National Grain and Feed Association

FDA's Implementation of FSMA Rules

Feed Management Workshop
Wisconsin AgriBusiness Association

January 14, 2016

Randy Gordon
NGFA President

NGFA Fast Facts

More than 1,000-Member Companies:

- Grain elevators
- Feed, feed ingredient manufacturers
- Oilseed processors
- Flour, corn mills
- Biofuels producers
- Many other related agribusinesses
- 26 State/Regional Associations – Tremendous leadership from Kansas Grain and Feed
- Strategic Alliances with PFI, NAEGA

Members Handle 70% of U.S. Grains and Oilseeds

Food Safety Modernization Act of 2011

- Signed into law on Jan. 4, 2011
- Greatly expands FDA's authority to regulate the U.S. food supply
  - Mandates that FDA create a **new prevention-based regulatory system** to ensure the safety of food/feed products
  - Requires FDA to develop and issue more than 50 regulations and/or guidance documents

FDA FOOD SAFETY MODERNIZATION ACT

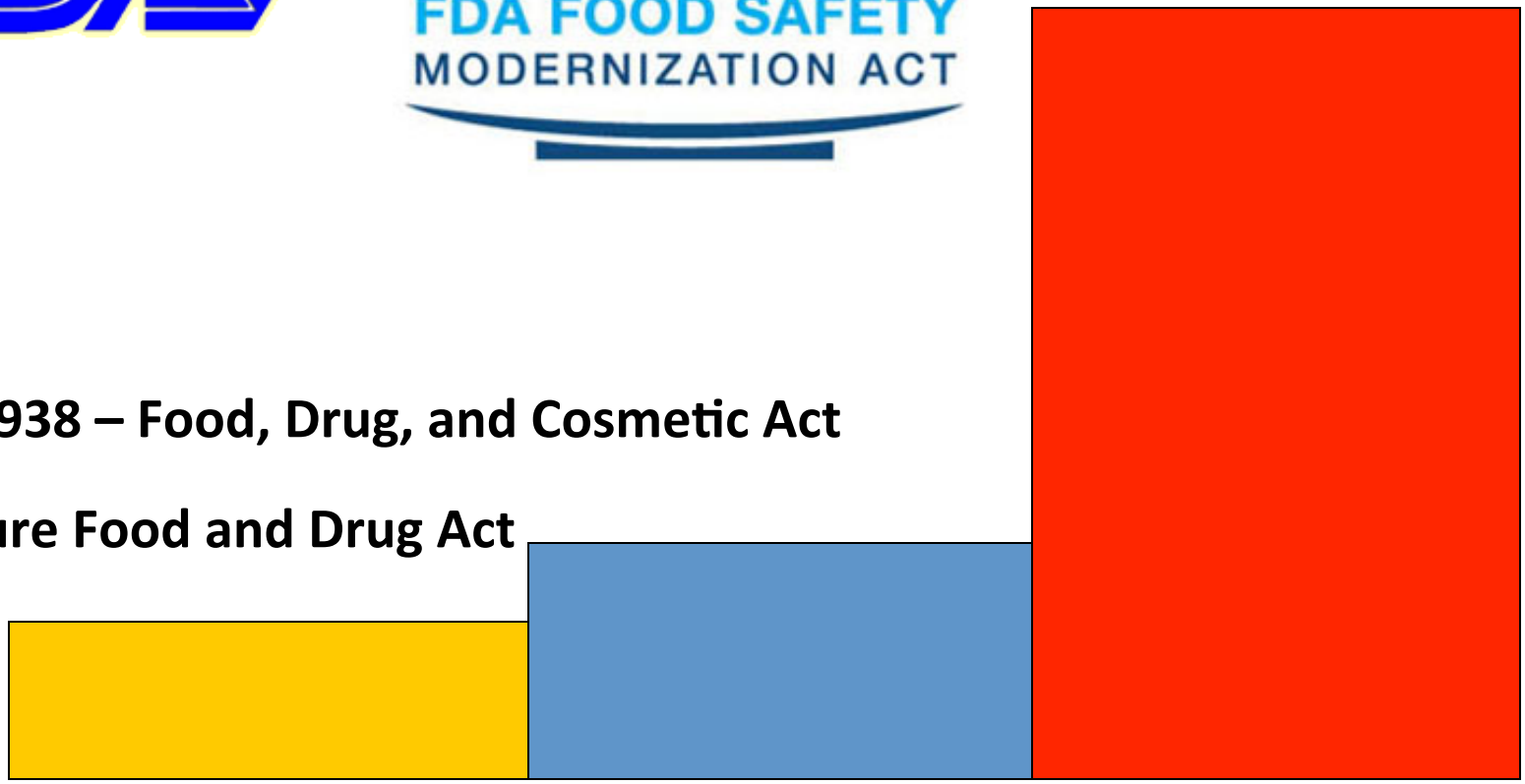
FSMA – How Significant?

