

Overview of FSMA Animal Food Rule

at

Vermont Public Meeting

by

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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

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

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
- Revised Definition of a ‘Farm’

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

Good Manufacturing Practices

- 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

Animal Food CGMPs Pre-FSMA

- Medicated feed CGMPs
 - Addressed building, grounds, equipment, etc
 - Addressed steps to follow to safely use drugs in feed
 - Have recordkeeping requirements

Animal Food CGMPs Pre-FSMA

- BSE regulations
 - Specific actions required when handling ruminant protein
 - Do not bring into facility
 - Make non-ruminant feed
 - Use FDA approved test to test for TSE agent
 - Use FDA approved method to inactivate TSE agent
 - Caution statement
 - Recordkeeping/documentation

Animal Food CGMPs FSMA

- Address building, grounds, equipment, personnel, etc
 - Mainly observational, and address routine operations

Food Safety Plan

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

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 likelihood of occurrence in the product subject to the analysis
 - Impact of prerequisite programs, formulation, ingredients, equipment, etc.
 - consideration of severity of illness/injury and probability of occurrence in absence of preventive controls

Food Safety Plan – Hazard Analysis

- Outcome of the analysis
 - determination of whether a hazard(s) require a preventive control or not

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 – 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 – Other Elements

- PC management components
- Monitoring
- Corrective Actions and Controls
- Verification
- Validation
- Verification of Implementation/effectiveness
- Reanalysis of Food Safety plan

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

Supply-Chain Program

- Manufacturing/processing facilities must have a risk-based supply-chain program to ensure control of hazards in raw materials and other ingredients when the control is applied before receipt (“supply-chain applied control”).

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

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

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.

What is a Farm? Two definitions

- Primary Production Farm
 - Under one management in one general, but not necessarily contiguous, location
 - Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
 - Packs and holds raw agricultural commodities; may conduct certain manufacturing/processing activities, such as dehydrating grapes to produce raisins, packaging and labeling

What is a Farm? Two definitions

- Secondary Activities Farm
 - An operation not located on the Primary Production Farm that is also devoted to farming operations. It is majority owned by the Primary Production Farm(s) that supplies the raw agricultural commodities harvested, packed or held by the Secondary Activities Farm.

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

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

For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)

