

NGFA Industry Notification: FDA Guidance on Mycotoxins

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The U.S. Food and Drug Administration (FDA) has issued regulatory guidance for three mycotoxins that may be present in raw grains, ingredients, animal feed and human food: aflatoxin, deoxynivalenol (vomitoxin) and fumonisin.

Types of Regulatory Guidance Issued by FDA

- Advisory Levels: Represent levels of a substance that, when present in food or feed, are believed by the agency to provide an adequate margin of safety to protect human and animal health. FDA has used advisory levels to provide guidance to the industry on vomitoxin and fumonisin.
- **Action Levels:** Specify a precise level of contamination at which the agency is prepared to take a regulatory action. FDA has used action levels to convey its regulatory policy to the industry on aflatoxin.
- **Regulatory Limits:** Create limits for the presence of toxins or contaminants that have been established after issuing valid regulations under the public notice-and-comment rulemaking procedures set forth in the Administrative Procedures Act. FDA currently has not established regulatory limits for mycotoxins found in food or feed, although it has stated its intent to eventually establish regulatory limits for aflatoxin.

In complying with federal and state law, for most purposes a grain, grain by-product, feed or other food product is considered to be adulterated if it contains a level of mycotoxin that is at or above the action or advisory level established by FDA for the product's intended purpose. Importantly, while FDA recognizes commingling, the agency does *not* permit grain, grain by-products, feed or other food products containing higher mycotoxin levels to be blended with commodities or products with lesser mycotoxin levels as a way to reduce the mycotoxin content of the resulting mixture to levels acceptable for human or animal food unless all of the mixed lots were at mycotoxin levels acceptable for the intended use. As an example, mixing corn containing aflatoxin at levels of up to 300 parts per billion (ppb) is permitted so long as the resulting mixture is fed only to finishing (i.e., feedlot) beef cattle (see nearby table). Conversely, the mixture resulting from blending corn with aflatoxin of 250 ppb with corn with lower aflatoxin levels could not be fed to breeding cattle, breeding swine or mature poultry *even if* the resulting mixture was 100 ppb or less since some of the corn used in the mixture was at a level greater than 100 ppb.

Aflatoxin: FDA's action levels for grain, grain by-products, feed and other products based upon intended use

Intended Use	Grain, Grain By- Product, Feed or other Products	Aflatoxin Level (B1+B2+G1+G2) [parts per billion (ppb)]	
Human consumption	Milk	0.5 ppb (aflatoxin M1)	
Human consumption	Foods, peanuts and peanut products, brazil and pistachio nuts	20 ppb	
Immature animals	Corn, peanut products, and other animal feeds and ingredients, excluding cottonseed meal	20 ppb.	
Pets (dogs, cats, rabbits, etc.) of all ages	Corn, peanut products, cottonseed meal, and other animal feed 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, and other animal feeds and ingredients	20 ppb	
Breeding cattle, breeding swine and mature poultry	Corn and peanut products	100 ppb	
Finishing swine 100 pounds or greater in weight	Corn and peanut products	200 ppb	
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	



Fumonisin: FDA's guidance levels for fumonisin for corn and corn by-products intended for human food

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

Fumonisin: FDA's guidance levels for fumonisin for corn and corn by-products intended for animal feed

Corn and corn by-product intended for:	Total Fumonisin (FB₁+FB₂+FB₃) [parts per million (ppm)]
Equids (i.e., horses) and rabbits	5 ppm (no more than 20% of diet)**
Swine and catfish	20 ppm (no more than 50% of diet)**
Breeding ruminants, breeding poultry and breedingmink*	30 ppm (no more than 50% of diet)**
Ruminants three months of age or older being raised for slaughter; mink being raised for pelt production	60 ppm (no more than 50% of diet)**
Poultry being raised for slaughter	100 ppm (no more than 50% of diet)**
All other species or classes of livestock and pet animals	10 ppm (no more than 50% of diet)**

^{*} Includes lactating dairy cattle and hens laying eggs for human consumption

Vomitoxin: FDA's advisory levels for vomitoxin in human food, animal feed and animal feed ingredients

Intended Use	Grain or Grain By-Products	Vomitoxin Levels in Grains or Grain By- Products and Total Ration** [parts per million (ppm)]	
Human Consumption	Finished wheat products	1 ppm	
Swine	Grain and grain by- products not to exceed 20% of diet	5 ppm	
Chickens	Grain and grain by- products not to exceed 50% of diet	10 ppm	
Ruminating beef and feedlot cattle older than 4 months, and ruminating dairy cattle older than 4 months	Grain and grain by- products*	10 ppm (10 ppm beef/feedlot)** (5 ppm dairy)**	
Ruminating beef and feedlot cattle older than 4 months, and ruminating dairy cattle older than 4 months	Distillers grains, brewers grains, gluten feeds, and gluten meals*	30 ppm (10 ppm beef/feedlot)** (5 ppm dairy)**	
All other animals not otherwise listed	Grain and grain by- products not to exceed 40% of diet	5 ppm	
* 88 percent dry matter basis			

⁸⁸ percent dry matter basis

NGFA Reference Corner

FDA Mycotoxin Regulatory Guidance -NGFA

FDA Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed

FDA Action Levels for Aflatoxins in Animal Food

FDA Advisory Levels for Deoxynivalenol (Vomitoxin) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed

FDA Fumonisin Guidance Levels in Corn for Human Consumption and Animal Feed

Find more safety and feed information at www.ngfa.org or contact Senior Vice President David Fairfield at 202-289-0873.

^{*} Dry weight basis

^{*} Total ration figures shown within parentheses