



National
Grain and Feed
Association

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NGFA Reminds Industry of FDA Policies for Mycotoxins

Given stressful weather conditions in the southwest this crop-growing season, the NGFA is providing the following reminder about the U.S. Food and Drug Administration's (FDA) action levels for aflatoxin in corn, as well as its regulatory guidance for fumonisin and vomitoxin.

Aflatoxin: FDA's current aflatoxin action levels, based upon intended use, are as follows:

FDA Aflatoxin Action Levels	
Aflatoxin Level (parts per billion)	Commodities and Species
20 p.p.b.:	For corn, peanut products, cottonseed meal and other animal feeds and feed ingredients intended for dairy animals; for animal species or uses not specified below, or when the intended use is not known.
20 p.p.b.:	For corn, peanut products and other animal feeds and feed ingredients, but excluding cottonseed meal, intended for immature animals.
100 p.p.b.:	For corn and peanut products intended for breeding beef cattle, breeding swine or mature poultry (e.g., laying hens).
200 p.p.b.:	For corn and peanut products intended for finishing swine (100 pounds or more).
300 p.p.b.:	For cottonseed meal intended for beef cattle, swine or poultry (regardless of age or breeding status).
300 p.p.b.:	For corn and peanut products intended for finishing beef cattle (e.g., feedlot cattle).

Importantly, with respect to aflatoxin and other mycotoxins, FDA generally does **not** permit blending with uncontaminated commodities to reduce the level of mycotoxins in the resulting mixture to levels acceptable for use in human food or animal feed; the resulting mixture is deemed by FDA to be adulterated within the meaning of the federal Food, Drug and Cosmetic Act. However, on occasion, FDA has relaxed this "no-blending" policy in response to widespread outbreaks of aflatoxin (as occurred in 1988) or in response to state-specific requests to address local outbreaks (as occurred with the states of Iowa and Missouri in 2005, and Missouri in 1993). FDA said that as of today (Aug. 27) no such requests have been received thus far this year, but some are expected shortly.

Further, it is important to note that FDA technically does **not** consider mixing of corn containing a level of aflatoxin **up to** the action level that is allowed for a given species to be a violation of its no-blending policy. For example, since corn containing aflatoxin of up to 300 p.p.b. that is intended to be fed to mature (feedlot) beef cattle is in compliance with FDA's action level for that species, technically **any corn containing less than 300 p.p.b.** can be mixed and fed to that particular species without violating FDA's

no-blending policy. By contrast, mixing corn containing up to 200 p.p.b. with corn with less than 20 p.p.b. so as to reduce the level of aflatoxin in the resulting mixture to 50 p.p.b. so it could be fed to laying hens **does** violate the FDA no-blending policy, since a 100 p.p.b. aflatoxin action level applies to mature poultry. Likewise, mixing corn containing up to 600 p.p.b. with aflatoxin with lower levels in an attempt to reduce the level in the resulting mixture to 300 p.p.b. for feeding to feedlot cattle is not permitted, since 600 p.p.b. aflatoxin is not permitted for any species.

Fumonisin: For fumonisin, FDA on Nov. 9, 2001 issued final guidance containing recommended maximum levels that the agency "considers adequate to protect human and animal health, and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices." Importantly, FDA's **guidance** does **not** constitute action levels or enforceable regulatory limits. But the agency states that fumonisins have been linked to "a variety of adverse health effects in livestock and experimental animals."

For corn and corn products intended for **human food**, the FDA-recommended maximum levels for total fumonisins (FB₁, FB₂ and FB₃) are shown in Table 1. For **animal feeds**, FDA-recommended maximum levels for total fumonisins are shown in Table 2.

FDA Guidance for Fumonisin

Table 1	
Product	Total Fumonisin (FB ₁ + FB ₂ + FB ₃) (parts per million)
Degemmed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of <2.25%, dry weight basis)	2 p.p.m.
Whole or partially degemmed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of ≥ 2.25% dry weight basis)	4 p.p.m.
Dry milled corn bran	4 p.p.m.
Cleaned corn intended for masa production	4 p.p.m.
Cleaned corn intended for popcorn	3 p.p.m.

Table 2	
Corn and Corn By-Products Intended For:	Total Fumonisin (FB ₁ + FB ₂ + FB ₃) parts per million (ppm)
Horses and Rabbits	5 p.p.m. (no more than 20% of diet)**
Swine and Catfish	20 p.p.m. (no more than 50% of diet)**
Breeding Ruminants, Breeding Poultry and Breeding Mink*	30 p.p.m. (no more than 50% of diet)**
Ruminants three months of age or older being raised for slaughter; Mink being raised for pelt production	60 p.p.m. (no more than 50% of diet)**
Poultry being raised for slaughter	100 p.p.m. (no more than 50% of diet)**
All other species or classes of livestock and pet animals	10 p.p.m. (no more than 50% of diet)**
* Includes lactating dairy cattle and hens laying eggs for human consumption	
** Dry weight basis	

Vomitoxin: FDA first established **advisory levels** for grain and grain products containing deoxynivalenol (vomitoxin) in 1982. On Sept. 16, 1993, in response to the outbreak of the mold in a significant portion of the wheat crop, FDA revised its advisory levels for vomitoxin in several important respects:

- The agency eliminated its previous 2-part-per-million (p.p.m.) advisory level that applied to vomitoxin present in raw wheat and wheat byproducts for all species. Instead, FDA said it would rely upon the purchasing specifications and cleaning practices used by millers and processors to reduce the vomitoxin level so that the level present in finished wheat products, such as flour, germ and bran, did not exceed 1 p.p.m.
- FDA increased its advisory levels for vomitoxin present in grain and grain products intended for animal feed. Previously, the agency had a single advisory level for animal feed -- 4 p.p.m., with the additional recommendation that such feed not exceed 10 percent of the ration for swine and pet diets, nor more than 50 percent of the ration for beef cattle, other ruminants and poultry. Further, the advisory level applied only to wheat and wheat products.

When revising the vomitoxin advisory level in 1993, FDA expanded the scope to apply to all grains and grain products. Further, the agency increased its advisory levels for commodities intended as feed to the following levels:

FDA Advisory Levels for Vomitoxin	
Product and Intended Use	Vomitoxin Level (parts per million)
For grain and grain byproducts destined for swine. (FDA advises that commodities containing this level of vomitoxin not exceed 20 percent of the ration.)	5 p.p.m.
For grain and grain byproducts destined for beef cattle and feedlot cattle older than four months, as well as for chickens. (FDA recommends that commodities containing this level of vomitoxin not exceed 50 percent of the ration for these species.)	10 p.p.m.
For grain and grain byproducts destined for all other animal species. (FDA recommends that commodities containing this level of vomitoxin not exceed 40 percent of the ration.)	5 p.p.m.

More Information Available: The NGFA has authored a concise guide for the industry on FDA's mycotoxin regulatory policies. Members may [click here](#) to obtain a copy.