2011

FDA FOOD SAFETY MODERNIZATION ACT

1938 – Food, Drug, and Cosmetic Act

1906 – Pure Food and Drug Act



FSMA Implementation: NGFA seeking common-sense, science-based outcomes

FSMA – Increased Powers for FDA

- **Facility Registration:** Required for grain elevators, feed mills, processing plants, other 'food' facilities every two years during last quarter of even-numbered years (e.g., 2016)
- **Administrative Detention:** Agency granted expanded authority to administratively detain food, feed products believed to be adulterated (akin to state "stop sale" authority)
- **Mandatory Recall Authority:** FDA granted authority to issue mandatory recall notices to facilities
- **Access to Records:** Major expansion of authority to FDA to access records related to food, feed safety

FSMA – Facility Registration

- **Recordkeeping:** Grain, feed facilities required to establish and maintain records concerning immediate previous source and immediate subsequent recipient of food (grain, feed, processed commodities, food, etc.)
  - Records are to contain "reasonably available" information linking inbound deliveries to outbound shipments
  - Commingling recognized
  - NGFA guidance available

Types of FDA Inspections

- **For Cause:** Pertains to public health concerns, animal illnesses/deaths
- **Surveillance:** Conducted to evaluate compliance with applicable regulations
- **Compliance:** Performed if FDA has reason to believe problems may or do exist at facility
- **Criminal:** Conducted when information suggests serious willful and/or egregious violations of applicable requirements occurring within facility

Subject of FSMA Rule	Date Regs Issued
Current Good Manufacturing Practice (CGMP) and Preventive Controls – Human Food	Aug. 30, 2015 *(Sept. 17, 2015)*
Current Good Manufacturing Practice (CGMP) and Preventive Controls – Animal Food	
Foreign Supplier Verification Programs	Oct. 31, 2015 *(Nov. 27, 2015)*
Accreditation of Third-Party Auditors	
Sanitary Transportation of Food	March 31, 2016
Food Defense/Intentional Adulteration	May 31, 2016

