OTSC Quarterly Newsletter

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Proposed Rules for Ammonium Nitrate Fertilizer

The Texas Feed and Fertilizer Control Service of the Office of the Texas State Chemist submitted the following to the Texas Register on May 9, 2014:

The Texas Feed and Fertilizer Control Service/ Office of the Texas State Chemist proposes to amend TAC Title 4, Part 3, Subchapter B, 65.6 concerning Ammonium Nitrate. The changes are to (b) Refusal of Sale added new text which reads "refusal of sale shall be reported to the Service at the time sale is refused."; (c) Training and Documentation: adding new text "Documentation shall include procedures for daily inspection as required in The Agriculture Code, Chapter 63 §63.153 and a record of the inspection. Evidence of vandalism or theft shall be reported to the Service at the time of daily inspection and corrective actions documented." And adding (d) Risk Management. A person that stores ammonium nitrate or ammonium nitrate material shall:

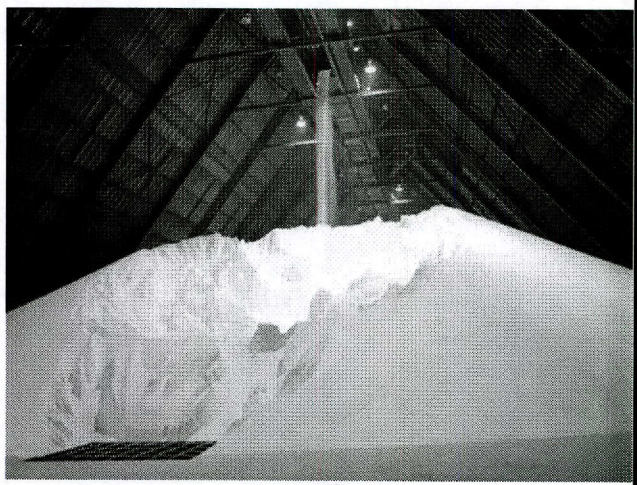
1) provide evidence of compliance with the Texas Department of State Health Services Tier II Chemical Reporting Program and Department of Homeland Security Chemical Facility Anti-Terrorism Standards registration requirements;
2) post the National Fire Protection Association 704 Warning Placards on the outside of the storage area; and
3) store ammonium nitrate or ammonium nitrate material in a separate structure. Combustible or flammable material must be separated by at least 30 feet.

The Office of the State Chemist's proposed amendments to the current rules are within its statutory authority and build on meetings with the House Homeland Security and Public Safety Committee and Interagency Committee following the incident at West, Texas.

- In requiring operators to provide evidence of compliance with state and federal registration requirements, the proposed rule codifies the existing practice of the Office of the State Chemist.

- In requiring separate structures, separated by at least thirty feet, for storage of AN, the rule is an evolution of current practice and in line with both Committee discussions and best practice.

While no amount of regulation may prevent a tragedy, this thoughtful exercise of our statutory authority is a responsive action considered to enhance public safety in connection with the storage of commercial fertilizer.



Service Focuses on 3 AV Chemical Violations

The Service monitors feed and fertilizer products to assess their conformance to the label guarantee. All product chemical violations are reported, but those far off the guarantee, whether above or below, indicate a significant manufacturing problem. Products that exceed by greater than three times the analytical variations (AVs) or investigational allowances (IAs) established by the Association of American Feed Control Officials (AAFCO) and the Association of American Plant Food Control Officials (AAPFCO), respectively, require an investigation and corrective action to prevent future occurrences.

AVs and IAs are considered in determining whether a sample meets the labeled guaranteed analysis or not. They are established for the inherent variability in laboratory analysis, do not include manufacturing variations, and are based on two standard deviations (SD) from the guarantee for a 95% confidence level.

When warranted, regulatory letters will be mailed indicating the need for **Corrective Action Requirements**. Firms must submit the corrective action to the Office to document the investigation. A follow-up investigation by OTSC field staff will be forthcoming to verify the investigation and implementation of corrective action. Additional samples may be collected to demonstrate the effectiveness of the action.

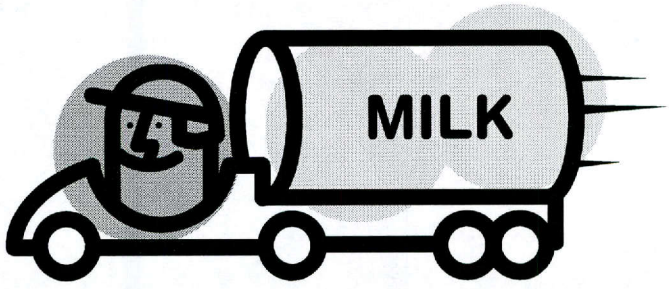
Questions concerning the investigation and corrective action requirement for samples with chemical violations which exceed the established AVs or IAs should be directed to Ben Jones, the Associate Director in charge of compliance.

DSHS Protocol for Diversion of Confirmed Positive Bulk Raw Milk

The Texas Department of State Health Services (DSHS) requested FDA acceptance of protocol to divert tankers of raw milk testing positive for beta lactam to be diverted as animal feed to calf ranches. Beta lactams are antimicrobials consisting of Penicillin G, Cephapirin, Amoxicillin, Ampicillin, Cloxacillin and Ceftiofur.

The protocol includes the following: Milk confirmed positive for beta lactam only shall be cleared for such use by a negative test obtained from a 1:100 dilution by the M-a-85 Screening Test, the sample must be diluted with negative milk, tests must be performed in an Interstate Milk Shippers (IMS) approved milk laboratory and loads testing positive with 1:100 dilution shall be disposed by an approved manner other than animal feed. The protocol requires the negative test results, the dilution, the test used, the recorded test results of the original tanker, the identification of the certified laboratory and the statement: "MEDICATED ANIMAL FEED – WITHDRAW 45 DAYS BEFORE SLAUGHTER" to be included with the shipping invoices. The calf rancher and the performing laboratory must maintain records of the origin of the milk and test results for 2 years and the laboratory must send results to DSHS. FDA did not object to the protocol.

