Molds and Mycotoxins: An Animal Feed Ingredient Outlook

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Mid-Atlantic Nutrition Conference
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Outline

• History of Mycotoxicosis

• Mycotoxins
  ➢ Optimal Conditions

• Implications

• FDA Limits

• Mycotoxin Report
History of Mycotoxicology

• St. Anthony’s fire
  • Gangrenous ergotism caused by *Claviceps purpurea*
    • Consumption of grains contaminated with ergots
  • Periodic outbreaks in central Europe
  • Became an epidemic in the Middle Ages
    • mid-16\textsuperscript{th} century

• Symptoms
  • Hallucinations $\rightarrow$ psychosis
  • Swollen limbs with burning sensation
  • Uncontrollable itching feeling
  • Diarrhea and vomiting
  • Necrosis
    • Led to loss of appendages
Modern Mycotoxicology

• Began with the discovery of aflatoxins in the early 1960’s
• Thousands of toxic metabolites of fungi
• Concern for both human and animal diseases
• Food safety concerns
• Other Impacts:
  • Grain trade
  • Marketing of food
  • Marketing of feed
Mycotoxins

• Term was derived from:
  • “mykes” → Fungi
  • “toxicon” → Poison

• Can be produced by over 200 species of molds

• Fungal growth → mycotoxin formation
  • Dependent on:
    • Season
    • Location of grain cultivation
    • Drought
    • Time of harvest

• Contaminated grains typically have more than a single mycotoxin

Murugesan et al., 2015
The effects of plant population and harvest date

Grain Yield

% Stalk Rot

Precipitation in 2018

Precipitation difference from normal in eastern United States in 2018. (Capital Weather Gang) – Jan. 2nd, 2019
Pennsylvania
Sept 4, 2018 – Dec 2, 2018

Mean Areal Precipitation (top)
Departure From Average (Bottom)

National Weather Service: www.weather.gov
Wetness Percentile: Relative to 1948-2012
What concerns does this record precipitation present to animal agriculture?

• Soil Quality
  • Excess soil moisture

• Crop Production
  • Planting/Harvesting Schedules
  • Crop Yield

• Ingredient and Feed Quality
  • Mycotoxins
  • Molds
Mold

• Contributors to mold proliferation:
  • Storage conditions
    • Faulty grain bins
    • Grain piles
  • Long-term storage
  • Wet/rainy season
  • Summer conditions
    • High heat
    • High relative humidity
Grain Storage

- Insufficient storage capacity results in the need to store grains in piles
  - Associated risks:
    - Biosecurity
    - Weather related factors like increased moisture and mold proliferation
Mold Proliferation: Optimal Conditions

- Most livestock feeds contain mold spores
  - $< 10^4$ cfu/g
- Molds become visible at $\sim 10^6$ cfu/g
- What does mold need to proliferate?
  - Moisture
    - Relative humidity +70%
  - Oxygen
    - 1-2%
  - Time
  - Correct temperature
    - Variable according to species

DiCostanzo and Murphy, 2012, University of Minnesota

Photo taken by Jeff Graybill, PSU Extension Agronomist, in Lancaster, PA in November 2018
Mold Inhibitors

- Substances designed to suppress the generation of mold and prevent the proliferation of toxins
  - Granulated
    - Traditional application
  - Liquid
    - Application technology development allows for addition at the mixer

- Improve animal performance
- Decrease production costs
  - Dependent on milling technique
    - Moisture-mold inhibitor combo

Hott et al., 2008
Mycotoxin-Producing Fungi

- Mycotoxins of concern
  - Produced by 3 genera of fungi
    - *Aspergillus*
    - *Penicillium*
    - *Fusarium*

- Occurrence depends on favorable conditions being met
  - May be limited to certain environments and specific crops

CAST, 2003
Economic Impacts of Mycotoxin Contamination

• Why is mycotoxin contamination expensive?
  • Reduction in animal performance
  • Reduction in animal health
  • Preventative practices
  • Mitigation practices
  • Reduced value of contaminated feed
  • Contamination of foods and products of animal origin

