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WHITE PAPER ON

AFLATOXIN RISK MANAGEMENT IN TEXAS PURSUIT OF A ONE SAMPLE STRATEGY

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Background

Aflatoxin is a biological toxin produced by fungi and is a group one carcinogen. Research in the United States (US) led to the 1969 establishment of an action level at 20 ppb, above which, product is consider unsafe for animal and human consumption. Further guidance for safe levels of consumption was established by the Food and Drug Administration in 1989 and 1994 that are presented in Compliance Policy Guide 683.100 as follows:

- 300 ppb for corn and peanut products intended for finishing (i.e., feedlot) beef cattle;
- 300 ppb for cottonseed meal intended for beef cattle, swine, or poultry (regardless of age or breeding status);
- 200 ppb for corn or peanut products intended for finishing swine of 100 pounds or greater;
- 100 ppb for corn and peanut products intended for breeding beef cattle, breeding swine, or mature poultry;
- 20 ppb for corn, peanut products, and other animal feeds and feed ingredients, but excluding cottonseed meal, intended for immature animals;
- 20 ppb for corn, peanut products, cottonseed meal, and other animal feeds and feed ingredients intended for dairy animals, for animal species or uses not specified above, or when the intended use is not known;

The Texas Agriculture Code, Chapter 141 (Texas Commercial Feed Control Act) exempts grain (§141.002(c)(2)) or whole seed that does not contain toxins or chemical adulterants. Grain or seed exceeding the 20 ppb aflatoxin action level is adulterated and subject to the Texas Commercial Feed Control Act. The Texas Feed and Fertilizer Control Service is the state regulatory agency responsible for administering TAC 141 and this agency is part of the Office of the Texas State Chemist (OTSC), which is administratively housed within the Texas Agriculture Experiment Station (recently renamed Texas AgriLife Research). OTSC provides additional science-based action levels to address unique the needs of Texas agriculture. Among these provisions include the establishment of a 50 ppb action level for wildlife feed, 100 ppb action level for non-lactating sheep and goats, and allowing corn containing over 300 ppb but not more than 500 ppb aflatoxin to be blended and feed to cattle in confinement for slaughter. Directions for blending and labeling blended corn are contained within the Feed Industry Memorandum 5-12 posted on the OTSC website at http://otscweb.tamu.edu.

The Office of the Texas State Chemist advisory committee recommended development of best management practices (BMP's) for producers and grain handlers to help mitigate this problem and ensure compliance with the Feed Control Act. Best Management Practices (BMP's) for post harvest grain management include:

- Collect a 10 pound sample from incoming grain
- Grind the entire grain sample using a Romer or Viking mill before sample reduction
- Use testing methods approved by either USDA or AOACI
- Test incoming unit trains
- Test incoming grain from farm storage

- Do not commingle grain exceeding the action level with grain below the action level during reclaim (This practice is not permitted by law)
- Correctly label grain exceeding the action level.

A Mycotoxin Working Group comprised of stakeholders, OTSC staff, and faculty identified research, education and regulatory priorities for Texas to mitigate mycotoxin occurrence in 2005 (Table 1). Progress in high priority areas including atoxigenic fungi, sampling, surveillance and monitoring of commercial grain handlers and mitigation techniques are addressed in greater detail in the section titled risk management strategy.

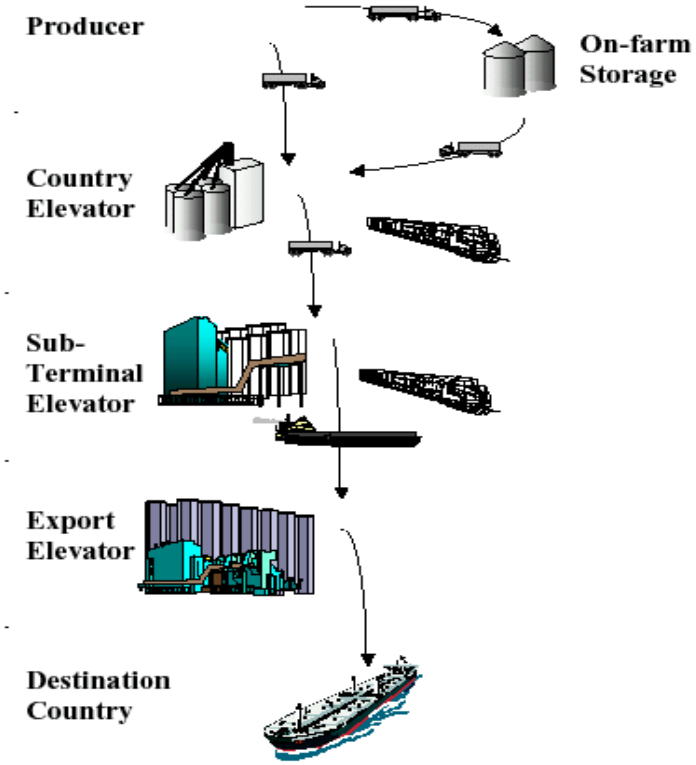
Table 1. List of research, regulatory and outreach priorities established by stakeholders

