under Bioterrorism Act requirements
  • Foreign Supplier Verification Program: Applies to importers bringing food/feed into United States, regardless of whether entities are required to register as food facilities with FDA
  • Sanitary Transportation of Food: Applies to non-farm shippers, carriers (truck and rail), and receivers of food/feed, interstate and intrastate
Coverage of FSMA Rules

• **Exemptions:**
  
  • Farms, as defined by regulation, are exempt from Bioterrorism Act facility registration requirements
  
  • Final FSMA rules also will include additional exemptions or modified requirements, as prescribed by the individual regulations
**Updated Farm Definition**

Farm means:

1) **Primary production farm.** A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

   i) Pack or hold raw agricultural commodities;

   ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

   iii) Manufacture/process food, provided that:

      A) All food used in such activities is consumed on that farm or another farm under the same management; or

      B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

         (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

         (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

         (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); OR
Updated Farm Definition

**Farm means:**

2) **Secondary activities farm.** A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.
Final CGMPs and Preventive Controls for Animal Feed – Overview

- 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
Final CGMPs and Preventive Controls for Animal Feed – Overview

• **New Training and Qualification Requirements:**
  - Individuals who manufacture, process, pack, or hold animal feed subject to the rule are to be qualified to perform their assigned duties
    - Each individual (including temporary and seasonal personnel), as appropriate to their assigned duties, must:
      1. Have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal feed; and
      2. Receive training in the principle of animal feed hygiene and animal feed safety, including the importance of employee health and personal hygiene, as appropriate to the animal feed, and the facility
  - FDA expects training to occur before working in production operations and periodic refresher training thereafter
  - Training records are to be maintained for at least two years
Final CGMPs Requirements – Overview

• **CGMPs** – Required conditions and practices to ensure that animal feed/pet food will not become adulterated

• **New** CGMPs requirements for animal feed/pet food facilities
  
  • Overarching requirements for all covered facilities
  
  • 21 CFR Part 225 CGMPs for medicated feed still apply

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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
Final CGMPs Requirements – Overview

- Establish requirements for follow conditions/practices:
  - Personnel – cleanliness and training
  - Plant and grounds – maintenance, design, construction
  - Sanitation – housekeeping, cleaning, pest control
  - Water supply and plumbing – water quality, plumbing design, rubbish control
  - Equipment and utensils – maintenance, design, construction
  - Plant operations – labeling, inspection of raw materials, ingredients, protection against metal/foreign objects
  - Holding and distribution – storage and transportation
  - Holding and distribution of human food by-products for use as animal feed
Some Key CGMP Provisions

• Personnel are to maintain adequate personal cleanliness, including washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against animal feed contamination.

• The overall cleanliness of the plant is to be under the supervision of one or more competent individuals assigned responsibility for this function.

• Materials not used in animal feed or those not necessary for plant and equipment maintenance and operation (e.g., fertilizers and pesticides) must be stored in an area of the plant where animal feed is not manufactured, processed, or exposed.

• Raw materials and other ingredients:
  • Must be examined to ensure that they are suitable for manufacturing and processing into animal feed and must be handled under conditions that will protect against contamination and minimize deterioration.
  • Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal feed that can cause injury or illness to animals or humans.
Some Key CGMP Provisions

• Water must be adequate for the facility’s operations, must be derived from an adequate source, and must be safe for its intended use.

• Plumbing must be designed, installed, and maintained to avoid being a source of contamination to animal feed, water supplies, equipment, or utensils, or creating an unsanitary condition.

• Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal feed must be examined prior to use to protect against the contamination of animal feed from the container or vehicle.

