

Guidance for Industry

Fumonisin Levels in Human Foods and Animal Feeds

**FINAL GUIDANCE
November 2001**

Comments and suggestions regarding this guidance document should be submitted to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket Number 00D-1277. Comments may be submitted at anytime.

For questions regarding this guidance document, contact Henry Kim, Center for Food Safety and Applied Nutrition (CFSAN), (202) 260-0631, for human food issues or Randall Lovell, Center for Veterinary Medicine (CVM), 301-827-0176, for animal feed issues.

This guidance represents the Agency's current thinking on the control of fumonisins in human foods and animal feeds as a prudent public health measure. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine**

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GUIDANCE FOR INDUSTRY

Fumonisin Levels in Human Foods and Animal Feeds

This guidance document has been prepared by the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine at the Food and Drug Administration. This guidance represents the Agency's current thinking on the control of fumonisins in human foods and animal feeds as a prudent public health measure. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The purpose of this guidance is to identify recommended maximum fumonisin levels that FDA 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. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds.

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BACKGROUND

Fumonisins are environmental toxins produced by the molds *Fusarium moniliforme* (*F. verticillioides*), *F. proliferatum*, and other *Fusarium* species that grow on agricultural commodities in the field or during storage. These mycotoxins have been found as contaminants worldwide, mainly in corn. More than ten types of fumonisins have been isolated and characterized. Of these, fumonisin B₁ (FB₁), fumonisin B₂ (FB₂), and fumonisin B₃ (FB₃) are the major fumonisins produced in nature. The most prevalent of these mycotoxins in contaminated corn is FB₁, which is believed to be the most toxic (1, 2).

Occurrence in Raw Corn

The extent of contamination of raw corn with fumonisins varies with geographic location, agronomic and storage practices, and the vulnerability of the plants to fungal invasion during all phases of growth, storage, and processing. The levels of fumonisins in raw corn are also influenced by environmental factors such as temperature, humidity, and rainfall during pre-harvest and harvest periods (3). High levels of fumonisins are associated with hot and dry weather, followed by periods of high humidity. High levels of fumonisins may also occur in raw corn that has been damaged by insects (4, 5). Further, fumonisin levels in raw corn can increase under improper storage conditions. For example, optimal growth of fumonisin-producing molds that lead to increased levels of fumonisins in raw corn can occur when the moisture content of harvested raw corn during storage is 18-23 percent (5).

Occurrence in Processed Corn Products

The levels of fumonisins in processed corn products for human consumption vary depending on the milling and manufacturing processes that raw corn undergoes. Discussion of the various milling and manufacturing processes of raw corn and their effects on fumonisin levels in various processed corn products can be found in CFSAN's "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption."

Animal and Human Health Effects

Fumonisin is associated with a variety of adverse health effects in livestock and experimental animals. Currently, there is no direct evidence that fumonisins cause adverse health effects in humans because available studies demonstrate only inconclusive associations between fumonisins and human cancer. The available toxicological information on the adverse health effects of fumonisins in animals can be found in CFSAN's "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption" and in CVM's "Background Paper in Support of Fumonisin Levels in Animal Feed." The available epidemiological information on the association between fumonisins and human disease can be found in CFSAN's "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption."

FDA STRATEGY

As part of a long-term strategy for the control of fumonisins in the U.S. food and feed supply, FDA will participate in national and international scientific workshops to gather information that may be used in further assessment of the potential risk to animals and humans from exposure to

fumonisin. For example, a Fumonisin Risk Assessment Workshop, sponsored by FDA, the Joint Institute for Food Safety and Applied Nutrition, the World Health Organization, and the United States Department of Agriculture, was held January 10-12, 2000 at College Park, MD to discuss the elements of risk assessment for fumonisins. FDA intends to use information from this and other sources as the scientific basis for developing a long-term risk management policy and program for the control of fumonisins in the U.S. food and feed supply.

GUIDANCE LEVELS

Based on the wealth of available information on the adverse animal health effects associated with fumonisins, human health risks associated with exposure to fumonisins are possible. Therefore, human exposure to such natural toxins should not exceed levels achievable with the use of good agricultural and good manufacturing practices.

The recommended maximum levels for fumonisins in human foods and in animal feeds that FDA considers achievable with the use of good agricultural and good manufacturing practices are presented below. FDA believes that controlling fumonisins to these recommended levels can reduce exposure to fumonisins that may be found in corn products intended for human and animal consumption.

Human Foods

<u>Product</u>	<u>Total Fumonisin (FB₁+FB₂+FB₃)</u>
➤ 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 parts per million (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

Animal Feeds

<u>Corn and corn by-products intended for:</u>	<u>Total Fumonisin (FB₁+FB₂+FB₃)</u>
➤ Equids 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 breeding mink*	30 ppm (no more than 50% of diet)**
➤ Ruminants ≥ 3 months old being raised for slaughter and 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

**Dry weight basis

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