Final Rule for Preventive Controls for Animal Food

http://www.fda.gov/fsma
Background

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

- Originally proposed: October 29, 2013
- Supplemental proposal: September 29, 2014
- Public comments: More than 2,400 for the original proposal; more than 140 for the supplemental proposal
- Final rule: September 17, 2015
Key Areas Addressed

• Establish Current Good Manufacturing Practices (CGMPs)

• Hazard Analysis and Risk-Based Preventive Controls
  – Each facility is required to implement a written food safety plan that focuses on preventing hazards in animal foods
Who is Covered?

• In general, facilities that manufacture, process, pack or hold animal food
  – Facilities required to register with FDA under sec. 415 of the FD&C Act
  – Not farms

• Applies to domestic and imported food

• There are some exemptions and modified requirements for certain facilities
Exemptions from CGMPs

- Establishments solely engaged in holding or transportation of one or more RACs
- **New:** Hulling, shelling, and drying nuts and hulls (without further manufacturing/processing)
- **New:** Cotton ginning (without further manufacturing/processing)
Definition of Holding

- Modified the definition of holding to include activities performed incidental to storage of an animal food (e.g., for safe or effective storage of that animal food) and activities performed as a practical necessity for distribution of that animal food. These include blending the same RAC and breaking down pallets, but not activities that would transform a RAC into a processed food.
Impact of Farm Definition on Feed Mills

• Feed mills that are part of a farm are exempt from registering as a food facility and are not subject to rule

• For the feed mill to be part of the farm:
  – Raising animals and feed mill are under same management in one general location, AND
  – Animal food made at the mill is ONLY fed to animals under the farm’s management
Impact of Farm Definition on Feed Mills – cont.

• Feed mills that are not part of a farm and are required to register as a food facility are subject to rule.

• Examples include:
  – Independent feed mill
  – Feed mill that makes food for contract farms
  – On-farm feed mill that makes food for animals under different management than the farm
Qualified Facilities

- Very small businesses are qualified facilities exempt from the full requirements for hazard analysis and risk-based preventive controls (but still have some requirements)
  - Average less than $2.5M per year in sales of animal food plus the market value of animal food manufactured, processed, packed or held without sale
Requirements for a Qualified Facility

• Attestation the facility is a qualified facility; AND

• Attestation that hazards have been identified and that preventive controls have been implemented and are being monitored; OR

• Attestation facility is in compliance with an applicable non-Federal food safety law
Requirement for Training

- Individuals who manufacture, process, pack, or hold animal food must be qualified to perform their assigned duties.
- Qualifications can come from education, training, or experience (or combination).
- Must have training in principles of animal food hygiene and animal food safety.
  - Training must be documented.
CGMPs

• FDA Action in Final Rule
  – Revised the CGMPs based on comments and existing industry standards
  – Modified the requirements to be less prescriptive while maintaining a baseline to protect animal food against contamination that would be harmful to public health
CGMPs

- Personnel
- Plant and grounds
- Sanitation
- Water supply and plumbing
- Equipment and utensils
- Plant operations
- Holding and distribution
- Holding and distribution of human food by-products for use as animal food
CGMPs (cont.)

- No requirements for hair nets, beard covers, special outer garments, or gloves
- Hand washing as necessary and appropriate
- Other precautions necessary to protect the animal food
CGMPs (cont.)

- Require cleaning of animal food-contact surfaces of equipment, no sanitizing requirement unless necessary
- Water that contacts animal food or animal food-contact surfaces or packaging materials must be safe for its intended use
CGMPs (cont.)

- Less emphasis on sanitation and more emphasis on producing safe animal food
- Less stringent requirements for raw materials and ingredients
- Less specific requirements for equipment and utensils
- Overall more flexibility
Human Food By-products for Use as Animal Food

- Human food by-products are not subject to animal food rule (except for provisions for holding and distribution) if:
  - Human food is produced in compliance with human food CGMPs and all applicable food safety requirements
  - Not further processed
Holding and Distribution of Human Food By-Products

• Must be held in a manner that protects against contamination
  – Containers cleaned as necessary
  – Must be accurately identified during holding
  – Labeling that identifies common or usual name must be affixed to or accompany when distributed

• Shipping containers examined before use
Further Processing of Human Food By-Product

- Further processing of by-products requires compliance with CGMPs
- Firm can choose to follow either the human food or animal food CGMPs for the processing
- Requires a hazard analysis
- If hazards identified, would need to implement a preventive control
Food Safety Plan

