WHITE PAPER ON

FUMONISIN RISK MANAGEMENT AND COMMUNICATION IN THE TEXAS HIGH PLAINS

Authored By:

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June 11, 2018

For:

OTSC Advisory Committee
&
Texas Legislature

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I. PURPOSE

This white paper provides background information on the fumonisin incident in the Texas High Plains during 2017 and commercial feed regulation in Texas, examines research needs, current and future communications strategies, and provides a roadmap to manage fumonisin risk in the future.

II. BACKGROUND

Fumonisin is a toxic fungal metabolite produced by *Fusarium verticillioides, F. proliferatum* and other *Fusarium* species that typically occurs in corn. These fungi infest corn roots, leaves, stalks, and kernels. The fungus is commonly seed borne.

> *Horses appear to be the most susceptible to fumonisin. This mycotoxin, when fed to horses, causes a unique neurotoxic syndrome called leukoencephlomalacia (ELEM). This disorder is characterized by liquefaction of the horse's brain. Neurotoxic symptoms include lowered feed consumption, lameness, oral and facial paralysis, seizures, and eventual death. It has been shown that the toxin is carcinogenic and also associated with pulmonary edema in swine (Herrman 2002). In humans, fumonisins have been associated with high rates of esophageal cancer and in Texas, is linked to neural tube defects in the human fetus.*

The regulation of fumonisin by the Texas Feed and Fertilizer Control Service (FFCS) of the Office of the Texas State Chemist (OTSC) is codified by rule (§61.61(a)(7)) and establishes maximum levels or MLs.

> *Grain, oilseeds, processed grain, and oilseed meal containing fumonisin above 5 parts per million (ppm) except that with proper labeling as approved by the Office of the Texas State Chemist and targeted for animal species as follows: ≤20 ppm for swine and catfish not to exceed 50% of diet; ≤30 ppm for breeding ruminants, breeding poultry and breeding mink not to exceed 50% of diet; ≤60 ppm for ruminants ≥3 months old being raised for slaughter, and mink being raised for pelt production not to exceed 50% of diets; ≤100 ppm for poultry being raised for slaughter not to exceed 50% of diets, all other species or classes of livestock and pet animals ≤10 ppm not to exceed 50% of the diet except equids and rabbits which should not exceed 5 ppm and 20% of diet; ≥100 ppm requires a blending permit issued by the Office of the Texas State Chemist.*

The Food and Drug Administration (FDA) has published advisory levels through a compliance policy guide (FDA 2001) that align with Texas regulatory limits. The FDA policy guide serves as guidance (non-regulatory) for the United States grain and feed industry. Unique within the FDA guidance is reference to dry weight measurement of fumonisin, which is intended to acknowledge that fumonisin may be present in high moisture (>20%) grain fed to the cattle industry (Michael Henry, personal communication 2018). FDA laboratories report fumonisin incidence on an as-is

moisture basis except for high moisture products including wet corn or wet corn distiller's grains where the moisture content is considered (Michael Henry, personal communication 2018). The OTSC reports the incidence of fumonisin on an as-is moisture basis as does the Federal Grain Inspection Service (FGIS) of the United States Department of Agriculture (USDA).

The 2001 FDA compliance policy guide also indicates that fumonisin may increase in storage, citing Bacon and Nelson (1994). In the Bacon and Nelson paper, the authors state that *F. moniliforme* and *F. proliferatum* are biotrophic pathogens, and this habit defines these fungi as field fungi, and indicates that they produce their toxins under field conditions. Since this relationship is not obligatory, toxin production could occur in storage on dead plant debris or kernel fragments. Studies done on the growth of this fungus under storage conditions, however, are limited and not designed to determine the production of toxin in storage. Other literature more emphatically states that fumonisin does not accumulate during storage (CAST 2003).

