Impacts of FSMA in the Grain Handling Business

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The Big Picture of FSMA

Create an integrated system that prevents human and animal food safety hazards from reaching the intended use of the food.

– Consistent definition and identification of hazards
– Consistent application across jurisdictions
– Consistent training basis across regulatory bodies
– Uniform regulatory process and audit results
– Flexibility of application rather than checklist
– Collaborative among regulatory bodies and industry
### The Seven Major Rules of FSMA

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<tr>
<th>Rule</th>
<th>Final Status</th>
<th>General Compliance Period</th>
<th>Small Business Compliance</th>
<th>Very Small Business Compliance</th>
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<td>Preventive Controls for Human Food</td>
<td>30-Aug-15</td>
<td>19-Sep-16</td>
<td>18-Sep-17</td>
<td>17-Sep-18</td>
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<tr>
<td>Preventive Controls for Food for Animals</td>
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<td>19-Sep-16</td>
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<td>31-Mar-18</td>
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[http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm)

**FSMA rules are audit-based not checklist-based.**
Preventive Controls (and CGMP) Practicalities for Grain Elevators

- Facilities that only handle and store raw commodities are exempt from documented cGMP, the Preventive Controls, and the PCQI. But:
  - The 5-7 year FDA routine surveillance inspection will probably still use the GMP’s.
  - Some buyers are looking for more documentation anyway.
  - Have you been asked to collect and pass-through information?
  - Or to be formally part of a supply chain preventive control?
  - Does your contract include legal requirements similar to FSMA?

And:
Elevators with Feed Mills, Processing

• Several arrangements:
  – On the same site and connected by conveyor. Yes
  – On the same site but not connected by conveyor Yes
  – On the same site but no product transfer ?

Current thought: By FEI number and general location

• Practicalities:
  – Get involved with your PCQI and be on the Food Safety Team for the mill.
  – Work through the CGMPs as applied to the elevator. Make steady improvements as needed. Keep records.
  – Understand what mill hazards could come from elevator.
  – If covered, grain employees will be QI’s…training records
QI vs PCQI

• **PCQI = Preventive Controls Qualified Individual**
  – Formal designation in the rule
  – Has specific designated duties and qualifications by Rule
  – Basically is responsible for the food safety plan and monitoring/review.

• **QI = Qualified Individual**
  – All employees doing tasks that impact food safety
  – Documented FS training on their specific tasks
  – Documented training on basic animal food safety principles that apply to their tasks.

**Practicality:** Training records are likely first items of audit/inspection. Remember: If there is a FS threat, anyone can be investigated.
Part 507, Subpart B – Current Good Manufacturing Practice

- 21 CFR 507.14 - Personnel
- 21 CFR 507.17 - Plant and grounds
- 21 CFR 507.19 - Sanitation
- 21 CFR 507.20 - Water Supply and plumbing
- 21 CFR 507.22 - Equipment and utensils
- 21 CFR 507.25 - Plant operations
- 21 CFR 507.27 - Holding and distribution
- 21 CFR 507.28 - Holding and distribution of human food by-products for use as animal food.
Purpose of CGMP

• Considered by FDA to be “...necessary to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health” (Preamble, II: Legal Authority).

• Establishes baseline standards for the production of safe animal food and the creation of a successful Food Safety Plan.
Example – Plant and Grounds

• Must protect animal food stored outdoors in bulk by any effective means when necessary or appropriate
Example – Sanitation

• Examples of toxic materials: fertilizers, cleaning compounds, treated seeds, and pesticides

• Toxic materials must be stored separately from materials intended for animal food and where animal food is manufactured, processed, packed, or stored.
Example – Plant operations

• Where appropriate, conduct appropriate evaluations to ensure inbound materials are safe
  ▪ Raw materials must be evaluated for suitability, and shipping containers inspected to verify adulteration has not occurred.

• Hold materials in a safe manner
  ▪ Flushes, rework, and rejected feed must be identified and utilized or disposed of appropriately.
  ▪ Work-in-progress and rework must be protected from contamination and growth of biological hazards.

