

Animal PC
Final

Final Rule for Preventive Controls for Animal Food

<http://www.fda.gov/fsma>

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW



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

Business Size	CGMP Compliance	PC Compliance
Other Businesses	1 year	2 years
Small Business*	2 years	3 years
Very Small Business◇	3 years	4 years

*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>