



OTSC Quarterly Newsletter



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Veterinary Feed Directive

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) to facilitate the approval and marketing of new animal drugs and medicated feeds. Prior to 1996, FDA had only two options for regulating distribution of animal drugs: 1) Over-the-counter (OTC) and 2) by prescription (Rx). The Federal Food, Drug and Cosmetic Act (FD&C) did not prohibit the approval of prescription drugs for use in animal feed, but approval would be impractical. Many



States have laws that would require a feed mill to have a pharmacist on staff to dispense prescription drugs. Furthermore, FDA determined that existing OTC and Rx options did not provide the needed safeguards or flexibility for these drugs to be prescribed for use in medicated feed. FDA decided that these drugs should be subject to greater control than the OTC status. Therefore, the ADAA created a new category of drugs called the veterinary feed directive drugs (VFD). VFDs were to be administered under a veterinarian's supervision.

In April of 2012, FDA published "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," as a framework for ensuring the appropriate or judicious use of medically important antimicrobial drugs

in food-producing animals. These measures include eliminating the feed and water use of medically important antimicrobial drugs for production purposes in food-producing animals and bringing all remaining therapeutic uses under the oversight of licensed



veterinarians. A new VFD rule was finalized on June 3, 2015 to accomplish these goals.

The final rule makes several important changes from the proposed rule and several major changes to the current VFD regulations in 21 CFR part 558. One major change is: The definition of "Category II" in 21 CFR part 558 is revised to remove the automatic Category II designation for VFD drugs. Instead, the categorization of VFD drugs will be determined case-by-case based on the likelihood that the particular drug at issue will produce an unsafe residue in edible products derived from treated animals, as is currently the case for non-VFD feed use drugs. This is important for two reasons. First, the Category I and II definitions are retained based on public health risk-based approach to designate drugs based on the potential for unsafe residues in edible products. Second, farm animals may not be able to receive proper therapeutic treatment due to supply chain disruptions without this change.

Ammonium Nitrate

On June 16, 2015, Governor Greg Abbott signed into law, House Bill 942 – The Ammonium Nitrate Fertilizer Safety Law. The new law strikes a balance between the protection of health and safety and the implementation of additional regulations to minimize risk at a reasonable cost to industry.

The new sections in the Texas Commercial Fertilizer Control Act, Chapter 63 codifies existing ammonium nitrate rules into law and requires the operators of ammonium nitrate facilities to: 1) provide evidence of compliance with the Texas Commission on Environmental Quality (TCEQ) Tier Two Chemical Reporting Program and the United States Department of Homeland Security (DHS) Chemical Facility Anti-Terrorism Standards (CFATS) registration; 2) post the National Fire Protection Association (NFPA) 704 warning placards on the outside of the storage area; 3) store ammonium nitrate or ammonium nitrate material in a fertilizer storage compartment or bin constructed of wood, metal, or concrete that is protected against impregnation by the ammonium nitrate or ammonium nitrate material; and 4) separate ammonium nitrate or ammonium nitrate material from combustible or flammable material by 30 feet or more.

RRT Activities

This summer was active for the Texas Rapid Response Team (TRRT), one of nineteen state emergency response teams funded through a grant from the United States Food and Drug Administration (FDA). The TRRT is comprised of the Texas Department of State Health Services (DSHS), the Office of the Texas State Chemist (OTSC), and the FDA. Two activations of the TRRT occurred.

Once on May 29, after the adverse weather events caused extensive flooding in Texas, the TRRT activated to determine the potential impact to food and feed products in the 72 counties identified from the Governor's disaster declaration, including 19 counties identified in the Federal Emergency Management Agency (FEMA) flood hazard zone. The mission tasks for the TRRT were: 1) develop and implement a coordinated risk matrix for surveillance of impacted facilities and products; 2) coordinate activities among

It also provides state and local fire marshals the authority to inspect ammonium nitrate storage facilities and issue citations for violations in the Health and Safety Code, Chapter 505 and 507. If hazardous conditions or safety violations are noted, state or local fire marshals shall notify the Office of the Texas State Chemist (OTSC), Feed and Fertilizer Control Service (FFCS) of the condition or violation and the FFCS may notify the owner or operator of the facility to correct the condition or violation by a specified period not to exceed 10 days. If the condition or violation is not remedied, the FFCS may suspend a person's registration for a period of 90 days for a first violation; and suspend a person's registration for a period of at least 90 days or revoke the person's registration for a second or subsequent violation.

