Food and Feed Safety: What Grain Operators Need to Know

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Agenda

• Overview of “Food”
• Current Legislation
• New Legislation
• Common Risks
• Best Practices
Key Concepts

1. Food is feed & feed is food
2. We (industry) are going to need to do things differently because of recent legislation
3. The grain industry is already subject to several regulations that have food safety implications
4. Many things we do for personal/occupational safety (OSHA) are also related to food safety
Food: Defined

• “Food” is defined by the Federal Food Drug and Cosmetic Act as:

   (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 (FFDCA, Section 201(f))

• For Example:
  – Raw Agricultural commodities for use as food or components of food
  – Animal feeds and pet food
Who Cares???

- Consumers
- Business owners
- Government/Legislators
- Customers
- Industry
Why???

• Food must be safe to eat
• Food safety programs protect everyone
• Poor standards of food safety threaten health, reputations and profits
• Food poisoning is caused by eating contaminated food
• Contaminated food is harmful to health because it contains something that should not be there
At the end of the day, as a primary step in the food supply chain, we want to provide a safe, nutritious food product to our customers.

Remember, you are what you eat, eats!
Impact
(Some Statistics)

• In the US, it is estimated that each year food borne diseases cause approximately
  – 76 million illnesses
  – 325,000 hospitalizations
  – 5000 deaths

• Costs around $35 billion in medical costs and lost productivity
Impact

• A 900-bushel truck (~25 mt) will make about 33,000 pounds of white bread flour.
• 33,000 lbs of flour will make about 60,000 1-pound loaves of bread
• Some 250,000 people could be affected
Current Legislation

Bioterrorism Act

• Effective 12/9/2005 with exceptions for small & very small businesses
• One step forward, one step backward traceability
  – Including transporter information
• Records retained for minimum of 2 yrs for grains
• 24 hrs to provide requested records
• Facility registration required
Current Legislation

Reportable Food Registry

• Reportable food – An article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals

• Effective September 8, 2009
Current Legislation

Reportable Food Registry

• Within 24 hours of determining a food is reportable, an entry must be made to the RFR
• What is an example of a potentially reportable food?
  – Lots of grain sampled within the official system that would be considered actionable by FDA
• Decisions to report should be made in conjunction with legal counsel and/or regulatory specialists
Current Legislation

US Warehouse Act

• The Warehouse Operator agrees to (each of the following):
  – Conduct a facility vulnerability assessment and establish written security procedures that address grain handled and stored under this Agreement with regard to (each of the following):
    • General security of the USWA-licensed physical structures and property on which the licensed warehouse is located;
    • Shipping and receiving procedures to ensure that grain is not subject to tampering;
    • Action to be taken in the event of a national emergency; and
    • Contact information for local emergency responders and law enforcement authorities.
  – Have a written facility security plan that includes measures which address the vulnerabilities found during the risk assessment and that protect the grain handled and stored under this License.
Current Legislation

FGIS-FDA Memorandum of Understanding

- FGIS reports to FDA certain lots of grain, rice, pulses, or food products which are considered actionable under the Food Drug and Cosmetic Act (FDCA)
- Only *OFFICIALLY* sampled domestic and export lots are subject to being reported to FDA
- Full set of review inspections (reinspection, Fed appeal, Board appeal) allowed
- Have to work with FDA on a reconditioning or diversion plan
Current Legislation

FGIS-FDA Memorandum of Understanding

• Examples applicable to grain
  – Aflatoxin exceeding 20 ppb
  – Bird or rodent droppings in wheat, rye, rice, and pulses
  – ≥ 32 IDK per 100 g of wheat
  – Two or more castor beans per 1000 g
  – Three or more crotalaria seeds per 1000 g
  – 20 or more treated seeds per 1000 g
  – COFO or DLQ grain
  – Metal fragments & stones
Food Safety Modernization Act

Overview

• Impacts grain elevators, feed mills, processors, millers, exporters, and importers
• No explicit exemption for grain handlers
• Science- and risk-based approach to food safety
• Significantly expands FDA’s authority and regulatory reach
• Implemented via guidance documents and rulemaking activities (~ 50 activities)
• Self-enacting law
Food Safety Modernization Act