Preharvest Research Objective	Priority	Priority	Stakeholder Issues/Needs
Identification and characterization of mycotoxigenic fungi		medium	Identify atoxigenic fungi strains
identify resistance	high	medium	Need atoxigenic products
Exploit fungal genomics			
non-toxigenic strains		high	Improved sampling of corn and sorghum
Management practices for mycotoxin		high	Management of crop to reduce mycotoxins
Build a database	low	high	Need improved host resistance
develop an early warning system	low	high	More rapid detection technology
practices to reduce mycotoxins	high	med-low	Improved remediation technology
Host plant resistance, characterization and selection of plant traits		high	federal insurance program (planting late is still allowed, shouldn't be after March 15)
characterize commercial corn hybrids	high		Policy issues related to insurance
develop corn germplasm	high		Insurance allows farmer to keep grain
peanut breeding to develop resistance	high		Lack of incentives to minimize practices to reduce aflatoxin
Post Harvest Research Objective			Feed lots not regulated
Sampling and detection for mycotoxins	high		Loop holes in law
individual kernel mycotoxin		high	Lack of investment by commercial seed companies in host resistance to mycotoxins in TX
sampling designs and probability		high	Economics of developing resistance (2%) seed sales and 1/3 has problem
individual kernel spectral analysis		high	Lack of uniformity between states on surveilllance
Detoxification using binding agents and enterosorbent clays	medium	high	Dairy feed problem with corn shipped from midwest
mechanisms for binding			Feed manufacturers having trouble getting low mycotoxin grain from midwest
Verify effectiveness		high	Need public corn breeders working on aflatoxin
criteria for approving binding agents			
Storage management to control mycotoxins			
build an educational outreach program	high		
establishing a faculty appointment	low		
Regulatory approaches to mitigating mycotoxin hazards in TX	high		
targeted surveillance			
verification of sampling, testing, records			
monitor mycotoxin nationally			

Texas Grain Industry

Texas on-farm storage totals 111 million bushels (NASS 2007), while the state's off-farm storage capacity total 630 million bushels (NASS 2009). In 2010, Texas grain producers planted 2,300,000 acres of corn with an estimated product of 294 million bushels, or approximately 2% of the nation's total corn production. Commercial elevators may serve as first collection point for most Texas corn, however, some grain is stored on-farm at harvest (Figure 1). Texas is a corn deficit state, with out-of-state shipments from the mid-western US accounting for the balance of the corn demand by Texas feed mills, integrators, and feedlot operations.

Figure 1. Movement of cereals and oilseeds for export in the U.S.
Source: http://www.vegrains.org/documents/em_chapter2.pdf



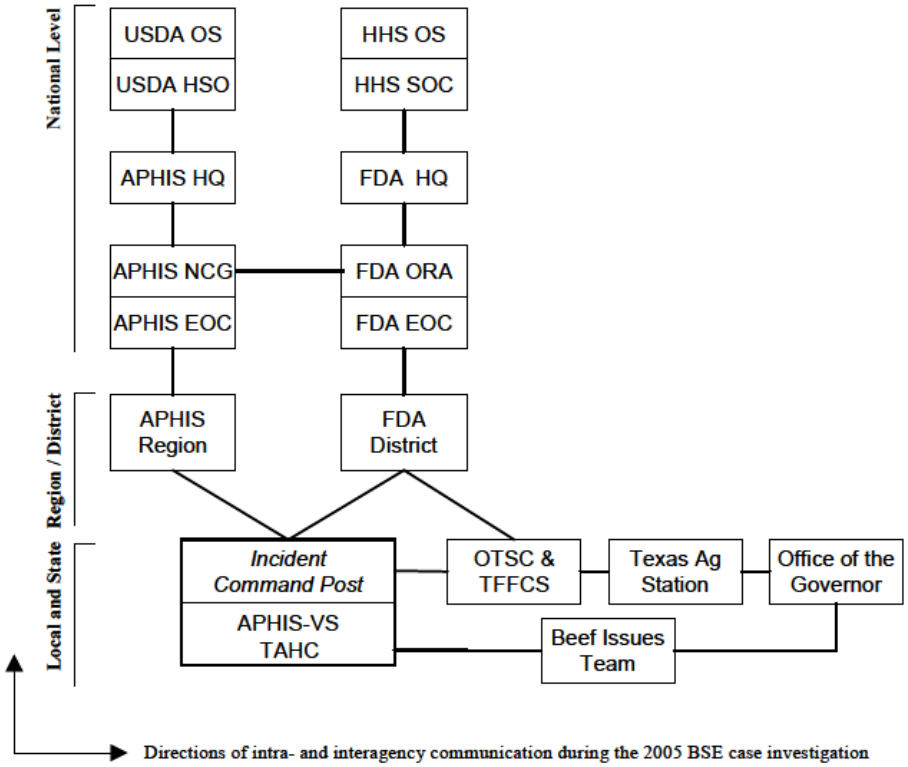
Commercial grain elevators must possess either a state for federal warehouse license and these entities are audited to ensure that the grain in storage coincides with the records of receipt. This activity resembles the auditing process for the banking industry where deposits and financial positions are monitored. In Texas, there are 354 state licensed warehouses with a collective storage capacity of 251 million bushels. There are 181 federally licensed warehouses in Texas. Of these 535 establishments, 266 receive corn. These establishments are visited each year by OTSC field investigators to ensure compliance with the Texas Commercial Feed Control Act as well as to collect samples to monitor the level of aflatoxin and fumonsin during the corn harvest.