Due to a vote of greater than two-thirds of all the members elected to each house, the definitions in Section 63.151 (3), (4), and (5) and Section 63.158 take effect immediately.

participating agencies to maximize efficiency and avoid duplicative efforts; and 3) develop and disseminate a coordinated risk communication to stakeholders. OTSC contacted 235 registrants and 60 salvagers to determine the impact to food and feed products and to manage any disposition of affected products. Demobilization of the TRRT occurred on June 30.

The second activation, on July 8, was due to a national *Cyclospora* outbreak with the majority of the cases in Texas. OTSC was not directly involved with the "food only" incident, but remained on stand-by to support traceforward and traceback investigations and provide lab surge capacity. Demobilization of the TRRT occurred on August 2015.

Aflatoxin & Fumonisin in Texas Corn: 2015 Harvest Update

The unusually wet conditions during the 2015 planting season provided a different challenge to Texas farmers. However, the USDA forecasts only a 1% decrease in acres of corn planted in Texas. Between mid-July and mid-August, 260 new crop corn samples were analyzed, representing 17 Texas counties. For aflatoxin, 18% of the corn analyzed at greater than 20 ppb total aflatoxin with 213 ppb being the highest level found. For fumonisin, 28% of the 2015 samples contained more than 5 ppm, with levels ranging up to 40 ppm.

For these same 17 counties during 2014, 760 samples were analyzed throughout the year. For aflatoxin, 26% of the corn ran above 20 ppb, with the highest result being 477 ppb. For fumonisin, 26% of 2014 crop year samples analyzed >5 ppm, with 62 ppm being the maximum found.

For current information about the mycotoxin samples tested by OTSC, please refer to the interactive mycotoxin maps on our website using this link: <http://mycotoxinbmps.tamu.edu/mapsupdate.aspx> Scrolling over the map will display a summary of sample results for the county selected.

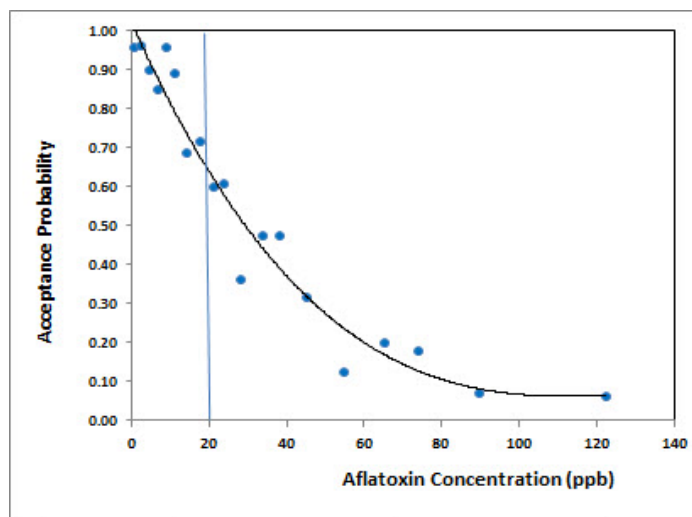
Co-regulation of Aflatoxin using the One-Sample-Strategy

The Texas Feed and Fertilizer Control Service (FFCS) of the Office of the Texas State Chemist (OTSC) is the Texas regulatory risk manager for aflatoxin in cereals and oilseeds. In 2011, OTSC implemented a “one-sample-strategy” to manage aflatoxin risk in collaboration with the Risk Management Agency of the United States Department of Agriculture and the Texas grain industry. This program represents the first implementation of a co-regulation governance option by OTSC.