Grenier and Applegate; 2013

• In 2003, estimated mean economic losses
  • $932 million annually
    • From aflatoxins, fumonisins, and deoxynivalenol

CAST, 2003
Mycotoxicosis

- Acute cases from ingestion of high levels of mycotoxins
  - Mortality
  - Declined productivity
    - Obvious clinical signs
    - Post-mortem lesions

- Chronic cases from ingestion of low level of mycotoxins
  - Measurable decline in performance
    - Subcutaneous hemorrhage
    - Immunosuppression

- Less than ideal performance without the presence of:
  - Infection
  - Environmental factors
  - Nutritional deficiency

Not typical

Most common

Suggests potential mycotoxicosis

Murugesan et al., 2015
Diagnosis of Mycotoxicosis

• Diagnosis in animals is difficult

• Observed effects may not be unique to a given mycotoxin

• Even more difficult when more than one mycotoxin is present
  • Additive or synergistic effects in animals
Diagnosis of Mycotoxicosis

- Diagnosis is based on data from controlled experiments
  - How well does this correlate to reality?

- Natural intoxicants and disease condition may be affected by:
  - Environment
  - Nutrition
  - Behavior
  - Husbandry
Ideal Diagnosis

• Collect samples from:
  • Living animals
  • Animals post-mortem

• Thorough chemical examination of the feed

CAST, 2003
Sampling for mycotoxin analysis

• Sampling technique
  • Sample is useless if taken incorrectly

• Obtaining adequate sample is crucial
  • Uneven distribution
  • Low concentrations of mycotoxins in grains
  • Greatest opportunity for variability in the testing process

CAST, 2003; Feed Manufacturing Technology, 2005
Sampling Procedures

**Ingredients**

- **Bulk Bags (totes)**
  - Lot of 1-4 bags
    - 5 probe samples
  - Lot of 5-9 bags
    - 1 probe sample per bag
  - 10+ bags
    - 1 probe sample per 10 bags

- **Bulk**
  - May consider automated sampling
    - Based on volume
  - 5 probe samples over the entire load
  - Only 1 probe from centerline
  - Not less than 4 oz per 1,000 lbs of ingredients
Sampling Procedures

**Finished Feeds**

- **Bagged Feed**
  - 1-4 bags
    - 5 core samples
  - 5-10 bags
    - 1 core sample from each bag
  - 11+ bags
    - 1 core sample from each of 10 bags

- **Bulk Feed**
  - 10 core samples from different regions of:
    - Bin
    - Truck
    - Railcar
  - May obtain sample while loading or unloading
    - Collected through entire stream of product

Feed Manufacturing Technology, 2005
Analytical Testing for Mycotoxins

• Quantification procedures
  • Liquid chromatography coupled to mass spectrometry
    • LC-MS
    • Detect hundreds of mycotoxins simultaneously
  • HPLC
  • ELISA
    • Used in the past
  • Thin-layer chromatography
  • GC
  • Fluorometry

• Quantification method validation
  • Known quantities of certified reference materials

CAST, 2003; Murugesan et al., 2015
Nutritional Implications

• GI tract functionality
  • Enterocyte integrity
    • High protein turnover
    • Protein synthesis inhibition
  • Endogenous nutrient loss

• Nutrient Digestion and Absorption
  • Reduced pancreatic enzyme activity
  • Reduced nutrient transporters
    • GLUT2
    • GLUT5
    • SGLT1
    • Palmitate
Nutritional Implications

• Intestinal barrier function
  • Inhibited active transport of glucose and amino acids
    [Awad et al., 2004]
  • Up-regulation of pro-inflammatory cytokines markers
    • IL-1β
    • IL-6
    • IL-8
    • TNF-α
    [Grenier and Applegate, 2013]
Immune System Implications

- Mycotoxins are **NOT** able to induce an immune response
- Mycotoxins interfere with signaling pathways
  - MAPKs
    - Cell growth
    - Apoptosis
    - Immune responses
  