• Manufacture in a way to ensure safety
  ▪ Reliance on water activity or pH to prevent growth of biological hazards must be monitored.
Note – Inbound Ingredient Evaluation

- Preamble points:
  - Weather can be considered when evaluating raw materials susceptible to mycotoxin contamination.
  - Not every load of grain needs to be tested as long as evaluation results in the facility using ingredients in a manner that does not result in harm to humans or animals.
  - Visual examination of ingredients or shipping containers is acceptable, with emphasis on observing any unusual residues that may contaminate the animal food.
Which CGMP does this Concern?

§ 507.14(b)(3) Personnel – Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers

§ 507.14(b)(4) Personnel – Storing clothing or personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned

Sunglasses and utility knife at open microingredient bin
Which CGMP does this Concern?

§ 507.17(a)(1) Plant and grounds— Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests
Which CGMP does this Concern?

§ 507.17(c)(1-3) Plant and grounds—The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including: 1) Using protective coverings where necessary and appropriate; 2) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and 3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.
§ 507.22(a)(1) Equipment and utensils—All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained.

**Utensils not cleanable or properly maintained**
CGMP - Inspection

• Split from Preventive Controls, at least initially.
• By FDA personnel or contracted personnel
  – State regulatory agencies
  – Inspector training is happening now.
  – Remember the documentation/justification basis for FSMA

• Likely target areas
  – Training records for each employee whose job affects food safety (QI’s)
  – Records of your plans for each CGMP.

• Likely will be unannounced.
CGMP - Impacts

• If covered by Rule, then required items for documentation.
• If not covered by Rule, then best practice expectations

• More third-party audits of suppliers are being done.
• Routine surveillance inspections….facilitated.
• Food safety culture
• Let your employees evaluate the facility
PREVENTIVE CONTROLS FOR ANIMAL FOOD
“STANDARDIZED CURRICULUM” RECOGNIZED BY FDA

PARTNERS:

Wednesday, August 9, 2017 – Friday, August 11, 2017

Registration deadline August 4, 2017.
Scheman Center, Iowa State University, Ames, IA. http://www.aep.iastate.edu/animalfood
21 CFR Part 507 – Preventive Controls for Animal Food

• **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
21 CFR 507.3 – Definition: “Hazard”

- Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.
21 CFR 507.3 – Definition: “Known or Reasonably Foreseeable Hazard”

- A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food.
“which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls”
Potential Hazards to Consider for Grains

- **Physical Hazards**
  - Non-grain material (glass, metal, wood, petroleum residue)
  - Animal excreta or carcasses

- **Chemical Hazards**
  - Treated seed
  - Allergen (other grains)

- **Microbial/Biological Hazards**
  - *Mycotoxins from fungi*
  - Flooded grain
  - Pathogens

There is no required list of hazards!!!!
Grain Submerged by Uncontrolled Stream or River Waters.

- Is Adulterated by Food Drug and Cosmetic Act
  - PCB’s, Pathogens, Mycotoxins, Excrement
- Cannot be placed in commerce.
- In 2008, corn in Cedar Rapids was destroyed
- Can be used on farm with Veterinary control
  - Complete testing for above.
  - Mostly applies to corn, Few on farm uses for soybeans.
## Process to Identify Hazards and Controls

### Hazard Evaluation Example

<table>
<thead>
<tr>
<th>SEVERITY</th>
<th>PROBABILITY</th>
<th>HIGH (I)</th>
<th>MEDIUM (II)</th>
<th>LOW (III)</th>
<th>VERY LOW (IV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH (A)</td>
<td>Immediate danger that the hazard will occur.</td>
<td>I-A</td>
<td>II-A</td>
<td>III-A</td>
<td>IV-A</td>
</tr>
<tr>
<td>MEDIUM (B)</td>
<td>Probably will occur in time if not corrected.</td>
<td>I-B</td>
<td>II-B</td>
<td>III-B</td>
<td>IV-B</td>
</tr>
<tr>
<td>LOW (C)</td>
<td>Possible to occur in time if not corrected.</td>
<td>I-C</td>
<td>II-C</td>
<td>III-C</td>
<td>IV-C</td>
</tr>
<tr>
<td>VERY LOW (D)</td>
<td>Unlikely to occur; may assume hazard will not occur.</td>
<td>I-D</td>
<td>II-D</td>
<td>III-D</td>
<td>IV-D</td>
</tr>
</tbody>
</table>
Background: This is a tool to assist animal food facilities fulfill the hazard analysis requirements specified in the Food Safety Modernization Act - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals rule. According to the rule, covered facilities must "conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control..." The hazard analysis must also include an evaluation to "assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of the preventive controls."

