



IOWA DEPARTMENT OF AGRICULTURE AND LAND STEWARDSHIP

Bill Northey, Secretary of Agriculture

August 15, 2012

Dan McChesney, Director
Office of Surveillance & Compliance, HFV-200
FDA Center for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855

Dear Mr. McChesney:

The existence of historically severe drought and high temperature conditions during Iowa's 2012 growing season have made it possible that Iowa's 2012 corn crop may be subject to aflatoxin levels that are of concern to the Iowa Department of Agriculture and Land Stewardship (IDALS) and to all of the participants in Iowa's vitally important grain industry. As all of Iowa has been subject to these extreme weather conditions, IDALS will be instituting a state-wide sampling program designed to provide data that can be used by IDALS, country grain elevators and Iowa farmers to identify the parts of Iowa that may potentially have the highest levels of aflatoxin in the 2012 corn crop.

IDALS has and will continue to advise Iowa's farmers and grain elevators that corn containing aflatoxin in concentrations of greater than 20 ppb cannot be used for human consumption nor can it be used for feed for dairy animals or for feed for immature livestock of others species. IDALS has also advised farmers and grain elevators that corn containing aflatoxin of greater than 20 ppb but less than or equal to 300 ppb can move through the intrastate and interstate marketing and distribution process as long it moves and is fed only to qualifying categories of livestock in compliance with the requirements established in Section 683.100 of the Food and Drug Administration Compliance Policy Guide (Action Levels for Aflatoxin in Animal Feeds).

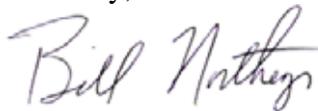
The above-referenced Compliance Policy Guide does not allow blending of corn containing greater than 20 ppb of aflatoxin with non-aflatoxin containing corn for animal feed. Based on the present historic shortage of corn and the resulting need to maximize the use of every bushel of corn harvested in 2012, IDALS is hereby requesting that the US Food and Drug Administration (FDA) exercise enforcement discretion and allow corn containing more than 20 ppb of aflatoxin to be blended with non-aflatoxin containing corn for animal feed. IDALS requests that the FDA not object to the blending of the State of Iowa's aflatoxin contaminated corn provided that the conditions stipulated below are met.

1. Prior to blending corn containing aflatoxin, the seller shall enter an Agreement with IDALS in which the seller expressly agrees to comply with the following provisions:

- a. Corn contaminated with aflatoxin above 20 ppb may be blended with other corn to the extent that the resulting product is below the appropriate aflatoxin action level in corn used as or in animal feed. The blended corn will be shipped in interstate commerce or for use as or in feed for mature poultry, breeding swine, and finishing swine over 100 pounds, breeding cattle and finishing (feedlot) cattle as long as the aflatoxin levels are below the action levels set forth in FDA Guidance Document, Compliance Policy Guide-Section 683.100, "Action Levels for Aflatoxin in Animal Feeds."
- b. Once the blending operation is completed, each batch of blended corn will be analyzed to determine its aflatoxin level. Said analysis shall be performed using US Department of Agriculture Grain Inspection, Packers & Stockyards Administration (GIPSA) - approved sampling and analysis protocols and testing procedures. Prior to the use of the blended corn, and before shipment in interstate commerce, the seller will certify that the aflatoxin level of the blended batch does not exceed the action level for the appropriate intended species.
- c. The Seller of corn blended pursuant to this process will provide the purchaser with a copy of the analytical results generated from the process described in subparagraph "b". In addition, the seller will obtain written assurance from the purchaser that blended corn will be used as or in feed for mature poultry, breeding swine, finishing swine over 100 pounds, breeding cattle and finishing (feedlot) cattle pursuant to the terms of Compliance Policy Guide-Section 683.100.
- d. The blended corn will be clearly identified and labeled for animal feed use only.

The Iowa Department of Agriculture and Land Stewardship is confident that the procedures contained in this proposal will allow the safe and efficient use of Iowa's 2012 corn harvest. As the historic drought conditions necessitating this request have also caused Iowa's corn crop to begin at a record early date, I greatly appreciate your prompt review and, hopefully, the receipt of a favorable response to this proposal.