On May 8, 2014, the OTSC Advisory Committee considered the DSHS protocol and recommended approval by OTSC. Under this approval, OTSC will require shippers of this "Medicated Feed" hold a license with the Office, properly label the milk and the Service will perform routine trace back investigations. OTSC will regulate this product as any other commercial feed.



OTSC 2014 Plan of Work

The OTSC Plan of Work utilizes a "statistically-derived risk-based approach to risk management" that is utilized to prioritize planned work assignments for Texas Feed and Fertilizer Control Service (FFCS) field investigators and Agricultural Analytical Service (AAS) chemists. The objective of this approach is the distribution of effort among agency priorities to:

- Provide effective surveillance and monitoring of animal and human health and environmental hazards;
- Ensure conformance to the Texas Commercial Feed and Fertilizer Control Acts;
- Make the best use of resources; and
- Produce reliable and timely laboratory results.

As a first step toward development of the annual plan of work, violation history is analyzed to determine inspectional frequency. This is a process that involves the multivariate statistical analysis of data from the last three years to categorize firms according to factors such as: compliance history, variation from the target nutrient content, and production volume.

FFCS field investigators meet each April to review the statistical projections, prioritize sampling and inspection assignments, divide the assignment among the three field investigator teams, and share the finalized plan of work with AAS to coordinate laboratory resources for the coming year.

OTSC projections for the 2014-2015 plan of work forecasts the collection of 8183 samples and completion of 811 inspections (including verification samples and monitoring visits for the One Sample Strategy).

These risk-based projections, which place an increased emphasis on higher risk products and on firms with a high violation history, align field and laboratory activities with the OTSC mission and goals to promote improved regulatory compliance.

The OTSC plan of work also aligns with the recently published Animal Feed Regulatory Program Standards (AFRPS) developed by the Food and Drug Administration (FDA). These standards, which are intended to establish a uniform foundation for the design and management of state programs that regulate animal feed, were developed as a collaborative effort with representatives from the Association of American Feed Control Officials (AAFCO). OTSC is currently in the early planning stages to adopt and implement the AFRPS program. A copy of the standards is available from the FDA web site (www.fda.gov).

OTSC Spring Advisory Committee Meeting

The OTSC Advisory Committee met on May 8, 2014 in College Station. Prior to the meeting, attendees participated in a tour of the OTSC laboratory and participated in a gap analysis comparing The Fertilizer Institute and Agricultural Retailers Association safety and security guidelines for ammonium nitrate fertilizer to current state regulation for storage of fertilizer grade ammonium nitrate.

The meeting was called to order by Darren Turley, current committee Chair. The committee recommended that OTSC approve the Texas Department of State Health Services protocol for the diversion of raw milk testing positive for Beta Lactams to calf ranches. In an effort to improve compliance activities as outlined in the Balanced Scorecard performance measures, the Service presented various compliance strategies. The committee recommended use of stronger language in compliance letters and a shortening of response time limits for licensing and registration issues.

A request was presented by a representative of the Texas Corn Producers Board (TCPB) to seek permanent nationwide approval by FDA for blending of corn containing greater than 20 ppb aflatoxin with other corn including corn free of aflatoxin, similar to FDA approval during 2012. TCPB will continue promoting the proposal. Progress and further action will be discussed at the fall Advisory Committee meeting.

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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 Dioxin Analysis

Dioxins are a highly toxic group of chemically related environmental pollutants that are produced as by-products in the pulp and paper industry, emissions from incinerators, wood and coal home heating systems, diesel engines, forest and grass fires, as well as agricultural and backyard fires. This means that dioxins can be spread over large areas and enter the food chain. Dioxins are persistent in the environment for thousands of years and accumulate in the food chain, such as in the body fat of food-animals. Naturally occurring dioxins have been detected in deep soils and clays in Germany and the United States. Exposure to small amounts of dioxins can cause skin, endocrine, thymus, spleen, liver, immune and reproductive adverse effects to include cancer and death in humans and animals.

The Office of the Texas State Chemist (OTSC) initiated the surveillance of dioxins in 2011 with the support from U.S. Food and Drug Administration (FDA) cooperative agreements program to monitor dioxin presence in the feed supply.

From calendar years of 2011-2013, 396 total feed samples were collected and subsequently evaluated for dioxin-like compound contamination using Xenobiotic Detection Systems (XDS) CALUX (Chemically-Activated Luciferase Expression) bioassay. In calendar year of 2013, OTSC established and validated the in-house XDS-CALUX method. This CALUX method uses a mouse hepatoma cell line modified with firefly luciferase gene, to sense the presence of dioxin-like compounds and therefore estimate the dioxin TEQ (toxic equivalence) of dioxin-like polychlorinated biphenyls (PCBs) and polychlorinated dibenzodioxins/dibenzofurans (PCDD/PCDF) in animal feeds and feed ingredients. The TEQ is based on the most toxic dioxin, 2, 3, 7, 8-tetrachlordibenzo-p-dioxin (TCDD). The TEQ is a weighted sum of all of the dioxins present in the sample. TCDD has a weighing factor of 1 with weighting factors of less than 1 for less toxic dioxins and PCBs. Samples with higher than 2 parts per trillion (ppt) dioxin or PCB TEQ are confirmed by high resolution gas chromatography/ high resolution mass spectrometry (HRGC/ HRMS) at FDA's Arkansas Regional Laboratory (Jefferson, Arkansas).