- Impaired ability to mount an immune response
  - More susceptible to infection

Murugesan et al., 2015
Susceptibility to Disease

• Mycotoxins can:
  • Affect activated and proliferating cells
  • Damage epithelial tissue
  • Increase intestinal permeability

Weakens the Immune System!
Susceptibility to Disease: Necrotic Enteritis in Broilers

• Control Diet vs Diet with 5 mg DON/kg of feed
  • Birds fed 5 mg DON/kg:
    • More prone to developing necrotic enteritis lesions
    • Predisposing factor for intestinal mucosa damage
    • Leakage of nutrients into the intestinal lumen
      • Growth substrate for proliferation of *C. perfringens*

Antonissen et al., 2014
Susceptibility to Disease: Coccidiosis in Broilers

• 1/2 the birds were given 25x-recommended dose cocci vaccine

• Control vs 1.5 mg DON/kg vs 20 mg FUM/kg vs DON+FUM
  • Mycotoxin fed birds:
    • Increased frequency of intestinal lesions
    • Increased number of oocysts in:
      • Jejunal mucosa
      • Feces
    • Upregulation of cytokines

• Subclinical doses of DON and FUM:
  • Unchallenged birds
    • Little effects
  • Challenged birds:
    • Cause metabolic and immunologic disturbances
    • Amplified the severity of coccidiosis
Susceptibility to Disease: Coccidiostat Impairment

• T-2 toxin exceeded 0.5 mg/kg in feed
  • Impaired effectiveness of coccidiostat
    • Increased occurrence of clinical coccidiosis
Mycotoxin presence in dog food

- 48 commercial dog food products
  - 24 standard products
  - 24 premium products
    - Based on price per unit

- 47/48 samples contained quantified amounts of at least 2 mycotoxins
  - Level of detection 1-2 μg/kg
  - Level of quantification 5 μg/kg

- 52% contained 3 mycotoxins
  - 15/24 of standard products
  - 10/24 of premium products

- 25% contained 4 mycotoxins
  - 6/24 standard products
  - 6/24 premium products

Gazzotti et al., 2015
Mycotoxin presence in dog food

• Quality and safety concerns
  • Pet health
  • Human health?

• Economic and emotional implications
  • Pet owners

• Symptoms of mycotoxicosis in dogs
  • When supplied a dose equaling 3 mg/kg
  • Loss of appetite
  • Vomiting
  • Still largely unknown

Gazzotti et al., 2015
FDA Maximum Levels for Equine: Aflatoxins

• Maximum level = 20 ppb
• Target organ → Liver
• Symptoms
  • Loss of appetite
  • Depression
  • Fever
  • Cough

• Necropsy findings
  • Yellow-brown liver with centrilobular necrosis
  • Tracheal exudates
  • Brown urine

Limited published information on aflatoxin exposure in horses
FDA Maximum Levels for Equine: Fumonisins

• Maximum level = 5 ppm
  • Corn-screenings should not be fed

• Equine leukoencephalomalacia
  • Moldy corn poisoning

• Symptoms may develop in 7-35 days
  • Disorientation → Blind staggers
  • Aimless walking
  • Deranged behavior
  • Colic
  • Death
  • Confirmation requires pathological examination of the brain

Grain not to exceed 20% of total diet

www.oisc.purdue.edu/feed/mycotoxins.html; www.ngfa.org
FDA Maximum Levels for Swine: Aflatoxins

• Marked age-related differences
  • Most susceptible
    • Nursing piglets
    • Weanlings
      • Maximum level = 20 ppb
  • Lactating dams may pass toxic metabolites in milk to piglets
    • Maximum level
      • Breeding swine = 100 ppb
      • Finishing swine = 200 ppb

• Symptoms
  • Reduced feed intake, feed efficiency, and daily gain
  • Secondary disease challenges
  • Acute aflatoxicosis → Rare
    • Necrotic and swollen liver
  • Chronic aflatoxicosis
    • Liver is fibrotic and small
    • Ascites
FDA Maximum Levels for Swine: Fumonisins