III. AGRICLTURE INDUSTRY INFRASTRUCTURE IN THE TEXAS HIGH PLAINS

Texas agriculture statistics list 6,012 farms with sales in excess of $500,000 and 1,102,000 irrigated corn acres in Texas and a total of 2,240,000 acres used to produce corn. The 2017 corn yield for Texas was 313 million bushels with an estimated market value of $1,193,422,000. In the High Plains, an estimated 723,900 planted acres yielded 98,998,700 bushels of corn. One hundred twenty-two commercial grain elevators with an estimated 71 million bushel storage capacity operate in the Texas High Plains. Cattle feedlots in the region total 116.

Approximately 2.6 million cattle are on feed with an estimated consumption of 6.5 million tons of corn (about 292 million bushels). Thus, a need exists to import about 200 million bushels of corn from other production regions of Texas or the United States to meet cattle production needs. Corn is harvested dry <16% moisture for storage and is harvested wet (>20% moisture) for direct delivery to feed yards. The amount of high moisture corn delivered at harvest is not available through the National Agricultural Statistics. However, assuming that harvest extends for 6 weeks, it is feasible that as much as 36 million bushels of high moisture corn could be delivered to feed yards each year.

IV. FUMONISIN RISK MANAGEMENT IN THE HIGH PLAINS

The pillars in mycotoxin risk management in Texas are presented in Figure 1. Pillars of a connected and transparent marketplace include: crop insurance, inventory tracking and reporting, laboratory quality systems, surveillance and monitoring and educational outreach.

