In Governor Perry’s inaugural address, he stated that, “Our vision must extend beyond the next 140 days across this new decade and the rest of this century.”

As OTSC looks across the new decade and beyond, our personnel continue to champion the “adoption of a science-based approach to risk management by trading partners, state, national and international regulators and industry.” Toward this end, the Office is working with university faculty to develop new training material in the field of regulatory science with financial support from the Food and Drug Administration (FDA). The Office has positioned itself to approve new feed ingredients that are generally recognized as safe (GRAS), as evidenced by the recent Texas register submission to approve aflatoxin binding agent in customer-formula feed. The Office continues to pursue a technology strategy that enables the laboratory (Agricultural Analytical Service) to adopt cost effective technology. Examples of recent purchases include real-time polymerase chain reaction (PCR) instrumentation for identifying bacterial pathogens based on DNA sequences and an inductively coupled plasma mass-spectrometer (ICP-MS) for analyzing heavy metal contaminants. The Office continues its active surveillance program for chemical hazards in feed ingredients including dioxin. This contaminant has been a problem in Europe within the past several months, leading to embargos by some European export customers. The Office is pursuing modern and more cost effective approaches to ensure feed and food safety and regulatory compliance. The “One Sample Strategy” utilizes a process approach to regulatory oversight for aflatoxin risk management. The intent of this program is to reduce the number of times a single load of corn will be analyzed for aflatoxin by developing a standardized approach that can be used for purchasing corn, crop insurance, and regulatory oversight. The use of one sample result for these activities will help remove the inconsistency inherent with multiple samples and provide greater confidence to the marketing of corn, leading to improved market liquidity.

Regulatory Science Curriculum Under Development

The increased focus on the science behind the regulation of food and feed products, the globalization of the economy and advances in analytical technology contribute to a growing need for research and education in the emerging field of regulatory science, which the Food and Drug Administration (FDA) defines as “the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.” A need exists for a multi-disciplinary understanding of international regulatory structures to enhance US business performance in global markets. Texas A&M faculty and Office of the Texas State Chemist personnel met in January in a brainstorming session to identify subject matter that would be included in the Regulatory Science core curriculum. These core competencies will be presented in four graduate level classes including: Introduction to Regulatory Science, Comparison of Global Regulatory Standards, Quality Control and Laboratory Method Development, and Regulatory
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Practices. These classes will also be offered for continuing education. All classes will be formatted for distance-learning delivery with a target audience including feed and food regulators and industry personnel in Texas, the U.S. and abroad. Similar curriculums are offered in regulatory science for the pharmaceutical and medical device industry, however, this represents the first program that addresses the feed and food industry. The program will also include mini-semester two week elective classes that focus on building skills using laboratory instrumentation including high performance liquid chromatography, mass spectrometry, elemental analysis using ICP and atomic absorption, and microbiology techniques including use of different PCR and ELISA platforms, offered on the Texas A&M campus.

Aflatoxin Binders: Proposed New Feed Rule

The Office of the Texas State Chemist responds to requests by feed and fertilizer manufacturers, distributors and consumers to approve new products or ingredients in consultation with the Advisory Committee and experts to ensure product safety and to protect the market place from fraudulent practices. In response to input by the OTSC Advisory Committee, stakeholders, and experts, the Office submitted to the Texas Register the General Provision for the Use of Aflatoxin Binding Agents in Customer Formula Feed, that will be published in the Texas Register Feb. 11, 2011. The public comment period is open for 30 days.

Aflatoxin binding agents represent a new product category. They are not a drug and subsequently, product labels may not contain a drug claim such as “improves liver health” or “makes product safe.” Neither do these products conform to the animal supplement category, since aflatoxin binders are included in animal feed.

Once the new rule is published, aflatoxin binders approved by the Service may be used in customer formula feeds which are defined in §141.001(7) 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.” Once the proposed new rule is published, aflatoxin binders may be used in feed manufactured on-farm, in feed lots, and by integrators.

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.

The Proposed rule is listed below:

61.67 General Provisions for the Use of Aflatoxin Binding Agents in Customer-Formula Feed.
(a) The provisions of this section apply to the use of aflatoxin binding agents in customer-formula feeds as defined in the Texas Agriculture Code §141.001(7). Labeling requirements for customer-formula feed set forth in §141.053 of the Texas Commercial Feed Control Act require the name and number of pounds of the binding agent to be included on the feed label, and the aflatoxin content to meet defined action levels as established of this title §61.61(a)(6), poisonous or deleterious substances.
(b) In addition to these provisions, the distributors of customer-formula feed shall comply with all applicable provisions of the Texas Feed Rules, and other applicable law.
(c) The specific binding agent must include directions for use approved by the Service prior to distribution of any binding product. Any claims for aflatoxin binding made on the product labeling must be approved by the Service.
(d) Processors shall keep records for two years to ensure correct use and quantity of the binding agents used in customer-formula feed for review by the Service pursuant to the Texas Agriculture Code §141.074, records; additional reports; audits.
(e) Each facility using aflatoxin binding agents must also have in its possession and provide on reasonable request a certificate indicating that the use of aflatoxin binding agents utilized in the formulation has been approved by the Service.
(f) Each facility must provide to the Service a record showing the name of the buyer, the amount of product sold to each buyer during the last two years, and the aflatoxin levels of grain, oilseeds, processed grain and oilseed meals containing aflatoxin B1, B2, G1, G2, and other records designated in subparagraph (d) of this section.
(g) Use of aflatoxin binders in non-customer-formula feeds is prohibited. Such use would result in an adulterated product within the meaning of §141.148 Distribution of Adulterated Feed of the Texas Commercial Feed Control Act.
ICS, What it means and how it’s implemented?