• Animal feed returned from distribution must be assessed for animal feed safety to determine the appropriate disposition. Returned animal feed must be identified as such and segregated until assessed.
Exempt from CGMPs

1. Farms
2. Establishments *solely* engaged in the holding and/or transportation of one or more raw agricultural commodities (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” 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
Final Preventive Controls for Animal Feed – Overview

• Requires covered facilities to develop and implement a written animal feed safety plan
  • Plan to be developed and overseen by a preventive controls qualified individual
    • Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA (Food Safety Preventive Controls Alliance), or is otherwise qualified through job experience to develop and apply a feed safety system.
Final Preventive Controls for Animal Feed – Overview

• Animal Feed Safety Plan to include a written hazard identification and analysis
  • Evaluation of “known or reasonably foreseeable hazards” – physical, chemical (radiological), biological, including those associated with intentional economic adulteration

• Plan to include implementation of controls effective in preventing any hazard identified during the hazard evaluation as being a hazard requiring a preventive control from adulterating product
Hazard Requiring a Preventive Control

- **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.
Hazard Evaluation Process

Universe of Hazards (human and animal)

Known or Reasonably Foreseeable Hazards

Preventive Controls Qualified Individual

Known or Reasonably Foreseeable Hazards

Likelihood and Severity

Hazard Requiring a Preventive Control

National Grain and Feed Association
Final Preventive Controls for Animal Feed – Overview

• **If a hazard requiring a preventive control** is identified, then a preventive control and appropriate management activities are to be implemented to ensure the preventive control is effective. As appropriate to the preventive control, such management activities are to include:
  - Monitoring of preventive controls
  - Validation of preventive controls
    - Before use, or, if not possible, within 90 days
    - Not necessary for sanitation controls, recall plan, supply-chain program, or other controls as justified
  - Verification of preventive controls
    - Reasonable time - product testing, environmental monitoring, calibration, supply-chain program
    - 7 days – monitoring records, corrective actions, unless other time frame justified
  - Corrective actions and corrections to be taken if preventive control is ineffective or an isolated, minor safety situation occurs
Final Preventive Controls for Animal Feed – Overview

• Recall plan is required for product associated with a **hazard requiring a preventive control**
• All required activities within the animal feed safety plan are to be documented and retained for at least two years; electronic records allowed
• Reassessment of animal feed safety plan is required –
  • Whenever a significant change occurs within facility that could introduce a new hazard
  • When new information about potential hazards associated with the animal feed becomes available
  • Whenever appropriate after an unanticipated feed safety problem
  • Whenever a preventive control or combination thereof is found to be ineffective
  • At least every three years – entire plan
The determination of whether a hazard is a *hazard requiring a preventive control* governs whether a facility needs to comply with other requirements within the preventive controls regulation.

The NGFA and other stakeholders are seeking further clarification on this issue –

For example, when does a good manufacturing practice used to address a hazard become a preventive control, which requires additional documentation and activities to show the control is working?
Exempt from Preventive Controls

• Farms

• Facilities *solely* engaged in the storage 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
“Other than Fruits and Vegetables”

- Grain elevator exemption is available only to facilities that solely store “grain,” as defined by FDA.
- Examples of products that are included within FDA’s definition of “grain” are barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cottonseed, flaxseed, rapeseed, soybeans, and sunflower seed).
- Among the products that FDA classifies as “fruit” are lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, peanuts, tree nuts and seeds for direct consumption.
- Facilities that store such “fruits” are exempt from FDA’s CGMP regulations, but are not exempt from the requirements established within the agency’s regulations for hazard analysis and risk-based preventive controls and supply-chain programs.
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
Final Supply-Chain Program Requirements for Animal Feed – Overview

• Applies to a covered facility that has identified a hazard requiring a preventive control and who relies on its supplier to control the hazard

• Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt
Final Supply-Chain Program Requirements for Animal Feed – Overview

• **If** a receiving facility has identified a hazard requiring a *supply-chain-applied control*, then the receiving facility is required to have a written supply-chain program to:
  
  • Receive that raw material or ingredient only from approved suppliers, or on a temporary basis from unapproved suppliers whose raw material or ingredient are subject to verification activities before being accepted for use
  
  • Written procedures are required for receiving raw materials and other ingredients to ensure receipt from approved suppliers
  
  • Use of written procedures is to be documented
Final Supply-Chain Program Requirements for Animal Feed – Overview

• **If** a receiving facility has identified a hazard requiring a *supply-chain-applied control*, then the receiving facility is required to:
  
  • Perform activities to verify that the supplier is adequately controlling the hazard, including, as appropriate to the raw material or ingredient and its supplier:
    
    • Conducting onsite audits of the supplier’s operations
    • Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility
    • Review of the supplier’s relevant feed safety practices and records
      
      • Supplier performance, history, compliance record
    • Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier
Final Supply-Chain Program Requirements for Animal Feed – Overview

• If the **hazard requiring a supply-chain-applied control** also presents a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, then the receiving facility is required to conduct an onsite audit of the supplier.
  