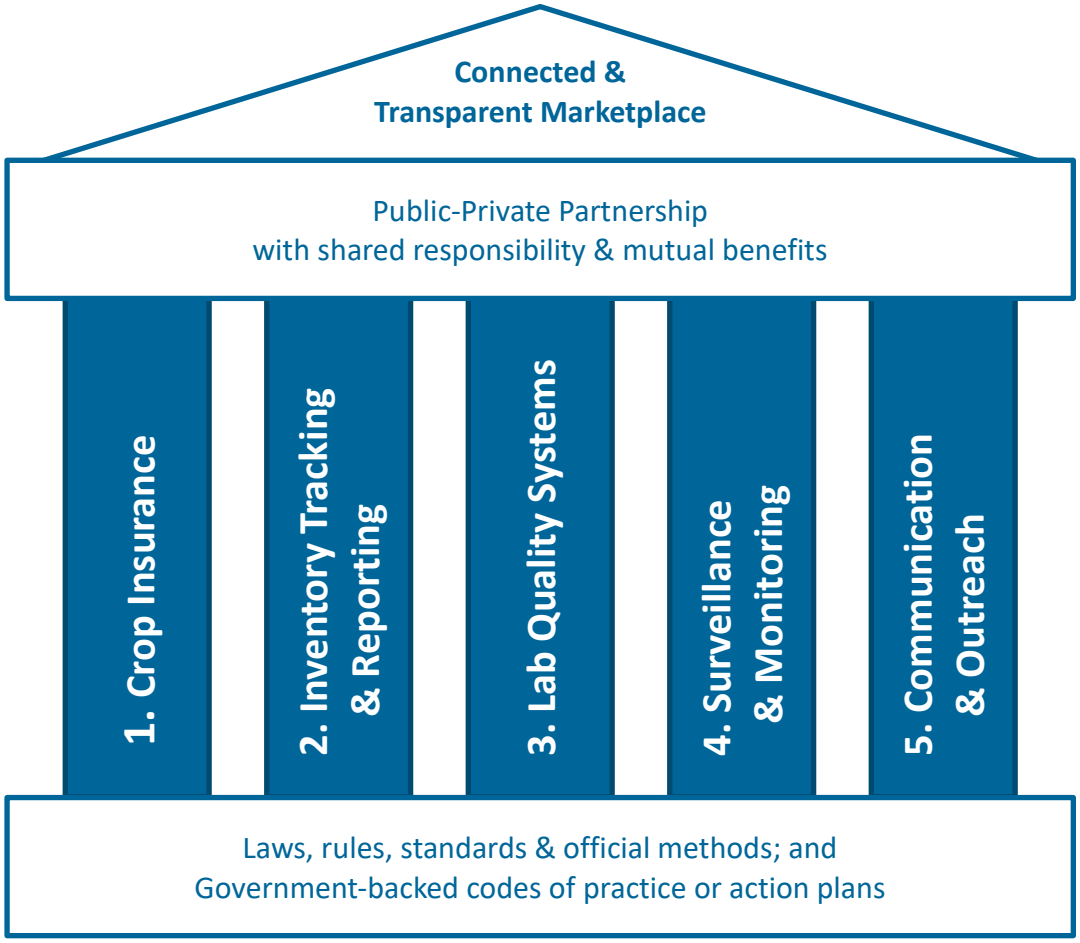

Figure 1. Pillars of mycotoxin management using co-regulation in development of a connected and transparent marketplace.

1. Crop Insurance: OTSC works closely with the Risk Management Agency (RMA) of the United States Department of Agriculture (USDA) to align methodology. As a result, the grain industry may supply both agencies with the same analytical report for use in crop insurance indemnification and regulation. The collaboration between agencies is formalized in a Managers Bulletin (MGR-17-015) which outlines RMA authorization of the "One Sample Strategy" (OSS) for mycotoxin testing for crop insurance purposes (Appendix 1). Qualified analysts at participating firms issue official mycotoxin results on OTSC certificates of analysis. Approved insurance providers (AIPs) utilize these certificates for timely crop insurance settlement. In 2017, 994 certificates were issued by seven laboratories that employed 25 OTSC-credentialed analysts for fumonisin in the Texas High Plains.

2. Inventory Tracking and Reporting: Firms participating in the OSS report quantitative official results to the Office of the Texas State Chemist who provides these results to RMA. Inventory of mycotoxin contaminated corn are reported to the agency as part of the Commercial Feed Control Act's reporting requirement found in §141.072. The purpose of this requirement is to ensure that mycotoxin contaminated corn is channeled to the appropriate animal species or end-use to protect consumers and the market. The reporting requirement and data sharing between agencies facilitates a seamless system of risk management that facilitates commerce and speeds the turn-around time for crop insurance settlements.

3. Laboratory Quality Systems: The OSS utilizes a laboratory quality systems approach to ensure testing accuracy by program participants. Elements in this system include development of a food safety plan by participating firms, description of sampling and testing methodology, analyst qualification and certification, use of working controls (reference material) to ensure testing accuracy and verification of official sample testing accuracy by OTSC's Agricultural Analytical Service (AAS). AAS is ISO/IEC 17025:2005 accredited for fumonisin and aflatoxin chemical analysis, ISO 17034:2016 accredited for fumonisin and aflatoxin reference material production, and ISO/IEC 17043:2010 accredited as an aflatoxin proficiency testing provider. The verification of sample testing accuracy (579 samples total during 2017) enables OTSC to monitor testing performance characterized in operating curves presented below with maximum levels (ML) of 5 ppm and 60 ppm (Figure 2).

