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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).


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"FDA Food Safety Modernization Act".

Signed on January 4, 2011

- **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**
 (b) References.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).
 (c) Table of Contents.—The table of contents for this Act is as follows:
- **TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS**
Sec. 101. Inspections of records.
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 Councils.
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. 102. REGISTRATION OF FOOD FACILITIES.

- Biennial registration renewal.
- During the period beginning on October 1 and ending on December 31 of each even-numbered year.



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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.**"

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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.
 "(E) A recall plan.
 "(F) Current Good Manufacturing Practices (cGMPs) under part 110 of title 21, Code of Federal Regulations (or any successor regulations)."

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FSMA Section 103

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FSMA Rules

- 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)

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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)

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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

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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.

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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




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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



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Hazard Identification

| Hazard | Hazard Type ¹ (P/C/B) | Location | Risk | Control Procedure Process |
|------------|----------------------------------|--|------|---|
| Paper/Wood | P | 1. Receiving 2. Mixing | Low | 1. Monitor unloading for physical hazard 2. Grate over receiving pit 3. Feed cleaner |
| Metal | P | 1. Receiving 2. Grinding 3. Mixing | High | 1. Magnets prior to bucket elevators 2. Magnets prior to grinder |
| Mycotoxins | C/B | 1. Ingredients 2. Storage | 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 |

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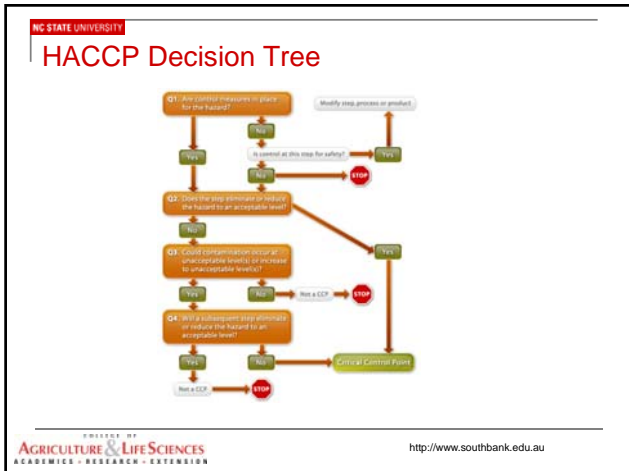
AFIA Safe Feed/Safe Food Hazard Guidelines

AFIA SAFE FEEDSAFE FOOD HAZARD GUIDELINES

| Class | Potential Hazards | Potential Sources |
|------------|--|---|
| Chemical | Dioxin/PCBs, ¹ Medicated Feed Additives, ² Feed Additives, ³ Heavy Metals, ⁴ Microtoxins, ⁵ Pesticides, ⁶ Industrial Contaminants ⁷ | Cross contamination in feed mill, batching error, weighing error during batching, ingredient, intentional or unintentional contamination. |
| Biological | ESF, ⁸ Pathogenic enteric microbes ⁹ | Contaminated feed ingredients, animal feces or urine, contamination during transport, contamination on farm |

¹Dioxin/PCB tolerance levels have not been established for feed. Generally, any levels 2 parts per trillion of dioxin (including PCBs) or higher in finished feed should result in consideration of sampling for the source of the dioxin. The government is attempting to establish guidelines of dioxin in various ingredients.

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Preventive Controls - Storage



Seal Bags

Store Bags Off the Floor



Secure Lids

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Preventive Controls - Micro System



Label Micro Bins



Micro Bin Log

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Preventive Controls - Mixing



Magnet



Lid on Hand-Add Opening



Feed Cleaner

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Preventive Controls - Pelleting



Food Grade Grease



External Mount Bearings

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Monitoring and Recordkeeping

Appendix A

Feed Mill Daily Checklist

| | |
|-----------------------------|--------------------|
| Receipts | Daily Activities |
| Ingredient Receipts | Magnets Cleaned |
| Drug Receipts | Feeding |
| | Harvest Mill |
| | Water Mill |
| | Math Log |
| | Production Log |
| | Production #2 |
| | Far Value Check |
| Inventory | Computer Off |
| Bulk Ingredient Inventory | Computer On |
| Bag Ingredient Inventory | Compressed |
| Micro-Inventories | Air Compressor Off |
| | Water Off |
| Production | |
| Micro-In Dump | |
| Drug Administration | |
| Production Records Reviewed | |
| Feed Production Summary | |
| Palen #1 Log | |
| Palen #2 Log | |

