Office of the Texas State Chemist

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Associate Director

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State Chemist and Director
Regulatory Relationships Between State and Federal Agencies.

- The United States Department of Agriculture (USDA) regulates raw meat, poultry, milk, and eggs and their processing. USDA also regulates live production medications such as vaccines, serums, and serum products.
- The Department of Health and Human Services, U.S. Food and Drug Administration (FDA) regulates food, and animal feed by reference, all other drugs, and water.
- States regulate food, feed and drugs at the local level.
State and Federal Processes.

- States began regulating animal feeds between 1850’s and 1900’s.
- Federal Agencies began appearing to regulate animal feeds in the early 1900’s and, in many cases, Federal laws developed to complement existing state programs and establish Federal jurisdiction in interstate commerce.
- FDA and USDA are coming under increasing pressures domestically and internationally to provide a central response from government.
Agriculture: USA’s Largest Industry

- Agriculture & Ag-related Industry = $789 billion to the US Gross Domestic Product (GDP)
- Agriculture-related employment = 16.9 million agriculture-related workers
- Animal Products > $100 billion/year
- US largest fed cattle production in the world, largest poultry producer and second largest exporter of poultry meat and eggs in the world.
- Milk is second only to beef and equal to corn.

(USDA/ERS, 2013)
Unique Risks to Texas Agriculture

- Largest Number of Cattle, Sheep, Goats, Horses and Exotic Hoof Stock Value = $8 Billion
- Livestock – over half the value of Texas Agriculture
- TX Exports over $7 billion as livestock and products
Unique Risks to Texas Agriculture

- 20 land ports • 9 seaports
- 4 international airports
- Top importer live animals -
- 1 million + per year
- Texas borders 8 states
- 1,237-mile border with Mexico
The Mission of OTSC

- The Office of the Texas State Chemist protects consumers and enhances agribusiness through its feed and fertilizer regulatory compliance program, surveillance and monitoring of animal-human health and environmental hazards, and preparedness planning.
The Office of the Texas State Chemist:

- Inspects products and facilities to determine compliance with both State and Federal Statutes;
- Investigates complaints involving crop loss, animal illness or death, zoonotic diseases and pathogens that are implicated by feeding practices;
- Investigates any improprieties reported to it or encountered during its normal business; and
- Performs Federal inspections/investigations per cooperative agreement and through grants with the Food and Drug Administration.
The Office of the Texas State Chemist

**FEED**
- ~16.3 million tons

**FERTILIZER**
- ~2.9 million tons

**INSPECTION FEES**
- $0.19 per ton
- $0.36 per ton

FY 2015
To Manufacture Feed or Fertilizer for Distribution in Texas

- To distribute feed, each facility must be licensed
- To distribute fertilizer the last registrant must have a current registration
- The guarantor must label the product properly
- And, must keep distribution records of the product(s) distributed
What is a label?

- “a display of written, printed, or graphic matter upon or affixed to the container in which a commercial feed is distributed, or on the invoice or delivery slip with which a commercial feed is delivered.”

- “labeling” is defined as all labels and other written, printed, or graphic matter, including advertisements, brochures, and internet.

- Most food products for humans could not be sold for animal use because of inadequate labeling.
PURPOSE OF LABELING

- PROVIDE PROTECTION FOR THE CONSUMER AS WELL AS THE REGULATED INDUSTRY
- SAFEGUARD THE HEALTH OF MAN AND ANIMAL
- PROVIDE A STRUCTURE FOR ORDERLY COMMERCE
Fertilizer Concerns

- Components used properly
- Product free of contamination
Mycotoxins in Agricultural Commodities

- Aflatoxin
- Fumonisin
- Ochratoxin
- Zearalenone
- Vomitoxin (DON, deoxynivalenol)
Best Management Practices to Reduce Mycotoxin Contamination

Website: http://mycotoxinbmps.tamu.edu/welcome.aspx
Mycotoxins

- Initial samples represent a survey of new crop, identified to county
- These account for 1200-1500 samples and target corn, peanuts, cotton seed, other grains and their screenings
- Additional samples result from follow-up inspections for regulatory compliance and “trace back” investigations
- average ~ 500 and includes dairy feeds, pet foods, horse feeds, starter rations, etc.
Aflatoxin Levels Enforced

<table>
<thead>
<tr>
<th>Level (ppb)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Lactating Dairy Cows, immature animals, Humans.</td>
</tr>
<tr>
<td>50</td>
<td>Wildlife corn, Deer corn</td>
</tr>
<tr>
<td>100</td>
<td>Breeding animals – Cattle Sheep, Goats, Swine, mature Poultry</td>
</tr>
<tr>
<td>200</td>
<td>Finishing Swine (100 lb)</td>
</tr>
<tr>
<td>300</td>
<td>Finishing Cattle (slaughter)</td>
</tr>
<tr>
<td>500</td>
<td>Must be destroyed</td>
</tr>
</tbody>
</table>
Fumonisin Levels Enforced

- 5 ppm  Horses and rabbits
- 20 ppm  Swine and catfish
- 30 ppm  Breeding Ruminants, Breeding Poultry, Breeding Mink, Lactating Dairy, Laying Hens
- 60 ppm  Cattle for slaughter, mink for pelts
- 100 ppm  Poultry for slaughter
- 10 ppm  All other species of livestock and pets
Aflatoxins are naturally occurring mycotoxins that are produced by a fungus (Aspergillus).

Commonly found in crops exposed to high-humidity environment or crops grown in stressful conditions such as drought.

Aflatoxins, especially B1, are carcinogenic and causes liver damage and cancer.
Fusarium verticilliodes, produces the mycotoxin fumonisin

Similar to Aspergillus, the Fusarium fungus infects kernels via the corn silk or in association with insect damage

Symptoms of Fusarium ear rot are a white-to-pink mold on scattered kernels about the ear
Laboratory Diagnosis of Prohibited Proteins

- Microscopy, still one of the best
- Rapid immunodiagnostic assays for screening
- PCR, both conventional and real-time PCR
Label Caution Statement

- “Do Not Feed To Cattle Or Other Ruminants”
- Required for all raw materials and finished products that contain prohibited material
- Pet food that is intended for retail sale and non-ruminant laboratory animal feed is exempt from this requirement
Regulatory Actions that May be Taken

- Stop Sales
- Voluntary Recalls
- Seizures of Feed
- Rescinding License
- Legal Actions, including Criminal and Civil
Each analytical result must be surrounded by sample integrity. Without proof of the sample chain of custody, an analytical result is just a number.

Sample Chain of Custody

- Sample Received
- Sample Prepared for Analysis
- Sample Information Stored
- Official Feed Seal Placed on Sample
- Information Entered
- Sample Shipped
- Official Sample
- Analytical Results to FFCS
- Reports Mailed to Manufacturer
Agricultural Analytical Service

- What analysis we currently perform:
  - Microbiology (Salmonella)
  - Trace Metals (Cu, Fe, Mg, Mn, Zn)
  - Antibiotics
  - Soluble Vitamins
  - Fumonisin
  - Vitamin A
  - Microscopy
  - PCR
  - Minerals (Ca, P, Na, K, NaCl, Chloride)
  - Mycotoxins
  - Nitrogen/Protein by combustion
  - Heavy Metals (Pb, Cd, Mo, Ni, Co, Se, As and Hg)
  - Phosphate (Available)/Potash/Sulfur
Wet analysis, from the simplest extraction and gravimetric analysis to more sophisticated techniques.
Protein With Leco Nitrogen Analyzer.
Analysis of Trace Metals by AA.
Microscopy
For the detection of prohibited materials in animal feed (BSE)
and as a tool to identify mislabeled samples.
Tour of the Laboratory
Safety Rules to Follow

- Safety Glasses will be Provided
- No Food or Drink may be taken in the laboratory
- No open-toe shoes
- Please stay with the group
The Food and Drug Administration is responsible for ensuring the safety of all feed and food moving in interstate commerce, except those under the Department of Agriculture; while State Agencies are responsible for the regulatory activities within their jurisdictions. And, because the programs often overlap and they need to synchronize both regulatory process and regulatory actions between the States and Federal Agencies, we are collaborating to improve regulatory programs and sharing resources and resulting data to protect food and feed.
The Food Safety Modernization Act (FSMA)

Provides further support for developing the Animal Feed Regulatory Program Standards (AFRPS) and the Integrated Food Safety System (IFSS).

Both FDA and USDA are working on overlapping programs for food safety.
Prerequisite Program

- Determine the appropriateness of the control systems:
- Choose the most effective and implementable system for your operation:
  - Good Manufacturing Practices (GMPs), HACCP, other programs (approved)
  - Develop appropriate Standard Operating Procedures (SOPs) to implement
  - Train and test the System for flaws
  - Adjust/implement the control system that works for your operation and meets the requirements of the regulatory agency assigned your oversight
Hazard Analysis and Critical Control Point (HACCP)

HACCP Principles:
1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures
Protecting consumers and enhancing agribusiness through its feed and fertilizer regulatory compliance program, surveillance and monitoring of animal-human health and environmental hazards, and preparedness planning.

Office of the Texas State Chemist

FDA Recall Notices & Alerts

<table>
<thead>
<tr>
<th>Date</th>
<th>Product Type</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Oct 02, 2012</td>
<td>Pet Food</td>
<td>Kasel Associated Industries Recalls Nature’s Deli Chicken Jerky Dog Treats Because of Possible Salmonella Health Risk...more</td>
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<tr>
<td>Sep 11, 2012</td>
<td>Pet Food</td>
<td>Breeder’s Choice Pet Food Recalls Avoderm Natural Lamb Meal &amp; Brown Rice Adult Dog Formula Because of Possible Salmonella Health Risk...more</td>
</tr>
<tr>
<td>Jul 27, 2012</td>
<td>Pet Food</td>
<td>Arthur Dogswell LLC Voluntarily Recalls Catwell Brand Vitality Chicken Breast With Flaxseed and Vitamins Because Of Possible Health Risk...more</td>
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What’s new
- Aug 2012 OTSC Newsletter
- New Regulatory Science Courses Offered - Spring 2013
- Food Industry HACCP Website
- One Sample Strategy Website
- OTSC Approves Aflatoxin Binders
- Testing on Private Samples (09-09-10)
- Chemical Facility Act and Appendix A
- Sale of Ammonium Nitrate in Texas
Advancing the science of creating tools, standards, and practices to improve the protection and compliance of food systems

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<thead>
<tr>
<th>Summer (May - August)</th>
<th>Fall (August - December)</th>
<th>Spring (January - May)</th>
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<tbody>
<tr>
<td>VTMI/SCSC 629</td>
<td>AGEC/SCSC 635</td>
<td>SCSC 634</td>
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<tr>
<td></td>
<td>SCSC 636</td>
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<tr>
<td>Regulatory Science Methodology in Food Systems (3 SCH)</td>
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<tr>
<td></td>
<td>AGEC 689</td>
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<tr>
<td>Managerial Economics for Regulatory Science (3 SCH)</td>
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