

Our Industry. Our Passion. Our Voice.

Safety: For the Employee, the Animal, the Consumer

Gary Huddleston – Director of Feed Manufacturing and Regulatory Affairs









- VOICE -

REPRESENTATION -

- EXPERTISE:

ENGAGEMENT -

Why should you have a safety program at your facility?

- Concern for your employees
- Cost of work-related accidents
- Compliance to government regulations





What should a safety program at a feed production facility look like?



- It should be written
- It should include documented job hazard analysis
- It should include employee training
- It should include a facility safety committee
- It should include accident/incident investigation
- It should include compliance to OSHA standards
- Your program should create a SafetyCulture



Start Here



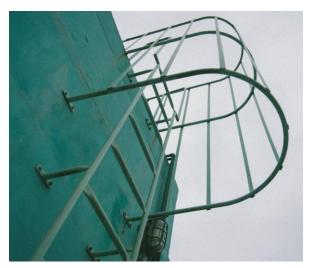
Regulations





Walking Working Surfaces – Fall Protection

- 29 CFR 1910 Subpart D (1910.21-30)
- Ladders, stairways, fall protection systems









Exit Routes and Emergency Planning

- 29 CFR 1910 Subpart E (1910.33-39)
- Emergency Action Plan (1910.38)
- Fire Prevention Plan (1910.39)







Powered Platforms, Manlifts

- 29 CFR 1910 Subpart F (1910.66-68)
- Manlifts (1910.68)







Occupational Health and Environmental Control

- 29 CFR 1910 Subpart G (1910.94-98)
- Noise Exposure (1910.95)









Hazardous Materials

- 29 CFR 1910 Subpart H (1910.101-126)
- Compressed Gasses (1910.101)
- Flammable Liquids (1910.106)
- Storage and Handling of LPG (1910.110)







Personal Protective Equipment

- 29 CFR 1910 Subpart I (1910.132-140)
- Eye and Face Protection(1910.133)
- Respiratory Protection (1910.134)
- Head Protection (1910.135)
- Foot Protection (1910.136)
- Electrical Protective Equipment (1910.137)
- Hand Protection (1910.138)
- Personal Fall Protection Systems (1910.140)







General Environmental Controls

- 29 CFR 1910 Subpart J (1910.141-147)
- Permit-required Spaces (1910.146)
- Hazardous Energy Lockout/Tagout (1910.147)









Fire Protection

- 29 CFR 1910 Subpart L (1910.155-165)
- Portable Fire Extinguishers (1910.157)
- Standpipe and Hose Systems (1910.158)
- Automatic Sprinkler Systems (1910.159)









Materials Handling and Storage

29 CFR 1910 Subpart N (1910.176-184)

Powered Industrial Trucks (1910.178)







Machinery and Guarding

- 29 CFR 1910 Subpart O (1910.211-219)
- General Requirements for All Machines (1910.212)

CAUTION

DO NOT OPERATE
THIS MACHINE WITHOUT
GUARDS IN PLACE







Hand and Portable Powered Tools

29 CFR 1910 Subpart P (1910.241-244)









Welding, Cutting and Brazing

- 29 CFR 1910 Subpart Q (1910.251-255)
- Hot Work permits and requirements (1910.252)









Special Industries

- 29 CFR 1910 Subpart R (1910.261-272)
- Grain Handling Facilities (1910.272)



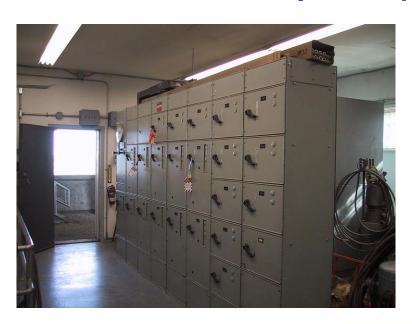
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Electrical

• 29 CFR 1910 Subpart S (1910.301-399)









Toxic and Hazardous Substances

- 29 CFR 1910 Subpart Z (1910.1000-1200)
- Hazard Communication (1910.1200)











What about COVID-19?

- No ETS that applies to our industry
- OSHA issues regularly updated guidance
- Recent guidance recommends masks for all employees
- Workplace exposures have to be reported on OSHA 300





State Regulations...

NYS HERO ACT

On May 5, 2021, NY's Governor signed the New York Health and Essential Rights Act (NY HERO Act) into law. The law mandates extensive new workplace health and safety protections in response to the COVID-19 pandemic. The **purpose of the NY HERO Act is to protect employees against exposure and disease during a future airborne infectious disease outbreak.**

Key Dates and Elements:

August 5th a plan must be in pace. Model Airborne Infectious Disease Exposure Prevention Plan, can be found at: https://dol.ny.gov/ny-hero-act

Plan must go into effect when an airborne infectious disease is designated by the New York State Commissioner of Health as a highly contagious communicable disease that presents a serious risk of harm to the public health. Currently, while employers must adopt plans as required by the law, as of the date of this writing no designation has been made and plans are not required to be in effect.