Sincerely,



Bill Northey
Iowa Secretary of Agriculture

**AGRIBUSINESS ASSOCIATION OF IOWA
DROUGHT, FEED & GRAIN QUALITY WORKSHOP**

August 16, 2012

Courtyard by Marriott Ankeny, Iowa

Steve Moline, Division Director

Consumer Protection & Industry Services

Food Safety and Animal Health Divisions

Iowa Department of Agriculture & Land Stewardship

IDALS' Role

- FDA Blending Waiver Request
- Raw Milk Testing Order
- Regulate Identity Preserved Storage
- Sampling and Analysis of 2012 Corn Crop
- Sampling and Analysis of Commercial Feed
- Iowa Code sec. 717.7 Neglected Livestock

IDALS' August 15, 2012 Request to the FDA for an Aflatoxin Blending Waiver

- The FDA established rules governing corn containing aflatoxin in its Compliance Policy Guides (CPG), section 683.100
- The FDA CPG prohibits corn containing over 20 ppb of Aflatoxin from being used for human consumption, being fed to dairy animals, or moving through the grain handling system if no end use has been identified
- The FDA CPG allows corn containing over 20 ppb to be fed or used in animal feed pursuant to the following guidelines:
 - Over 20 ppb to 100 ppb can be fed to breeding beef cattle, breeding swine, or mature poultry
 - Above 100 ppb to 200 ppb can be fed to finishing swine of 100 pounds or greater
 - Above 200 ppb to 300 ppb can be fed to finishing (feedlot) beef cattle

IDALS' August 15, 2012 Request to the FDA for an Aflatoxin Blending Waiver

- The FDA CPG does not allow corn contaminated with aflatoxin at levels higher than 20 ppb to be blended with corn that does not contain aflatoxin
- In 2003 and in 2005 IDALS requested and received a blending “exercise of enforcement discretion” from the FDA that allowed the blending of corn containing in excess of 100 ppb with corn that did not contain aflatoxin as long as certain stipulated conditions were met

IDALS' August 15, 2012 Request to the FDA for an Aflatoxin Blending Waiver

- The conditions for blending contained in the 2003 & 2005 FDA “blending waivers” were as follows:
 - Corn contaminated with aflatoxin above 100 ppb may be blended with other corn to the extent that the resulting product is below the appropriate aflatoxin action level in corn used as or in animal feed. The blended corn can be shipped in interstate commerce and for use as or in feed for mature poultry, breeding swine, and finishing swine over 100 pounds, breeding cattle, and finishing (feedlot) cattle, as long as the aflatoxin levels are below the action levels set forth in the FDA guidance document, Compliance Policy Guide – Section 683.100, “Action Levels for Aflatoxin in Animal Feeds.”
 - The blending operation should be performed by, or in the presence of, a licensed state inspector and each batch of blended corn should be analyzed to determine its aflatoxin level. Prior to the use of the blended corn, and before shipment in interstate commerce, a state inspector shall certify that the aflatoxin level of the blended batch does not exceed the action level for the appropriate intended species.
 - The seller should provide the purchaser of the blended corn with a written copy of the analytical results, and obtain written assurances from the purchaser(s) that the blended corn will be used as or in feed for mature poultry, breeding swine, finishing swine over 100 pounds, breeding cattle, and finishing (feedlot) cattle.
 - The blended corn should be clearly identified and labeled for animal feed use only to prevent its diversion to human food. We suggest that approved coloring materials or other marking agents be added in order to prevent any such diversion.

IDALS' August 15, 2012 Request to the FDA for an Aflatoxin Blending Waiver

- IDALS' 2012 request for an "Aflatoxin Blending Waiver" contains some alterations to the conditions approved by the FDA in 2003 & 2005. IDALS made these changes in an effort to adapt the previous "waivers" to the more wide-spread and severe drought situation facing Iowa in 2012 as compared to the circumstances faced in 2003 & 2005.

