FSMA and Grain Handlers

Regulatory Obligations and Supplier Expectations

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- **U.S. Law: *Grain and Feed* are Food**
  - Section 201(f) Federal Food, Drug and Cosmetic Act:
    “The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”
  - Federal Food, Drug and Cosmetic Act provides FDA broad authority to ensure that food is produced, held, distributed under appropriate sanitary conditions and applicable regulations.
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 – Some Key Provisions

- **Food Facility registration** is required with FDA every two years on even numbered years
  - 2016 is a re-registration year
  - Registration is free through FDA’s electronic system
- FDA granted authority to **issue mandatory recall** notices to facilities
- FDA granted **expanded** authority to **administratively detain** food products
- FDA mandated to **inspect** all registered food facilities
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<th>Subject of FSMA Rule</th>
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<td>Current Good Manufacturing Practice (CGMP) and Preventive Controls – Human Food</td>
<td>Sept. 17, 2015</td>
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<td><strong>Current Good Manufacturing Practice (CGMP) and Preventive Controls – Animal Food</strong></td>
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<td>Produce Safety Standards</td>
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<td><strong>Foreign Supplier Verification Programs</strong> **</td>
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** Can apply 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 [e.g., grain elevators] **exempt** from both rules
  - Different treatment for elevators handling “fruits” [e.g., lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, peas, peanuts, tree nuts, seeds for direct consumption]
  - 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
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 clearly 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 that is not “holding” of raw agricultural commodities, e.g.,
  - Grain elevator plus feed mill
  - Grain elevator plus bag feed warehouse
  - Grain elevator plus transloading operations
Definition of “Facility”

- Established under Registration of Food Facilities Rule, Oct. 10, 2003
  - *Facility* means any establishment, structure, or structures under one ownership at one general physical location ... that manufactures/processes, packs, or holds food for consumption in the United States. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership.
Definition of “Facility”

- Registration of Food Facilities Rule, Oct. 10, 2003
  - FDA: “One factor for determining whether a business is one or two facilities is through real estate records, because a property line could demonstrate that several buildings are on the same lot, and therefore, are the same facility.”
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*
CGMPs and Preventive Controls

• **CGMPs**
  - Required conditions and practices to ensure that food will not become adulterated
  - Human food CGMPs have been in place since 1969, with significant revisions made in 1986
  - Medicated animal feed CGMPs established in 1976
  - FSMA CGMPs issued in 2015 for animal food set forth first comprehensive requirements for all sectors of animal food industry
Animal Food FSMA CGMPs

• § 507.14 Personnel – cleanliness and training
• § 507.17 Plant and Grounds – maintenance, design, construction
• § 507.19 Sanitation – housekeeping, cleaning, pest control
• § 507.20 Water supply and plumbing – water quality, plumbing design, rubbish control
• § 507.20 Equipment and utensils – maintenance, design, construction
• § 507.25 Plant operations – labeling, inspection of raw materials, ingredients, protection against metal/foreign objects
• § 507.27 Holding and distribution – storage and transportation
• § 507.28 Holding and distribution of human food by-products for use as animal food
§ 507.25 Plant Operations – Raw Materials and Ingredients

- Raw materials and other ingredients:
  - 1) Must be examined to ensure that they are suitable ... and must be handled under conditions that will protect against contamination and minimize deterioration.
    - (i) Shipping containers ... and bulk vehicles holding raw materials and other ingredients must be examined upon receipt to determine whether contamination or deterioration ... has occurred
    - (ii) Raw materials must be cleaned as necessary to minimize contamination
    - (iii) Raw materials and other ingredients, including rework, must be stored ... in a way that protects against contamination and deterioration, and held under conditions ... that will minimize ... growth of undesirable microorganisms and prevent the animal food from becoming adulterated
  - 2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans
Preventive Controls Requirements

• Requires covered food facilities to 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
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, but not waterborne or air transportation.
- Exempt transportation activities include:
  - Activities performed by “non-covered businesses” - 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

• 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 ... 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

- **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

- **Loaders** 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 [e.g., 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.
# 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>
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</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>
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<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>
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<td>Sept. 18, 2017 (PCs)†</td>
<td>Sept. 17, 2018 (PCs)†</td>
<td>Sept. 17, 2019 (PCs)</td>
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<tr>
<td>Foreign Supplier Verification Program</td>
<td>May 27, 2017§</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Third Party Accreditation</td>
<td>Requirements go into effect after FDA publishes Model Accreditation Standards – Issued Dec. 6, 2016</td>
<td></td>
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<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>
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*Large Business*: Businesses with more than 500 employees in the United States.