FSMA's Big 6 Rulemakings

1-2. Human Food and Animal Food CGMP and Preventive Controls

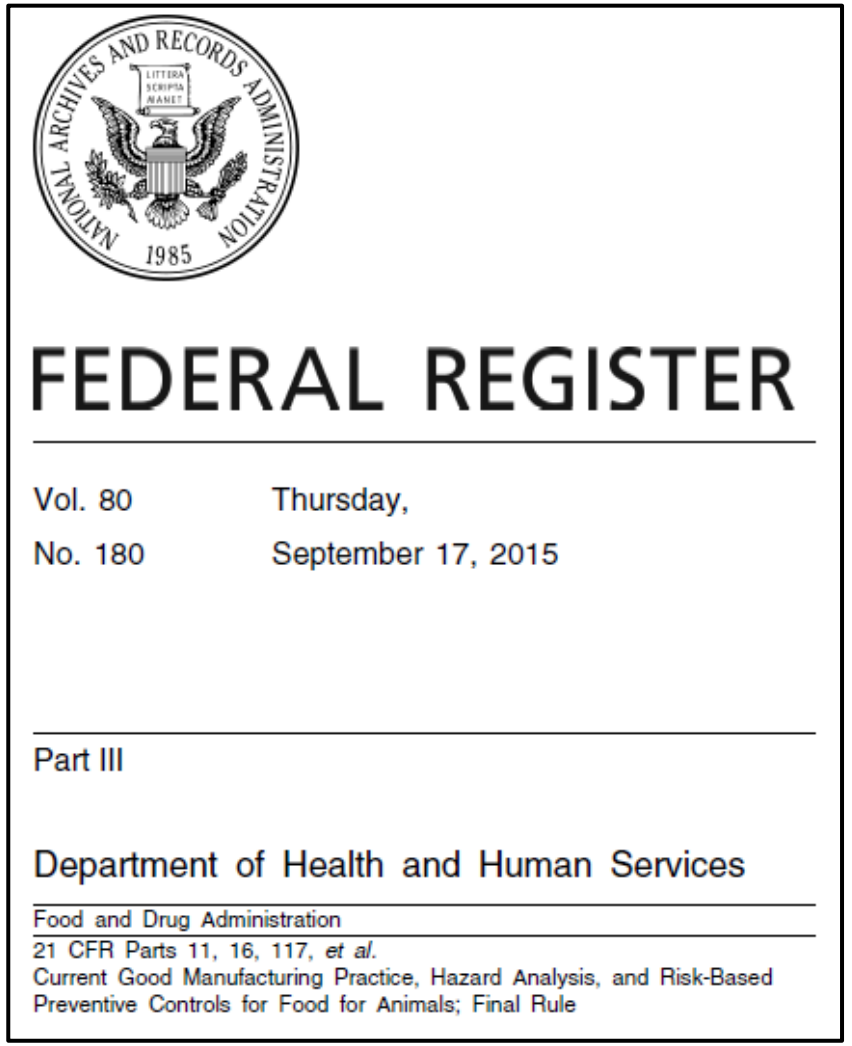
- Facilities ***"solely engaged"*** in storing grain and oilseeds exempt from requirements to implement CGMPs, conduct hazard analysis, implement preventive controls (and associated recordkeeping), develop written food safety plan, or supply chain verification
  - Different treatment for elevators handling "fruits" [i.e., lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, peanuts, tree nuts and seeds for direct consumption (e.g., sunflower seeds)]
  - Elevators solely engaged in storing, handling such "fruits" exempt from CGMP requirements, but not exempt from the preventive controls and supply chain program requirements
- Nuance for elevators importing, storing, distributing foreign grain
- Millers, processors covered by human, animal feed rules
- Feed facilities covered by animal food rule

FSMA's Big 6 Rulemakings

3. **Supplier-Verification Programs**
   - Applies to ***importers*** of grains and oilseeds, feed ingredients - ***could include a grain elevator***
4. **Accreditation of Third-Party Auditors**
   - Applies to foreign food in certain circumstances; i.e., high-risk designation by FDA or participation in Voluntary Qualified Importer Program (VQIP)
5. **Sanitary Transportation of Food**
   - Will apply to grain elevators and feed facilities
6. **Food Defense/Intentional Adulteration**
   - FDA proposed that animal food be exempt

Final CGMP and Preventive Controls for Animal Feed – Overview

- **PART 507—Current Good Manufacturing Practice, Hazard Analysis, and Risk–Based Preventive Controls for Food for Animals:**
  - **Subpart A—General Provisions**
  - **Subpart B: Current Good Manufacturing Practices (CGMPs)**
  - **Subpart C: Hazard Analysis and Risk-Based Preventive Controls**
  - **Subpart D—Withdrawal of a Qualified Facility Exemption**
  - **Subpart E: Supply-Chain Program**
  - **Subpart F: Recordkeeping**



NATIONAL ARCHIVES AND RECORDS ADMINISTRATION 1985

FEDERAL REGISTER

Vol. 80 Thursday,
No. 180 September 17, 2015

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11, 16, 117, *et al.*
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Final Rule

Treatment of Farms in FSMA Final Rule

- **Exemption from Preventive Controls applies to:**
  - Primary Production Farms: Operation under 1 management in 1 general (but not necessarily contiguous) location that grows, harvests crops, raises animals (including seafood) or both
    - Farms allowed to pack or store raw ag commodities (except fruits or vegetables) grown on farm under different ownership)
    - Feed mill on cattle feedlot considered part of farm if managed by farm or same company as farm; is in same general location; and produces feed only for animals on that farm or farm under same company management (poultry integrators may not qualify)
    - FDA: Exemption for feed mills at fully integrated livestock operations a gap – will propose regs in future to address
  - Secondary Activities Farms: Operation not located on primary production farm that is devoted to harvesting, packing and/or storing raw ag commodities (except fruits and vegetables)

Final CGMP Requirements – Overview

- **CGMP** – Required conditions and practices to ensure that animal feed/pet food will not become adulterated
- ***New*** baseline CGMP requirements for animal feed/pet food facilities
  - Overarching requirements for **all** covered facilities
- 21 CFR Part 225 CGMP for medicated feed still apply

