



**National Grain
and Feed Association**

Food Safety Modernization Act

Impacts on the Grain and Feed Industry

Safety and Grain Quality Conference

Aug. 4, 2016



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 – New Authority to FDA

- ***Facility registration*** is required with FDA every two years on even numbered years
- FDA granted authority to ***issue mandatory recall*** notices to facilities
- FDA to ***collect fees*** for cost of
 - Reinspecting facilities that fail an original inspection
 - Conducting mandatory recalls
 - Hourly rate: \$217 for domestic work



Subject of FSMA Rule	Date Regs Issued
<p>Current Good Manufacturing Practice (CGMP) and Preventive Controls – Human Food</p>	<p>Sept. 17, 2015</p>
<p><i>Current Good Manufacturing Practice (CGMP) and Preventive Controls – Animal Food **</i></p>	
<p>Produce Safety Standards</p>	<p>Nov. 27, 2015</p>
<p><i>Foreign Supplier Verification Programs **</i></p>	<p>Nov. 27, 2015</p>
<p><i>Accreditation of Third-Party Auditors **</i></p>	
<p><i>Sanitary Transportation of Human and Animal Food **</i></p>	<p>April 6, 2016</p>
<p>Food Defense/Intentional Adulteration</p>	<p>May 27, 2016</p>

***** Applies to animal food facilities***

Applicability of FSMA Rules

- **Who's In, Who's Out ...**
 - **Generally**, FSMA rules apply to facilities required to register as a “food facility” with FDA under Bioterrorism Act requirements
 - Exception: Foreign supplier verification programs; carriers under sanitary transportation of food rule
 - **Farms** (operations meeting FDA's definition of a “*farm*”) are exempt
 - Individual rules also specify certain exemptions and modified requirements

Applicability of FSMA Rules

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

- Facilities “solely engaged” in storing grain and oilseeds exempt from both rules
 - Different treatment for elevators handling “fruits” [e.g., lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, sunflower seeds, peas, peanuts, tree nuts]
 - Elevators solely engaged in storing, handling such “fruits” exempt from CGMP requirements, but not exempt from the preventive controls
- Grain millers, processors potentially covered by both human, animal food rules
- Animal feed and pet food facilities covered by animal food rule

Solely Engaged in Holding

- The definition of “holding” expressly “includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity))”
- Examples of activities cited by FDA as being incidental to “holding” of grain include:
 - Drying grain
 - Fumigating grain
 - Cleaning grain
 - Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation
 - Using modified atmosphere treatments to control pests
 - Using biological controls for pests
 - Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds
 - Weighing grain
 - Blending grain
 - Sampling and grading grain
 - Aerating grain to control temperature

Solely Engaged in Holding

- Grain elevator exemption applies when holding grain is the only food-related activity at the facility
- Exemption is not clearly defined when a facility consists of a grain elevator plus some other food-related activity, e.g.,
 - Grain elevator plus feed mill
 - Grain elevator plus bag feed warehouse
 - Grain elevator plus transloading operations

Applicability of FSMA Rules

3. Foreign Supplier Verification Programs

- Applies to *importers* of grains and oilseeds, feed ingredients, human food - *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 Human and Animal Food

- Applies to grain and feed facilities; truck and rail transportation

6. Food Defense/Intentional Adulteration

- Applies to human food, *animal food exempt; grain elevators exempt*

CGMP and Preventive Controls for Animal Food

- **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: Requirements Applying to Records That Must Be Established and Maintained**



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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

Qualified Individual Requirements

- Individuals who manufacture, process, pack, or hold animal food subject to the rule are to be qualified to perform their assigned duties
- Each individual (including temporary, seasonal and contract personnel) must:
 1. Have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties; and
 2. Receive training in the principle of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, and the facility

Animal Food CGMP Requirements

- CGMP subpart establishes *new* requirements for *all* animal food facilities covered by the rule
 - Required conditions and practices to ensure that animal food will not become adulterated
 - All other applicable regulations still apply
 - BSE-prevention requirements
 - 21 CFR Part 225 CGMPs – Medicated Feeds
 - Others ...

