Office of the Texas State Chemist

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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.

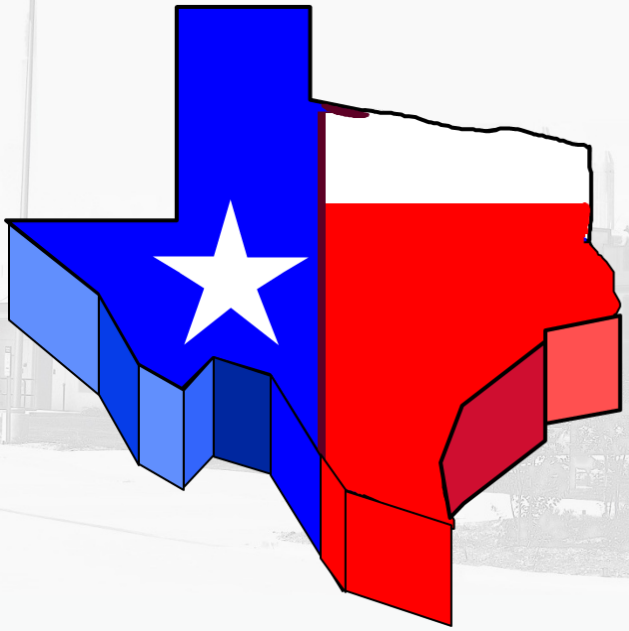
- States began regulating animal feeds between 1850's and 1900's.
- Federal Agencies began appearing to regulate animal feeds in the early 1900's and, in many cases, Federal laws developed to complement existing state programs and establish Federal jurisdiction in interstate commerce.
- FDA and USDA 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	**INSPECTION FEES**
~16.3 million tons	$0.19 per ton
FERTILIZER	
~2.9 million tons	$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

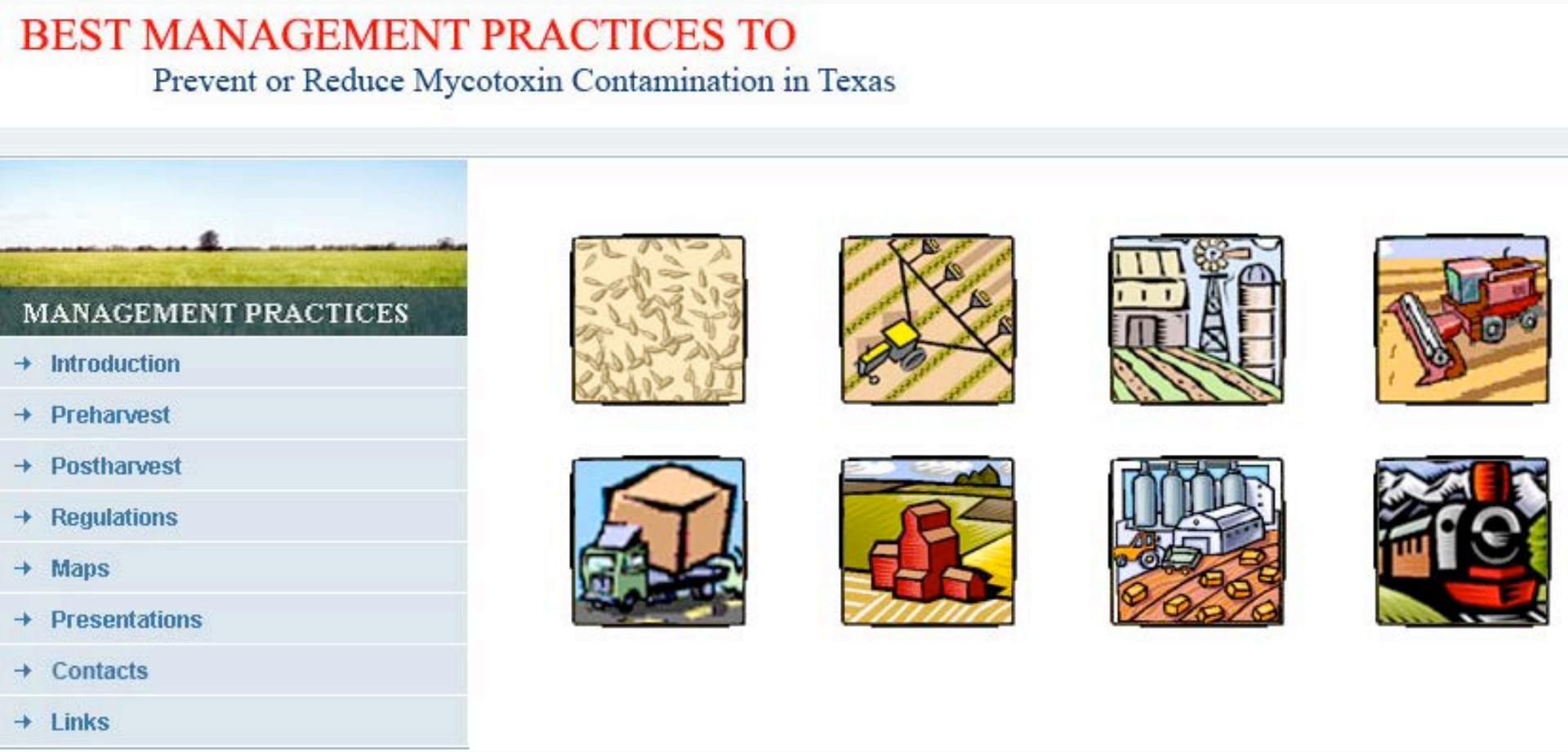
Fertilizer Concerns

- 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

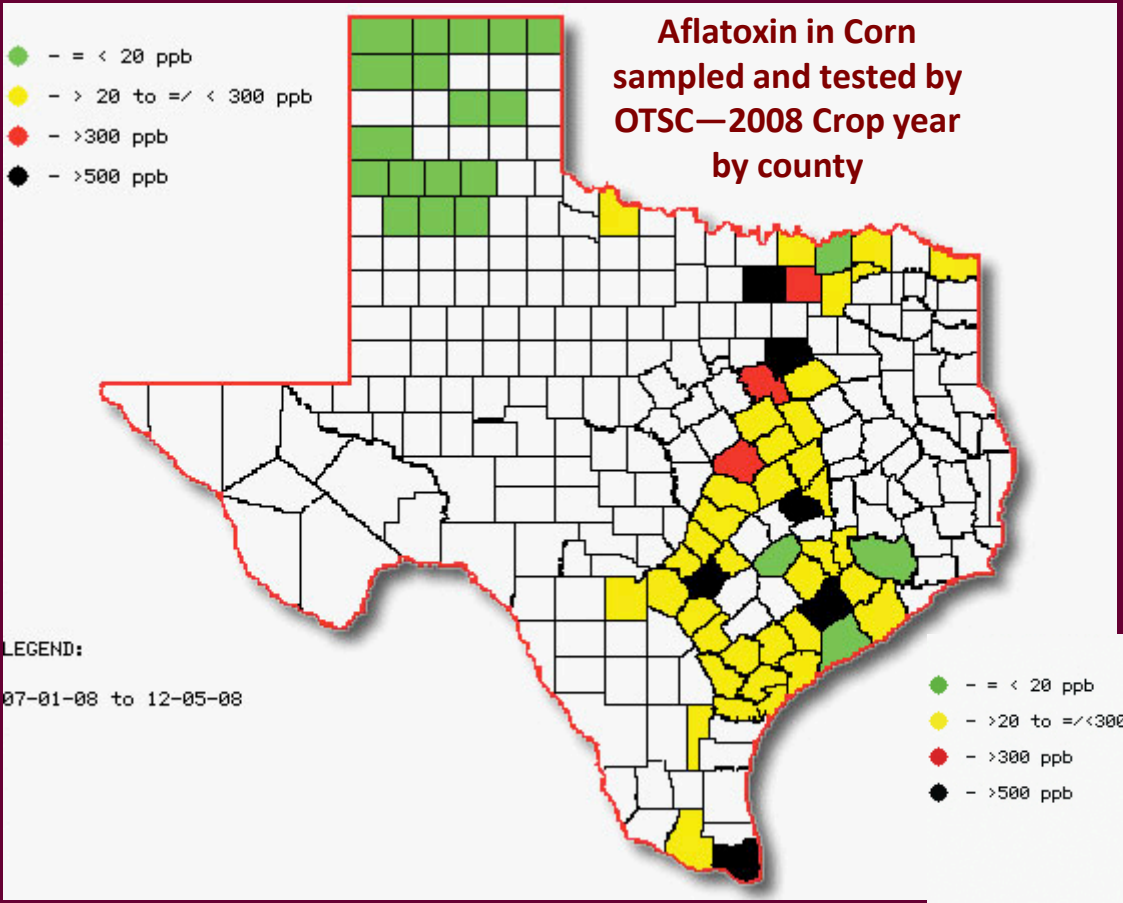
- Initial samples represent a survey of new crop, identified to county
- These account for 1200-1500 samples and target corn, peanuts, cotton seed, other grains and their screenings
- Additional samples result from follow-up inspections for regulatory compliance and “trace back” investigations
- average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

Aflatoxin Levels Enforced

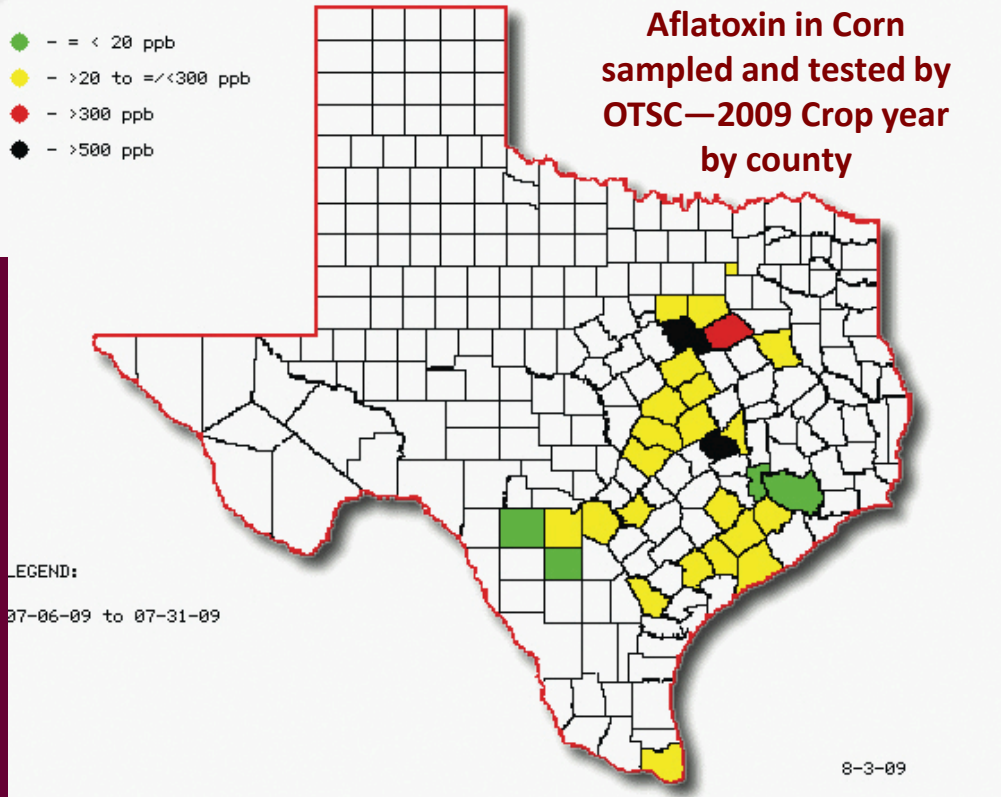
20 ppb	Lactating Dairy Cows, immature animals, Humans.
50 ppb	Wildlife corn, Deer corn
100 ppb	Breeding animals – Cattle Sheep, Goats, Swine, mature Poultry
200 ppb	Finishing Swine (100 lb)
300 ppb	Finishing Cattle (slaughter)
500 ppb	Must be destroyed

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

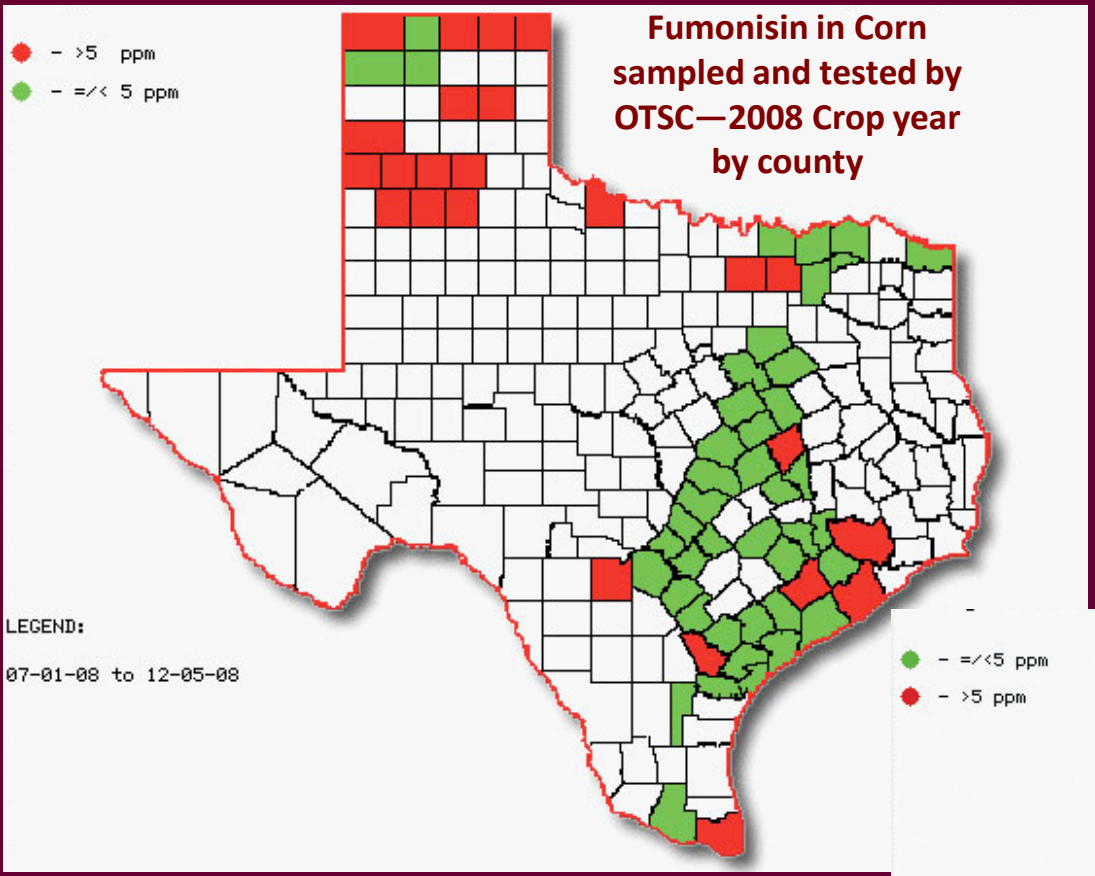


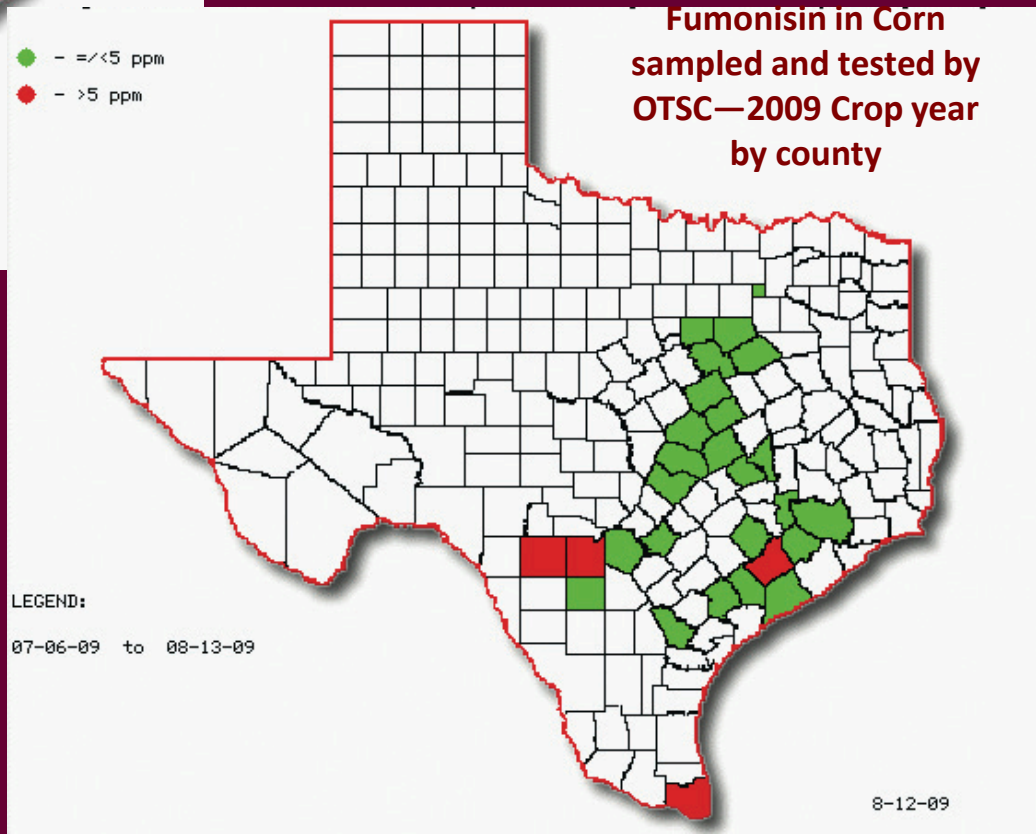
Aflatoxin in Corn sampled and tested by OTSC—2008 Crop year by county



Aflatoxin in Corn sampled and tested by OTSC—2009 Crop year by county

- ✓ **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

Sample Chain of Custody

Official Sample

Official Feed Seal Placed on Sample

Information Entered

Sample Shipped

Sample Received

Sample Information Stored

Sample Prepared for Analysis

Analytical Results to FFCS

Reports Mailed to Manufacturer

Each analytical result must be surrounded by sample integrity. Without proof of the sample chain of custody, an analytical result is just a number.

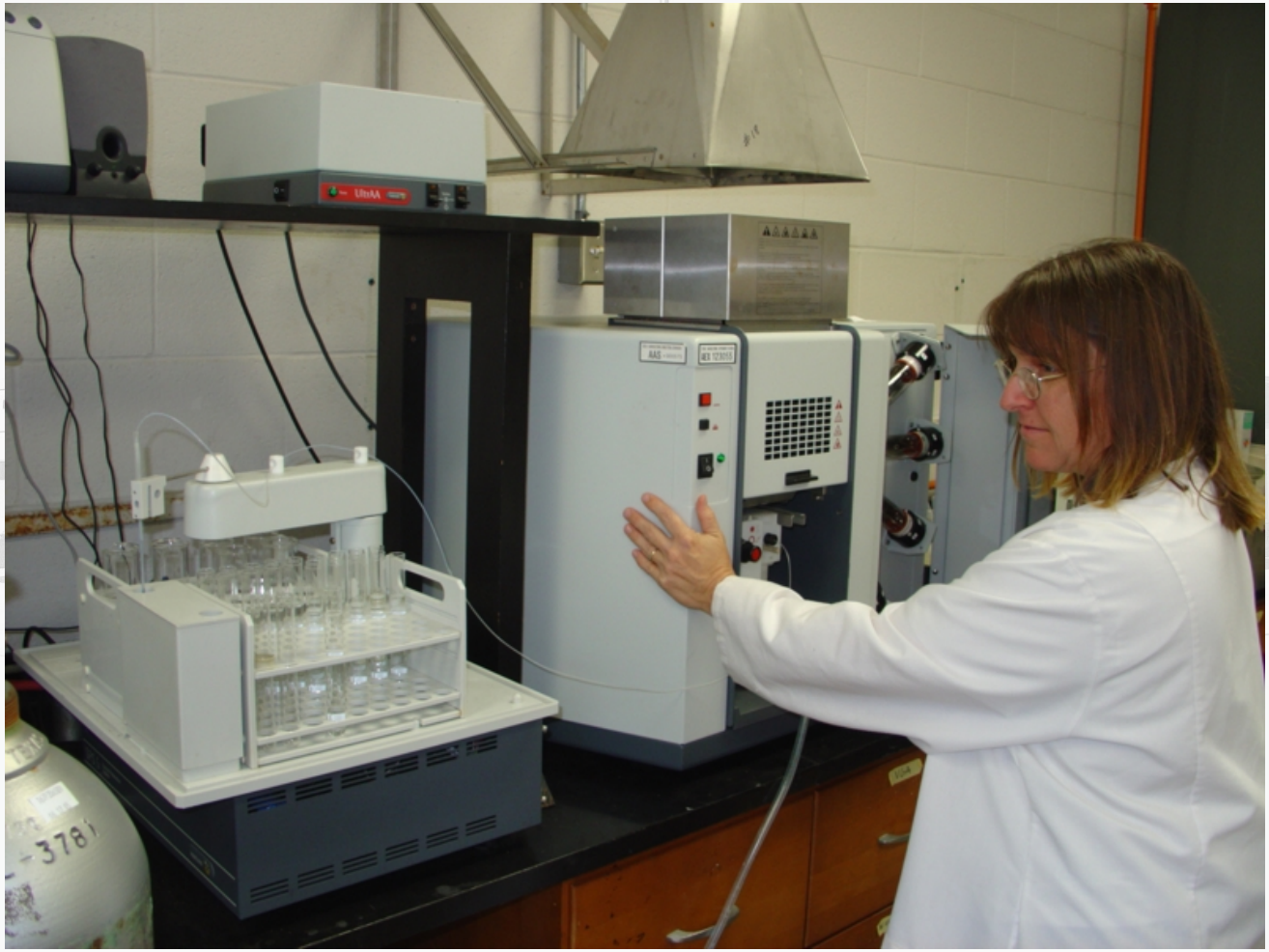
Agricultural Analytical Service

- What analysis we currently perform:
- Microbiology (Salmonella)
- Antibiotics
- Fumonisin
- Microscopy
- 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
- Trace Metals(Cu, Fe, Mg, Mn, Zn)
- Soluble Vitamins
- Vitamin A
- PCR

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

AFRPS

Animal Feed Regulatory Program Standards

National Animal Feed Regulatory Program Standards - A joint project between the U.S. Food and Drug Administration and the Association of American Feed Control Officials

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 there 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 you 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

http://otscweb.tamu.edu

OFFICE OF THE TEXAS STATE CHEMIST

TEXAS A&M AGRILIFE RESEARCH

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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

Date	Product Type	Short Description
Oct 02, 2012	Pet Food	Kasel Associated Industries Recalls Nature's Deli Chicken Jerky Dog Treats Because of Possible Salmonella Health Risk ...more
Sep 11, 2012	Pet Food	Breeder's Choice Pet Food Recalls AvoDerm Natural Lamb Meal & Brown Rice Adult Dog Formula Because of Possible Salmonella Health Risk ...more
Jul 27, 2012	Pet Food	Arthur Dogswell LLC Voluntarily Recalls Catswell Brand Vitakitty Chicken Breast With Flaxseed And Vitamins Because Of Possible Health Risk ...more

Next Last

What's new

- Aug 2012 OTSC Newsletter
- New Regulatory Science Courses Offered - Spring 2013
- Feed 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

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TEXAS A&M UNIVERSITY — Regulatory Science in Food Systems Graduate Program

Advancing the science of creating tools, standards, and practices to improve the protection and compliance of food systems

Summer (May - August)	Fall (August - December)	Spring (January - May)
VTMI/SCSC 629 Laboratory Quality Systems (3 SCH)	AGEC/SCSC 635 Comparative Global Standards in Food Systems (3 SCH)	SCSC 634 Regulatory Science: Principles & Practices in Food Systems (3 SCH)
	SCSC 636 Regulatory Science Methodology in Food Systems (3 SCH)	AGEC 689 Managerial Economics for Regulatory Science (3 SCH)

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Control Service ● Agriculture Analytical Service