- Maximum level = 20 ppm
  - No more than 50% of the diet
- Porcine Pulmonary Edema (PPE)
  - Fatal disease from 1989 corn crop
  - Contaminated corn-screenings
- Symptoms
  - Hepatic lesions
    - Apoptosis
    - Necrosis
    - Hepatocyte proliferation
  - Acute left-sided heart failure

Haschek et al., 2001; www.ngfa.org
Zearalenone Toxicity in Swine

- Chemical structure is similar to estrogen
  - Estrogenic effects
  - Affects all age groups

Clinical Effects of Zearalenone Toxicosis

Chi, Broomhead, and Chen, 2011
FDA Maximum Levels for Dairy Cattle: Aflatoxin

• Maximum level = 20 ppb
• Young are more susceptible than mature animals

• Symptoms
  • Reduced feed intake
  • Reduced performance
  • Reduced milk production
  • Impaired reproductive efficiency
    • Abnormal estrus cycle
    • Abortions

• Aflatoxins will show up in milk before these symptoms present themselves
FDA Maximum Levels for Dairy Cattle: Fumonisins

- Maximum level = 30 ppm
- Rumen microbes do not tend to metabolize Fumonisins
  - Dairy cattle seem to be tolerant
- Some reports of reduced milk production at 100 ppm
- The literature is not in agreement on milk contamination
  - Some reported contaminations
  - Not extensively studied
  - May be an area of interest with LC-MS

Grain not to exceed 50% of total diet

www.ngfa.org; Becker-Algeri et al., 2016; Diaz et al., 2000
FDA Maximum Levels for Beef Cattle: Aflatoxin

- Immature animals
  - Maximum level = 20 ppb
- Breeding cattle
  - Maximum level = 100 ppb
- Finishing cattle
  - Maximum level = 300 ppb
- Symptoms
  - Hepatic damage → lesions
  - Rectal prolapse
  - Decreased performance
  - Recovery after exposure → very slow
  - Death

Metabolic and physiological responses are similar to nonruminants

www.ngfa.org; Osweiler and Trampel, 1985
FDA Maximum Levels for Beef Cattle: Fumonisins

• Maximum level = 60 ppm

• Beef cattle appear to be less susceptible than other species when consuming Fumonisins naturally present in grains

• Symptoms
  • Some liver lesions
  • Reduced feed palatability/intake
    • At high contamination rates
  • Immunosuppression

Grain not to exceed 50% of total diet

www.ngfa.org; Osweiler et al., 1993
FDA Maximum Levels for Poultry: Aflatoxins

- Immature poultry
  - Maximum level = 20 ppb
- Mature poultry
  - Maximum level = 100 ppb
- Avian species are variable in sensitivity to chronic aflatoxicosis
  - Most sensitive
    - Turkey poults and Ducklings
      - Dietary levels at 0.25 ppm reduced growth
  - A little less sensitive
    - Broilers
      - Dietary levels of 1.5 ppm reduced growth
  - Not very sensitive
    - Japanese Quail
      - Dietary levels of 4 ppm reduced growth
Symptoms of aflatoxicosis in poultry

- Reduced growth rate
- Decreased resistance to infection
- Impaired blood coagulation
  - Increased susceptibility to carcass bruising
- Hemorrhage
- Hepatic necrosis
- Death
FDA Maximum Levels for Poultry: Fumonisins

• Hens laying eggs for human consumption
  • Maximum level = 30 ppm
• Poultry raised for slaughter
  • Maximum level = 100 ppm

• Symptoms
  • Decreased performance
  • Immune suppression
  • Rickets
  • Reduced egg quality parameters

• Necropsy results
  • Enlarged proventriculus
  • Gizzard erosion
  • Increased weight of liver, kidneys, and heart

