



August 7, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Attention: Docket No. 00D-1277

Dear Sir or Madam:

The Corn Refiners Association, Inc. (CRA) appreciates the opportunity to comment on the draft of the Agency's *Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds* released on June 6, 2000. The Association would like to commend the Agency for well-constructed guidance that provides assurances for a safe food supply while the effects of fumonisin on human health are further studied.

The CRA is the national trade association representing the corn wet milling industry. Members of the Association produce starches, sweeteners, alcohol, feed ingredients and vegetable oil using the corn wet milling process. Products of the corn wet milling industry are produced in accordance with Food and Drug Administration (FDA) Current Good Manufacturing Practices as well as in accordance with food standards and specifications of the FDA, Food Chemicals Codex and Codex Alimentarius Commission. A list of Association members is attached.

FDA Approach

The fumonisin levels proposed in the guidance are achievable with the use of good agricultural and good manufacturing practices. Thus, these levels will serve to protect the public health without causing an undue burden on the corn industry. Safety of the U.S. food supply is of paramount importance, and the proposed levels in the guidance document will assure that safety while FDA continues to evaluate the data on fumonisin.

The Agency has done a commendable job of communicating the importance of developing a comprehensive risk assessment for fumonisin without causing consumer alarm. The background papers in support of the guidance developed by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) provide useful information on the potential effects of fumonisin in a transparent manner.

As important as it is to acknowledge the various human epidemiological studies available, it is equally important to put these studies into context. The CFSAN background paper provides details crucial to understanding the impact of several studies, in particular, the South African study linking fumonisin to esophageal cancer.

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"Investigators in South Africa suggested an association between high levels of fumonisin-producing molds on corn used to make alcoholic beverages and esophageal cancer in human subgroups (Rheeder *et al.*, 1992). However, those studies were limited by the lack of controlled conditions, particularly for established confounding risk factors (e.g., alcohol consumption), and therefore do not allow any definitive conclusions to be made about cancer causation in humans."¹

Additionally, the CFSAN paper points out environmental differences that reassure consumers of the safety of the U.S. food supply.

"Other factors that make it difficult to extrapolate the results of these [foreign] studies are the differences in agricultural and nutritional conditions in those countries relative to those in the U.S. For example, the U.S. corn supply generally contains significantly lower levels of fumonisins than corn from the rural areas in the South African study. Additionally, in some instances the study populations were significantly malnourished in comparison with the U.S. population."²

The conclusions in the CFSAN background paper are stated clearly. They inform the public of FDA's reasons for establishing guidance levels while making evident that there is not a present health risk to consumers.

"Based on the current available occurrence data, levels of fumonisins in human foods derived from corn are normally quite low. At the present time, FDA believes that these levels present a negligible public health risk. Nevertheless, FDA considers the fumonisin guidance levels 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."³

¹ Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption*, June 6, 2000.

² Food and Drug Administration, Center for Food Safety and Applied Nutrition, *ibid.*

³ Food and Drug Administration, Center for Food Safety and Applied Nutrition, *ibid.*

Fumonisin Does Not Occur in Foods from Corn Wet Milling

The CRA agrees with FDA's approach to developing guidance for industry based on the various types of processing techniques. As noted in the CFSAN background paper, the CRA has found through research and communication with member companies that corn refiners are able to significantly reduce fumonisin in food products through good manufacturing practices and high quality standards.

Corn used by all U.S. corn processing industries meets U.S. Department of Agriculture and FDA standards for human consumption. Corn refiners test incoming corn for these quality standards set by the government. While there is no current or proposed grain standard for fumonisin for the wet milling industry, corn processors monitor weather conditions and survey crop conditions to determine when increased surveillance for mycotoxins may be necessary. In addition, processing effects remove fumonisin from food products produced by corn wet millers.