IDALS' August 15, 2012 Request to the FDA for an Aflatoxin Blending Waiver

- Prior to blending corn containing aflatoxin, the seller shall enter an Agreement with IDALS in which the seller expressly agrees to comply with the following provisions:
 - Corn contaminated with aflatoxin above 20 ppb may be blended with other corn to the extent that the resulting product is below the appropriate aflatoxin action level in corn used as or in animal feed. The blended corn will be shipped in interstate commerce or for use as or in feed for mature poultry, breeding swine, and finishing swine over 100 pounds, breeding cattle and finishing (feedlot) cattle as long as the aflatoxin levels are below the action levels set forth in FDA Guidance Document, Compliance Policy Guide- Section 683.100, "Action Levels for Aflatoxin in Animal Feeds."
 - Once the blending operation is completed, each batch of blended corn will be analyzed to determine its aflatoxin level. Said analysis shall be performed using US Department of Agriculture Grain Inspection, Packers & Stockyards Administration (GIPSA) - approved sampling and analysis protocols and testing procedures. Prior to the use of the blended corn, and before shipment in interstate commerce, the seller will certify that the aflatoxin level of the blended batch does not exceed the action level for the appropriate intended species.
 - The Seller of corn blended pursuant to this process will provide the purchaser with a copy of the analytical results generated from the process described in subparagraph "b". In addition, the seller will obtain written assurance from the purchaser that blended corn will be used as or in feed for mature poultry, breeding swine, finishing swine over 100 pounds, breeding cattle and finishing (feedlot) cattle pursuant to the terms of Compliance Policy Guide-Section 683.100.
 - The blended corn will be clearly identified and labeled for animal feed use only.

IDALS MAY ISSUE AN ORDER REQUIRING THE SCREENING OF RAW MILK FOR AFLATOXIN IN IOWA

- In 2003 and in 2005, the existence of localized drought conditions and the resulting potential for the development of aflatoxin in corn harvested from those areas led IDALS to issue Orders requiring the screening of all raw milk produced from the identified Iowa counties for aflatoxin.
- In 2012, drought conditions are more widespread and may necessitate the need to require testing of raw milk for aflatoxin on a state-wide basis.
- IDALS has been in consultation with its Dairy Advisory Board (made up of representatives from all facets of Iowa's dairy industry) regarding these issues
- IDALS is closely monitoring harvest conditions and will make a decision to issue an Order if and when it becomes necessary

IDALS' REGULATION OF CORN CONTAINING AFLATOXIN STORED IN IOWA LICENSED GRAIN WAREHOUSES

- Corn containing above 20 ppb of aflatoxin must be stored in an “identity preserved” manner
 - Using the same requirements that would be applied to storing a specialty crop in a state licensed grain warehouse
 - These requirements include setting up a separate Daily Position Record (DPR)
 - If there are any questions, please contact IDALS' Grain Warehouse Bureau at (515) 281-5987 and they will get you the information you need

IDALS' SAMPLING OF THE 2012 CORN CROP

- In 2011, IDALS began a program of taking 2 corn samples per county for analysis of grain quality. The samples were analyzed for several grain quality factors including aflatoxin levels.
- Based on the drought and after consulting with adjacent state Departments of Agriculture, IDALS will be expanding its sampling to include 4 samples per county in 2012. The samples will be analyzed in the same manner as in 2011.

IDALS' SAMPLING OF COMMERCIAL FEED IN 2012

- IDALS has historically taken samples of commercial feed in Iowa and analyzed the samples, including analysis for mycotoxins.
- IDALS will continue its normal sampling and analysis procedure in 2012.

IDALS' NEW ROLE UNDER IOWA'S "NEGLECTED LIVESTOCK"

PROVISIONS FOUND IN IOWA CODE CHAPTER 717.

- In 2011, Iowa Code Chapter 717 was amended and IDALS was given additional responsibilities in situations involving "neglected" livestock in "immediate need of sustenance."
 - IDALS' responsibilities involve "Livestock" which is defined as "cattle, sheep, swine, or poultry."
 - Given the economic strain caused by high feed costs, there may be a potential for situations where livestock may be in danger of not having access to the sustenance they need. If any of the participants in this meeting become aware of such a circumstance, IDALS would ask that you contact our Animal Industry Bureau as soon as possible as time is of the essence in these circumstances. The telephone number for the Bureau is (515) 281-6358

Thank you

Steve Moline

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