Grain not to exceed 50% of total diet
## FDA’s Advisory Levels for DON

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Grain or Grain By-products</th>
<th>DON levels in grains/by-products (Complete Diet)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swine</td>
<td>Grain and grain by-products not to exceed 20% of the diet</td>
<td>5 ppm (1 ppm)</td>
</tr>
<tr>
<td>Chickens</td>
<td>Grain and grain by-products not to exceed 50% of the diet</td>
<td>10 ppm (5 ppm)</td>
</tr>
<tr>
<td>Beef Cattle (4months +)</td>
<td>Grain and grain by-products</td>
<td>10 ppm</td>
</tr>
<tr>
<td>Dairy Cattle (4 months +)</td>
<td>Grain and grain by-products not to exceed 50% of the diet</td>
<td>10 ppm (5 ppm)</td>
</tr>
<tr>
<td>All other animals</td>
<td>Grain and grain by-products not to exceed 40% of the diet</td>
<td>5 ppm (2 ppm)</td>
</tr>
</tbody>
</table>
Biological Effects of Aflatoxin

• Interaction with protein synthesis
  • Inhibiting nucleic acid synthesis
    • Interference with transcription
  • Inhibiting protein synthesis
    • Interference with translation
Toxic Responses

• Alteration of basic metabolic processes

• Interference with:
  • Lipid metabolism
    • Accumulation of lipid in the liver
    • Impaired transport of lipids out of the liver
  • Carbohydrate metabolism
    • Decreased hepatic glycogen
    • Increased serum glucose
  • Mitochondrial respiration
Biological Effects: Enzyme Inhibition in Oxidative Phosphorylation

Godfrey et al., 2013
Biological Effects: ETC Inhibition in Oxidative Phosphorylation

Godfrey et al., 2013
Deactivating Mycotoxins

• Large variety of mycotoxin structures
  • No single method for mycotoxin deactivation

• Difficult to predict which mycotoxins will be present in complete feed
  • Complex diets
  • Various sources of ingredients
Deactivating Mycotoxins

• Binders, absorbents, enterosorbents
  • Organic
    • Microbial
  • Inorganic
    • Clay mineral products

• Bio-protection
  • Algae/plant materials
    • Protects vulnerable organs
    • Boosts immune system

• Biotransformation
  • Microorganisms or purified enzymes
    • Catabolize entire mycotoxin
    • Transform mycotoxin
    • Cleave mycotoxin
Can mold/mycotoxin prevalence be affected by on-farm management strategies?
As we may expect

Average Bird Weight

FCR

Producer Ranking

Above Avg  Avg  Below Avg

Above Avg  Avg  Below Avg

[Graphs showing average bird weight and FCR for producer ranking with different categories: Above Avg, Avg, Below Avg, with numerical values and trend lines indicating expected relationships.]
Maybe a little more surprising
Can mold/mycotoxin prevalence be affected by on-farm management strategies?

YES!

Opportunity to identify low performing growers for training efforts
2017 world compound feed production by species

- Poultry
- Swine
- Ruminant
- Aqua

Penn State College of Agricultural Sciences

WATTAgNet.com
Total Diet Composition For Top Livestock and Poultry in 2016

Source: www.afia.org/feedindustrystats
Figure 1. Global map of mycotoxin occurrence and risk in different regions.

Legend:
- Moderate risk: 0-25% of samples above risk threshold
- High risk: 26-50% of samples above risk threshold
- Severe risk: 51-75% of samples above risk threshold
- Extreme risk: 76-100% of samples above risk threshold
- No samples tested
Mycotoxin Report: Annual Report Produced by Biomin

North America

<table>
<thead>
<tr>
<th>Total samples: 1124</th>
<th>Afla</th>
<th>ZEN</th>
<th>DON</th>
<th>T-2</th>
<th>FUM</th>
<th>OTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of samples tested</td>
<td>1049</td>
<td>1116</td>
<td>1087</td>
<td>1086</td>
<td>1093</td>
<td>1117</td>
</tr>
<tr>
<td>% Contaminated samples</td>
<td>8%</td>
<td>26%</td>
<td>65%</td>
<td>3%</td>
<td>39%</td>
<td>2%</td>
</tr>
<tr>
<td>% Above risk threshold</td>
<td>7%</td>
<td>23%</td>
<td>56%</td>
<td>3%</td>
<td>24%</td>
<td>0%</td>
</tr>
<tr>
<td>Average of positives (ppb)</td>
<td>11</td>
<td>410</td>
<td>660</td>
<td>526</td>
<td>2507</td>
<td>20</td>
</tr>
<tr>
<td>Median of positives (ppb)</td>
<td>4</td>
<td>105</td>
<td>349</td>
<td>598</td>
<td>702</td>
<td>2</td>
</tr>
<tr>
<td>Maximum (ppb)</td>
<td>223</td>
<td>10790</td>
<td>11600</td>
<td>1143</td>
<td>50734</td>
<td>317</td>
</tr>
</tbody>
</table>
Conclusions: Back to the basics