Incident Command System, ICS, was developed to aid response after the devastating California wildfires of the 1970’s. Many of the firefighters, responding from all over the country, had never worked together and were unfamiliar with the existing chain of command and basic operational function for communication, equipment acquisition, etc. Case histories were reviewed to improve and correct response problems and inadequate management was discovered, more than any other reason, to be the cause of failure. ICS was developed to allow all commanders and functionaries to communicate and safely respond in any incident by integrating facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. It is designed to be used at all levels of government from local to Federal and can be applied within the private sector as well. ICS is applicable across all disciplines and is structured to address the 5 major functional areas: command, operations, planning, logistics, and finance administration.

The strength of ICS flexibility is in its modular structure and its use of management by objectives in following an incident action plan. ICS uses common terminology, no number or acronym codes, and a common chain of command structure, which eliminates confusion. ICS incorporates a unified command concept which allows it to cross multi-agency and multi-jurisdiction boundaries without sacrificing authority, responsibility, or accountability of its individual participants. Deployment is flexible and can occur as needed from on-site operations to multiple support operations, the manageable span of operation control generally ranging from 3-7 subordinates who have a clearly defined single supervisor.

ICS serves as one component of the National Incident Management System (NIMS). Presidential Directives 5 (HSPD-5) Management of Domestic Incidents and 8 (HSPD-8) National Preparedness charged the Department of Homeland Security (DHS) to address shortcomings identified following the 9/11 response, to improve coordination in response to incidents by establishing a National Response Plan (NRP) and to describe the way Federal departments and agencies will prepare to coordinate with State local and tribal governments to develop a National Preparedness Goal. ICS was known as the most effective and comprehensive fire and disaster response and had become the standard for emergency management across the country, being capable of being used for any size incident and from planned event to disaster. But, DHS needed to expand the scope to include terrorism response and the National Incident Management System (NIMS) was developed utilizing those principles that make ICS function so well. Together, NIMS, the NRP, and a National Preparedness Goal, incorporating ICS principles, define what needs to be done to prevent, protect against, respond to, and recover from a major event.

OTSC Advisory Committee Meeting

The Advisory Committee met in College Station on January 20, 2011. The two main items discussed were the proposed rule allowing for the use of aflatoxin binders in customer formula feeds and the “one sample strategy” for aflatoxin sampling and analysis.

Dr. Tim Herrman, State Chemist, introduced the proposed rule and guidance document. Elaboration on licensing, labeling, customer formula feeds, and adulterants were discussed. Sections of the Feed Control Act Chapter 141 and Commercial Feed Rules Chapter 61 were reviewed.

Dr. Tim Phillips, TAMU College of Veterinary Medicine, gave a presentation on the use of clay enterosorbents (Novasil) in binding aflatoxin. Data from in vitro and in vivo studies were reviewed. Both animal and human data was presented along with a review of procedures needed to characterize clay binders. The need to demonstrate the safety of the products was emphasized. The use of the Langmuir equation to characterize the binding capacity was discussed.

Mr. Marc Herpfer, Oil-Dri, gave a presentation on the use of Oil-Dri clay products in the binding of mycotoxins. The features and characteristics of types of clays was summarized and the per cent binding
Protects consumers & enhances Agri-Business through its Feed & Fertilizer Regulatory Compliance Program, surveillance & monitoring of Animal-Human health & environmental hazards, & preparedness planning.

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efficiency was discussed.
Dr. Alexandros Yiannikouris, Alltech, presented data summarizing the use of a non-clay mycotoxin binding product, Yeast Cell Wall Extract. The characterization of the carbohydrate composition of the cell walls was presented. The modification/manipulation of the glu- can, mannan, and chitin levels in the cell wall was shown to be capable of producing extracts that are optimized for the binding of mycotoxins. Various in vitro and in vivo studies were summarized.
Ms. Mary Sasser, OTSC Distance Learning Coordinator, then presented details of the “One Sample Strat-

Heavy Metals Analysis by ICP-OES

A simple, robust and reliable Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES) method for simultaneous detection of heavy metals Arsenic (As), Cadmium (Cd) and Lead (Pb) was developed and validated in the OTSC laboratory based on AOAC Official Method 2006.03. This new method was developed for the analyses of minerals, mineral mixes and fish meal to satisfy a portion of our commitment with the BSE/Feed Safety Cooperative Agreement. The optimized work conditions of the ICP-OES, enabled us to achieve good lineairities of calibration curves in a broad calibration range, acceptable Limit of Quantification (LOQ), and excellent reproducibility with satisfied relative standard deviations. The sensitivity of this method will allow us to detect Lead at 10 ppm, As at 10 ppm and Cd at 1 ppm. Standard Operational Procedures (SOPs) for As, Cd and Pb have been established and are already being used in the lab for analyses. To date, approximately 50 samples have been analyzed by this method.