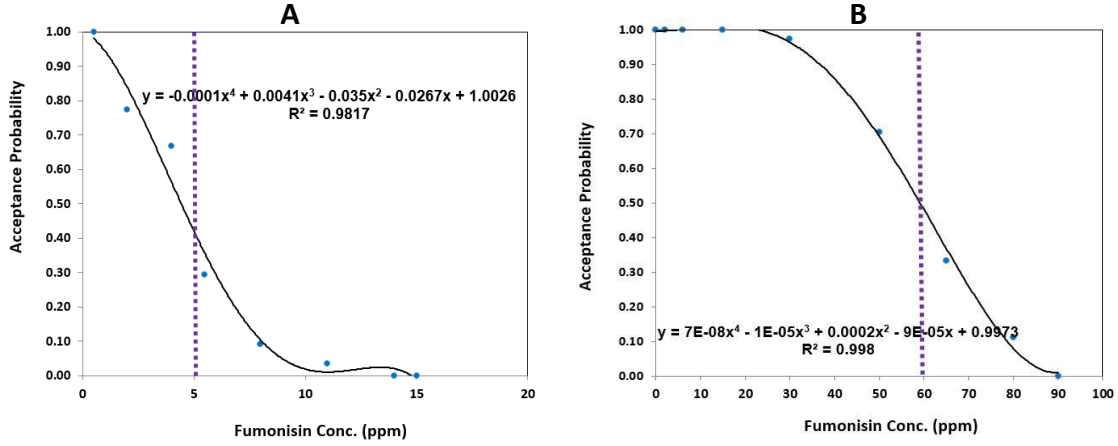

Figure 2. Fumonisin performance curves calculated using a 5 ppm (A) and 60 ppm (B) regulatory limit.

The operating curve in Figure 2(A) intersects the 5 ppm vertical axis at the 45% acceptance level. The area above the operating curve and less than the 5 ppm ML represents the portion of samples categorized by the OSS facilities as adulterated (>5ppm fumonisin) that OTSC found to contain fumonisin at or below the ML. This area is referred to as seller's risk, false positive or type I error. The area below the operating curve and greater than or equal to the ML represents the portion of sample categorized by the OSS facility as not adulterated (≤5 ppm Fumonisin) that OTSC analysis results were greater than the ML. This area of the

operating curve is referred to as buyer's risk, false negative, or type II error. The cumulative percentage of samples categorized as type I was 23% and the type II error represented 4% of the cumulative percentage of samples greater than 5 ppm. The 4th order polynomial model yielded a coefficient of determination (R^2) of 0.98 indicating that it explains 98% of the variability in analytical variation between OSS laboratories and OTSC.

The operating curve in Figure 2(B) intersects the 60 ppm vertical axis at the 55% acceptance level, indicating a nearly equal probability of a type I and type II error. In this situation, the area above the operating curve and less than the 60 ppm ML represents the portion of samples categorized by the OSS facilities as >60 ppm fumonisin that OTSC found to contain fumonisin below the ML. This would lead a firm to implement a blending plan when not required. The area below the operating curve and greater than the 60 ppm ML represents the portion of sample categorized by the OSS facility as not requiring a blend plan (<60 ppm Fumonisin) for OTSC results that were greater than the 60 ppm ML (requiring a blend plan). The 4th order polynomial model yielded a coefficient of determination (R^2) of 0.998 indicating that it explains 99.8% of the variability in analytical variation between OSS laboratories and OTSC. The probability of type I and type II error in Figure 2(B) is 15%.

These performance curves resemble those characterizing aflatoxin testing performance in Texas through the One Sample Strategy aflatoxin risk management program (Sasser 2018) and theoretical performance curves established through experiment data.

4. Surveillance and Monitoring: FFCS field investigators inspect establishments participating in the OSS to ensure accurate sampling and testing techniques are followed and to collect verification samples. The verification samples are analyzed within five working days and results are sent to the participating firms as objective feedback for their continuous improvement to measure accurately. Firms that are unable to accurately test for aflatoxin or fumonisin are removed from the program and are prohibited from issuing official certificates of analysis on behalf of OTSC for crop insurance.

   The OSS for fumonisin was piloted in 2016 for establishments selling contaminated corn containing greater than 60 ppm fumonisin to feedlots. Pilot program activities included field validation of one rapid test kit capable of measuring fumonisin up to 100 parts per million (ppm). OTSC had previously validated the test kit using procedures prescribed by the Federal Grain Inspection Service (FGIS) of the Grain Inspection, Packers, and Stockyards Administration (GIPSA-USDA 2016).