Manager: _____

NC State Feed Mill 2013 Manual SFSF Model Program

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Batch Production Report

Batching

Mixer: Mixer 1 **N.C. State Batch Report** 1-02-2013 8/20/2010

| 2 | Finished Feed Code | Finished Feed Description | Dest Bt Bin | Serial | Total Tons | Batch Number | Batch Size (Tons) |
|---|--------------------|---------------------------|-------------|--------|------------|--------------|-------------------|
| | PK1200001 | SEU Gestation | 37 | 1339 | 3 | 1 of 3 | 3.00 |

| 3 | Ingredient Code | Ingredient Description | Bin | 4 | Target Weight | Actual Weight | Dev | Comment |
|---|-----------------|------------------------|-----|---|---------------|---------------|-------|-----------|
| | 11100 | Grd Coss HA | N/A | | 20.00 | 20.00 | 0.00 | |
| | 101250A | Mono-Dical 210 HA | N/A | | 65.00 | 65.00 | 0.00 | |
| | 10100 | Grd Coss HA | N/A | | 15.00 | 15.00 | 0.00 | |
| | 10101 | Fat - Poultry | 100 | | 20.00 | 20.00 | 0.00 | over 2000 |
| | 11100 | Core #2- Southern | 7 | | 5.00 | 5.00 | 0.00 | low bin |
| | 11100 | States (Mid West) | 3 | | 2404.00 | 2408.00 | 4.00 | no 2000 |
| | 21100 | States (Mid West) | 5 | | 415.50 | 413.00 | -2.50 | |
| | 21100 | SSB 48 | | | 2824.50 | 2820.00 | -4.50 | |
| | 32100 | Mono-Dical 211 P | MD | | 16.50 | 16.48 | -0.02 | No Flow |
| | 32100 | Limestone | MD | | 27.28 | 27.27 | -0.01 | 2000 |
| | 32100 | Salt | MD | | 15.00 | 15.10 | 0.10 | |
| | 71100 | Pulse Dow/Fig Vit | MD | | 1.13 | 1.23 | 0.10 | |
| | 71000 | Flow (DM) | MD | | 4.50 | 4.71 | 0.21 | 2000 |
| | 71000 | Wilde DM Fems/SSV | MD | | 10.00 | 10.00 | 0.00 | Accepted |

| 6 | Start Time | Stop Time | Slipped Time |
|---|------------|-----------|--------------|
| | 11:38:11 | 4:30:00 | 7:58:19 |

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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

NGFA

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

CERTIFIED SAFE FEED SAFE FOOD FACILITY

TRAC/TRACE

HAZARD ID

VERIFICATION


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Representing the Total Feed Industry

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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

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Safe Feed/Safe Food Guidelines

AFIA SAFE FEED/SAFE FOOD GUIDELINES AUDIT

| Facility Information | | SAFE FEED SAFE FOOD FACILITY |
|---|---|------------------------------|
| Facility Name | Date of Audit | |
| Facility Address | | |
| Facility City/State/ZIP | | |
| Person conducting audit | | |
| Product Label | | |
| A. Safe Feed/Safe Food Policy, Management, Control of Documents and Records, Communication and Review | | SF SF Reference |
| 1 | A food-feed safety policy has been defined, reviewed and implemented by top management. Has the policy been communicated to each employee? | |
| 2 | Document control procedures are in place, and documents are accessible to appropriate personnel | |
| 3 | The physical and chemical feed safety hazards in the AFIA Hazard Guide have been identified, reviewed and have control procedures, where applicable. | |
| 4 | Records retention procedures are defined and followed. Records must be maintained for one year from the date of manufacture of the finished product or the receipt of ingredients. | |
| 5 | The following records are maintained as appropriate to the product: BSE, feed rules, medicated feed, formula/mixing instructions, production records, drug assays, and label files. | |
| 6 | Responsible personnel review the following: audit results, customer feedback, process performance and product conformity, status of preventative and corrective actions, follow-up action from previous management reviews, planned changes that could affect the food/feed system and recommendations for improvement. | |
| B. Human Resources / Training | | |
| 1 | Personnel are competent for assigned tasks and received initial training and at least annual recertification. | |
| 2 | Job descriptions are maintained that include the responsibility and skills required by the employee to complete the job. The employee is evaluated to determine knowledge of the required skill. | |
| 3 | Personnel are properly trained in SOPs for restricted areas, and where appropriate, to avoid. | |

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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**

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Questions



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