National Grain and Feed Association

FDA Inspections of Grain Elevators

NGFA Country Elevator Conference

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Presentation Outline

- Food Safety Modernization Act
- FDA's Authority to Regulate the U.S. Food Supply
- FDA Regulatory Requirements for Grain Elevators
- FDA Inspections – Before, During and Afterwards
- Questions and Answers

Food Safety Modernization Act

- Signed into law Jan. 4, 2011
- "Historic" legislation
  - It's **NOT** just recalls and inspections
  - It's a call for a **new, prevention-oriented food safety system** to ensure the safety of feed/food products
  - Requires FDA to develop and issue more than 50 regulations and/or guidance documents

FSMA – Some Key Requirements

- **Facility Registration** is required with FDA every two years during last calendar quarter of even numbered years
  - ***2014 is a re-registration year***
  - Registration is free through FDA's electronic system
- FDA granted expanded authority to **administratively detain** food/feed products

FSMA – Some Key Requirements

- FDA granted authority to issue **mandatory recall** notices to facilities
- FDA granted expanded authority to **access food-records**
- FDA authorized to **collect fees** for cost of
  - Reinspecting facilities that fail an original inspection
  - Conducting mandatory recalls
  - Hourly rate: $217 for domestic work

Inspections – Inspections – Inspections

- FSMA mandated that FDA **inspect** all food/grain/feed facilities
  - Initial inspections within 5 years (high-risk), 7 years (low-risk)
  - Subsequent inspections every 3 years (high-risk) to 5 years (low-risk)
- Number of domestic facilities registered as of Feb. 2014 – **81,575**
- Number of FDA inspections for F'2012 (Oct. 1, 2011- Sept. 30, 2012) – **24,462**

Subject	Deadlines		
	Publishing Proposed Rule	Close of Comment Period	Publishing Final Rule
Produce Rule **	Published Jan. 16, 2013	Nov. 22, 2013	Oct. 31, 2015
CGMPs and Preventive Controls - Human Food **	Published Jan. 16, 2013	Nov. 22, 2013	Aug. 30, 2015
Foreign Supplier Verification Programs **	Published July 29, 2013	Jan. 27, 2014	Oct. 31, 2015
Accreditation of Third-Party Auditors			
CGMPs and Preventive Controls - Animal Feed **	Published Oct. 29, 2013	March 31, 2014	Aug. 30, 2015
Food Defense/ Intentional Adulteration	Published Dec. 24, 2013	June 30, 2014	May 31, 2016
Sanitary Transportation of Food/Feed	Published Feb. 5, 2014	May 31, 2014	March 31, 2016

** Supplemental proposals published Sept. 29, 2014; Comments due Dec. 15, 2014

Federal Food, Drug and Cosmetic Act

- **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."

Adulteration of Food

- **According to the Act, a food shall be deemed to be adulterated if it:**
  - consists of any filthy, putrid, or decomposed substance or it has been prepared, packed, or held under insanitary conditions
  - is not produced and distributed in conformance with applicable FDA requirements
  - contains any poisonous or deleterious substance which may render it injurious to health
  - contains any added poisonous or added deleterious substance that is unsafe or pesticide residue that is unsafe
  - is missing a valuable constituent

Misbranding of Food

- **According to the Act, a food shall be deemed to be misbranded if:**
  - its labeling is false or misleading in any particular
  - it is offered for sale under the name of another food
  - it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard
  - any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon

FDA Inspection Authority

- Broad authority provided under federal Food, Drug and Cosmetic Act for FDA to inspect to ensure compliance with applicable requirements:
  - Adequate sanitation – ensure food is not "adulterated" during manufacturing, packing or storage
  - FDA action, advisory, guidance levels for mycotoxins
  - 21 CFR 589.2000-2001 – BSE-Prevention Regulations
  - 21 CFR Part 1.361-362 – Records access in the event of food-related serious adverse health consequence