1. Mycotoxicosis should be considered as possible primary factor:
   a. Production losses
   b. Increased incidence of disease

2. Documented symptoms can be a guide in the field

3. Guide to probable cause
   a. Specific damage to target tissues

4. Post-mortem examinations may only indicate
   a. Gut irritation
   b. Edema
   c. Tissue inflammation

5. Feed analysis should be performed
   a. Accurate sampling is the challenge

Schiefer, 1990
Thank You!

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Feed Industry Update

Gary Huddleston – Director, Feed Manufacturing and Regulatory Affairs
American Feed Industry Association

AFIA members include:
- Ingredient Suppliers
- Feed Manufacturers
- Associations
- Industry Support
- Pet Food Manufacturers
- Educational Institutions
- Pharmaceuticals
- Equipment Manufacturers
- Media

Represents 75% of the feed in the U.S. and 70% of the non-grain ingredients

Over 680 members

More than 100 years representing the industry

Based in Arlington, VA
Tons of Livestock Feed Manufactured in the US in 2016

Total Tons - 236.3 Million

- Cattle on Feed – 74.7 Million
- Broilers – 56.3 Million
- Hogs – 46.3 Million
- Dairy Cows – 23.8 Million
- Layers – 16.4 Million
- Turkeys – 9.9 Million
- Horses – 8.0 Million
- Aquaculture – 708,000
- Sheep – 157,000
Top 5 States in Animal Food Consumption
(in 1,000 tons in 2016)

- NEBRASKA: 15,446.2
- MINNESOTA: 11,331.1
- TEXAS: 17,316.4
- IOWA: 21,063.1
- NORTH CAROLINA: 12,558.7
Ingredient Usage Breakdown

Estimated 2016 U.S. Total Diet Composition

- Corn, 50.3%
- Soybean Meal, 12.7%
- DDGS, 12.6%
- Wet Distillers Grains, 8.5%
- Bakery Meal, 4.2%
- Corn Gluten Feed, 1.7%
- Cottonseed Meal, 1.7%
- Wheat Midds, 1.6%
- Grain Sorghum, 1.5%
- Soybean Hulls, 1.2%
- Oats, 1.0%
- Other, 3.1%
Feed Mill Distribution in the US

U.S. Feed Mill Distribution
FDA Licensed and FDA Non-Licensed Feed Mills

Feed Mills
The Production of Animal Food Contributes Billions to the Economy

<table>
<thead>
<tr>
<th></th>
<th>Animal Feed</th>
<th>Pet Food</th>
<th>TOTAL*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Sales</strong></td>
<td>$170 B</td>
<td>$127 B</td>
<td>$297 B</td>
</tr>
<tr>
<td><strong>Including Value-Add</strong></td>
<td>$58 B</td>
<td>$44 B</td>
<td>($102 B)</td>
</tr>
<tr>
<td>(i.e., sales minus the</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cost of inputs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Taxes</strong> (local, state &amp;</td>
<td>$13 B</td>
<td>$9 B</td>
<td>$22 B</td>
</tr>
<tr>
<td>national)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Based on 2016 data, in billions of dollars
### Animal Food Manufacturing Contributes to U.S. Labor Force

<table>
<thead>
<tr>
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<th>Animal Feed</th>
<th>Pet Food</th>
<th>TOTAL*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jobs (including full &amp; part-time)</td>
<td>545,000+</td>
<td>398,000+</td>
<td>944,000+</td>
</tr>
<tr>
<td>Paid Wages</td>
<td>$33 B</td>
<td>$23 B</td>
<td>$56 B</td>
</tr>
</tbody>
</table>

