

Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds (CPG 7126.33)

BACKGROUND:

Aflatoxins 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 ppb for all foods, including animal feeds, 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. On the basis of these scientific studies, the agency revised its action level in 1982 to 300 ppb for aflatoxins in cottonseed meal intended for use as a feed ingredient for beef cattle, swine, and poultry; in 1989 to varying levels for corn intended for use as a feed ingredient for subgroups of the same animals. In 1990, FDA issued guidance that aflatoxins in peanut products (i.e., peanuts, peanut meal, peanut hulls, peanut skins, and ground peanut hay) intended for use as a feed ingredient are no more toxic to these same subgroups of animals than is aflatoxin in corn.

These changes in the action levels were premised on two underlying principles: (1) that FDA must show that an amount of aflatoxins in the feed of a particular animal will support a charge of adulteration under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, and (2) that FDA can confirm the ultimate use of the animal feed ingredient in question.

Action levels are not binding on the courts, the regulated industry, or the agency (see: 55 FR 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.*

REGULATORY ACTION GUIDANCE:

When samples of import or domestic shipments are analyzed in accordance with applicable methods of the current Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), contact Case Guidance Branch (HFV-236) if:

1. The original and check analysis show the presence of aflatoxins above the applicable action level, as follows:

*- 300 ppb for corn and peanut products intended for finishing (i.e., feedlot) beef cattle;

- 300 ppb for cottonseed meal intended for beef cattle, swine, or poultry (regardless of age or breeding status);

- 200 ppb for corn or peanut products intended for finishing swine of 100 pounds or greater;
- 100 ppb for corn and peanut products intended for breeding beef cattle, breeding swine, or mature poultry;
- 20 ppb for corn, peanut products, and other animal feeds and feed ingredients, but excluding cottonseed meal, intended for immature animals;
- 20 ppb for corn, peanut products, cottonseed meal, and other animal feeds and feed ingredients intended for dairy animals, for animal species or uses not specified above, or when the intended use is not known;*

and

2. The identity of aflatoxin B1 is confirmed by chemical derivative formation.

Before consulting with HFV-236, determine, if possible, the intended use of the feed or feed ingredient (animal species, age, etc.) as well as the proportion of the ingredient in the mixed feed (number of pounds per ton). If information concerning the intended use is not available, consult with CVM 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.

Material between asterisks is new or revised

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