**Small Business**: Businesses with more than 20 employees in the United States.

***Very Small Business***: Businesses with more than 10 employees in the United States.

†Compliance will continue to require a separate variance petition for a period of up to 4 years after the compliance date.

§The foreign supplier verification program is not applicable to importers of low-risk foods.

‡Sanitary Transportation requirements apply to both human and animal food.

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FSMA Compliance Dates

* Large Business Definitions: *All Rules* – Business that does not meet the definitions for “small business” or “very small business”

** Small Business Definitions:
- *CGMP and Preventive Control Rules for Human and 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
- *Food Defense/Intentional Adulteration* – Business with less than 500 full-time equivalent employees

*** Very Small Business Definitions:
- *Preventive Controls Human Food* – Business with less than $1 million in annual human food sales plus market value of human food not sold;
- *Preventive Controls for Animal Food* – Business with less than $2.5 million in annual animal food sales plus market value of animal food not sold;
- *Food Defense/Intentional Adulteration* – Business averaging less than $10,000,000 in annual human food sales plus market value of human food not sold

† Supply Chain Program Compliance: *Human Food* – Later of: 1) six months after supplier is required to comply with the applicable rule; or 2) March 17, 2017 (large business) or Sept. 18, 2017 (small business); *Animal Food* – Later of: 1) six months after supplier is required to comply with the applicable 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 $1 million for human food and $2.5 million for animal food plus market value of human food or animal food not sold) and “importers of food from very small foreign suppliers” are subject to modified requirements.
Customer Expectations

• Food safety expectations for suppliers of raw materials and ingredients are growing, and may include requests for:
  • Certificate of Analysis (COA) for specified nutritional values and/or potential contaminants
  • Submission of a hazard analysis of products and description of controls applied to mitigate potential hazards
  • Assurances that suppliers have developed and implemented an effective written food safety plan for its operations
  • Assurances about prior loads transported on bulk conveyances and attestations about cleaning and suitability of the conveyance for the current load
  • Use of seals on conveyances and associated documentation
NGFA FSMA Resources

- **NGFA Feed Education** - [http://feed.ngfa.org/](http://feed.ngfa.org/)
  - **White Papers:**
    - [NGFA Summary of FSMA Final Regulations For Human and Animal Food Sept. 22, 2015](http://feed.ngfa.org/)
    - [NGFA Summary on FSVP and Third-Party Accreditation Rules Nov. 16, 2015](http://feed.ngfa.org/)
    - [NGFA Summary on FSMA Final Rule on Sanitary Transportation of Human and Animal Food June 2016](http://feed.ngfa.org/)
  - **Webinars:**
    - What You Need to Know About FSMA (55 mins.) | Oct. 5, 2015 | [View webinar](http://feed.ngfa.org/) | [View presentation slides](http://feed.ngfa.org/)
    - FDA Final Rule For Sanitary Transportation of Human and Animal Food (60 mins.) | July 7, 2016 | [View webinar](http://feed.ngfa.org/) | [View presentation slides](http://feed.ngfa.org/)
  - **Other:**
    - [Summary of Compliance Dates for Major FSMA Rules](http://feed.ngfa.org/)
    - [Food Safety Modernization Act Q&As](http://feed.ngfa.org/)
NGFA FSMA Resources

• NGFA FSMA Guidance Task Force, developing
  • Overview of FDA regulatory requirements applicable to grain and feed companies
  • Detailed information of FSMA-related requirements
  • Example Food Safety Plan information and templates
Questions – Comments?

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