

OFFICE OF THE TEXAS STATE CHEMIST

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FEED INDUSTRY MEMORANDUM NO. 5-23

Criteria for Aflatoxin Binding Agents in Customer Formula Feeds

OBJECTIVE:

Explain active ingredient, licensing, recordkeeping, labeling, and aflatoxin binding agent measurement requirements to conform with rule §61.67 General Provision for the Use of Aflatoxin Binding Agents in Customer Formula Feed

BACKGROUND:

The Texas Commercial Feed Control Act 141.004 and the Commercial Feed Rules 61.22(5)(B)(iii) define the Texas State Chemist's authority to approve new products and name of those products. The Office of the Texas State Chemist responds to requests by feed manufacturers and consumers of feed to approve new products or ingredient in consultation with the Advisory Committee and experts to ensure the safety of feed and to protect the market place from fraudulent practices. In response to input by the OTSC Advisory Committee, stakeholders, and experts, the Office submitted to the Texas Register the General Provision for the Use of Aflatoxin Binding Agents in Customer Formula Feed in January, 2011 and has approved for publication this new rule in May 19, 2011.

The Office approved the use of aflatoxin binding agents in customer formula feeds which are defined in 141.001(7) as a "mixture of commercial feed or feed material all or part of which is furnished by the person who processes, mixes, mills, or otherwise prepares the mixture and which is mixed according to the specific instructions of the purchaser. The term includes a special formula feed or made-to-order feed." Additionally, aflatoxin binding agents may be used in feed manufactured on-farm, in feed lots, dairies, and by integrated operations and are subject to the same inspection authority that currently exists within the Texas Commercial Feed Control Act and Commercial Feed Rules. An essential component of the label for aflatoxin binding agents is binding activity, expressed as Q_{max} using the Langmuir equation. As scientific advances in the measurement of aflatoxin binding quantification occurs, the Office will consider other methods for measuring binding activity.

POLICY:

A. Active Ingredient

The active ingredient in the aflatoxin binding agent must be a defined feed ingredient or generally regarded as safe (GRAS) as delineated by the AAFCO Official Publication or other mechanism including, but not limited to, the self-affirmed process. Inert materials or carriers may not exceed 2% of the aflatoxin binding agent by weight.

B. Licensing

Establishments selling aflatoxin binding agents and manufacturing customer formula feeds using aflatoxin binding agents must hold a license with the Office (§141.021). In addition, a firm must amend their license and receive a certificate of approval by the Office to distribute or use the aflatoxin binding agent §61.25 (a)(1). The Office will issue a certificate of approval to distribute the aflatoxin binding agent in Texas following completion of form R-168 and evidence of this certificate must be shared with individuals purchasing aflatoxin binding agent and customer formula feeds containing the aflatoxin binding agent.

C. Recordkeeping

Record keeping for the purposes of monitoring the distribution of aflatoxin binding agents to customer formula feed manufacturers include the identity of the entity purchasing the binder including the name of business, address, and contact information and the amount of material sold. Entities/individuals manufacturing customer formula feed must record the amount of material used, feed product and its distribution (either for internal use or the name of the customer) and the level of aflatoxin in grain, oilseeds, processed grain and oilseed meals containing aflatoxin B1, B2, G1, G2. An example of the record keeping forms are found in appendix I and will be made available for review by the Office during reasonable business hours. If the customer formula feed product does not include grain, oilseeds, processed grain and oilseed meals, no record of corresponding aflatoxin measurement is required.

D. (i) Labeling and Measurement

To facilitate conformance in the measurement and reporting of aflatoxin binding activity, procedures for measuring aflatoxin binding performance are cited in appendix II. Labels must contain the binding capacity expressed as Qmax. Aflatoxin binding agents must not contain a drug claim to diagnose, cure, mitigate, treat or

prevent disease such as “improves liver health” or “prevents aflatoxicosis.” An example of the aflatoxin binding agent label and customer formula feed containing an aflatoxin binding agent is included in appendix III.