Overview

• No explicit exemption for grain handlers
  – Provision allowing FDA to exempt or modify requirements for grain facilities
  – Not a blank “hall pass”
  – Facilities will still be inspected, and not all inspectors are created equally

• Does contain provision that guidance/regulation must differentiate between human food and food for animals, where appropriate
Food Safety Modernization Act

Covered Facilities

- Grain elevators
- Feed, feed ingredient, and pet food manufacturers
- Grain processors, including corn and flour mills and soybean crush plants
- Biofuels producers manufacturing coproducts like DDG for use as feed ingredients
- Exporters of grains, feed & feed ingredients, and processed commodities
Food Safety Modernization Act

Significant Requirements

• HACCP* that is not being called a HACCP
  – Written Hazard Analysis of hazardous that are known or reasonably foreseeable that may exist
  – Implementation of controls that minimize or prevent identified hazards
  – Written plan that describes procedures to comply with hazard analysis and preventative controls

*Hazard Analysis and Critical Control Points
Food Safety Modernization Act

Significant Requirements

• Preventative controls
  – Risk-based, science-based, and reasonably appropriate
  – Monitored and verified, including product and environmental testing
  – Includes process to prevent adulterated or misbranded product from entering into commerce
Food Safety Modernization Act

Significant Requirements

• FDA has proposed separate, but compatible HAPC regulations for human food and animal feed.
  – Strongly supported by NGFA
  – Provides flexibility to tailor regulation to be appropriate for differing industry segments
  – Salmonella Guidance is good example
Food Safety Modernization Act

Regulatory Update

• FDA has sent proposed regulations to OMB
  – Preventative Controls for Food, Feed, and Produce Safety
  – Foreign Supplier Verification Program

• It’s an election year...
  – Food -> Imminent. Would like FSVP coupled
  – Feed & Produce???
Food Safety Modernization Act

Significant Requirements

• Food defense regulations
  – Limited to high-risk products
  – Industry-wide vulnerability assessments suggest regulations will not be imposed on the grain industry

• Reanalyze/update food safety plan every three years
  – Needs to be updated if significant change creates reasonable potential for change in hazard analysis
Food Safety Modernization Act

Other Requirements

• Update facility registration between Oct 1 and Dec 31 every-other-even-numbered year, starting in 2012

• Facility inspections
  – Within seven years of enactment of law
  – Every five years thereafter
  – Subject to funding and hiring goals
  – May leverage state regulatory officials (e.g., state feed inspectors)
Food Safety Modernization Act

New/Increased Authorities

• Setting contaminant-specific standards
  – Regulations/guidance specific to products or product classes, not facility-specific
  – Includes provision requiring FDA, where appropriate, to distinguish between animal food and human food

• Suspension of Facility Registration
  – Effectively shuts plant down
  – Need reasonable probably that products could cause serious adverse health consequences or death to humans or animals
Food Safety Modernization Act

New/Increased Authorities

• Records access
  – Can access existing records if reasonable belief that products could cause serious adverse health consequences or death to humans or animals and FDA reasonably believes other products are similarly affected. This provision took affect immediately

• Mandatory recall
  – FDA only needs reasonable probability
  – Facility given opportunity for voluntary recall
Food Safety Modernization Act

New/Increased Authorities

• Enhanced product tracing
  – Law prohibits FDA from imposing recordkeeping requirements that would limit commingling (blending) of grains.
  – Grain handlers will remain subject to requirements set forth in Bioterrorism Recordkeeping requirements, for now.
  – Negligible impact to grain facilities, at this time
Food Safety Modernization Act

New/Increased Authorities

• Administrative Detention
  – Lower threshold than Bioterrorism Act
  – Reason to believe vs. credible evidence

If FDA *thinks* you have adulterated product, they can seize it.
Food Safety Modernization Act

New/Increased Authorities

- Administrative Detention
  - Interim Final Rule published 5 May 2011
  - Effective 3 July 2011

What the heck does that mean? Effective July 3rd, if FDA ‘thinks’ you have an adulterated or misbranded food in your facility, they can detain it (for 20 days)!
Food Safety Modernization Act

New/Increased Authorities

• Fees
  – Reinspection
  – Mandatory recalls
  – Voluntary Qualified Importer Program
  – Export certificates