- Hazard analysis
- Preventive controls
- Supply-chain program
- Recall plan
- Procedures for monitoring
- Corrective action procedures
- Verification procedures
PC Qualified Individual

• 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 or is otherwise qualified through job experience to develop and apply a food safety system.
Food Safety Plan – Hazard Analysis

• Hazard identification must consider known or reasonably foreseeable biological, chemical, and physical hazards
  – These could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain
Food Safety Plan – Hazard Analysis

• Evaluation of hazards must include:
  – consideration of severity of illness/injury and probability of occurrence in absence of preventive controls
  – consideration of effect of factors such as formulation and processing of animal food, facility, equipment, ingredients, intended use

• Evaluation outcome is whether there is a hazard(s) requiring a preventive control
Food Safety Plan – Preventive Controls

• Measures required to ensure that hazards are significantly minimized or prevented. These include:
  – Process controls
  – Sanitation controls
  – Supply-chain controls
  – Recall plan
Food Safety Plan – Preventive Controls

• Not required when hazard is controlled by another entity later in the distribution chain
  – Disclose that animal food has not been processed to control an identified hazard
  – Obtain assurances hazard will be controlled
Food Safety Plan - Monitoring

- Facility must have written procedures, including the frequency they are to be performed, for monitoring the preventive controls (as appropriate to the nature of the preventive control)
- Monitoring must be documented in records subject to verification
Food Safety Plan – Corrective Actions and Corrections

• Facility must have written corrective action procedures for when preventive controls are not properly implemented
  – Identify and correct a problem
  – Reduce likelihood of occurrence
  – Evaluate animal food for safety
  – Prevent adulterated animal food from entering commerce
Food Safety Plan - Verification

• Includes (as appropriate to the facility, animal food and nature of the preventive control):
  – Validation of preventive controls
  – Verification of monitoring and corrective actions
  – Calibration of process monitoring and verification instruments
  – Product testing, environmental monitoring
  – Records review
Reanalysis of Food Safety Plan

• At least every three years, or:
  – Whenever there is a significant change in activities at the facility that creates the potential for a new hazard or a significant increase in one previously identified
  – When there is new information about potential hazards associated with an animal food
  – After an unanticipated food safety problem
  – When a preventive control is ineffective
Supply-Chain Program

- When the control is applied before receipt ("supply-chain applied control")
  - Must have a risk-based supply-chain program to ensure control of hazards in raw materials and other ingredients.
Supply-Chain Program

• Use of approved suppliers

• Determine, conduct, and document appropriate supplier verification activities
  – Onsite audits (default for most serious hazards)
  – Sampling and testing
  – Review of relevant food safety records
  – Other as appropriate

Activity and frequency based on nature of hazard, where it is controlled and supplier performance
Compliance Dates – Supply-Chain Program

• Separate compliance dates have been established for the supply-chain program provisions to accommodate compliance dates for suppliers of different sizes and subject to different rules (e.g., Produce Safety Standards, Foreign Supplier Verification Program)
Records

• Original or true copies with actual values and observations
• Identify the facility, lot code, date/time, signature/initials
• Exempt from part 11 requirements unless required by another regulation
• Retain for 2 years
## Compliance Dates

<table>
<thead>
<tr>
<th>Business Size</th>
<th>CGMP Compliance</th>
<th>PC Compliance</th>
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<tbody>
<tr>
<td>Other Businesses</td>
<td>1 year</td>
<td>2 years</td>
</tr>
<tr>
<td>Small Business*</td>
<td>2 years</td>
<td>3 years</td>
</tr>
<tr>
<td>Very Small Business◊</td>
<td>3 years</td>
<td>4 years</td>
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</tbody>
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*Small Business – business with fewer than 500 full-time equivalent employees

◊ Very Small Business – Average less than $2.5M per year in sales of animal food plus the market value of animal food manufactured, processed, packed or held without sale
PC Training

• Food Safety Preventive Controls Alliance was established to develop the standardized curriculum for the PC rules
• 2.5-day training
• Train-the-Trainers (2 days)
• Learning Management System to manage course administration
Planned Guidances

- 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
Training and Technical Assistance

• Plans include:
  – Collaborating with the Food Safety Preventive Controls Alliance to establish training and technical assistance programs
  – Establishing a Food Safety Technical Assistance Network within FDA
For More Information

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- To contact FDA about FSMA and find the new online form for submitting questions: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm