The Food Safety Modernization Act (FSMA) was signed into law in January 2011. The 1906 Pure Food and Drug Act were enacted due to unsanitary practices in the meat packing industry. The 1938 Food, Drug and Cosmetic Act was a reaction to about 100 people that were poisoned after taking a sulfa drug with diethylene glycol as a carrier to dissolve the drug. The FSMA was historic because science-based prevention rather than “knee-jerk” reaction will be the driving force for determining risk to animals and humans.

Today’s food safety system must meet the demands of a food supply that is enormously different from the early 1900’s and even the 1990’s. Our food supply is technologically advanced and complex. Over 15% of the total US food supply is imported. There are emerging food safety hazards consisting of pathogens and toxins. The centralization of food production and distribution has made the food supply more vulnerable to intentional and unintentional hazards. For example, food borne illness accounts for 48 million Americans (1 out of 6) that become ill each year; 128,000 are hospitalized; and 3,000 die.

The new law has a big impact for four reasons: First, it creates a system that covers the entire spectrum of food safety issues and the roles of the players. Second, it makes each player, both the domestic and foreign food industry, responsible for preventing problems. Third, since much of our food is imported, the prevention principle applies to imported food to the country of origin and not solely at the US border. Fourth, the FDA will not be alone in this undertaking. The FDA will need to partner with other government agencies at the federal, state and local level and work with industry and consumer.

Prevention is the keystone of the legislation. Food facilities will be responsible for identifying hazards, establish control points, monitor their systems, fix problems and keep records. While prevention is not new, Congress has granted FDA the authority to use the tool more widely. The application of preventive controls will be ensured by compliance through inspections and response by FDA. All high risk facilities in the US will be inspected within 5 years and then every 3 years. FDA will inspect at least 600 foreign facilities within one year of enactment and double those inspections every year for the next 5 years.

The FDA will have new and enhanced tools to support the increased number of inspections. FDA will have access to all records, including industry food safety plans, if there is a reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death in humans or animals. Increased access to food records means: 1) The FDA now has the authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food. 2) The FDA now has a more flexible standard for administratively detaining products that are potentially hazardous. 3) Registration can be suspended for a facility if the food poses a reasonable probability of serious adverse health consequence or death. 4) There will be enhanced product tracing from “farm” to “fork.” 5) A program of laboratory accreditation will ensure that US food testing laboratories can support work generated by increased inspections by meeting high-quality standards.

Increased inspection frequency will require FDA to rely on other agencies at the federal, state and local levels. Subsequently, State, local and international capacity building will be necessary to improve food surveillance, develop a national agriculture and food defense strategy and establish a laboratory network. One outcome will be an easier way for consumers to find recall information in a searchable database.

The immediate challenge is the completion of 50 new rules, guidance documents and reports in the next 3 years. Finding appropriate resources to build the new system will be a long range process.
Aflatoxin Binding Agent Rule §61.67 - Effective May 19, 2011

The Office of the Texas State Chemist published proposed rules for the use of Aflatoxin Binding Agents in Customer Formula Feeds in the Texas Register last January, 2011. The Office received comments from the Texas Corn Producers Board in support of the rule change, stating they favored anything “that can assist corn producers in gaining value for their corn when affected by aflatoxin while maintaining a safe food and feed supply.” A second comment letter was offered by a feed company in which they objected to several provisions in the rule involving aflatoxin measurement and record-keeping provisions and requested a better definition of these requirements. These concerns were addressed in Feed Industry Memorandum 5-23 titled “Criteria for Aflatoxin Binding Agents in Customer Formula Feeds” and is available for viewing on the OTSC website http://otscweb.tamu.edu/Laws/Policy.aspx.

The Office also communicated with stakeholders about the aflatoxin binding agent policy in the last OTSC newsletter on February, 2011, Vol. 18, No. 1. Following this newsletter, FDA expressed their concern to the following statement:

Regulatory oversight involving the proper use of these products will be performed under the authority provided within the Texas Commercial Feed Control Act, Commercial Feed Rules, and the Food, Drug and Cosmetic Act by State and the Food and Drug Administration (FDA) commissioned investigators.

In response, FDA personnel offered the following statement for newsletter readers:

“FDA was not involved in the approval of the aflatoxin binders which are not legal under the Federal Food, Drug and Cosmetic Act. This means that the feed containing aflatoxin binders is adulterated once it enters into interstate commerce outside of Texas.”

Feed Industry Memorandum 5-23 adds further clarity to this point. The labeling requirements for aflatoxin binders must designate that aflatoxin binding product is for use in Texas only.

Aflatoxin binding agents represent a dual product category; 1) defined feed ingredients for nutritional purposes or GRAS feed additives; and 2) non-feed ingredients for binding aflatoxin within the State of Texas. Aflatoxin binding agents intended for non-feed use for binding aflatoxin may not contain a drug claim to diagnose, cure, mitigate, treat or prevent disease such as “improves liver health” or “prevents aflatoxicosis.” Neither do these products conform to the animal supplement category, since aflatoxin binders are included in animal feed. As a result of the distinct dual product category of aflatoxin binders and because this action represents the first approval of aflatoxin binders in the United States, Feed Industry Memorandum 5-23 was authored to explain how these products may be used, labeled, sold and evaluated in Texas.

Feed Industry Memorandum 5-23 does not alter existing Action Levels for aflatoxin contained in the Texas Administrative Code Title 4 Agriculture Chapter 61 titled: Commercial Feed Rules §61.61 Poisonous or Deleterious Substances (a)(6) “grain, oilseeds, processed grain and oilseed meals containing aflatoxin B1, B2, G1, G2 above 20 parts per billion (ppb) individually or total except that with proper labeling as approved by the Office of the Texas State Chemist as follows: <50 ppb may be distributed when destined for wildlife; <100 ppb may be distributed when destined for breeding cattle and breeding goats not used in production of milk for human consumption, breeding swine, mature poultry, and sheep; <200 ppb may be distributed when destined for finishing swine (more than 100 lbs. body weight); <300 ppb may be distributed when destined for finishing cattle in confinement; grain containing >300 to <500 ppb requires a blending permit issued by the Office of the Texas State Chemist; aflatoxin >500 ppb in grain and >300 ppb in oilseed, processed grain, and oilseed meal may not enter commerce and a record of disposition shall be submitted to the Office of the Texas State Chemist.”

Aflatoxin binders may only be added to customer formula feeds which are defined as a “mixture of commercial feed or feed material all or part of which is furnished by the person who processes, mixes, mills, or otherwise prepares the mixture and which is mixed according to the specific instructions of the purchaser. The term includes a special formula feed or made-to-order feed.” Additionally, aflatoxin binders may be used in feed manufactured on-farm, in feed lots, dairies, and by integrated operations and are subject to the same inspection authority that currently exists within the Texas Commercial Feed Control Act and Commercial Feed Rules. The use of aflatoxin binders in non-customer-formula feeds is prohibited.
FFCS Review

Fiscal Year (FY) 2011 is quickly disappearing. The FY2011 annual plan of work included routine monitoring of feed, fertilizer and feed and fertilizer ingredients for economic conformance to the label, as well as surveillance for adulterants (toxins, microbial contaminants, dioxins, heavy metals and antibiotic residues). The end of April marked the 66% point for the annual plan of work and sampling schedule. To date, a combined total of 4,576 samples (80%) out of a projected 5740 have been collected. This includes 3,114 samples (78%) of feed and 1,462 (84%) samples of fertilizer.

In addition, a U.S. Food and Drug Administration (FDA) contract and grant has OTSC field investigators conducting 375 BSE and Current Good Manufacturing Practices (cGMP) inspections and collecting 400 feed samples to determine the presence of prohibited animal protein products. To date, field staff has performed 232 inspections (62%) and collected 371 samples (93%).

OTSC field investigators are also preparing to conduct training and oversee the activities launched this summer as a result of grain elevators enrolling in the voluntary “One Sample Strategy” program.

AAFCO Update

The Association of American Feed Control Officials (AAFCO) held their Midyear meeting in St. Petersburg, FL on January 16th through January 20th. Chad Linton, WV, was installed as the new President of AAFCO. A Pet Food Labeling Workshop was held on January 17th providing training to both industry and regulators on the AAFCO Pet Food Rules. At the General Session a new Board of Directors structure was passed. The new structure will consist of a President, President-Elect, Secretary -Treasurer, Immediate Past-President, two Senior Directors and three Junior Directors. The Junior Directors may serve a maximum of two successive one year terms and do not progress into the Executive positions unless voted into a Senior Director Position. Also during the General Session the following ingredient definitions were moved from tentative to official: Ground Pecan Shell, L-Carnitine, Salvage Pet food, Distressed Pet Food and Selenium Yeast. Biodiesel-derived glycerin and Ammonium Formate were accepted as new tentative definitions. Editorial changes or modifications were made to Table No. 36.14 Megasphaera elsdenii (cattle only) and to Formaldehyde. Charcoal was withdrawn from the Feed Term section. FDA has announced that in the near future, FDA will not provide reviews for the AAFCO Ingredient Definition process. A taskforce has been established to review options and determine AAFCO’s future in the ingredient process. AAFCO and FDA have established a Feed Standards Working Group to develop a set of standards to provide a greater understanding of the National feed inspection and enforcement system. Also the Strategic Affairs Committee has established a subcommittee to determine if AAFCO needs to hire an Executive Director/Executive Secretary/Operational Manager, establish the required duties of the position and pay structure.

Now accepting applications for the One Sample Strategy!

Contact the program coordinator:
Mary Sasser
Technology Manager
Office of the Texas State Chemist
Phone: (979) 845 1121
Email: mary@otsc.tamu.edu

Or, visit our Website to complete your application online.
http://otscweb.tamu.edu/risk/onesample
Protects consumers & enhances Agri-Business through its Feed & Fertilizer Regulatory Compliance Program, surveillance & monitoring of Animal-Human health & environmental hazards, & preparedness planning.

Office of the Texas State Chemist

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Join us at the Association of American Control Officials (AACO) 2011 Annual Meeting at the Hyatt Regency in Austin, Texas!

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<tr>
<th>Association of American Feed Control Officials (AAFCO)</th>
<th>Association of American Plant Food Control Officials (AAPFCO)</th>
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<tr>
<td>July 29th - August 1st</td>
<td>August 1st - 3rd</td>
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BOD meets Friday, July 29th

BOD meets Monday, August 1st

Hotel Reservations:

Hyatt Regency
208 Barton Springs
Austin, Texas 78704
(512) 477-1234
http://austin.hyatt.com

Online reservations: https://resweb.passkey.com/go/AACO
Phone reservations: (800) 233-1234
Reservation Code: 2011 AACO Annual Meeting
June 27, 2011: Deadline for preferred guest room registration

- $104.00 (single occupancy)
- $129.00 (double occupancy)
- No charge for additional occupants under 18 years of age
- Additional room types (Riverview and Business Plan Upgrade) are available upon request. Rates vary.

Meeting Registration:

Registration is coming soon! Check the Association Web sites for registration forms and payment information.
AAPFCO: http://www.aapfco.org
AAFCO: http://aafco.org