FDA Inspection Authority

- Broad authority provided under federal Food, Drug and Cosmetic Act for FDA to inspect to ensure compliance with applicable requirements *(cont.)*:
  - FDA Food Facility Registration
  - FDA Reportable Food Registry
  - FDA Recordkeeping Requirements for Food
  - 21 CFR 225 – Medicated Feed CGMPs
  - 21 CFR Part 110 – CGMPs for Human Food
    - Do not apply to grain elevators; exemption provided - 21 CFR Part 110.19(a)

FDA Sanitation Requirements

- FDA uses realtively subjective evaluations to determine whether conditions within a facility are "insanitary" and will cause products to be "adulterated"
  - FDA's ***Investigator Manual*** – "Observations that dirt, decomposed materials, feces or other filthy materials are present in the facility and there is a reasonable possibility these filthy materials will be incorporated in the food are ways of determining products may have become contaminated *[to the point of adulteration]*

FDA Sanitation Requirements

- Suggestions for complying with FDA sanitation requirements
  - Have a written housekeeping policy and plan that is effectively implemented and documented. The plan should address all aspects of operations, including:
    - Exterior facility grounds
    - Receiving areas
    - Shipping areas
    - Housekeeping methods/schedules
    - Employee responsibilities
  - Have a written pest control plan that is effectively implemented and documented

FDA Regulatory Guidance for Mycotoxins

- Aflatoxin (action levels)
  - 20 – 300 p.p.b., depending on commodity and species to which fed
- Vomitoxin (advisory levels)
  - 5 – 30 p.p.m., depending on commodity and species to which fed; 5 – 10 p.p.m in total ration
- Fumonisin (guidance levels)
  - 5 – 100 p.p.m., depending commodity and species to which fed; 1 – 5 p.p.m. in total ration
- FDA policy prohibits blending different lots of grain to reduce the mycotoxin level in the resulting lot
- NGFA guidance for industry available

BSE-Prevention Regulations

- Prohibits the feeding of certain mammalian protein products to ruminant animals
- Requires that firms use process and control systems to ensure that grain/feed for ruminants does not contain prohibited mammalian tissue
  - Appropriate labeling of prohibited protein products – ***"Do not feed to cattle or other ruminants"***
  - If producing or distributing grain or feed for ruminants, adequate safeguards to assure that incoming ingredients and outbound shipments are not contaminated with prohibited proteins

BSE-Prevention Regulations

- Suggestions for complying with FDA BSE-prevention requirements
  - Consider obtaining letters of assurance from outside contractors involved in transporting grain into and from the facility that indicate awareness and compliance with BSE-prevention requirements
  - Document “previous load hauled” on inbound truck shipments
  - Inspect conveyances used for outbound shipments for cleanliness and document findings
  - NGFA guidance for industry available

Food Facility Registration and Recordkeeping

- **Facility registration** – Grain elevators are obligated to register with FDA as food facilities every even-numbered year, during the last calendar quarter
- **Food recordkeeping** – Grain elevators are to establish and maintain records that contain required information about the immediate previous source of food received and the immediate subsequent recipient of food distributed.
  - Records also are to contain "reasonably available" information linking inbound deliveries with outbound shipments
- NGFA guidance for industry available

FDA Reportable Food Registry

- Beginning Sept. 8, 2009, requires food facilities registered under the Bioterrorism Act to file a report within 24 hours with FDA through an electronic portal when there is “a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals”
- It is the facility’s responsibility to determine whether the reporting threshold has been met

FDA Inspections

- FDA is authorized to :
  - Enter “any factory, warehouse, or establishment in which food [is] manufactured, processed, packed, or held …” and “any vehicle….”
  - Inspect “at reasonable times and within reasonable limits and in a reasonable manner”
  - Inspect “all pertinent equipment, finished and unfinished materials, containers, and labeling thereon”
- No warrant necessary for inspection

Types of FDA Inspections

- **For Cause:** Pertain to public health concerns or animal illness and/or death
- **Surveillance:** Conducted to evaluate compliance with applicable regulations
- **Compliance:** Performed because FDA has information that suggests problems may or do exist at a facility
- **Criminal:** Conducted when information suggests that serious willful and/or egregious violations of applicable requirements are occurring within a facility

