One-Sample Strategy

Texas offers an aflatoxin risk management program that approves grain elevator operators and feed manufacturers to issue aflatoxin results that are accepted by crop insurers and feed control officials. Recently, other states and associations have taken notice of this program and have begun to adopt policies that mirror the goals of the One-Sample Strategy for Aflatoxin Risk Management in Texas, which is administered by the Office of the Texas State Chemist (OTSC).

The Illinois Farm Bureau’s 2013 policy statement for grain and hay grading supports a policy to “standardize and certify local elevator’s aflatoxin testing equipment and operators,” and the National Corn Growers Association Mycotoxin Task Force voted in support of a similar nationwide approach.

What drives expansion of the One-Sample Strategy approach? Some evidence is anecdotal. Lindsey Bowers, Grain Merchandiser at United Agricultural Cooperative in El Campo, says that, “the One-Sample Strategy is cost effective, only requires grain to be tested once and is accepted by RMA [USDA Risk Management Agency] for crop insurance claims and the Office of the Texas State Chemist for regulatory purposes. The Certificates of Analysis are generated faster and are readily available for producers and insurance agents.” In addition, “we are confident that the grain that is being shipped out is within the range that we specify,” says United Ag’s Grain Merchandiser, Steven Craig.

But as Gary Bruggman, Manager at Lone Star Grain (formerly Blackland Grain) in Heidenheimer describes, the impact of the program extends beyond the initial point of commerce and into the retail sector. “We have one satisfied feed store owner that particularly liked picking up a load of deer corn and having it tested by a One-Sample Strategy participant where they didn’t have to worry when the OTSC inspector paid them a visit later.”

Measuring Effectiveness

The One-Sample Strategy participant uses a control sample (Fig. 1) to measure testing accuracy. The control sample contains a known level of aflatoxin and is run twice daily to ensure aflatoxin test result accuracy. These control test results act as ‘canaries in the coal mine’ that warn the analyst when procedures, equipment or solutions have produced erroneous results. The use of Control Charts in an effective way of demonstrating to the grain elevator personnel and their customers the accuracy of the aflatoxin test (Fig. 2). Control samples and control charts are provided to program participants free of charge. The OTSC field investigators provide onsite training and program approval process, also at no cost.

http://otscweb.tamu.edu/risk/OneSample

Figure 1. OTSC aflatoxin control sample
**Continued: One Sample Strategy**

Figure 2 demonstrates a control chart used to monitor daily aflatoxin results from control samples. In this example, – all of the results are within the upper and lower control limit. The application of this technique enables a firm to communicate to their employees and customers the importance of accurate aflatoxin measurements and how the firm is performing. This will create increased confidence among all individuals who have a stake in accurate aflatoxin test results.

![Control chart used to track daily aflatoxin control sample results](image)

Table 1 illustrates the different levels of participation that include “No Commitment” where OTSC provides a working control and onsite training, but the firm doesn’t issue a “Certificates of Analysis.” “Partial” involvement enables firms to test incoming loads of corn for aflatoxin and issue official “Certificates of Analysis” to those customers for crop insurance purposes but not every load is tested during harvest, which may be beneficial in years where the aflatoxin level (or frequency) is low. The “Full” participation option includes testing every load delivered to a grain elevator and requires no further testing for outbound shipment (if grain was segregated by aflatoxin level). Commercial feed manufacturers may also find the One Sample Strategy beneficial in managing risk by accurately measuring aflatoxin. OTSC field investigators will visit with grain establishment managers this spring about the opportunities this program offers. We encourage early enrollment in preparation for this year’s corn harvest.

<table>
<thead>
<tr>
<th>Level of Participation &amp; Benefits</th>
<th>RMA approved laboratory facility</th>
<th>Test all incoming truckloads</th>
<th>Segregate grain by aflatoxin level</th>
<th>Issue official results for crop insurance</th>
<th>Apply OTSC seals to outbound shipments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No Commitments:</strong></td>
<td>No</td>
<td>Optional</td>
<td>Optional</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Reduce variability of test results</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Partial:</strong></td>
<td>Yes</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Issue OTSC Certificates of Analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Full:</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>OTSC doesn’t collect regulatory samples or seize grain</td>
<td></td>
<td></td>
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</tbody>
</table>
AAFCO Mid-Year Meeting

The Association of American Feed Control Officials (AAFCO) 2013 Mid-Year meeting was held Tuesday, January 22\textsuperscript{nd} through Thursday January 24\textsuperscript{th} in Albuquerque, New Mexico. During this meeting it was announced the Association of Public Health Laboratories (APHL), Association of Food and Drug Officials (AFDO), and AAFCO have entered into a Cooperative Agreement with FDA. Financial support has been provided through a grant for ISO accreditation of the AAFCO Check Sample Program, ISO/IEC 17025 (2005) guidance/assistance for accreditation of regulatory food-contract program laboratories, and review of QC/QA guidelines for regulatory program laboratories.