• Sanitary transportation of food
  – Reiterates mandate to implement Sanitary Food Transportation Act
  – Could have significant impact to grain industry
Common Food Safety Risks

- Mycotoxins
- Pests (rodents, birds, insects, other animals)
- Foreign material (glass, metal, tools)
- Tobacco/Tobacco Juice
- Food Waste
- Others???
Simple Practices

Mycotoxins

• Know the mycotoxin requirements
  – FDA regulations
  – Domestic customer requirements
  – International customer requirements

• Develop a mycotoxin management plan

• Educate your team on the risks associated with mycotoxins
Simple Practices

Pest Control

• Develop a strong pest control program
• Keep doors and windows closed
  – Have screens or netting on doors/windows
• Keep the facility clean
  – Clean up grain spills as soon as possible
  – Minimize harborage (weeds, brush, etc.) around the exterior of the plant
• Work with a reputable pest control supplier
• Ground piles???
Simple Practices

Pest Control

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• Ground piles???
Prevent access

Prevent roosting

Pigeons

Scarers
Rats

Mice

Bait boxes and poison
Simple Practices

Foreign Materials

• Keep pit grates clear/watch the pit during unloading operations
• Utilize scalpers/cleaners
• Are magnets feasible?
• Lighting
  – Are shatter proof/resistant coverings used?
  – Can bulbs be positioned such that they aren’t directly over the grain path?
• Keep equipment in good repair
• Inspect transportation equipment
  – What type of service did a barge or rail car come out of?
Coal

Asbestos

Glass

Dead vermin
Maintenance & Sanitation
Simple Practices

Tobacco & Food

• Limit areas of the plant where employees can have food and tobacco products
• Provide proper trash receptacles (this will also help with pest control)
• What about customers (Farmers/truck drivers)?
  – Establish programs that face the customer
  – Be frank that we are handling a food product
  – Monitor operations
Simple Practices

Others

• Ensure contractors understand requirements regarding food safety
• Make food safety a regular discussion
• Follow good management practices for quality grain storage (e.g., CO₂, Mycotoxin management, aeration, etc.)
• Grade inbound grain
Food Safety Plan Checklist*

• Make a flow diagram of your operation
  – Traceability

• Building and grounds
  – Pest management
  – Grain spills & grounds maintenance
  – Chemical management

• Personnel
  – Personal hygiene
  – Training

*Adapted from Iowa State University, as presented in *Feed & Grain*, June/July 2012
Food Safety Plan Checklist*

• Sanitation
  – Policies on transportation sanitation
  – Housekeeping policies/programs
  – Pest waste management
  – Recordkeeping: When, who, how often

• Biosecurity
  – Facility security
  – Previous loads
  – Visitor policy

*Adapted from Iowa State University, as presented in Feed & Grain, June/July 2012
Food Safety Plan Checklist*

• Allergen control (grain intended for food)
  – Harvesting protocol
  – Plans for preventing cross contamination
• Foreign material control (i.e., glass, wood, metal, stones)
• Recall procedure
• Customer complaint policy
• Use of data – Do you regularly review your records and programs and make improvements?

*Adapted from Iowa State University, as presented in Feed & Grain, June/July 2012
Key Takeaways

1. As a primary link in the food supply chain, we need to change the way we think about food safety in our operations

2. There are a number of laws currently in place that industry needs to follow

3. The new FFSMA will have implications for the grain industry

4. There are some simple actions elevators can take to minimize food safety risks
Resources/References

• Bioterrorism Recordkeeping

• Facility Security

• H.R. 2751 – FDA Food Safety Modernization Act
  – http://thomas.loc.gov/home/gpoxmlc111/h2751_enr.xml
Resources/References

• FDA/FGIS MOU

• FDA Mycotoxin Guidelines
  – http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/NaturalToxins/default.htm

• RFR Guidance
  – http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm180761.htm
Resources/References

• Food Drug and Cosmetic Act

• US Warehouse Act
  – http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=815ef8b4e9359df0cfefcd1e45235ea2&rgn=div5&view=text&node=7:7.1.1.3.7&idno=7#7:7.1.1.3.7.1.1.1