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

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This document supersedes "Letter to State Agricultural Directors, State Feed Control Officials, and Food, Feed, and Grain Trade Organizations" issued on September 16, 1993

Contains Nonbinding Recommendations

June 2010

Additional copies are available from:
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Or

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Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
June 2010

Contains Nonbinding Recommendations

Guidance for Industry and FDA[i]
Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

Deoxynivalenol (DON), commonly called vomitoxin, is produced by several molds of the genus *Fusarium*, especially *F. graminearum*, which causes pink scab disease in wheat. It is not possible to completely avoid the presence of DON in wheat. DON is sometimes found in wheat grown under normal weather conditions, however, the fungus thrives in cool, wet conditions. When DON occurs in wheat, the levels are reduced by the processing of wheat into wheat products like flour, but processing does not totally eliminate DON.

The matter of DON in wheat was the subject of an FDA advisory issued in 1982. At that time, the agency noted the levels of DON in wheat and wheat products that it believed would not present a public health hazard. However, because only limited toxicological data on DON were available at that time, FDA stated that it was difficult to estimate the potential public health hazard posed by DON.

In 1993, FDA received numerous reports indicating that a significant portion of the hard red spring wheat crop from the upper Midwest states may contain high levels of DON due to the cool, wet conditions that occurred in the Midwest in the spring and summer of

1993. The agency reviewed additional data on DON that had become available since 1982. These data included reports of outbreaks of DON-associated acute gastrointestinal illness in humans in China in 1984/85 and in India in 1987. Although uncertainties existed concerning the precise role played by DON in these outbreaks, the data provided a clearer picture of the factors associated with human exposure to DON contaminated wheat.

On September 16, 1993, FDA issued a letter to State Agricultural Directors, State Feed Control Officials, and Food, Feed, and Grain Trade Organizations stating that, based upon the available data and information, FDA could now state with more confidence the levels of DON in wheat and wheat derived products that would not appear to present a public health hazard. Thus, FDA updated its advisory levels for DON in finished wheat products for human consumption. Advisory levels were also updated for grain and grain by-products used for animal feed. The letter stated that the updated advisory levels for DON were in response to the conditions experienced in the Midwest in 1993. This letter was subsequently incorporated into a final guidance that FDA placed on its guidance page website for ease of accessibility.

In response to a May 14, 2010 letter to Dr. Bernadette Dunham, Director, Center for Veterinary Medicine (CVM), from the National Grain and Feed Association and American Feed Industry Association, CVM conducted a review of the recent scientific literature and has determined that the 1993 advisory levels for DON in grains and grain by products destined for cattle can be revised. Recent studies demonstrate that higher levels of DON in feed for cattle would not appear to present an animal or public health hazard.

The advisory levels for DON are as follows:

1. 1 ppm DON on finished wheat products, e.g. flour, bran, and germ, that may potentially be consumed by humans. FDA is not stating an advisory level for wheat intended for milling because normal manufacturing practices and additional technology available to millers can substantially reduce DON levels in the finished wheat product from those found in the original raw wheat. Because there is significant variability in manufacturing processes, an advisory level for raw wheat is not practical.
2. 10 ppm DON on grains and grain by-products (on an 88% dry matter basis) and 30 ppm in distillers grains and brewers grains (on an 88% dry matter basis) destined for ruminating beef and feedlot cattle older than 4 months and ruminating dairy cattle older than 4 months, with the added recommendations that the total ration[1] for ruminating beef and feedlot cattle older than 4 months not exceed 10 ppm DON, and the total ration for ruminating dairy cattle older than 4 months not exceed 5 ppm DON. For chickens, 10 ppm DON with the added recommendation that these ingredients not exceed 50% of the diet of chickens.

[1] The total ration includes grains, all grain by-products including distillers and brewers grains, hay, silage, and roughage.

3. 5 ppm DON on grains and grain by-products destined for swine with the added recommendation that these ingredients not exceed 20% of their diet.
4. 5 ppm DON on grains and grain by-products destined for all other animals with the added recommendation that these ingredients not exceed 40% of their diet.

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[i] This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition and the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the Food and Drug Administration (FDA).