5. Communication and Outreach: The Office of the Texas State Chemist works through their Advisory Committee, which includes representatives from the Texas Cattle Feeders Association (TCFA) and Texas Corn Producers Board (TCPB), to review and communicate policy to manage risk (Appendix 2). In September 2017, the Advisory Committee reviewed OTSC guidance on fumonisin risk management and a notice offering fumonisin testing assistance to the Texas grain industry (Appendix 3). The OTSC Director and the Senior Manager for Quality Assurance also participated in a series of stakeholder meetings in the Texas High Plains in September 2017. Other outreach activities included

communication through its quarterly newsletter and weekly reporting of aflatoxin and fumonisin contamination in corn by county during harvest through stakeholder newsletters and the OTSC website (http://otscweb.tamu.edu).

Despite OTSC's communication efforts, producers and feedlots appeared unaware of the economic and food safety risks associated with fumonisin and unprepared to respond to the 2017 fumonisin outbreak. A need exists for a new risk communication strategy that involves Texas A&M AgriLife Extension and utilizes other public information outlets to communicate risk to producers, processors and the public including: newspaper and trade magazine articles, television, radio, and social media directed toward producers and consumers.

V. 2017 LEVELS AND PREVALANCE OF FUMONISIN IN THE TEXAS HIGH PLAINS

Nineteen counties in the Texas High Plains were sampled for fumonisin. Sixteen of those counties experienced fumonisin greater than 5 ppm with the highest level of adulteration occurring in Potter County (214 ppm). Samples collected during the 2017 harvest reveal that 17% of the harvested corn was below 5 ppm, the lowest regulatory limit for animal feed (Figure 3). Corn containing greater than 60 ppm is subject to a blend plan and 33% of the Texas High Plains corn contained fumonisin contamination levels exceeding 60 ppm. Nine blend plans for grain elevators receiving fumonisin contaminated corn containing greater than 60 ppm were prepared in 2017, compared to six blend plans for fumonisin in 2016.

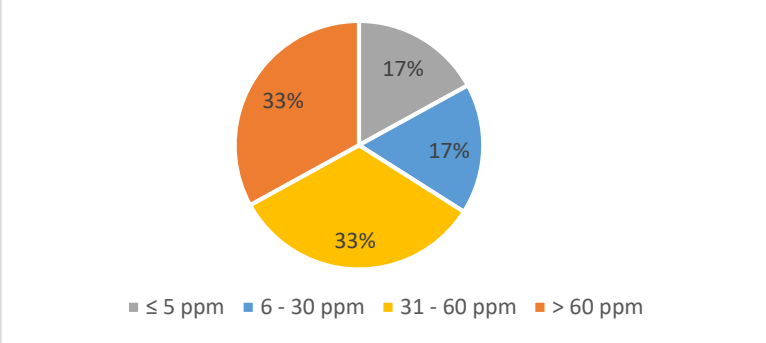

Figure 3. Whole corn (2017 new crop) samples collected (8/24/17 - 9/30/17) at Grain Elevators in the Texas High Plains by Fumonisin concentration in parts per million (ppm).

VI. RESEARCH

A need exists to develop a rapid method for testing high moisture corn. One of the principle constraints in fumonisin testing is grinding high moisture grain. Most laboratory mills are attrition mills that utilize grinding plates, which turn at a different speed and include both a shearing and compression force to reduce particle size. Higher moisture corn display plastic properties, thus presenting a challenge for reducing particles to the desirable size (GIPSA 2015). As a result, it takes longer to grind, particles are larger, and the time to clean the grinder is longer. Typical grain moisture content targeted for storage is between 13% to 16%. High moisture corn is typically in excess of 20% moisture. Thus, it may be necessary to dry grain prior to grinding for fumonisin extraction. As an alternative, a slurry method could be used to perform wet analysis without drying.