CGMP Requirements – Overview

- **CGMPs: Establish requirements for following conditions, practices:**
  - Personnel – cleanliness (including hand-washing to prevent feed contamination) and training
  - Plant and grounds – maintenance, design, construction; designate individual(s) responsible
  - Sanitation – housekeeping, cleaning, pest control
  - Adequate, suitable water supply and plumbing – water quality, plumbing design, rubbish control
  - Equipment and utensils – maintenance, design, construction
  - Plant operations – labeling; inspection of raw materials and ingredients to ensure suitable for use in feed (e.g., mycotoxins); protection against metal/foreign objects
  - Materials not used in animal feed (e.g., fertilizer, pesticides) to be stored apart from animal feed mfg. activities
  - Holding and distribution – storage and transportation
    - Shipping containers, transport vehicles examined prior to use for cleanliness

Preventive Controls for Animal Feed – Overview

- Requires covered facilities to develop and implement written animal feed safety plan
  - Plan to be developed and overseen by "***preventive controls qualified individual***"
    - *Qualified by taking, passing 16-hour training course developed by Preventive Control Alliance*
    - *Qualified through work experience*
  - Plan required to include a written **hazard identification and analysis**
    - Evaluation of "known or reasonably foreseeable hazards" – physical, chemical, biological, including those associated with intentional economic adulteration (e.g., melamine)
  - Plan required to include implementation of **preventive controls** effective in minimizing or preventing any hazard identified during the hazard evaluation as being a ***hazard requiring a preventive control*** from adulterating product and posing danger to human or animal health

Preventive Controls for Animal Feed – Overview

- **Paramount Importance:** Determination of whether hazard is a ***hazard requiring a preventive control*** – vs. one that can be addressed by CGMPs – determines whether facility needs to comply with other requirements within the preventive controls regulation (including monitoring, recordkeeping)

- NGFA and other stakeholders seeking further clarification on this issue
  - Hazard determinations left to facilities
  - Need to provide guidance on whether hazards reach threshold of requiring preventive control
  - University of Minnesota study planned

Preventive Controls for Animal Feed – Overview

- **If *hazard is identified requiring a preventive control***, rules require management controls be implemented to ensure preventive control effective. Management controls to include:
  - Monitoring of preventive controls
  - Validation and verification of preventive controls' effectiveness
  - Corrective actions and corrections to be taken if preventive control is ineffective or an isolated, minor safety situation occurs
- All required activities within feed safety plan to be documented and retained for at least two years; electronic records allowed
- Periodic reassessment of safety plan required, at least every three years
- Recall plan required for products associated with a ***hazard requiring a preventive control***

Final CGMP and Preventive Controls for Animal Feed – Overview

New Training and Qualification Requirements:

- Individuals who manufacture, process, pack, or hold animal feed subject to the rule are to be qualified and trained to perform their assigned duties
  - FDA expects training to occur before working in production operations and periodic refresher training thereafter
  - Training records are to be maintained for at least two years

Supply-Chain Program Requirements for Animal Feed – Overview

- Applies to a covered facility that has identified a ***hazard requiring a preventive control*** **and** who relies on its supplier to control hazard
- If there is a ***hazard requiring a preventive control*** associated with a supplier's raw material or ingredient and the facility relies on the supplier to control the hazard, then the receiving facility is required to:
  - Receive that raw material or ingredient only from approved suppliers
  - Perform activities to verify that supplier adequately controlling hazard
  - Receive written assurance from customer (downstream processor) that it agrees to take actions to control hazard

FDA Guidance Documents – In Process

- Current Good Manufacturing Practices
- Human Food By-Products for Use as Animal Food
- Hazard Analysis and Preventive Controls
- Small Entity Compliance Guide explaining actions a small or very small business must take to comply with FSMA regulations

Compliance Dates for CGMP and PCs

Business Size	CGMP Compliance Date	Preventive Controls Compliance Date
Business Other than Small and Very Small	Sept. 19, 2016	Sept. 18, 2017
Small Business	Sept. 18, 2017	Sept. 17, 2018
Very Small Business	Sept. 17, 2018	Sept. 17, 2019

- **Small Business**: A business employing fewer than 500 full-time equivalent employees. The rule specifies that all employees within the business and all of its subsidiaries and affiliates, regardless of whether an employee is involved in animal feed-related activities, is to be counted in this determination.
- **Very Small Business**: A business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal feed plus the market value of animal feed manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).

