Presentation Outline

• FSMA Overview
  • Rules
  • Compliance Dates
  • Applicability

• FSMA and Regulatory Reform

• Overview of Major Requirements for Grain Handling/Grain Processing Operations
Food Safety Modernization Act of 2011

- Signed into law on Jan. 4, 2011
- Amended Federal Food Drug and Cosmetic Act and greatly expanded FDA’s authority to regulate the U.S. food supply
- Mandated that FDA create a new prevention-based regulatory system to ensure the safety of food products
## FSMA Compliance Dates

<table>
<thead>
<tr>
<th>Final Rule</th>
<th>Compliance Date - Large Business</th>
<th>Compliance Date - Small Business</th>
<th>Compliance Date - Very Small Business</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGMP Preventive Controls – Human Food</td>
<td>Sept. 19, 2016</td>
<td>Sept. 18, 2017</td>
<td>Sept. 17, 2018</td>
</tr>
<tr>
<td>CGMP Preventive Controls – Animal Food</td>
<td>Sept. 19, 2016 (CGMP)</td>
<td>Sept. 18, 2017 (CGMP)</td>
<td>Sept. 17, 2018 (CGMP)</td>
</tr>
<tr>
<td>Foreign Supplier Verification Program</td>
<td>May 30, 2017</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Third Party Accreditation</td>
<td>Model Accreditation Standards – Issued Dec. 6, 2016; First FDA accredited accreditation body announced Jan. 31, 2018</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sanitary Transportation Human and Animal Food</td>
<td>April 6, 2017</td>
<td>April 6, 2018</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Food Defense/Intentional Adulteration</td>
<td>July 26, 2019</td>
<td>July 26, 2020</td>
<td>July 26, 2021</td>
</tr>
</tbody>
</table>

*Rules listed in italicized, red font have potential to impact animal food facilities*
Applicability of FSMA Rules

• Who’s In, Who’s Out …

• **Generally**, FSMA rules apply to food-related operations 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 Current Good Manufacturing Practice (CGMP) and Preventive Controls (PC)

- Facilities “solely engaged” in storing grain and oilseeds [e.g., a “facility” consisting only of a grain elevator] exempt from both rules
  - Different treatment for elevators handling commodities that FDA characterizes as “fruits or vegetables” or “produce” [e.g., dried beans, dried peas, chickpeas, lentils]
  - Elevators solely engaged in storing, handling “produce” not subject to human or animal food PCs or animal food CGMPs, but are subject to human food CGMPs if products intended for human food
  - “Solely engaged” exemptions apply only when no other food-related activity that is subject to the rule(s) occurs at the facility

- Grain manufacturers/processors potentially covered by both human, animal food rules
- Animal feed and pet food facilities covered by animal food rule
Applicability of FSMA Rules

3. Foreign Supplier Verification Programs
   • Generally, applies to importers of human and animal food
   • **EXEMPT:** (1) Importers of grain that are solely engaged in the storage of grain intended for further distribution or processing; and (2) Importers of grain that do not take physical possession of the grain they import

4. Accreditation of Third-Party Auditors
   • Applies *only* 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*
The TRUMP Administration, Congress and FSMA

MAKE AMERICA GREAT AGAIN!
Republican Majorities in Senate and House for 115th Congress

**House**
- Before: 247 Republicans, 188 Democrats
- Turnover: Republicans -8, Democrats +5
- 2018: All seats up; Party of newly elected President suffers average loss of 23 seats during mid-term election

**Senate**
- Before: 54 Republicans, 46 Democrats
- Turnover: Republicans -3, Democrats +1
- *two Independents caucus with Democrats*
- 2018: Democrats defend 23 seats (+2 Ind.), Republicans defend 8 seats
Regulatory Reform

• Jan 30, 2017: EO 13771 – Reducing Regulation and Controlling Regulatory Costs

• Feb. 24, 2017: EO 13771 – Enforcing the Regulatory Reform Agenda

• Oct. 1, 2017: “Cut The Red Tape” Initiative
21 CFR Parts 117 and 507 –
Current Good Manufacturing Practice,
Hazard Analysis, and Risk–Based Preventive Controls

- Subpart A: General Provisions
- Subpart B: Current Good Manufacturing Practice
- 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
• FSMA CGMPs
  • Set baseline standards/conditions for which FDA believes need to be present to assure safety of food products
  • Animal food CGMPs are new; many provisions have qualifiers – e.g., “as necessary and appropriate” – to accommodate the scope of animal food facilities covered under requirements

• Qualified Individual Training
  • Required, documented training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual’s assigned duties.
  • Requirement extends to all individuals who supervise or perform manufacturing, processing, packing or holding food at the facility, not just employees
21 CFR Parts 117 and 507 – Preventive Controls

• A written food safety plan is required
  • Plan to be developed, implemented, overseen by “preventive controls qualified individual” (PCQI)
  • Documents need for and implementation, if any, of “preventive controls”

• Hazard evaluation is the cornerstone of the food safety plan
  • Assess the severity of the illness or injury to man and/or animals if the hazard were to occur
  • Assess the probability that the hazard will occur in the absence of preventive controls

RISK = Severity x Probability
Inspections – Inspections – Inspections

• FDA initial enforcement and compliance approach: “Educate Before and While We Regulate”

• Small “cadre” of federal and state investigators trained to perform initial inspections
  • Inspectional focus still may vary depending on investigator’s own interests

• FDA “Program Alignment Initiative” intended to improve investigator expertise related to specific inspection assignments
Inspections – Inspections – Inspections

- Issuance of FDA Form 483’s – “Notice of Observations” – if any, are made in consultation with FDA headquarters

- FDA typically does not impose monetary penalties, instead agency has authority to:
  - Detain product
  - Mandate recalls
  - Impose consent decrees
  - Suspend facility registration
Part 507
Animal Food CGMP Inspections