What's on everyone's mind when it comes to FDA?





FSMA Snap Shot

Signed into law January 4, 2011

- The current food safety system has opportunity for improvement.
 - ➤ 1 in 6 Americans (48 million) sickened, 128,000 hospitalized, 3,000 die each year from foodborne diseases (CDC, 2011)
- Identified by FDA as the most sweeping reform of food safety laws in more than 70 years.
 - ➤ GOAL: Aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from <u>responding</u> to contamination to <u>preventing</u> it.



What Does FSMA Require?

- Facilities that only <u>hold</u> animal food must (includes retail):
 - ➤ Comply with CGMP requirements
 - ➤ Train Qualified Individuals
- Facilities that manufacture, process or pack must also:
 - ➤ Designate and train a Preventive Controls Qualified Individual (FSPCA Animal Food Course best method)
 - ➤ Conduct a Hazard Analysis
 - Develop a written Food Safety Plan to address the hazards identified



What is a FSMA Hazard Analysis?



- Varies by facility
- Consider ingredients and processes
- Identify hazards to animals as well as humans
- Most difficult part of FSMA compliance



Does the agent have the potential to cause illness or injury in humans or animals?

Hazard

Is the hazard associated with the:

- Facility or
- Type of animal food?

Known or Reasonably Foreseeable Hazard

Is the hazard:

- Severe and
- Probable?

Hazara Requiring a Preventive Control

Customer

Supply-Chain-Applied Controls

Process, Sanitation, Other Controls



21 CFR 507.36

5-27

Hazard Analysis Process

List Ingredients and Steps/Equipment within the Process Flow (recommended) Identify *Known or Reasonably Foreseeable Hazards* Assess Severity of Illness or Injury if Hazard were to Occur Assess Probability that the Hazard will Occur in the Absence of Preventive Controls Determine if the Hazard Requires a Preventive Control Justify the Classification of the Hazard **Determine the Control** for the Hazard Requiring a Preventive Control Assign a Preventive Control Number (recommended)





Required Documentation

All of this information should be assembled into a written Food Safety Plan

- The format is flexible
- Describes the facility's risk-based approach to managing the identified hazards



Applicable FDA FSMA Guidance for Industry



#235 Current Good Manufacturing Practice Requirements for Food for Animals

- No real surprises or enlightening interpretations
- Final document after comment period not bad
- Almost all of AFIA's suggestions were accepted
- Good explanation about the different types of facilities
- Does a good job highlighting flexibility of the rule
- Best part of the document is Appendix B Self-Assessment Tool (Inspection Checklist)



Applicable FDA FSMA Guidance for Industry



#245 Hazard Analysis and Risk-Based PreventiveControls for Food for Animals

- This document is still in the draft stage (169 pages)
- AFIA submitted 36 pages of comments (lots of issues!)
- A lot of the language was devoted to hazards not relevant to most of the industry (pet vs livestock)
- Not enough qualifying language on the <u>intended use</u> of the animal food
- The list of hazards in Appendix E is concerning



Applicable FDA FSMA Guidance for Industry



#246 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program

- This document is still in the draft stage (53 pages)
- It addresses Subpart E (not very relevant to animal food)
- Not nearly as many issues as GD #245
- AFIA submitted 8 pages of comments
- It's unlikely feed mills will have a supply-chain-applied control



Primary Types of FSMA Inspections



- Sanitary Transportation
- FSVP





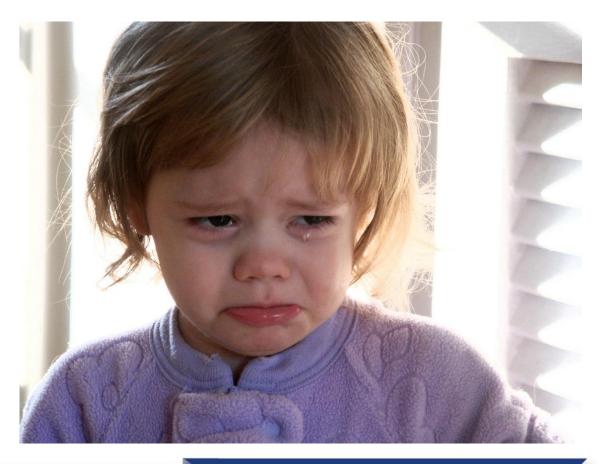




Hopefully, it will end like this:



But... With poor preparation it could end like this:





You want to avoid it ending like this:





CGMP Inspections: Frequent 483 Citations

Personnel

Failed to enforce hygienic practices

Grounds & Maintenance

Facility housekeeping and maintenance

Holding & Distribution

Failed to hold under proper conditions

Records Requirements

 Failed to initial, sign off on or their records were inaccurate or illegible

A few regarding...