*Based on 2016 data, wages listed in billions of dollars
Animal Food Industry Supports Trade

- $13.1\ B = \text{total U.S. animal food exports, including:}$
  - $11.6\ B = \text{feed \& feed ingredients}$
  - $1.5\ B = \text{pet food products}$

- Supports U.S. agriculture’s $20B+ \text{ trade surplus}$
With over 9.6 billion food-producing animals & 144 million dogs & cats to feed annually, the demand for animal food is strong.... and growing!
But Many Factors Impact Continued Growth in Animal Food Sector

- Overly burdensome food safety regulations
- Trade policies at the national level
- Ingredient approvals
- Consumer transparency
What’s on everyone’s mind when it comes to FDA?

FSMA!
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 responding to contamination to preventing it.
What Does FSMA Require?

• **Facilities that only hold 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
Food Safety Plan

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
Complete Framework of FSMA for Animal Food

- **Preventive Controls for Animal Food (Part 507)**
  - CGMPs
  - Hazard Analysis
  - Food Safety Plan
- **Foreign Supplier Verification Program (FSVP) for Importers**
- **Sanitary Transportation of Human and Animal Food**
- **Accredited Third-Party Certification (for certifying importers – not very applicable)**
Primary Types of FSMA Inspections

- CGMP
  - Subpart B

- HA/PC
  - Subparts C&E

- Sanitary Transportation
- FSVP
FSMA Compliance – Apr 2019
Everyone except very small businesses (<$2.5M)

- Qualified Individual Training should be in place
- Facilities should have a designated PCQI in place
- Compliance to CGMPs required
- Hazard Analysis and Food Safety Plans are required
- Sanitary Transportation Rule compliance required
- FSVP Rule compliance required
- HA/PC inspections in full swing for large businesses
- Small business inspections (<500 FTE) will start in the fall
- Will be combined with CGMPs, med feed, BSE, etc.
FDA CGMP Inspections & FOIA Data

• 622 inspections performed and completed during calendar year 2018
• Inspections held in 47 states, 1 US Territory (PR) & 4 foreign countries (CA, India, Indonesia, MX)
• 58% feed/integrators; 11% pet food; 24% ingredients/renderers; 6% warehouses; 1% food & beverage or other/unknown
• 28 Form 483s were issued, 14 VAIs were issued, 8 were not classified; 5 NAI and 1 OAI
• AFIA has copies of most 483s issued
• Facility type and geographic diversity consistent
CGMP Inspection Activity Calendar 2018

• What we’ve learned so far:
  • They usually do a thorough walk-thru of the plant
  • Pest control seems to be a major focus
  • Unlabeled containers and trash cans is a frequent observation
  • They are asking to see QI training documentation
  • They are asking about the PCQI and training
  • They have visited a few retail commodity blenders
  • Frequently, they are asking to see records for which they are not entitled to see

• The best preparation for an inspection is familiarity with the rule
FDA VFD Inspections FOIA

- 269 inspections performed and completed during calendar 2018
- Inspections held in 30 states, with more than 52% in IA, KS, NE and MO
- 85% Distributors (Retailers), 11% Farms and 4% at Veterinary facilities
- 21 Form 483s were issued, 8 VAls were issued, 2 were not classified; 11 were NAI
- Facility type and geographic diversity questionable
FDA HA/PC Inspections FOIA

- 7 inspections performed and completed during calendar 2018
- Inspections held in 4 states, KS (3), KY (2), MS and NE
- 5 Feed, 1 Integrator and 1 Pet Food facility
- 6 Form 483s were issued, 1 VAI, balance unclassified
- **Evidence suggests these facilities may have had a recent Animal Food Safety incident.**
FDA HA/PC Inspections Learnings