Preparing for an FDA Inspection

- **Have an inspection plan in place**
  - Know your rights and obligations
  - Designate employee(s) to accompany investigator
  - Establish policies pertaining to:
    - Responsibilities of employees directly involved with handling the inspection
    - Employee interviews – FDA does not have express authority to interview employees
    - Pictures – FDA's authority to use cameras during inspection is not well established
    - Providing copies of records, confidential records
    - Signing Affidavits/Declarations

During the Inspection

- **When the investigator arrives** –
  - Ask for credentials - investigators should have proper identification, often they have a badge
  - Investigator should provide notice of inspection – Form FDA-482
  - Its appropriate (and often helpful) to ask why the inspection is being conducted
  - The first point of contact at the facility should notify the "designated" employee of the investigator's presence
  - Minimize the investigator's waiting time – its appropriate to notify personnel of the inspection, but too late to try to make major "improvements" in the facility

During the Inspection

- The investigator should be required to comply with all applicable personnel safety requirements
- The "designated" employee should:
  - Accompany the investigator at all times (except for restroom or lunch breaks)
  - Be cordial, while realizing the investigator is present to collect evidence of alleged non-compliant conditions
  - Know the facility's rights and obligations – the investigator may ask for more information than they are expressly authorized to review
  - Provide direct answers to questions, but not offer "excess" information – its acceptable to not immediately provide a response if the answer is not readily available
  - Always provide truthful information
  - Remedy issues/conditions raised by the inspector immediately, if possible and if warranted

During the Inspection

- The investigator typically will want to begin the inspection with a tour of the facility, then focus on specific areas of interest
  - Have a tour route planned
- FDA has authority to take samples
  - If taken, ask for a “split” sample or obtain one from the same lot
  - If taken, ask the investigator what the sample will be tested for and expected timing of the results
- Taking pictures
  - If the facility’s inspection policy doesn’t allow, the investigator likely will assert FDA has authority to take photos
  - If the facility’s inspection policy allows, it is advisable to take “identical” pictures

During the Inspection

- Interviewing employees
  - If the facility's inspection policy allows, the "designated" employee should be present to correct any potential inaccuracies provided during the interview
- FDA does not have authority to disrupt the facility's normal operations
- Grey Areas: If a questionable request is made during the inspection, it is acceptable to ask the investigator to put the request in writing and the basis for why the information is needed to allow for further management and/or legal review
  - Request for "excessive" review of records, etc.

Post Inspection

- Investigators typically conduct inspection exit interviews with facility management
- Form FDA-483 is used to document inspectional observations (alleged violations)
- It typically is in the facility's best interest to not express agreement with alleged violations
- Facility management should provide basis for any disagreement with inspectional findings
- Investigators often ask management to sign an Affidavit or Declaration during exist interview – it is advisable not to sign without review by legal counsel; have a policy in place

After the Inspection

- If Form FDA-483 issued, promptly begin work on developing a response to alleged violations
  - It may be beneficial for the facility to formally respond to FDA about the alleged violation
  - FDA policy provides 15 days for such a response if the facility wishes the agency to consider the facility's position/actions prior to FDA determining whether enforcement action will be taken

After the Inspection

- FDA, if agency believes it is warranted, may issue either an “Untitled Letter” or “Warning Letter” to the facility based upon Form FDA-483 observations
  - Always provide a response to such letters in a timely manner. If more time is needed, inform FDA
  - It is advisable to not admit to violations of the law or regulations when responding. Instead, note the observation(s) and state how facility will address the condition or observations made
  - It is advisable to consult legal counsel when responding to an untitled or warning letter
  - Always follow through on any corrective actions that the response letter commits the facility to perform

FDA Enforcement Actions

- Depending upon the significance of the non-compliant condition, FDA may:
  - Conduct rigorous re-inspection activities, at the expense of the facility
  - Seize products
  - Initiate injunctions or consent decrees
  - Suspend a facility's registration – making it illegal to distribute food

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Questions / Comments ?

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