

# **Sec. 683.100 Action Levels for Aflatoxins in Animal Food**

## **Compliance Policy Guide**

### **Guidance for FDA Staff**

*This version of the Compliance Policy Guide replaces the version made available August 1994. The document has been revised to current CPG formatting standards, update contact information, and clarify existing language.*

*Additional copies are available from:*  
Policy and Regulations Staff (HFV-6)  
Center for Veterinary Medicine  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855

<https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm>

Submit either electronic or written comments on this compliance policy guide (CPG) at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-1989-D-0239.

For further information regarding this document, contact [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov).

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
and  
Center for Veterinary Medicine**

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*This compliance policy guide represents the current thinking of the Food and Drug Administration (FDA) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.*

#### **I. Introduction**

The purpose of this compliance policy guide (CPG) is to provide guidance for FDA staff on action levels for aflatoxins in animal food and animal food ingredients.

In general, FDA's guidance documents, including this CPG, do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on various topics and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

#### **II. Background**

Aflatoxins (i.e., aflatoxin B1, B2, G1 and G2) are toxic by-products of mold growth on certain agricultural commodities. Since their discovery in the early 1960's, aflatoxins have been shown to be carcinogenic to laboratory test animals. In 1969, FDA set an action level for aflatoxins at 20 parts per billion (ppb) for all foods, including animal food, based on FDA's analytical capability and the agency's aim of limiting aflatoxin exposure to the lowest possible level.

Animal feeding studies conducted in the 1970's and 1980's, however, demonstrated that levels of aflatoxins above 20 ppb could be fed to certain food-producing animals without presenting a danger to the health of these animals or posing a risk to consumers of food derived from the exposed animals. Based on these scientific studies, the agency revised its action levels for aflatoxins in animal food and animal food ingredients for beef cattle, swine, and poultry.

Aflatoxins can be present in dog and cat food as well. In 1998, 2005, 2011, and 2013 aflatoxin contamination of dog and cat food resulted in illness, dog mortalities, and extensive recalls of affected dog and cat food.

### *Contains Nonbinding Recommendations*

Action levels are not binding on the courts, the regulated industry, or the agency (see 55 Federal Register 20782, May 21, 1990). There may be situations where circumstances warrant enforcement action at levels below an action level or where enforcement action is not warranted even though an action level is exceeded.

### **III. Regulatory Action Guidance**

To take regulatory action, FDA must (1) confirm the intended use of the animal food and animal food ingredient, and (2) show that the levels of aflatoxins in the animal food and animal food ingredient will support a charge of adulteration under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act.

When samples are analyzed in accordance with applicable methods of the current Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), contact the CVM Post-Market Compliance Animal Food Team (HFV-236) if both of the following conditions are met:

1. The original and check analyses confirm the level of total aflatoxins (B1, B2, G1 and G2) in the animal food or animal food ingredient is above the following action levels:

Intended Use	Animal Food and Animal Food Ingredient	Action Level
finishing (i.e., feedlot) beef cattle	corn and peanut products	300 ppb
beef cattle, swine, or poultry (regardless of age or breeding status)	cottonseed meal	300 ppb
finishing swine of 100 pounds or greater	corn and peanut products	200 ppb
breeding beef cattle, breeding swine, or mature poultry	corn and peanut products	100 ppb
immature animals <sup>1</sup>	corn, peanut products, and other animal food and food ingredients, but excluding cottonseed meal	20 ppb
pets (dogs, cats, rabbits, etc.) of all ages	corn, peanut products, cottonseed meal, and other food ingredients and complete pet food	20 ppb
dairy animals and other animal species (including wildlife), or other uses not specified in this table; or, when the intended use is not known	corn, peanut products, cottonseed meal, and other animal food and food ingredients	20 ppb

<sup>1</sup> For example, chickens and ducks less than 8 weeks of age; turkeys less than 12 weeks of age; goats, sheep, and pigs less than 4 month of age; cattle and equine less than 6 months of age.

*Contains Nonbinding Recommendations*

2. The identity of any aflatoxin present (i.e., aflatoxin B1, B2, G1 and G2) is confirmed by chemical derivative formation.

Before consulting with HFV-236, determine, if possible, the intended use of the food or food ingredient (animal species, class, age, etc.) as well as the proportion of the ingredient in the mixed food (number of pounds per ton). If information concerning the intended use is not available, consult with the CVM Post-Market Compliance Animal Food Team when the presence of aflatoxins has been confirmed at levels above 20 ppb.

In considering enforcement action for aflatoxin levels below an action level, consideration must be given to the agency's ability to support the adulteration charge. Discussions of possible enforcement actions at levels below an action level should include consideration of all compelling reasons for pursuing the action. Similar consideration is required if a field office believes that enforcement action at levels above an action is not warranted.

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