• Multiple day inspections (3-5 average)
• Documents thoroughly reviewed:
  – Food Safety Plan
  – Hazard analysis
  – Supplier approval program
  – Training documentation (PCQI and QI)
  – Others related to other parts of the inspections (medicated feed, BSE, CGMP)
• Federal and State investigators
• Seem to be in “educate” mode…but issue 483
FDA HA/PC Inspection Plan

• Large firms – compliance as of Sept. 2017
  – Delayed inspections until Oct. 2018
    • New FY and inspections should be occurring

• Small firms – compliance Sept. 2018
  – Inspections will start fall of 2019

• May do CGMP and HA/PC inspections at same time
  – May add in BSE, medicated feed inspections
  – Sanitary transportation readiness questions
FDA FY 2019 Inspection Plan

• FY is Oct 1, 2018 through Sep 30, 2019
• Complete 250 domestic and 15 foreign CGMP inspections (Large and Small Facilities)
  – As of mid-Mar: 99 completed (58-FDA; 41-States)
• Complete 150 domestic and 10 foreign HA/PC inspections (Large Facilities)
  – As of mid-Mar: 14 completed (11-FDA; 3-States)
• Current contracts in place for HA/PC inspections with CA, IA, KS, MI, MN, MO, NC, NE, TN, and TX
#235 Current Good Manufacturing Practice Requirements for Food for Animals

- No real surprises or enlightening interpretations
- Final document after comment period not bad (51 pages)
- 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)
#245 Hazard Analysis and Risk-Based Preventive Controls 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 intended use 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
Meetings and Calls with FDA

Meetings with Jenny Murphy & Staff
- Meetings have mostly been about GFI #245
- We don’t feel they will adopt all of our comments
- We walked away with concerns about PC/HA inspections
- Concerns about possible required PCs

Call with Glenn Bass and ORA Staff
- Left us with same general feeling about inspections
- They expect the facility to be a completely open book
- We did petition them to consider giving advance notice
Organic Feed Update

Organic Trade Association (OTA) lawsuit against USDA proceeding

• USDA withdrew the Organic Livestock Rule
• OTA claims that has caused harm to the organic sector
• USDA claims that the Organic Food & Production Act (OFPA) does not give the National Organic Program the authority to regulate animal welfare
• The U.S. District Court for the District of Columbia agreed with the OTA and decided to let the lawsuit proceed
OSHA Update

Electronic Reporting Rule

• Form 300A data must be submitted through the agency’s Injury Tracking Application (ITA) on their website by July
• OSHA announced the initiation of their Site-Specific Targeting 2016 (SST-16) Program (will use submitted data)

Workplace Incentive Programs (memorandum)

• You must make sure your program does not discourage the reporting of workplace injuries and illnesses by employees
• OSHA also clarified that most instances of workplace drug testing are permissible
Federal Motor Carrier Safety Administration

Hours of Service Rules

• FMCSA released a guidance document in May that provided more clarity on the 150-air mile radius exemption for agricultural commodities (Feed not included)
• Livestock Feed is considered in the definition of “farm supplies” and is exempt from HOS rules inside the 150-air mile radius under 40 CFR Part 395
• The ELD requirement was permanently suspended for haulers of livestock in late 2018
Federal Motor Carrier Safety Administration

Proposed HOS rule changes (released in Aug 2018)

- Expanding the 100 air-mile "short-haul" exemption from 12 to 14 hours
- Extending the current on-duty hours limitation in adverse driving conditions
- Revising the current mandatory 30-minute break
- Reinstating the option for splitting up the off-duty rest break for drivers operating trucks that are equipped with a sleeper-berth compartment
EPA Update

• CERCLA & EPCRA Reporting Requirements – Manure reporting exemption for farms reinstated
• Tier II Reporting – Combustible Dust
  – EPA revised the report to better align EPCRA with the revised OSHA 2012 Hazard Communication Standard (HCS 2012)
  – AFIA and NGFA had discussions with EPA on the issue
  – AFIA put out guidance Jan 15
  – Guidance is to report combustible dust, but below reporting threshold (check the box)
THANK YOU

AFIA’S 4 PROMISES

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AFIA

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