



OCT 12 2012

Dr. Darrell D. Johnson,  
Director of Regulatory Services  
University of Kentucky  
103 Regulatory Services Building  
Lexington, KY 40546-0275

Dear Dr. Johnson:

Thank you for your letter dated October 12, 2012, regarding the possibility of high aflatoxin levels that may affect the 2012 Kentucky corn harvest. Your letter requests 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 corn found to have lower or negative aflatoxin levels in animal feed.

Given the recent weather conditions this year and aflatoxin data provided by the University of Kentucky, we do not object to providing temporary relief to allow the mixing or blending of corn with aflatoxin levels above 20 parts per billion (ppb) with corn found to have lower or negative aflatoxin levels. This relief is based on the conditions stipulated below.

1. Prior to blending corn containing aflatoxin, the seller must enter an Agreement with The Division of Regulatory Services 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 used 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. The analysis should be performed using US Department of Agriculture Grain

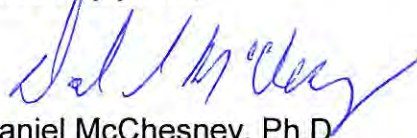
Inspection, Packers & Stockyards Administration (GIPSA) - approved sampling and analysis protocols and testing procedures. Prior to the use of the blended corn, and before shipment in interstate commerce, the seller needs to certify that the aflatoxin level of the blended batch does not exceed the action level for the appropriate intended species.

- c. The Seller of corn blended pursuant to this process needs to provide the purchaser with a copy of the analytical results generated from the process described in subparagraph “b”. In addition, the seller needs to 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 needs to be clearly identified and labeled “For Animal Feed Use Only” and indicating for which class(es) the corn may be appropriately fed.
- e. Corn containing aflatoxin levels greater than 500 ppb cannot be blended.

The enforcement discretion provided is contingent on you providing aflatoxin sampling data as the harvest progresses.

If you have any additional questions or concerns, please do not hesitate to contact us.

Sincerely yours,



Daniel McChesney, Ph.D  
Director  
Office of Surveillance & Compliance  
Center for Veterinary Medicine