Co-regulation as a governance option denotes shared responsibility in a public-private partnership. The one-sample-strategy model utilized a quality system approach, incorporating government standards that were implemented by a private entity, monitored and verified by a state regulatory agency and results were deemed official by crop insurers, regulators, and market participants. The participating firms create a plan that identifies equipment and procedures outlined in the OTSC Handbook. An annual report of one-sample-strategy results is submitted to the Risk Management Agency (RMA) as part of the agreement with OTSC.

Aflatoxin testing accuracy is measured several ways in the one-sample-strategy. The first involves proficiency testing, where grain elevator employees test samples and their results are compared with assigned aflatoxin values based on OTSC analysis. The proficiency test results improved from a 45% deviation in 2010 to 17% in 2013. Second, a company’s testing accuracy during harvest is verified by OTSC, which collects and retests 5% of the company samples. The 2014 results depicted as a performance curve characterizes the overall consistency between Texas grain companies and OTSC.

The left axis in the figure is titled acceptance probability (by the grain elevator) and the horizontal axis is titled aflatoxin concentration in parts per billion (ppb) measured by OTSC. Note how the performance curve line intersects the 20 ppb regulatory limit for aflatoxin concentration at about 65%. This means 65% of the grain samples containing 20 ppb (measured by OTSC) were accepted by one-sample-strategy grain elevators as containing less than or equal to 20 ppb aflatoxin.



At 0 ppb aflatoxin concentration, grain elevators acceptance probably was nearly 100%. The performance graph indicates that grain elevators and OTSC results are aligned. The close alignment in test results between grain elevators and OTSC is one benefit companies experience through the adoption of the one-sample-strategy.

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Protects consumers & enhances Agri-Business through its Feed & Fertilizer Regulatory Compliance Program, surveillance & monitoring of Animal-Human health & environmental hazards, & preparedness planning.

OTSC Advisory Committee

The Advisory Committee consists of 16 members with equal representation in membership from the following four groups: (1) feed manufacturers/distributors; (2) feed users; (3) fertilizer manufacturers/distributors; and (4) fertilizer users.

The Committee meets twice a year and other meetings may be called as circumstances warrant. The purpose of the meetings is to review and discuss issues, policies, finances, statutory requirements, operational procedures and other matters that impact operations of the Office of the Texas State Chemist.

The Advisory Committee has the general responsibility for preparing independent advisory recommendations to the Director and to the Texas State Chemist and have the specific responsibilities to: review and recommend on internal and external issues relating to structure, operations, policies, plans and long range goals of the Office of the Texas State Chemist; review and recommend on budget and finance matters; and review and recommend proposals for statutory changes and modification of rules and regulations relating to the Texas feed and fertilizer regulatory, analytical, licensing/registration and service programs.

Ad hoc committees may be established by the Director, his designees or by the Chairman of the OTSC Advisory Committee to address special issues and concerns that impact operations of the Office of the Texas State Chemist or the feed and fertilizer industries.

OTSC Advisory Committee Meeting Fall 2015 Agenda Oct 2, 2015 Koldus Room 110

9:00 A.M.	Advisory Committee, call to order by Chairman Hebert
9:05	Agenda review and additions
9:10	Review of minutes and agenda
9:15	Comments by Dr. Craig Nessler
9:25	One Sample Strategy, Report of Progress for 2015 by Mary Sasser
9:45	Animal Feed Regulatory Program Standard and VFD update by Lynn Post
10:00	Ractopamine in deer feed by Ben Jones
10:15	Break
10:45	Fertilizer grade by James Embry
11:00	Responsible Ag by Donnie Dipple
11:30	Discussion by Advisory Committee discussion led by Scott Piercy
12:15 P.M.	Lunch
1:15	Tonnage and budget update by Tim Herrman
1:40	Building Progress by Roger Hoestenbach
2:00	Recommendations by Mark Hebert
2:25	Election of Vice Chair and Chair
2:30	Adjourn