Some Perspectives on Animal Food CGMP Requirements

- Approximately **85 provisions** establish a variety of requirements; **but** there's flexibility – not all apply to all facilities ...
 - **4 provisions** contain the word “suitable”
 - **11 provisions** contain the word “appropriate”
 - **16 provisions** contain the word “adequate”
 - **14 provisions** use the phrases “as necessary”, “where necessary” and “when necessary”
- Flexibility is necessary so that CGMP can be applied to the broad range of animal food facilities covered by the rule
- **No** recordkeeping requirements for CGMP
 - **FDA:** *Generally*, CGMP required under the final rule are things that can be observed

Preventive Controls Requirements

- Preventive controls subpart mandates that food facilities identify and evaluate “***known and reasonably foreseeable ‘hazards’***” associated with the facility and its food and implement one or more “***preventive controls***” and components to manage such controls (monitoring, verification, corrections and corrective actions, records, and recall plans) for “***hazards requiring a preventive control***”
- A **written food safety plan** must be developed



Preventive Controls Requirements

- Outcomes of required hazard analysis drive compliance obligations
 - If there are no **“hazards requiring a preventive control”**, then compliance obligations are limited - no need to implement preventive controls or required management components to control hazards
 - If one or more **“hazards requiring a preventive control”** are identified, then one or more preventive controls and associated management components must be implemented
- A **“preventive controls qualified individual”** is to oversee the hazard analysis and develop and implement the required food safety plan



Grain Elevators and CGMP and PC Requirements

- Facilities “solely engaged” in storing grain and oilseeds are exempt from requirements to implement CGMP and preventive controls
 - Elevators solely engaged in storing, handling grains plus “fruits” exempt from CGMP requirements, but not exempt from the preventive controls
- Facilities that only hold food (grain or fruit) are not defined to be “suppliers” by the rules
- The rules establish no new regulatory obligations for a grain elevator pertaining to customer requests



Some Perspectives on Preventive Controls Requirements

- Documentation, documentation, documentation ...
- When does a hazard reach the threshold of becoming a “hazard requiring a preventive control”?
- What level of documentation will be needed to be justify determinations made during the hazard analysis?
- Validation of preventive controls – what are FDA’s expectations?
- Inspection focus – educate before regulate
- FDA Guidance documents being developed

NGFA-AFIA Hazard Evaluation Project

- NGFA and AFIA co-sponsoring a hazard evaluation of typical ingredients and processes associated with the manufacturing and distribution of animal food being conducted by the University of Minnesota College of Veterinary Medicine's Center for Animal Health and Food Safety
- Goal of project is to provide a strong scientific basis for identifying hazards and developing a hazard analysis that companies can adapt to their specific operations
- Target Date for Completion: November 2016



Food Safety Preventive Controls Alliance

- Background
 - FDA recognized the need to assist the regulated industry in complying with preventive control rules
 - FSPCA was established by a grant from FDA to the Institute for Food Safety and Health (IFSH) at the Illinois Institute of Technology
 - Private-Public Partnership
 - Regulatory Agencies
 - Industry Trade Associations
 - Land Grant Universities