Previous research indicates drying grain using a microwave can reduce moisture content from 30% to below 20% within 150 seconds (Velu et al 2005). However, this research has not investigated the impact of microwave drying on the fumonisin and its extraction from corn. The slurry method could provide a more rapid and affordable method but needs to be validated with the existing rapid test kit technology. Rapid testing, as defined by FGIS, is 30 minutes or less.

An investigation into cultural practices and climatic variables that contribute to fumonisin needs further evaluation. Antidotal information suggests that drought followed by abundant moisture near harvest could lead to increased fumonisin. Currently, there exists a paucity of scientific literature to explain why fumonisin occurs in high levels, although its incidence has increased in the Texas High Plains over the past decade according to OTSC regulatory data. Consequently, messaging by crop production specialists and risk managers about the likelihood of fumonisin to facilitate planting decisions is challenging.

Similarly, despite the reference to fumonisin increasing in storage by the FDA guidance document, there is no definitive research to quantify if this occurs, under what condition, nor does there exist a biological explanation behind the etiology of *Fusarium* in storage and the production of fumonisin. RMA policy is shaped around FDA guidance and a need exists to explore whether fumonisin does increase in storage and what conditions for managing stored grain to avoid such an increase.

VII. MYCOTOXIN REGULATION

Whole grain or whole seed containing toxins or chemical adulterants, such as aflatoxin and fumonisin, are a commercial feed §141.002(c)(2). A person may not manufacture or distribute commercial feed without a valid current license issued by the Service §141.021(a).

The Service assigns legal responsibilities for adulterated and misbranded product to the person responsible for meeting the product guarantee. For example, if an adulterated or misbranded feed ingredient from company X is encountered during an inspection at company Y, company X is assigned a violation, receives the violation notice and a copy of this notice sent to company Y.

The Service implements a statistically derived risk based plan-of-work and the mycotoxin plan-of-work results are on the OTSC website: http://mycotoxinbmps.tamu.edu/mapsupdate.aspx.

If the level of mycotoxin (aflatoxin or fumonisin) is severe, additional sampling and testing are required from firms and results from this additional testing are monitored by the Service. To assist the industry manage mycotoxin risk, the Service implemented a One Sample Strategy program where firms submit a sampling and testing plan and their analysts are qualified to perform analysis under OTSC authority. Test results performed by firms under the One Sample Strategy are official, meaning they are recognized by the Service for the purposes of regulation and the Risk Management Agency of the United States Department of Agriculture for the purposes of crop insurance indemnification.

Producers, grain handlers, feed manufacturers, integrators and the public can expect consistent application of the Texas Commercial Feed Control Act and Texas Commercial Feed Rules by the Service. This includes enforcing the regulatory maximum levels published for aflatoxin §61.61(a)(6) and fumonisin §61.61(a)(7) using inspection, sampling and analysis authority prescribed in Subchapter E and enforcement remedies prescribed in Subchapter F of the Texas Commercial Feed Control Act Chapter 141.

Multiple options are available to manage uncertainty surrounding high moisture corn and are listed below:

1) The Office of the Texas State Chemist is validating rapid testing technology for high moisture corn. This will enable producers or feedlots to test for fumonisin contamination before or at the point of delivery.

2) Through the adoption of the One Sample Strategy, feedlots could issue an official certificate of analysis to the producer for the purpose of crop insurance. Feedlots could license as a testing entity, thereby not assuming legal responsibility for the grain on behalf of the farmer nor would they be responsible for inspection fees. An official certificate issued through the One Sample Strategy also provides producers legal certainty.

3) Farmers can allow grain to dry in the field to a moisture acceptable to commercial grain elevators participating in the One Sample Strategy. These firms can accurately test for aflatoxin and fumonisin and issue official certificates of analysis for regulatory and crop insurance purposes.