(ii) Directions for Use

Directions for use must accompany aflatoxin binding agent. Elements within the instruction for use include the following:

1. directions for use must coincide with OTSC feed memorandum 5-12 describing how to safely use the product in customer formula feed containing aflatoxin contaminated cereal, oilseeds, and meals at the appropriate action levels by species (Appendix IV),
2. directions for use must clearly explain that the aflatoxin binding agent is for customer formula feed only,
3. directions for use must clearly describe inclusion levels and how to calculate the correct level of inclusion and recordkeeping requirements as defined by the Commercial Feed Rules §141.074 and §61.67,
4. directions for use must clearly designate that aflatoxin binding agent approval is for use in Texas only,
5. directions for use must include in-vivo study results on the efficacy of the aflatoxin binding agent,



Dr. Timothy J. Herrman
State Chemist and Director
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Appendix II

“Isothermal Adsorption of Aflatoxin B1 on HSCAS Clay”, Patrick G. Grant and Timothy D. Phillips*,
J. Agric. Food Chem. 1998, 46, 599-605

“Smectite Clays as Adsorbents of Aflatoxin B1: Initial Steps”, Ines Kannewischer, Maria Guadalupe,
Tenorio Arvide, G. Norman White and Joe B. Dixon**, Clay Science 12 Supplement 2, 2006, 199-204

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Appendix III

PROPOSED LABEL FOR AFLATOXIN BINDING AGENT

Product Name

Qmax Value _____ mol/kg

Active Ingredient: _____

Inert Ingredients: _____

Directions for use: "Product name" must be mixed into a customer formula feed containing aflatoxin contaminated cereal, oilseed or meal at a rate of _____ lbs per ton of feed.

Warnings: "Product Name" can only be distributed in Texas. "Product name" can only be used in customer formula feeds. "Product name" can only be mixed in customer formula feeds containing aflatoxin contaminated cereal, oilseed or meal at the appropriate action levels by species (See The Office of the Texas State Chemist Feed Industry Memorandum No. 5-12). Records of aflatoxin binding agent and customer formula feeds containing aflatoxin binding agents must be kept for two years in accordance with the Texas Commercial Feed Rules §141.074 and §61.67.

Firm Name

Address, Zip Code

Net weight _____ lbs (_____ kg)

Attachments: (In-vivo studies)

EXAMPLE LABEL FOR CUSTOMER FORMULA FEEDS CONTAINING AN AFLATOXIN BINDING AGENT

CUSTOMER FORMULA FEED FOR:
XYZ FEEDYARD
000 ABC DRIVE
ANYWHERE, TX 00000
January 1, 2012

Active Ingredient: _____

Active Ingredient inclusion: _____

Other Ingredients/Commercial Feeds: # of pounds

- | | | |
|----|-------|-------|
| 1. | _____ | _____ |
| 2. | _____ | _____ |
| 3. | _____ | _____ |
| 4. | _____ | _____ |

Warnings: This feed is only approved for use in Texas. Feeds containing aflatoxin binding agents can only be used with aflatoxin contaminated cereal, oilseed or meal at the appropriate action levels by species (See The Office of the Texas State Chemist Feed Industry Memorandum No. 5-12).

FIRM NAME
ADDRESS, ZIP CODE

Net Weight: _____ lbs (_____ kg)

Appendix IV

Aflatoxin Action Levels:

Texas Administrative Code Title 4 Agriculture Chapter 61 titled: Commercial Feed Rules **§61.61 Poisonous or Deleterious Substances (a)(6)** “grain, oilseeds, processed grain and oilseed meals containing aflatoxin B1, B2, G1, G2 above 20 parts per billion (ppb) individually or total except that with proper labeling as approved by the Office of the Texas State Chemist as follows: <50 ppb may be distributed when destined for wildlife; <100 ppb may be distributed when destined for breeding cattle and breeding goats not used in production of milk for human consumption, breeding swine, mature poultry, and sheep; <200 ppb may be distributed when destined for finishing swine (more than 100 lbs. body weight); <300 ppb may be distributed when destined for finishing cattle in confinement; grain containing >300 to <500 ppb requires a blending permit issued by the Office of the Texas State Chemist; aflatoxin >500 ppb in grain and >300 ppb in oilseed, processed grain, and oilseed meal may not enter commerce and a record of disposition shall be submitted to the Office of the Texas State Chemist.