Research has shown that wet-milled food products carry little or no fumonisin residue. A study jointly conducted by researchers from the Department of Agriculture's National Center for Agricultural Utilization Research and the University of Illinois in Champagne-Urbana, examined the effects of the wet milling process. The researchers conducted tests on corn screenings and whole kernel corn with naturally occurring levels of fumonisin and corn with no detectable levels of fumonisin. Corn starch milled from all samples was found to contain almost no fumonisin residues. Starch is the raw material for corn syrups, high fructose corn syrups, food grade starch, dextrin, food starch modified, polyols and a number of other food ingredient items. Germ, which is further processed into corn oil, also contained substantially reduced levels of fumonisin.

These findings concur with the statements made on corn wet milling in the CFSAN background paper.

"Wet milling of whole corn generally results in the production of fractions called starch, germ, gluten, and fiber. Data indicate that this process results in fumonisin-containing fractions in descending order of highest to lowest fumonisin levels: gluten, fiber, germ, and starch (Bennett and Richard, 1996). No fumonisins have been detected in the starch fraction obtained from wet milling of fumonisin contaminated corn. The starch fraction is further processed for the production of high fructose corn syrups and other corn sweeteners (Bennett and Richard, 1996). Therefore, these types of products do not contain any detectable levels of fumonisins. Corn oil, extracted from corn germ and refined, does not contain any detectable levels of fumonisins (Patel *et al.*, 1997)."⁴

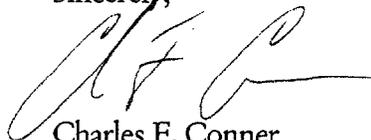
⁴ Food and Drug Administration, Center for Food Safety and Applied Nutrition, *ibid.*

Occurrence of Fumonisin in Corn Wet Milled Feed Products

While the wet milling process is effective in significantly reducing the amount of fumonisin in the human food products, research has shown that the fumonisin tends to follow the fiber content, which is used in animal feed products. Due to the high quality standards and the quality of corn available to wet millers in the U.S., fumonisin levels in these feed products is not expected to create health problems for animals when fed according to good feeding practices in compliance with FDA's draft guidance on animal feed.⁵

In conclusion, the CRA would like to emphasize the safety of the U.S. food supply due to the efforts of the food industry and federal government to protect the public health. The CRA believes that the FDA has taken into consideration the complexity of fumonisin as well as the quality of corn produced in the U.S. in the development of this guidance. With this guidance, FDA has established a strong base to further study fumonisin while securing public health without disrupting the U.S. food supply. We thank you for the opportunity to comment on this very important issue to the corn refining industry. If you have any questions, please contact Shannon Shoemith of my staff.

Sincerely,



Charles F. Conner
President

Attachment

⁵ Food and Drug Administration, Center for Veterinary Medicine, *Background Paper in Support of Fumonisin Levels in Animal Feed*, June 6, 2000.

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Decatur, Illinois
Clinton, Iowa
Montezuma, New York

Cargill, Incorporated
P. O. Box 9300
Minneapolis, Minnesota 55440
tel: 612-742-7575/fax: 612-742-7580

Plants:
Blair, Nebraska
Cedar Rapids, Iowa
Eddyville, Iowa
Dayton, Ohio
Memphis, Tennessee
Wahpeton, North Dakota

Cerestar USA, Inc.
(A company of Eridania Béghin-Say)
1100 Indianapolis Boulevard
Hammond, Indiana 46320-1094
tel: 219-659-2000/fax: 219-473-6600

Plants:
Hammond, Indiana
Decatur, Alabama
Dimmitt, Texas

Corn Products International, Inc.
6500 South Archer Avenue
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Plants:
Argo, Illinois
Stockton, California
Winston-Salem, North Carolina

Minnesota Corn Processors
901 North Highway 59
Marshall, Minnesota 56258
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Plants:
Marshall, Minnesota
Columbus, Nebraska

National Starch and Chemical Company
P. O. Box 6500
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Plants:
Indianapolis, Indiana
North Kansas City, Missouri

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Plant:
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A. E. Staley Manufacturing Company
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