VIII. RISK COMMUNICATION STRATEGY

The 2017 harvest in the Texas High Plains revealed a need to improve OTSC's risk communication strategy involving fumonisin. Previously, OTSC management and agriculture association personnel agreed that the Office of the Texas State Chemist would communicate levels of aflatoxin and fumonisin contamination to associations who would then directly communicate the risk posed by these toxins to producers, grain elevators, and feed mills. OTSC also communicates mycotoxin results through its website with daily updates to a State of Texas map depicting counties and mycotoxin contamination. For both mycotoxins, descriptive statistics including the maximum, minimum, and average and the number of samples collected by county are published daily on the OTSC website http://mycotoxinbmps.tamu.edu.

A need exists for a more comprehensive means of education and a collaboration with Texas A&M AgriLife Extension. Outreach activities by AgriLife will include but are not limited to public meetings, press releases, one-on-one consultation, demonstrations and newsletters. The State Chemist is considering risk management strategies to encourage regulatory compliance in the Texas High Plains that includes working with feedlots to become participants in the One Sample Strategy and issuing certificates of analysis to producers who are licensed with OTSC. These certificates can be used for crop insurance indemnification. Feedlots would license with OTSC as

laboratories, not as feed entities. This aligns with the current exemption of feedlots under the Texas Commercial Feed Control Act.

During 2018, OTSC will pursue an educational strategy to achieve regulatory compliance among farmers and feedlot personnel. Public meetings to promote this new approach and train feedlots in sampling and testing of high moisture corn will be performed in collaboration with Texas A&M AgriLife Extension and will be promoted by the Texas Corn Producers Board and the Texas Cattle Feeders Association.

The advantage of this approach includes providing legal certainty to producers of high moisture corn and feedlots, assurance to the public that fumonisin risk is being managed under the same process used throughout Texas, and uniform regulation throughout the state of Texas. OTSC has communicated this plan to RMA of USDA and is seeking an expansion of the Managers Bulletin to include feedlots.

Potential pitfalls of this approach include the possibility that the Service will not be able to validate methods to test fumonisin in high moisture corn. At this time, the Service views this risk as moderate. A second pitfall includes the possibility that RMA will not approve an expansion of the One Sample Strategy to feedlots. At this time, the Service views this risk as low since the determination by RMA will likely be based on the validation of testing fumonisin at high moisture. A third potential pitfall involves an unwillingness of agribusiness not collaborating in this process. At this time, the Service believes this risk is low due to the economic and legal benefit of implementing the OSS co-regulation shared governance options and the historic success of this program over the past 7 years.

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Appendix 1. One Sample Strategy for Mycotoxins in Texas (USDA 2017)

United States Department of Agriculture

Farm Production and Conservation

Risk Management Agency

1400 Independence Ave, SW,
Mail Stop 0801
Washington, DC 20250

BULLETIN NO.: MGR-17-015

TO: All Approved Insurance Providers
All Risk Management Agency Field Offices
All Other Interested Parties

FROM: Heather Manzano */s/ Heather Manzano* *10/6/2017*
Acting Administrator

SUBJECT: One Sample Strategy for Mycotoxins in Texas

BACKGROUND:

The Risk Management Agency (RMA) issued Manager's Bulletin MGR-11-011 on July 26, 2011, authorizing the "One Sample Strategy (OSS)" for aflatoxin testing in approved Texas elevator facilities for the 2011 crop year. The Bulletin stated RMA would annually reauthorize the program. RMA held discussions with the Office of the Texas State Chemist (OTSC), Regional Offices, and other interested parties and received written summary results from OTSC to determine whether to continue the program beyond the 2011 crop year. RMA issued Manager's Bulletin MGR-12-004 on April 12, 2012, authorizing the "One Sample Strategy" for aflatoxin testing in approved Texas elevator facilities for the 2012 and succeeding crop years.

