FSMA Regulations

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Food Safety Modernization Act

- The Food & Drug Administration Food Safety Modernization Act (FSMA) that was signed into law by President Obama on Jan. 4, 2011, will create a shift in how federal regulators approach the feed manufacturing process.
- The aim of FSMA is to ensure that the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it (FDA, 2011).

"FDA Food Safety Modernization Act". Signed on January 4, 2011

- **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**
  - biennial registration renewal.
  - during the period beginning on October 1 and ending on December 31 of each even-numbered year.

- **TITLE I--IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS**
  - Sec. 102. Registration of food facilities.
  - Sec. 103. Hazard analysis and risk-based preventive controls.
  - Sec. 104. Performance standards.
  - Sec. 105. Standards for produce safety.
  - Sec. 106. Protection against intentional adulteration.
  - Sec. 107. Authority to collect fees.
  - Sec. 108. National agriculture and food defense strategy.
  - Sec. 109. Food and Agriculture Coordinating Council.
  - Sec. 110. Building domestic capacity.
  - Sec. 111. Sanitary transportation of food.
  - Sec. 112. Food allergy and anaphylaxis management.
  - Sec. 113. New dietary ingredients.
  - Sec. 114. Requirement for guidance relating to post harvest processing of raw oysters.
  - Sec. 115. Port shopping.
  - Sec. 116. Alcohol-related facilities.

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SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

(a) In General.--Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end the following: “SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

“(a) In General.--The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.”

Preventive Control Definition - FSMA

“(3) Preventive controls.—The term ‘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 food would employ to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (b) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Those procedures, practices, and processes may include the following:

[A] Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment.

[B] Supervisor, manager, and employee hygiene training.

[C] An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.

[D] A food allergen control program.


[F] Current Good Manufacturing Practices (cGMPs) under part 110 of title 21, Code of Federal Regulations (or any successor regulations).

FSMA Feed Rule for Preventive Controls for Animal Food (Feed) has not been published.

FSMA Proposed Rule for Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food - Updated January 14, 2013

Regulations are based on the principles of Hazard Analysis and Critical Control Points (HACCP)

HACCP is a process management system that was developed to address food safety through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product (FDA, 2013)
HACCP Program Is Based Upon 7 Principles:

1. Conduct a hazard analysis
2. Determine critical control points (CCP)
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish recordkeeping and documentation procedures

HACCP Plans

- HACCP plans also rely on pre-requisite programs and education and training programs for employees.
- Pre-requisite programs are based on current Good Manufacturing Practices.

Preventive Controls/Pre-requisite Programs

- Employee Training Program
- Feed Mill Quality Assurance Program
- Pest Control
- current Good Manufacturing Practices for Medicated Feeds cGMP’s
- Preventive Maintenance Program
- Written Recall Plan

Hazard Analysis Team

- The team is responsible for identification of potential feed hazards, evaluation of the manufacturing process, review of internal audits, and making recommendations to the senior management for continuous quality improvement and control of potential feed and food safety hazards.

- Feed Mill Manager
- Feed Mill Operator
- Feed Mill Maintenance
- Quality Assurance
- Purchasing
### Hazard Identification

<table>
<thead>
<tr>
<th>Hazard Type</th>
<th>Hazard Type (P/C/B)</th>
<th>Location</th>
<th>Risk</th>
<th>Control Procedure Process</th>
</tr>
</thead>
</table>
| Paper/Wood  | P                  | Receiving | Low  | 1. Monitor unloading for physical hazard  
                             2. Grate over receiving pit  
                             3. Feed cleaner |
| Metal       | P                  | Receiving | High | 1. Magnets prior to bucket elevators  
                             2. Magnets prior to grinder |
| Mycotoxins  | C/B                | Ingredients | Med  | 1. Purchase from approved supplier  
                             2. Ingredient specification sheets  
                             3. In-house testing of grains  
                             4. Monitor moisture content of received and stored grain |

### AFIA Safe Feed/Safe Food Hazard Guidelines

#### HACCP Decision Tree

#### Preventive Controls - Receiving

- Grate On Receiving Pit
- Magnet
- Receiving Checklist

Source: AFIA Safe Feed/Safe Food Hazard Guidelines

http://www.southbank.edu.au

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Preventive Controls - Storage

- Seal Bags
- Secure Lids
- Store Bags Off the Floor

Preventive Controls - Micro System

- Label Micro Bins
- Micro Bin Log
- POULTRY TM PRMX (TM-80)

Preventive Controls - Mixing

- Magnet
- Lid on Hand-Add Opening
- Feed Cleaner

Preventive Controls - Pelleting

- Food Grade Grease
- External Mount Bearings
Monitoring and Recordkeeping

Batch Production Report

Resources - Quality Assurance Manual
- Mission Statement
- Job Descriptions
- Training Program
- Quality Team
- Purchasing and Receiving
- Feed Manufacturing and Process Control
- Finished Feed Sampling, Inspection and Labeling
- Feed Shipment and Delivery
- Sanitation and Pest/Rodent Control
- Feed Product Investigations/Recalls
- Reports and Charts
- Preventive Control Points

Based on National Grain and Feed Association – Model Program and AFIA Safe Feed/Safe Food

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Safe Feed/Safe Food Sections

A. Safe Feed/Safe Food Policy, Management, Control of Documents & Records, Communication and Review
B. Human Resources – Training
C. Facility Planning and Control
D. Manufacturing & Processing
E. Monitoring Devices
F. Infrastructure - Building, Equipment and Grounds
G. Ingredient Purchasing Process & Controls
H. Identification and Traceability
I. Customer Related Processes
J. Control of Nonconforming Product

Safe Feed/Safe Food Guidelines

Take Home Message

- Implement Written Pre-requisite Programs
  - Quality Assurance
  - Pest Control
  - Housekeeping
  - Preventive Maintenance
- Create a QA Team to Identify Hazards
- Begin to Identify Potential Hazards
- Begin to Identify Preventive Controls
- Wait for FSMA Proposed Rule for Preventive Controls for Animal Feed

Questions

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