Purpose of the Scientific Literature Database Tool: This tool provides data obtained from a review of scientific literature and recall data that may be used to assess the documented occurrence of hazards in animal food and data describing the severity of hazards to sixteen animal species groups. Summary scores for documented occurrence of hazards in animal food and severity in animal species groups are also provided.

Scope: The following sources were used to create this database
- Scientific papers from the past 10 years that were published in the United States and Canada
- FDA Class I recalls from 2009 to present
- FDA Class II and III recalls from 2012 to present

CAUTION: The data and scores provided in this tool may serve as a starting point for a facility specific hazard analysis which must also include other facility specific information such as facility experience and other factors specified in the Preventive Controls Rule.
Types of Preventive Controls

- Hazard Requiring a Preventive Control
  - Process Control (internal)
  - Sanitation Control (internal)
  - Supply–Chain–Applied Control (external)
  - Other Control
Types of Supply Chains

Supplier
- Grain producer
- Ingredient supplier

Manufacturing/Processing/Receiving Facility
- Manufacturer/processor/receiving facility

Customer
- Animal feeder

Source: Microsoft Office Clipart
Types of Supply Chains

- **Supplier**
  - Grain producer / Ingredient Supplier

- **Intermediary**
  - Holder / Broker / Distributor

- **Manufacturing/Processing/Receiving Facility**
  - Animal Food Manufacturer/Processor

Source: Microsoft Office Clipart
Preventive Controls - Practicalities

• Animal food buyers: The hardest issue will be mycotoxins.

• Human food buyers: The hardest issue will be allergens (A.K.A. Other grains)

• No preset hazard list, but pay attention look for those that are mentioned in the Rule and the training course.

• Use external resources.

• Not covered? Those you sell to probably are!
Sanitary Transportation

- **Shipper** must load a clean and safe container with documentation of previous load, cleaning if needed.

- Receiver must retain documentation from shipper.

- **Loader** has responsibility for last check.

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April 2016
Sanitary Transportation

• Vehicles and transportation equipment:
The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe. For example, they must be suitable and adequately cleanable for their intended use and capable of maintaining temperatures necessary for the safe transport of food.
Sanitary Transportation

• Transportation operations:

The measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready to eat food from touching raw food, **protection of food from contamination by non-food items in the same load or previous load**, and protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.
Sanitary Transportation

• Training:
Training of carrier personnel in sanitary transportation practices and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.

The rest of the Sanitary Transportation training requirements are in the CGMP.

Carriers not accepting responsibility are the responsibility of the shipper.
Sanitary Transportation

• Records:
Maintenance of records of written procedures, agreements and training (required of carriers). The required retention time does not exceed 12 months.
Sanitary Transportation

• Practicalities
  – Record trailer, railcar, barge identification
  – Update inbound and outbound shipping records.
  – IT system upgrades to retain increased documentation.
  – Written procedure for loading
  – Cleanout procedure if a hazard was a previous cargo.
  – Contract haulers/brokers will need training.
  – Debates with transportation companies are likely.

• No exemptions except farmer movements
• Complicates supply chain recordkeeping

• Impact: Gradual reduction in brokers, middle entities.
FSMA over time will:

• Require expansion of data collection and management capabilities. Especially transportation.
• Require more documented training
• Increase the cost of intermediaries, brokers, etc.
• Be an incentive for more exacting inventory control
• Create more direct discussion between internal divisions and across external supply chain
• Create a legal liability pathway
• The Goal: remove food hazards before point of use
Where To Find Us

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