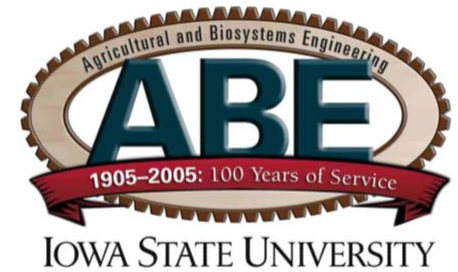


Practical Impact of the Food Safety Modernization Act on Grain Handling Industries – An Update

A GEAPS-Grain Journal Webinar

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Dr. Charles R. Hurburgh

Agricultural and Biosystems Engineering Department
Iowa State University



The Seven Major Rules of FSMA

Rule	Final Status	General Compliance Period	Small Business Compliance	Very Small Business Compliance
Preventive Controls for Human Food 	30-Aug-15	19-Sep-16	18-Sep-17	17-Sep-18
Preventive Controls for Food for Animals 	30-Aug-15	19-Sep-16	18-Sep-17	17-Sep-18
Produce Safety	31-Oct-15	31-Oct-17	31-Oct-18	31-Oct-19
Food Supplier Verification Programs (FSVP)	31-Oct-15	1-May-17	1-May-17	1-May-17
Accreditation of Third-Party Auditors	31-Oct-15			
Food Defense	31-Mar-16	31-Mar-17	31-Mar-18	31-Mar-19
Sanitary Transportation 	31-Mar-16	31-Mar-17	31-Mar-18	



Preventive Control Rules - cGMP

- **Personnel (training)**
- **Plant and Grounds**
- **Sanitation**
- **Water supply**
- **Equipment and Utensils**
- **Plant Operations**
- **Storage and distribution**

cGMP = current good manufacturing practices in areas listed in the Rule for each GMP topic.

Documented as to how each is being addressed.

Basis for 5-7 year surveillance inspection as well as Food Safety Plan



Preventive Control Rules - PCQI

- **PCQI = Preventive Controls Qualified Individual**
- **Is designated by:**
 - 1. Statement of career experience, job training or;
 - 2. Attending a Standardized PCQI Training Course
<http://www.aep.iastate.edu/animalfood/>
 - Taking the course is good liability protection.
- **Is responsible for creating and operating the Food Safety Plan**
 - Hazard Analysis Risk Based Preventive Controls for documented hazards that could cause injury or death to humans or animals.
- **Is the point of contact for FDA at a facility.**



Hazard Analysis – Is a FSMA PC Needed?

Example of an assessment matrix. Not required to use.

Important point is the scientific and operating justification.

RISK ASSESSMENT CHART				
PROBABILITY \ SEVERITY	FREQUENT (A) HIGH - Immediate danger to health and safety of the animal or humans.	LIKELY (B) MEDIUM - Probably will occur in time if not corrected, or probably will occur one or more times.	OCCASIONAL (C) LOW - Possible to occur in time if not corrected.	RARE (D) VERY LOW - Unlikely to occur; may assume hazard will not occur.
CATASTROPHIC (I) HIGH - Imminent and immediate danger of death or severe sickness.	I-A	I-B	I-C	I-D
MAJOR (II) MEDIUM - Danger and sickness may be severe, but it is not imminent or immediate.	II-A	II-B	II-C	II-D
MODERATE (III) LOW - Sickness or injury may occur, but impact is reversible.	III-A	III-B	III-C	III-D
MINOR (IV) VERY LOW - Sickness or injury is minor.	IV-A	IV-B	IV-C	IV-D

CRITICAL
AVERAGE
NEGLIGIBLE

Probability is relative to whatever documentable management you have now, before FSMA.



Potential Hazards to Consider for Grains

- **Physical Hazards**
 - Non-grain material (glass, metal, wood, petroleum residue)
 - Animal excreta or carcasses
- **Chemical Hazards**
 - Treated seed
 - Antibiotic residue in by-products
 - **Allergen (other grains)**
- **Microbial/Biological Hazards**
 - **Mycotoxins from fungi**
 - Flooded grain
 - Pathogens

There is no required list of hazards!!!!



Source: Cargill, Inc.



Treated seed (pink and green)
Source: LSU Extension Service



Preventive Controls for Documented Hazards

- **Process (receiving/inspection, heating, cleaning, etc)**
- **Sanitation (oil slicks, grease, biofilms, residues, etc)**
- **Supply Chain (Done before you get the product)**

NOTE!! FDA considers the farmer as the supplier for grains.

Last entity to make a meaningful change to the product.

Your current levels of management, if documented, could prove that you do not need a specific preventive control.

Must be verified to work, and based on valid science or internal study.

Three year review and update is required.



Preventive Control Example

Hazardous mycotoxins occur periodically and there is no documented record of control.

- **Preventive control might contain:**
 - A systematic review of weather conditions each season
 - A statistical plan for collecting periodic composite samples
 - A plan for action if certain limits are exceeded.
 - Control-chart documentation, and scientific justification
- **Verification might contain:**
 - A statistical plan for finished product testing.
 - Feedback (corrective action) if limits are exceeded.

Mycotoxin science: <http://www.iowagrains.org>



Preventive Controls - Practicalities

- **Elevators that only handle and store raw commodities are exempt from documented cGMP, the Preventive Controls, and the PCQI.**
 - The 5-7 year FDA inspection will still use the GMP's.
 - Buyers likely will require more documentation anyway.
 - Are you a supply chain PC in any buyer's plan?
- **Buyers: Do you want a supply chain PC that traces back to farmers? Or that is hard to verify?**



Preventive Controls - Practicalities

- **Human food buyers: The hardest issue will be allergens (A.K.A. Other grains)**
- **No preset hazard list, but inspectors will naturally look for those that are mentioned in the Rule and the training course.**



Elevators with Feed Mills

- **This is an uncertain area of application right now.**
- **Several arrangements:**
 - On the same site and connected by conveyor
 - On the same site but not connected by conveyor
 - On the same site with a separate mill elevator
- **Best advice at the moment**
 - You will have a PCQI for the mill. Use that person everywhere.
 - Work through the CGMPs as applied to the elevator. Make steady improvements as needed.
 - Understand what hazards for the mill could come from elevator.
 - Demonstrate positive intent.



Sanitary Transportation

- **Shipper** has the responsibility to load a clean and safe container with documentation of previous load.
- **Receiver** must retain documentation from shipper.
- **Practicalities**
 - Add to inbound and outbound shipping records.
 - Written procedure for loading
 - Cleanout procedure if a hazard was a previous cargo.
 - Trailer ID for Semi's
 - Contract haulers/brokers will need training on this.
 - IT system upgrades; increases documentation.
 - Debates with transportation companies are likely.

Virtually no exemptions that would apply to elevators.



Intentional Adulteration



Wrap up

- **FSMA creates preventive inspections- more like audits, with judgment and discretion on both sides.**
- **Have justification for actions.**
- **Document what you do and why.**
- **Raw commodity PC exemption may reduce formalities but likely will not be a pass on the intent of FSMA.**
- **Know your buyers' FSMA program.**



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