NGFA Plans for CGMP and PC Outreach and Training

- **NGFA 1-Day Awareness, Outreach Education Events**
  - In cooperation with State Feed Regulatory Agencies and NGFA State/Regional Affiliate Associations
  - Being planned for late April-May
  - California, Indiana, Iowa, Kansas, Minnesota, Nebraska, Oklahoma, Wisconsin
- **FSPCA Training**
  - FDA-recognized hazard analysis and preventive controls training for food/feed industry and regulatory personnel --
    - Developed by subject-matter experts from government, industry, academia – Animal Food Subgroup chaired by NGFA's Dave Fairfield
    - Individuals completing training will be "preventive controls qualified individuals"
    - Curriculum to be available in May 2016
    - Likely will be a 16-20 hour course
    - Pilot to be reviewed week of Jan. 18

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Foreign Supplier Verification

- Applies to importers of foreign food (i.e., grains and oilseeds, feed ingredients - could include a grain elevator)
- Importers required to only import food from foreign suppliers approved under rule's requirements
- Importers required to conduct hazard analysis of foreign food
  - If "hazard requiring a preventive control" is identified, importer is required to:
    - Conduct supplier verification activities to ensure hazard is being controlled by supplier, **or**
    - Control the hazard, **if** importer is subject to FDA's preventive control rule, **or**
    - Obtain assurances from downstream customers they will control hazard
- Modified requirements apply to "very small importers" ($1 million per year in sales of human food and $2.5 million per year in sales of animal food) and "importers of food from certain small foreign suppliers"
  - Obtain written assurance at least every 2 years for each food imported that foreign supplier is producing food in compliance with the U.S. standards

Compliance Dates – Foreign Supplier Verification

- **Latest of the following dates:**
  - 18 months after publication of final rule (May 2017)
  - For importation of food from supplier subject to preventive controls or produce safety rules, six months after the foreign supplier is required to meet relevant regulations
  - For importer that is a manufacturer or processor subject to the supply-chain program provisions in preventive controls regulations, the date by which it has to comply with those provisions

FDA's Implementation of FSMA Rules

Questions / Comments ?

Randy Gordon, President
rgordon@ngfa.org

David Fairfield, Senior Vice President,
Feed Services
National Grain and Feed Association
dfairfield@ngfa.org

NGFA's Major Issues, Concerns

1. **Grain Elevators: Clarify Proposed Exemption from CGMPs, Hazard Analysis, Preventive Controls:**
   - Covers storage, packing activities of low-risk raw ag commodities
   - Proposed definition would cause exemption to be "lost" if facility engaged in cleaning, screening, conditioning, fumigating, etc.

2. **CGMPS: Implement realistic, practical, outcome-based rules**
   - Proposed CGMPs akin to human food CGMPs (e.g., hygienic safety standards, facility sanitation, employee illnesses, etc.)
   - Need to be appropriate, reasonable for full range, scope of feed facilities (undesirable organisms should be considered as potential "hazard" only if appropriate for particular feed, facility)
   - NGFA submitted complete redraft of CGMPs for FDA's consideration

NGFA's Major Issues, Concerns

3. **Preventive Controls: Limit Scope to Feed Safety Issues Truly Meriting Rigorous Management Oversight**
   - FSMA does ***not*** mandate HACCP regulatory approach
     - FDA proposal to require preventive controls for hazards "reasonably likely to occur" inconsistent with FSMA language; would subject plethora of potential hazards to hazard analysis, preventive controls
     - FDA proposal would require preventive controls to be managed similar to critical control points
   - FDA proposal would create extremely burdensome regulatory framework; divert scarce resources from existing effective food, feed safety measures
     - NGFA: Both likelihood and severity need to be considered, as do impacts of prerequisite programs like CGMPs
4. **Compliance Dates: Extend, Stagger**
   - **CGMPs:** 1 year for larger businesses; 2 years for small businesses; 3 years for very small businesses
   - **Preventive Controls:** 2 years for larger businesses; 3 years for small businesses; 4 years for very small businesses

NGFA's Major Issues, Concerns

5. FDA's Estimated Cost Vastly Understated

- **FDA Estimate:** Annual costs $93.45 million for entire animal feed, pet food industry (ranging from $13,200 to $18,300 per facility)
- **NGFA Economic Analysis for <u>Just Animal Feed Facilities</u>:** Annual cost ranges from $430 million to $723 million
  - $56,000 to $127,715 per facility (depending on extent hazard analysis required; and whether hazards addressed through GMPs)