Utensils, pest control, handling rework

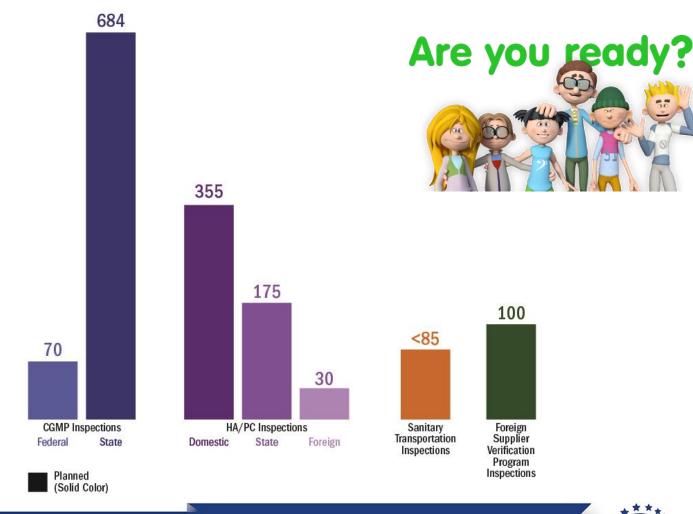


HA/PC Inspections: Frequent 483 Citations

- Not identifying the need for and implementing a PC
- Failed to have a Food Safety Plan
- Failed to evaluate all known or reasonably foreseeable hazards
- Process PC failed to minimize or prevent the hazard
- Effectiveness of PCs not effectively verified via product testing
- Sanitation PCs not effectively verified via environmental monitoring
- Failed to conduct reanalysis of FSP

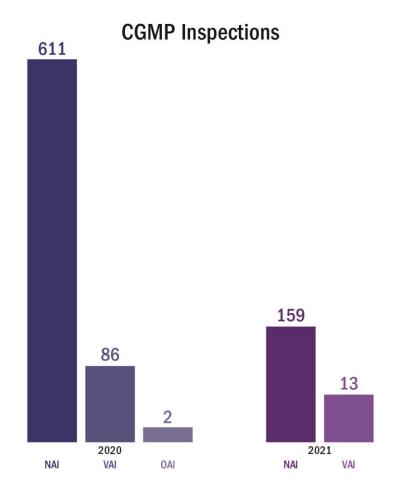


FDA FY 2021 Inspection Goals



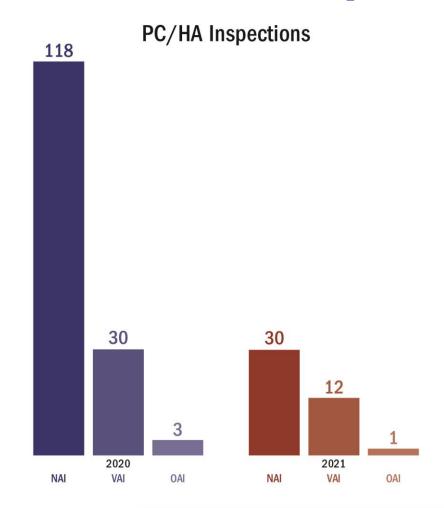


2020 and 2021 Inspections





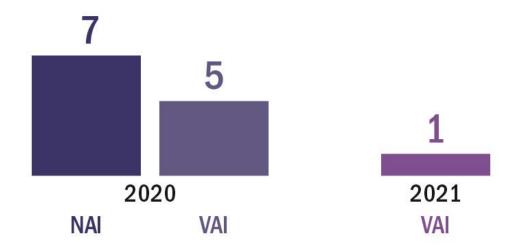
2020 and 2021 Inspections





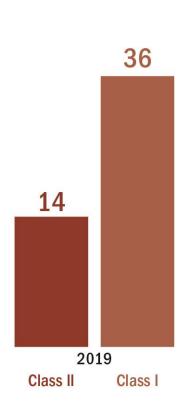
2020 and 2021 Inspections

FSVP Inspections

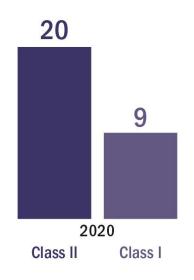


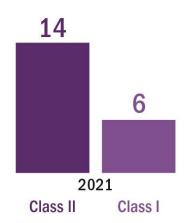


2019 - 2021 Recalls



Recalls







Inspections Beyond 2020?

- The new world of inspections
- What will it look like?
- Will the pandemic change the inspectional landscape permanently?





The best way to prepare for an inspection is to know the Regulations

- Attend a FSPCA PCQI Training
 - Ohio Agribusiness Association in Columbus,
 OH September 27-29: oaba.net/events.
 - See Barbara Simeon for other offerings







Barbara Simeon Contact Information

Training Webpage https://fsma.cfd.coop/training/

Cell Number 607-759-4175



Two Great AFIA Programs







THANK YOU

AFIA'S

4 PROMISES









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