



Food Safety Modernization Act of 2010 – Impacts on the Grain and Feed Industry

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Food Safety Modernization Act



- Signed into Law – Jan. 4, 2011 (P.L. 111-353)
- Paradigm Shift – Biggest Change in U.S. Food/Feed Safety Law Since 1938
- Major Principles
 - Covers all ‘food’ (*food for humans or animals*)
 - Prevention-based focus
 - Import provisions ‘groundbreaking’



Food Safety Modernization Act



- **Law Requires 50 New Regulations, Guidance Documents, Reports**
- **While Timelines Mandated, Implementation Will Be Multi-Year Process**
 - Heavily dependent upon FDA resources
 - Will necessitate phased approach



Key Provisions, Requirements of New Law



- Expanded FDA access to food records
- Increased food facility registration requirements
- Increased food facility inspections
- Provides authority for FDA to collect fees
- Requires FDA to develop regulations for the safe transport of food
- Requires importers to verify safety of foreign foods
- Expanded FDA authority to detain food
- Provides authority to FDA to mandate food recalls
- **Requires written food safety plans – use of hazard analysis and risk-based preventive controls**

Who's Covered by New Food/Feed Safety Law?

- **All Facilities Registered with FDA under Bioterrorism Act of 2002**
 - Domestic and foreign (*shipping food products for consumption in U.S.*)
 - Interstate or intrastate commerce
 - Commercial feed mills, feed ingredient manufacturers, pet food manufacturers
 - Grain elevators, grain processors, flour/corn millers
 - Biofuel facilities manufacturing coproducts used as feed ingredients (*e.g., distillers grains*)



Hazard Analysis and Preventive Controls (Section 103)

1. Conduct hazard analysis
2. Implement “risk-based” preventive controls to “significantly minimize or prevent” identified hazards
3. Develop and implement written food/feed safety plan



Hazard Analysis



- Conduct and document a written analysis of hazards that are “known or reasonably foreseeable that may be associated with the facility”
 - Types of hazards:
 - Biological, chemical, physical hazards; natural toxins (*e.g., mycotoxins*), pesticides, drug residues, decomposition, unapproved additives
 - Unintentional and intentionally introduced hazards (*e.g., by acts of terrorism or troubled insider*)
 - NGFA Facility Risk Assessment /Security Guide:
[http://www.ngfa.org/files//misc/Facility_Risk-Assessment_and_Security_Guide\(Sept2009\).pdf](http://www.ngfa.org/files//misc/Facility_Risk-Assessment_and_Security_Guide(Sept2009).pdf)

Risk-Based Preventive Controls



- Identify, implement controls to “significantly minimize or prevent” occurrence of identified hazards so food product not adulterated or misbranded
 - Preventive controls defined as “risk-based, reasonably appropriate” measures “consistent with current scientific understanding” that a person “knowledgeable about safe” manufacturing, processing, packing or storage of food products would use
 - HACCP principles, CGMPs expressly recognized

Examples of Risk-Based Preventive Controls

- Supplier Verification
- CGMPs
- Sanitation
- Training
- Environmental monitoring
- Recall Plan



Monitoring and Corrective Action



- “Periodically” **monitor** the effectiveness of preventive controls to provide assurances that food is not adulterated or misbranded
- Establish and implement **corrective action** procedures to be used when it becomes apparent that necessary controls are not implemented or found to be ineffective
 - Procedures to ensure:
 - Action is taken to prevent likelihood of reoccurrence of control failure
 - All affected food is evaluated for safety
 - Adulterated or misbranded food is prevented from entering commerce

Verification Activities

- Perform activities to verify that:
 - Preventive controls are adequate to control hazards
 - Monitoring activities are occurring as planned
 - Appropriate corrective actions are taken, as needed
 - Preventive controls are effectively minimizing or preventing the occurrence of hazards, including through the use of product and environmental testing

Verification Activities (cont.)