• CGMP inspections began first quarter 2017 for “large businesses” – about 250 inspections conducted through Sept. 2017 (federal fiscal year: Oct 1 – Sept. 30)

• Sept. 18, 2017 – CGMP compliance date for “small businesses”

• Inspections are “conversation- and systems-based”
Part 507
Animal Food CGMP Inspections

• **NO** recordkeeping requirements for CGMPs, but records will be useful

• Sanitation conditions and pest control practices are expected to be focal points during inspections

• October 2017: FDA issued Final Animal Food CGMP Guidance for Industry
Part 507
Animal Food PC Inspections

• Sept. 18, 2017 – PC compliance date for “large businesses”
• Sept. 17, 2018 – PC compliance date for “small businesses”
• **Routine** PC inspections slated to begin fall 2018
• FDA will inspect for PC compliance at “large companies” **before** fall 2018 when investigating an animal food safety incident
• Records to be established and maintained for all activities required under PC regulation
• First section of **FDA Draft PC Animal Food Guidance** issued in Jan. 2018
FSPCA Preventive Controls for Animal Food

Training

FSPCA Preventive Controls for Animal Food Course
FSPCA Preventive Controls for Animal Food Lead Instructor Training
FSPCA Preventive Controls for Animal Food Course AND Lead Instructor Training
Selection Criteria for Lead Instructor
Animal Food Lead Instructor Course Schedule

FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD

COURSE DESCRIPTION

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Animal Food regulation (referred to as the Preventive Controls for Animal Food regulation) is intended to ensure safe manufacturing/processing, packing and holding of food products for human consumption in the United States. The regulation requires that certain activities must be completed by a “preventive controls qualified individual” who has “successfully completed training in the development and application of risk-based preventive controls, or is otherwise qualified through job experience to develop and apply a food safety system”. This course
21 CFR PART 1 –
Sanitary Transportation of Human and Animal Food

• **Subpart O**

  • **General Provisions** – 1.900 Who is subject?
  
  • **Vehicles and Transportation Equipment** – 1.906 What requirements apply to vehicles and transportation equipment?
  
  • **Transportation Operations** – 1.908 What requirements apply to transportation operations?
  
  • **Training** – 1.910 What training requirements apply to carriers engaged in transportation operations?
  
  • **Records** – 1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?
  
  • **Waivers**

---

**FEDERAL REGISTER**

Vol. 81

No. 66

April 6, 2016

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11
Sanitary Transportation of Human and Animal Food; Final Rule

---

**GEAPS**

**GRAIN JOURNAL**

**EDUCATIONAL WEBINAR SERIES**
21 CFR PART 1 – Sanitary Transportation of Human and Animal Food

• **Generally,** applies to:
  • Intrastate and interstate food transportation, including grain and feed
  • Truck and rail transportation operations, not waterborne or air

• Compliance dates
  • “Large Businesses” – April 6, 2017
  • “Small Businesses” – April 6, 2018

• Exempt transportation activities include:
  • Activities performed by a “farm”
  • Activities performed by “non-covered businesses.” A “non-covered business” is defined as “a shipper, loader, receiver, or carrier engaged in transportation operations that has less than $500,000 in average annual revenues
Requirements for Shippers

- Shippers must specify in writing to the carrier and, when necessary, to the loader, all sanitary specifications necessary for the carrier’s vehicle and transportation equipment pursuant to the product to be transported
  - One time notification is sufficient, unless specifications change
- Shippers must develop and implement written procedures to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition
- Shippers of food transported in bulk must develop and implement written procedures to ensure that a previous cargo does not make the food unsafe
• **NO** requirement for “Shipper” or “Loader” to know last load hauled, cleanout information, but “Shipper” needs to establish adequate written procedures to ensure a prior load does not cause food to become unsafe during transportation

• **NO** training requirements, except for carriers when the carrier agrees to take on responsibility under rule

• “Loaders” are to determine that conveyances are suitable for bulk cargoes prior to loading
Sanitary Transportation Inspections

• Inspections likely to begin fall 2018
• For grain and feed facilities, inspections likely will be combined with evaluation of other topics, e.g., CGMPs/PCs, BSE, general sanitation, etc.
• FDA has issued Small Entity Compliance Guide
21 CFR PART 1 –
Foreign Supplier Verification Program for Food Importers

• Subpart L
  • 1.501 To what foods do the regulations in this subpart apply?
  • 1.502 What foreign supplier verification program (FSVP) must I have?
  • 1.503 Who must develop my FSVP and perform FSVP activities?
  • 1.504 What hazard analysis must I conduct?
  • 1.505 What evaluation for foreign supplier approval and verification must I conduct?
  • 1.506 What foreign supplier verification and related activities must I conduct?
21 CFR PART 1 – Foreign Supplier Verification Program for Food Importers

• Currently applies to:
  • Importers of foreign human and animal foods, including brokers with no facility
  • **EXEMPT:** (1) Importers of grain that are solely engaged in the storage of grain intended for further distribution or processing; and (2) Importers of grain that do not take physical possession of the grain they import
  • **EXEMPT:** Users of foreign food are **not** covered if they are **not** the importer

• Importer is required to perform a hazard evaluation of foreign food to identify if any hazards exist that require control

• Hazard evaluation and controls, if needed, are subject to FDA review
  • Under this rule, FDA has authority to request that importer send FSVP to FDA upon request
21 CFR PART 1 –
Foreign Supplier Verification Program for Food Importers

• Compliance dates are complicated….

• Depends on applicable compliances dates for importer and foreign supplier under other FSMA rules

• Earliest date – May 30, 2017
Food Safety Modernization Act (FSMA) Regulatory Update

Questions