Texas and US Regulatory Structure

The 26th Texas Legislature (1899) enacted the first Fertilizer Control Law and placed responsibility for its administration in the Division of Chemistry which was in the Chemistry Department, Texas Agricultural and Mechanical College. The 29th Legislature (1905) enacted the first Feed Control Law and located the responsibility for carrying out its statutory requirements with the Director, Texas AgriLife Research. Both Acts provided for the appointment of a Texas State Chemist. In 1984, the Texas Feed and Fertilizer Control Service (TFFCS) and the Department of Agricultural Analytical Services were combined to establish the Office of the Texas State Chemist (OTSC).

AgriLife Research is supervised by the Board of Regents of the Texas A&M System, who are appointed by the governor of Texas. The communication structure for reporting to the governor and interaction of state and federal agencies tasked with food safety is depicted in Figure 2. This diagram was drawn from a report by The CNA Corporation, which was tasked with analyzing the federal and state response to the interagency incident management of the 2005 BSE case investigation in Texas.

Figure 2. Communication lines during the 2005 BSE response



The TFFCS field investigators and management team are commissioned FDA officers and conduct inspections of feed establishments under federal and state authority. The OTSC advisory committee is comprised of 16 stakeholders who represent consumers and industry groups for feed and fertilizer, providing advice on regulatory policy, priorities, and budget. The advisory committee conducts 2 face-to-face meetings annually.

Risk Management Strategy

Risk management is that part of risk analysis that involves weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options (2006, WHO-FAO).

The Office of the Texas State Chemist policies outlining the management of aflatoxin risk are contained in Feed Industry Memorandums 5-12 "Distribution of Aflatoxin-Containing Whole Grain and Oilseed in Commercial Channels and Their Use in Mixed Feeds" and 5-17 "Distribution of Aflatoxin-Containing Oilseed Meals/Processed Grains in Commercial Channels and Their Use in Mixed Feeds.'

At the request of stakeholders during the January 11, 2010 meeting in College Station, TX, the director of OTSC began to explore the concept of using a single sample for managing aflatoxin risk at the first commercial collection point (e.g. grain elevators). Presently, many commercial grain operations test incoming grain for aflatoxin. Samples are collected by grain elevators and picked up by crop insurance adjusters to assess toxin level for quality adjustments, and OTSC field investigators collect official regulatory samples to monitor the incidence of aflatoxin entering commerce. Because aflatoxin is measured in part per billion (ppb), there exists a high probability that the above mentioned three samples will yield different results when measured for aflatoxin.

To protect consumers and facilitate commerce, the Office of the Texas State Chemist proposes adoption of a risk management strategy that includes monitoring aflatoxin in corn using a single sample.

During the 2010 harvest, OTSC field investigators monitored grain elevator sampling and aflatoxin testing procedures to assess conformance to OTSC best management practices (BMPs) and the US Department of Agriculture's Risk Management Agency's procedures contained in the Loss Adjustment Manual (LAM). Known samples containing three levels of aflatoxin were used to evaluate commercial grain elevator testing proficiency. The results of these activities are presented below.

Verifying Grain Industry Sampling and Testing Procedures

An evaluation of grain industry conformance to OTSC BMPs and LAM procedures was performed during the 2010 harvest at 87 commercial grain elevators in Texas. Only 10% of the respondents were aware of the crop insurance procedures involving sampling. Of these 87 establishments, 8 grain elevators were not sampling or testing for aflatoxin, 31 establishments collected 2 sample probes, 22 collected 4 sample probes and 19 grain elevators collected more than 5 probes. The official sample collection procedure requires 10 sample probes during the collection of a representative sample.