- **Verification** requirements also include:
 - Re-analysis of hazards and preventive controls -
 - Earlier of:
 - Every three years; or
 - Whenever “significant change” in facility operations that creates “reasonable potential” for new hazard or “significant increase” in previously identified hazard
 - Upon completing reanalysis, document:
 - Why additional preventive controls unneeded; or
 - Implementation of additional preventive controls before facility renews operations

Recordkeeping and Written Plan

- Maintain **records** for “not less than” two years documenting monitoring of controls, instances of nonconformance, testing results and other verification steps, and correctives actions taken
- Prepare a **written plan** that documents, describes results of hazard analysis and resulting preventive controls implemented
 - Modify written plan to reflect any newly implemented preventive controls resulting from re-analysis of facility operations
 - Make written plan and required records available to FDA “promptly” upon oral or written request

Potential Exemptions

- FDA may, by regulation, exempt or modify the hazard analysis and preventive control requirements with respect to facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment

Regulation Timetable

- FDA mandated to issue hazard analysis and preventive control regulations by July 2012
- Proposed regulations currently under review
 - One set for human food
 - 400-page preamble and 200 pages of economic analysis (estimated \$1-2 billion), plus the text of proposed regulations
 - One set for animal food (including pet food)
 - 200-page preamble and 100-page economic analysis (estimated \$100 million), plus the proposed regulations
 - Likely 90-day comment period, 3 public meetings
 - Once final, compliance phase-in period likely – based upon business size



Food Safety Preventive Control Alliance

- Consists of government officials, academia, and industry representatives
- Goals are to:
 - Develop standardized hazard analysis and preventive controls training and distance education modules for food industry and regulatory personnel
 - Develop commodity/industry sector-specific guidelines for hazards and preventive controls

Risk-Based Food Safety Plans

- **Key Elements of ISO-Based Plans:**
 - Management responsibility and commitment
 - Prerequisite programs
 - Hazard analysis and control



Management Responsibility



- **Commitment to Food Safety**
 - Committed to developing and implementing a system and that it is continually improving
- **Setting the Food Safety Policy**
 - Define, document, and communicate
 - Supported by measurable objectives
- **Planning the Food Safety Management System**
 - Network of interrelated elements that combine to ensure that food safety
 - Elements could include programs, plans, policies, procedures, practices, processes, goals, objectives, methods, controls, roles, responsibilities, relationships
- **Establishing responsibility and authority**
 - Defined and communicated
 - All personnel responsible to report non-compliances

Adapted from ISO 22000, section 5

Management Responsibility

- **Designating a Food Safety Team Leader**
 - Appointed by top management
 - Responsible for effectiveness of system
- **Communication (internal and external)**
 - Responsibility and authority established to communicate externally and internally about food safety issues
- **Emergency Preparedness and Response**
 - Procedures to manage emergency situations
- **Review by Management**
 - Conduct at planned intervals
 - Review system inputs
 - Generate outputs – decisions and actions to improve system

Food Safety Resource Requirements



- **Food Safety Management System resources**
 - Adequate to establish, implement, maintain and update
- **Human resources**
 - Appropriate training of food safety personnel
- **Infrastructure**
 - Establish and maintain appropriate infrastructure
- **Work environment**
 - Establish, manage and maintain appropriate environment
- **Planning and realization of safe products**

Adapted from ISO 22000, section 6 & 7

Prerequisite Programs (PRPs)

- Basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for consumption
- Specific to:
 - Segment of the food chain
 - Type of organization

Adapted from ISO 22000, section 3.8

PRP - Examples

- Existing FDA Current Good Manufacturing Practice Regulations
 - FDA cGMP for medicated feed (21 CFR 225)
 - http://www.access.gpo.gov/nara/cfr/waisidx_11/21cfr225_11.html
 - FDA cGMP for human food (21 CFR 110)
 - http://www.access.gpo.gov/nara/cfr/waisidx_11/21cfr110_11.html