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

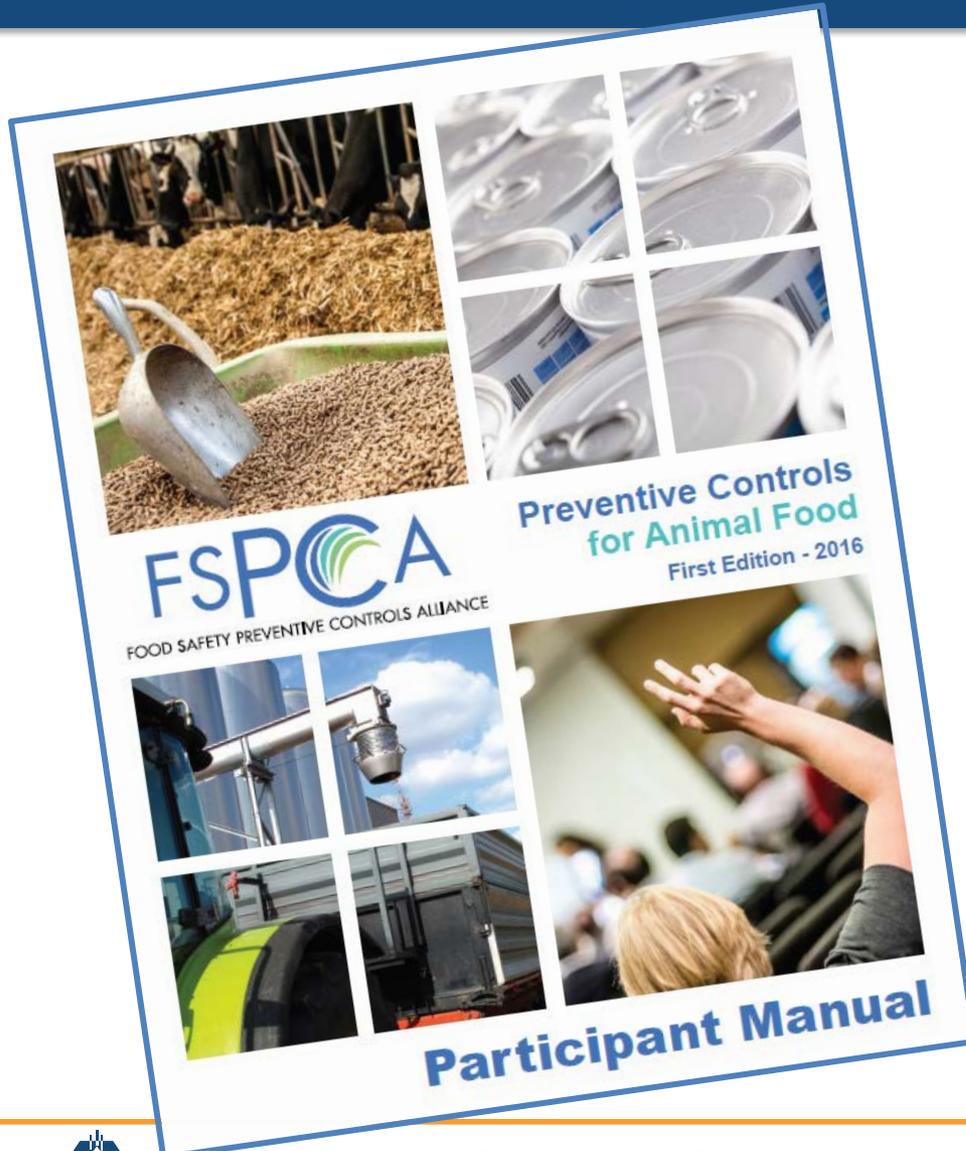


National Grain and Feed Association

FSPCA Deliverables

- Develop standardized hazard analysis and preventive controls curriculums for human food and animal food
 - Successfully completing training under the curriculum is one means to become a “**preventive controls qualified individual**” as specified by the animal food rule. Individuals may also be a “**preventive controls qualified individual**” because of their job experience
- Develop training materials for FSVP and food defense rules

FSPCA Animal Food Curriculum



Overview of Curriculum Content:

1. Regulatory Overview and Introduction to the Rule
 2. Current Good Manufacturing Practice
 3. Animal Food Safety Hazards
 4. Overview of the Food Safety Plan
 5. Hazard Analysis and Preventive Control Determination
 6. Required Preventive Controls Management Components
 7. Process Preventive Controls
 8. Sanitation Preventive Controls
 9. Supply-Chain Applied Controls
 10. Recall Plan
- Appendix: Regulatory Text**
Appendix: Example Pet Food Safety Plan



Delivery of the Curriculum

- FSPCA human food and animal food participant manuals are available for public electronic download free of charge
 - <https://fspca.force.com/FSPCA/s/article/Animal-Foods-Participant-Manual>
- For the purpose of using the curriculum to become a **“preventive controls qualified individual,”** an individual must successfully complete a training course registered with the FSPCA that is delivered by a FSPCA lead instructor
 - Courses began in June 2016
 - Certificates will be issued to individuals who successfully completed the course

Sanitary Transportation of Human and Animal Food

- Establish requirements for shippers, loaders, carriers, and receivers engaged in the transportation of human and animal food by truck or rail
- Requirements apply to both interstate and intrastate truck or rail transportation of food
- Exempt transportation activities include:
 - Activities performed by “non-covered businesses.” FDA’s rule defines a “non-covered business” as “a shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000 in average annual revenues.
 - Activities performed by a “farm”
 - Activities associated with the transportation of food that is completely enclosed by a container (e.g., a sealed bag, box, can, jar) except for food that requires temperature control for safety

Requirements for Shippers

- Final rule places most of the responsibility on the shipper for ensuring sanitary transportation of food and feed
- Unless the shipper itself develops and implements written procedures to ensure appropriate conditions throughout the transportation operations, shippers must specify in writing to the carrier and, when necessary, to the loader, all sanitary/design/temperature control (as necessary) specifications necessary for the carrier's vehicle and transportation equipment pursuant to the product to be transported to prevent food from becoming unsafe

Requirements for Shippers

- Must develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe.

Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement

Requirements for Loaders

- Must before loading food not completely enclosed by a container onto a vehicle or into transportation determine, considering, as appropriate, specifications provided by the shipper that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, e.g., it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. This may be accomplished by any appropriate means.



Requirements for Carriers

- Carrier requirements generally are limited to those established by a written agreement between the shipper and carrier
- When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must:
 - Provide adequate training to carrier personnel on practices necessary for safe transportation of food and document such training

Requirements for Carriers

- As applicable per the written agreement between shipper and carrier, the carrier is responsible for the following functions:
 - Ensuring that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe
 - If requested, provide information to the shipper that identifies the previous cargo transported in the vehicle
 - If requested, provide information to the shipper that describes the most recent cleaning of the bulk vehicle

Requirements for Receivers

- If a covered entity [receiver] becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe the food shall not be sold or otherwise distributed until it is determined that the temperature deviation or other condition did not render the food unsafe.
- Upon receipt of a food requiring temperature control for safety, receivers must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle, or smelling for off-odors.



Transloading Operations

- An entity that only transfers food cargo from one mode of transportation to another, e.g., from a railcar to a truck, would be subject to the rule as a receiver of food arriving by rail vehicle and as a loader of food onto trucks.
- A transloading entity is not considered to be a shipper if it simply holds the food pending transport and does not arrange for its transport

Intra-Company Transportation Activities

- Intra-company transfers of food are not exempt from the rule's requirements
- However, shippers, carriers, loaders and receivers that are under the ownership or operational control of a single legal entity can rely on compliance with common, integrated written procedures for transportation activities as an alternative to developing written procedures and agreements as specified in the FDA regulations

Some Perspectives on Sanitary Transportation Requirements

- NGFA is concerned that carriers have very limited obligations under the final rule
 - Unless a written contract between the shipper and carrier specifies carrier responsibility, carrier is not obligated to:
 - Provide information about last load hauled on conveyance
 - Provide information on last cleaning of the conveyance
 - Train carrier personnel in sanitary transportation practices

FSMA Compliance Dates – Animal Food Rules

Final Rule	Compliance Date - Large Business*	Compliance Date - Small Business**	Compliance Date - Very Small Business***
CGMP Preventive Controls - Animal Food	Sept. 19, 2016 (CGMP) Sept. 18, 2017 (PCs)†	Sept. 18, 2017 (CGMP) Sept. 17, 2018 (PCs)†	Sept. 17, 2018 (CGMP) Sept. 17, 2019 (PCs)
Foreign Supplier Verification Program	May 27, 2017§	Not applicable	Not applicable
Third Party Accreditation	Requirements go into effect after FDA publishes Model Accreditation Standards		
Sanitary Transportation - Human and Animal Food	April 6, 2017	April 6, 2018	Not applicable

* **Large Business Definition:** Business that does not meet definitions for “small business” or “very small business”

** **Small Business Definitions:**

- ✓ *CGMP and Preventive Control Rules for Animal Food* – Business with less than 500 full-time equivalent employees
- ✓ *Sanitary Transportation* – Business, other than a motor carrier who are not also shippers and/or receivers, employing fewer than 500 persons and motor carriers having less than \$27.5 million in annual receipts

*** **Very Small Business Definition:** *Preventive Controls for Animal Food* – Business with less than \$2.5 million in animal food sales plus market value of animal food not sold

† **Supply Chain Program Compliance:** *CGMP and Preventive Control Rules for Animal Food* – Later of: 1) six months after supplier is required to comply with the rule; or 2) Sept. 18, 2017 (large business) or Sept. 17, 2018 (small business)

§ **All importers** are to comply with FSVP requirements 18 months after the final rule or six months after their foreign suppliers’ reach their FSMA compliance deadlines, whichever is later. “Very small importers” (importers with average annual sales of less than \$2.5 million for animal food plus market value of animal food not sold) and “importers of food from very small foreign suppliers” are subject to modified requirements.

FSMA Resources

- NGFA Website:
 - Summary of Rules for CGMP and Preventive Controls
 - Summary of FSVP and Third-Party Accreditation Rules
 - Summary of Rule for Sanitary Transportation
 - Summary of Compliance Dates for FSMA Rules
 - NGFA Regional FSMA Seminars

Food Safety Modernization Act

Questions – Comments?

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