While 38 percent of the respondents stated that they split their samples with the crop insurance companies, only 3 establishments have trained their personnel in correct sampling procedures. While 44 percent of the respondents receive crop insurance results

back from the farmer, adjuster or lab, only 22 percent of the crop insurance samples can be referenced back to the placement of the grain in a particular bin. Respondents in the Blackland area of Texas indicated that 100 percent of the farmers use crop insurance to manage aflatoxin risk, 50% in the Costal Bend area, 80% in South Texas and zero percent in the Panhandle and Southern Plains of Texas.

Grain elevator operators were requested to run control samples containing three levels of aflatoxin to evaluate testing proficiency. Of the 40 initial participants, 23 were using test kits that were not capable of measuring aflatoxin at 300 ppb and 500 ppb, according to manufacturer directions. Of those grain elevators that did possess the appropriate test kits, 7 were able to accurately measure the higher control sample (370 and 580 ppb).

Validating Aflatoxin Tests

The OTSC Best Management Practices to Prevent or Reduce Mycotoxin Contamination in Texas includes "Use GIPSA verified test kits or AOACI official methods when analyzing mycotoxin." The quantitative test kits approved by the Federal Grain Inspection Service (FGIS) of the Grain Inspection, Packers and Stockyard Administration (GIPSA) have been validated for aflatoxin levels up to 100 ppb. A need exists to validate that test kits used by the grain elevator industry can accurately test aflatoxin at levels as high as 500 ppb.

Protocol developed by the Federal Grain Inspection Service (FGIS) will be followed for aflatoxin test kit validation titled "Design Criteria and Test Performance Specifications for Quantitative Aflatoxin Test Kits." Validation criteria include:

1. Time required for completion of an analysis
2. Comparative accuracy of test kits on corn samples naturally contaminated with aflatoxin
3. Suggested additional commodities
4. Avoidance of toxic or hazardous substances
5. Sensitivity to electromagnetic fields
6. Temperature sensitivity
7. Stability
8. GIPSA performance verification on naturally contaminated samples
    a. Three operators will conduct all analyses. All operators shall receive up to two days of training in the use of each test kit
    b. If an observation is a suspected outlier, the available documentation will be reviewed to identify the source of the error and make corrections where possible.

Test kit manufacturers will be notified of the program offered by OTSC and will be provided an opportunity to participate during November 2010. OTSC will purchase test kits and perform tests during December.

Voluntary Program

Participation in the proposed "One Sample Strategy" will be offered to the Texas commercial grain industry on a voluntary basis. Firms that choose to participate in the

program will use aflatoxin test kits that have been validated to measure aflatoxin at 300 ppb and 500 ppb. A prescribed sampling pattern, amount of material ground, amount of material tests, and demonstrated performance including running control samples and record keeping must be followed to participate in the program. Establishments that utilize third party labs may also participate in the program if the outside laboratory conforms to the above mentioned criteria. OTSC will monitor company records including performance on control samples and perform routine spot checks. However, it is the intention of the Service to accept commercial grain elevator results for those firms choosing to voluntarily participate in the "One Sample Strategy."

Some companies may choose not to participate in the proposed program. The "One Sample Strategy" may result in additional testing cost and potential delay during harvest, which are offset by improved risk management (e.g. assurance that grain elevator tests are correct and accepted by the Service). OTSC adopted a science-based approach to risk management as a regulatory strategy in 2007. This strategy enables the Service to focus resources on areas of greatest risk. Subsequent to implementing the "One Sample Strategy" decreased surveillance will occur at firms participating in the voluntary program.

Regulatory Considerations

A need exists to bring the entire grain and feed industry into conformance involving managing the risk of aflatoxin. Distribution of contaminated feed (Texas Commercial Feed Control Act §141.002(c)(2)) resulting from dangerously high levels of aflatoxin is a violation of the Texas Administrative Code Commercial Feed Rules § 61.61(a)5 and the Food and Drug Administration aflatoxin action levels CPG Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds.

Because there is reasonable probability that the article of feed will cause serious adverse health consequences, Federal Statute (Public Law 110-85) requires this incident be self-reported using the electronic portal. The FDA-NIH Safety Reporting Portal is an outcome of the Food and Drug Administration Amendment Act of 2007. Firms that distributed aflatoxin contaminated grain to species above the target action level are obliged to report this occurrence to FDA.

Summary and Recommendations

The proposed "One Sample Strategy" will be discussed among OTSC Advisory Committee members Nov 4, 2010 in Amarillo, TX. A timeline will be established at the advisory committee meeting and a pilot program will be implemented in time for the 2011 Texas corn harvest. The program will be discussed at multiple public venues including the BIG conference in Waco, TX, Farm Bureau annual meeting in Austin, and the Texas Grain and Feed regional and annual meetings. OTSC will seek producer, grain and feed industry association endorsement of the program. The Office possesses ample financial resources and control samples to successfully implement the program within the proposed timeframe.