The mid-year meeting discussions focused on the pet food and livestock labeling workshop, and revisions to the labeling manual and references on the websites are being developed and prepared for future posting and scheduling. There was also an update on the FDA Draft Compliance Policy Guide for Labeling and Marketing Nutritional Products Intended for Use to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases in Dogs and Cats; comments are under review.

FDA Proposed Rule and its Impact on Soil Amendments

On Jan. 16, the Food and Drug Administration (FDA) released for public comment its proposed rule, \textit{Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption} to establish science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms. While FDA does not seem focused on inorganic fertilizers, there are provisions within the rulemaking that may impact fertilizer manufacturers and distributors. The introduction in the proposed rule states that the use of animal manure and other materials of animal origin as fertilizer are one of the many factors that affect the occurrence of microbial contamination of fresh produce.

\textbf{Background - Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption}

The proposed produce rule covers most fruits and vegetables while they are in their raw or natural (unprocessed) state. It does not apply to raw agricultural commodities that are rarely consumed raw, those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms. Farms would be partially exempt if they have food sales averaging less than $500,000 per year during the last three years and, their sales to qualified end-users exceed their sales to others during the same period. FDA may withdraw this partial exemption if the farm is directly linked to an outbreak, or if FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak. FDA is also exempting the smallest farms with an average annual value of food sold during the previous three-year period of $25,000 or less.

\textbf{Summary - Biological Soil Amendments: Subpart F}

The proposed rule identifies possible routes of microbial contamination of produce and sets requirements to prevent or reduce the introduction of pathogens. “Soil amendments” are any chemical, biological, or physical material intentionally added to the soil to improve the chemical or physical condition of the soil in relation to plant growth or to improve the capacity of the soil to hold water. “Biological soil amendments of animal origin” are biological soil amendments which consist, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination. The FDA proposed rule focuses on biological soil amendments of animal origin because of the potential for these types of soil amendments to contaminate produce with pathogens of public health concern. Specific provisions under the proposed rule:

- Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (proposed §§ 112.51, 112.52);
- Prohibit the use of human waste for growing covered produce except in compliance with EPA regulations for such uses, or equivalent regulatory requirements (proposed § 112.53);
- Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that meet or exceed specific microbial standards (proposed §§ 112.54 and 112.55);
- Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (proposed § 112.56); and
- Require certain records, including documentation of application and harvest dates relevant to application intervals; documentation from suppliers of treated biological soil amendments of animal origin, and scientific data or in-
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Protected consumers & enhances Agri-Business through its Feed & Fertilizer Regulatory Compliance Program, surveillance & monitoring of Animal-Human health & environmental hazards, & preparedness planning.

Continued: FDA Proposed Rule and its Impact on Soil Amendments

formation relied on to support any permitted alternatives to requirements (proposed § 112.60). Alternatives to the composting treatment processes established in §112.54(c)(1) and (c)(2), and for the minimum application intervals established in § 112.56(a)(1)(a) and in § 112.56(a)(4)(a) may be used, provided adequate scientific data exists that the alternative would provide the same level of public health protection as the proposed rule and would not increase the likelihood that covered produce will be adulterated.

Potential Issues - Biological Soil Amendments: Subpart F

The rule may have consequences for fertilizer manufacturers and distributors to the extent that biological soil amendments of animal origin are used as surfactants, binders, filler or amendments to chemical or physical soil amendments. Producers, distributors and retailers may be required to provide a “Certificate of Conformance” to purchasers of chemical or physical soil amendments if biological soil amendments of animal origin are used as surfactants, filler or amendment material or to state that biological soil amendments of animal origin are not used in products offered for sale. Proposed § 112.60(b)(2) requires documentation (such as a Certificate of Conformance) for a treated biological soil amendment of animal origin received from a third party. Proposed rule, § 112.51(b) categorizes a biological soil amendment of animal origin as untreated if it has become contaminated after treatment, if it has been recombined with an untreated biological soil amendment of animal origin, or if it contains a component that is untreated waste reasonably believed to be contaminated with a hazard or associated with foodborne illness.

Potential issues with the FDA proposed rules include, but are not limited to:
1. To what extent are substances of animal origin used in the fertilizer production process as surfactants, binders and/or filler material? To what extent are biological soil amendments of animal origin used to blend finished fertilizer products at the retail level?
2. To what extent will producers and retailers need to ask suppliers for Certificates of Conformance from third-party vendors to reasonably ensure that biological soil amendment of animal origin are not used, or that these amendments are treated in compliance with the proposed FDA rule?
3. Will producers, distributors and retailers be required to provide Certificates of Conformance down the supply chain so that end-use farms have documentation of compliance?
4. How best to work with the Association of American Plant Food Control Officials (AAPFCO) to ensure that proposed rules are implemented consistently across states?

DATES: Submit either electronic or written comments on the proposed rule by May 16, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0921 and/or Regulatory Information Number RIN 0910-AG35, by any of the following methods.

Electronic Submissions
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions
• Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HPA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.