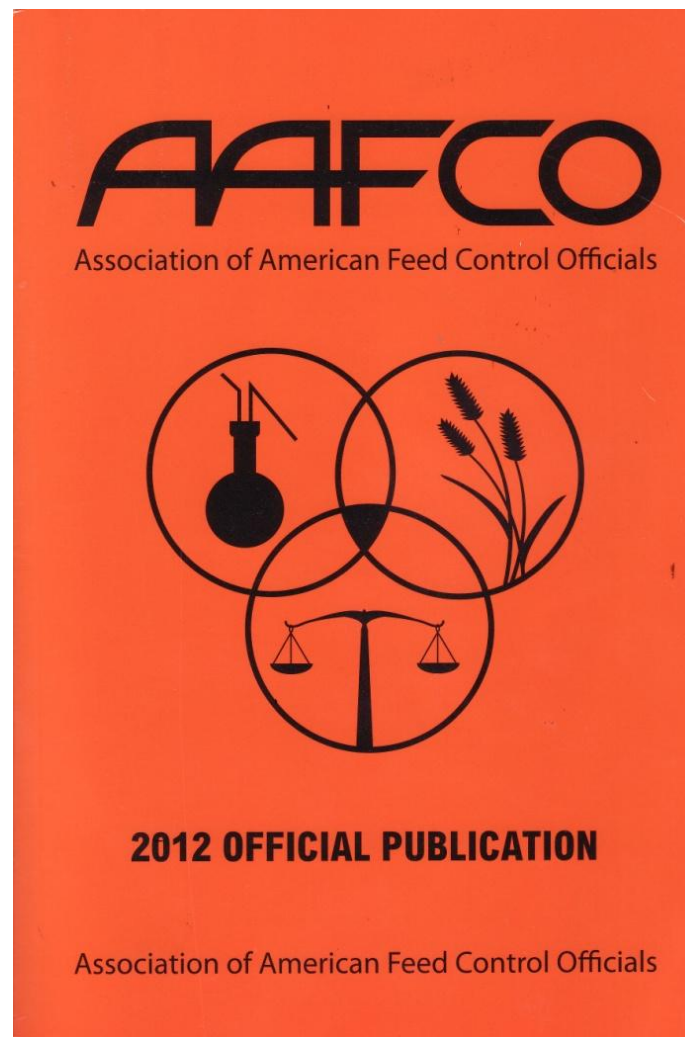
Association of American Feed Control Officials (AAFCO)



AAFCO Model Good Manufacturing Regulations for Feed and Feed Ingredients

- Purchase using order form available at:

www.aafco.org




PAS 222 Animal Feed

SCOPE

- Commercial animal food/feed and ingredients
- Hazards affecting animal and/or human health
- Pertains to all animal classes and uses
- Download free at:

www.bsigroup.com

PAS 222:2011
Prerequisite programmes for food safety in the manufacture of food and feed for animals



SSAFE
Sustainable Supply Assurance Framework

BSI
British Standards Institution

cGMPs for Human Food (21 CFR 110)



- **Personnel**

- Are to conform to hygienic practices necessary to protect against contamination of food
- Are to be educated, trained, and supervised as necessary for production and distribution of safe food

- **Plant and Grounds**

- Are to be kept in a condition that will protect against the contamination of food
- Buildings and structures are to be suitable for safe production of food
 - Space for cleaning maintenance
 - Constructed of appropriate materials
 - Adequate lighting

cGMPs for Human Food (21 CFR 110)



- **Housekeeping/Sanitation Practices**

- Maintain facility in a condition to prevent food from becoming adulterated
- Cleaning compounds are to be safe for food under conditions of use
- Rubbish/waste is stored, handled, disposed of as to protect against contamination of food

cGMPs for Human Food (21 CFR 110)



- **Equipment** is to be designed to:
 - Adequately withstand the environment and food product so as to avoid contamination of food from corrosion
 - Facilitate adequate cleaning and maintenance
 - Prevent adulteration of food with lubricants, or other chemicals not approved for food
 - Minimize potential of accumulation of food, dirt, and organic matter that could cause contamination of food

cGMPs for Human Food (21 CFR 110)



- **Processes and Controls**

- Raw materials and ingredients are to:
 - Be inspected to ascertain they are suitable for use and processing into food
 - Comply with current FDA regulations and action levels for aflatoxin and natural toxins before these materials or ingredients are incorporated into finished food
 - Stored in a manner to protect against contamination and adulteration
- Equipment is to be:
 - Constructed, handled, and maintained in a manner that protects against food contamination
- Storage and transportation of finished food is to be under conditions that protect food from contamination

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