

Food Safety Modernization Act - Implications for the Grain and Feed Industry



**Iowa Grain Quality Initiative
Advisory Committee Meeting**

Jan. 6, 2012

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FDA Food Safety Modernization Act of 2011

- Signed into law Jan. 4, 2011
- “Historic” legislation
 - It’s **NOT** just recalls and inspections
 - It’s a call for a **new, prevention-oriented food safety system** to ensure the safety of feed/food products
 - Requires FDA to develop and issue more than 50 regulations and/or guidance documents over the next two-plus years

FSMA: Historic Legislation

2011 – Food Safety Modernization Act

1938 – Food, Drug, and Cosmetic Act

1906 – Pure Food and Drug Act



Hazard Analysis and Preventive Controls (Section 103)

- Evaluate hazards
- Implement risk-based preventive controls
- Perform monitoring activities
- Take corrective actions, when needed
- Perform verification activities
- Establish and maintain records
- Have a documented, written food/feed safety plan

Examples of Risk-Based Preventive Controls

- Supplier Verification Programs
- Current Good Manufacturing Practices (CGMPs)
- Sanitation
- Training
- Environmental monitoring
- Food allergen control program
- Recall Plan

Exemptions

- **Exempted Facilities**

- Very Small Businesses – yet to be defined by FDA

- Qualified Facilities

- During the 3-year period preceding the applicable calendar year, the average annual food sales (including sales by affiliates/subsidiaries) sold directly to “qualified end-users” exceeds the average annual value of food sold to all other purchasers; and
 - Average annual monetary value of all food sold by such facility during such period (including sales by affiliates/subsidiaries) was less than \$500,000, adjusted for inflation

Partial or Modified Exemptions

- Facilities already covered under FDA Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers Standard (e.g., canned pet food)
 - Exemption only applies to microbiological hazards addressed within standard
- Facilities “solely engaged” in manufacturing animal food (including pet food) and storage of raw ag commodities (other than fruits, vegetables)
 - FDA “may” exempt or modify requirements for such facilities

Regulation Timetable

- FDA mandated to issue hazard analysis and preventive control regulations by July 2012
- Proposed regulations likely to be issued later this month
 - 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

NGFA Perspectives

- Regulations need to closely adhere to the statutory language, i.e., be science- and risk-based, non-prescriptive, and provide sufficient flexibility
- Compliance guidance for regulatory officials and industry needs to be developed
 - What hazards need to be addressed? What controls will be deemed to be effective?
- Regulations should appropriately differentiate between human food and animal feed
- Written food/feed safety plans are proprietary and FDA should protect the confidentiality of such documents



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Food Safety Preventive Control Alliance

Name	Organization
Purnendu C. Vasavada	Coordinator – University Wisconsin- River Falls
Jenny Scott	FDA-CFSAN
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Kim Young	FDA-CVM
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Glenn Black	GMA
Diane Barrett	UC –Davis
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Marion Aller	Florida Department of Agriculture
Benjamin Chapman	NC State University
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William Dardick	FDA-ORA-DHRD
Allan Bateson	FDA-ORA-DHRD



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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- Develop standardized hazard analysis and preventive controls training and distance education modules for food industry and regulatory personnel
- Design and deliver a distance learning training portal at the IIT IFSH Moffett Campus in Bedford Park, Ill.
- Develop “train-the-trainer” materials and student education delivery systems
- Create a technical assistance network for small- and medium-sized food companies
- Develop commodity/industry sector-specific guidelines for preventive controls
- Assess knowledge gaps and research needs for further enhancement of preventive control measures
- Identify and prioritize the need for, and compile, critical limits for widely used preventive