  • The onsite audit is to be conducted annually by a **qualified auditor**, unless there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazard is controlled.

• All required records associated with supply-chain program are to be maintained for at least two years; electronic records allowed.
Exempt from Supply-Chain Program

1. Farms
2. Facilities that are a very small business
3. Facilities solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, e.g., grain elevators
4. 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
5. Facilities who do not identify a hazard requiring a preventive control that is associated with an incoming ingredient or raw material
6. Facilities who do identify a hazard requiring a preventive control that is associated with an incoming ingredient or raw material, but choose not to rely on the supplier to control the hazard
### Compliance Dates for CGMPs and PCs

<table>
<thead>
<tr>
<th>Business Size</th>
<th>CGMPs Compliance Date</th>
<th>Preventive Controls Compliance Date</th>
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<tbody>
<tr>
<td>Business Other than Small and Very Small</td>
<td>1 year – Sept. 19, 2016</td>
<td>2 years – Sept. 18, 2017</td>
</tr>
<tr>
<td>Small Business</td>
<td>2 years – Sept. 18, 2017</td>
<td>3 years – Sept. 17, 2018</td>
</tr>
<tr>
<td>Very Small Business</td>
<td>3 years – Sept. 17, 2018</td>
<td>4 years – Sept. 17, 2019</td>
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- **Small Business**: A business 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 feed-related activities, is to be counted in this determination.
## Compliance Dates for Supply-Chain Program

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<tr>
<th>Situation</th>
<th>Compliance date:</th>
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<tr>
<td>A receiving facility is a small business and its supplier will be subject to the CGMPs, but not the preventive control requirements, of the animal food preventive controls rule</td>
<td>6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule</td>
</tr>
<tr>
<td>A receiving facility is a small business and its supplier is subject to the animal food preventive controls rule</td>
<td>The later of: <strong>September 17, 2018</strong> or 6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with this rule</td>
</tr>
<tr>
<td>A receiving facility is not a small business or a very small business and its supplier will be subject to CGMPs, but not the preventive control requirements, of the animal food preventive controls rule</td>
<td>6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule</td>
</tr>
<tr>
<td>A receiving facility is not a small business or a very small business and its supplier will be subject to the animal food preventive controls rule</td>
<td>The later of: <strong>September 18, 2017</strong> or 6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the applicable rule</td>
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Food Safety Preventive Controls Alliance

- Consists of government officials, academics, and industry representatives

- Goals are to:
  - Develop standardized hazard analysis and preventive controls training and distance education modules for food/feed industry and regulatory personnel
  - Assist in FDA in developing commodity/industry sector-specific guidelines for hazards and preventive controls
• Current Good Manufacturing Practices
• Human Food By-Products for Use as Animal Food
• Hazard Analysis and Preventive Controls
• A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule
Contact FDA About FSMA

You may contact FDA about FSMA by submitting an inquiry form.

The modified form is designed to facilitate questions that are specific to FSMA and its implementation. Your use of the form will provide the FSMA Technical Assistance Network with the information needed to give accurate and timely responses and to improve our customer service. We hope you find our online form useful in identifying the specific nature of your inquiry and we remain open to suggestions about improving the form to meet your needs.

Submit Inquiry

You may also mail your question to the address below:

Food and Drug Administration
5100 Paint Branch Pkwy
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

NOTE: For Food Safety Preventive Controls Alliance Training questions, please direct inquiries to fs pca@ill. edu.
NGFA Summary of Final Rule

• Download from NGFA’s website at:

FDA Final Rule for CGMPs and Preventive Controls for Animal Feed and Pet Food

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