ACTION:

For the 2017 and succeeding crop years, Approved Insurance Providers (AIPs) may consider OTSC-approved Texas grain elevator facilities to be approved laboratories for Mycotoxin testing for crop insurance purposes unless RMA or OTSC announces the suspension of OSS. The OTSC will provide a list of participating elevator facilities they have certified to test for Mycotoxins on their website for verification purposes at the following address: http://otscweb.tamu.edu/Risk/OneSample/Default.aspx

This list will be updated weekly. If an elevator is decertified by the OTSC, Mycotoxin tests conducted by that elevator after the date of decertification must not be used for Federal crop insurance purposes.

The OTSC will provide official test certificates of analysis documenting the level of Mycotoxin, which will be completed by the participating elevator and provided to the insured. AIPs using these test results for claims settlement must maintain a copy of this official test certificate for the claim file.

For fumonisin, the FDA has no published action levels or use restrictions for crops with 0 to 2.0 parts per million (ppm). Therefore, crop insurance policy provisions will provide quality adjustments for levels 2.1 ppm and above.

Appendix 2. OTSC 2018-2019 Advisory Committee

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2018-2019 Advisory Committee
Updated: March 27, 2018

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Appendix 3. 2017 Fumonisin Letter to Texas

OFFICE OF THE TEXAS STATE CHEMIST

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Fumonisin Sampling, Testing, and Risk Management in Corn

Associations representing producers, grain handlers, and processors are working with the Office of the Texas State Chemist (OTSC) to manage fumonisin risk in the 2017 corn crop in the Southern Plains and Panhandle of Texas. Cereal grains and oilseeds containing mycotoxins, such as aflatoxin and fumonisin, meet the definition of adulterated and fall under the authority of the Texas Feed and Fertilizer Control Service of OTSC per the Texas Commercial Feed Control Act (§141.002 and §141.148).

OTSC recognizes the challenge associated with sampling and testing for fumonisin. To address this concern, OTSC implemented a program referred to as the One Sample Strategy (OSS) to measure and manage mycotoxin risk using official equipment and methods. Both the aflatoxin and fumonisin programs provide guidance for creating a plan for representative sampling and accurate testing. By participating in OSS, grain operators can become qualified to conduct onsite fumonisin tests. OSS establishes criteria for proper sampling pattern, sample size, sample preparation, testing, and record keeping.

Grain, oilseeds, processed grain, and oilseed meal containing fumonisin above 5 parts per million (ppm) require proper labeling as approved by OTSC. The regulatory limits contained in the Texas Commercial Feed Rules (Chapter 61) are as follows:

≤ 20 ppm for swine and catfish not to exceed 50% of diet

≤ 30 ppm for breeding ruminants, breeding poultry, and breeding mink not to exceed 50% of diet

≤ 60 ppm for ruminants greater than 3 months old being raised for slaughter, and mink being raised for pelt products not to exceed 50% of diet

≤ 100 ppm for poultry being raised for slaughter not to exceed 50% of diet

≤ 10 ppm for all other species or classes of livestock and pet animals not to exceed 50% of diet except equids and rabbits which should not exceed 5 ppm and 20% of diet.

Facilities may implement blending as an approved method to reduce fumonisin below the regulatory maximum levels. Each facility must provide to OTSC a blending plan using OSS methodology. OTSC will issue credentials to qualified analysts employed by firms that submit an OSS plan or an approved blend plan. Firms participating in these programs may issue official results on behalf of OTSC for the purposes of buying, selling, and regulation.

> "The One Sample Strategy is so named because it utilizes the concept of 'test once, use multiple times.' The objective of this program is to provide legal certainty to the agriculture community while preserving market integrity through accurate sampling and testing," according to State Chemist, Dr. Tim Herrman.

The Office of the Texas State Chemist monitors performance and verifies test results to ensure testing accuracy. As an additional service, firms participating in the OSS program receive reference material at no cost to ensure accurate testing.

For more information about the One Sample Strategy, log onto http://otscweb.tamu.edu/risk/OneSample/ or call the Office of the Texas State Chemist 979-845-1121.

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