



## **North American Millers' Association**

600 Maryland Avenue, SW · Suite 825 West · Washington, DC 20024

202.484.2200 · Fax 202.488.7416

[www.namamillers.org](http://www.namamillers.org)

### **North American Millers' Association Background/Briefing Paper**

#### **Mycotoxins**

##### **Background**

Mycotoxins are naturally occurring toxic compounds that are by-products from the growth of fungi. The mycotoxins common in cereal grains are produced by three different fungi – Fusarium, Penicillium and Aspergillus.

Mycotoxins produced by Fusarium include Deoxynivalenol (DON), Fumonisin, Zearalenone, and T-2. Deoxynivalenol occurs primarily in wheat, but also in oats and corn. The incidence is strongly associated with wet and cool weather at the time of flowering. Fumonisin occurs in cool, wet weather, principally on corn. Zearalenone can affect corn, oats and wheat. T-2 is a mycotoxin that can occur in wheat, oats or corn. It thrives over a wide temperature range but is most productive at cool temperatures.

According to the FDA “the occurrence of mycotoxins in foods and feeds is not entirely avoidable; therefore small amounts of these toxins may be in foods and feeds. Strategies used by FDA to minimize mycotoxins in the food supply include establishing guidelines in compliance policy guides, and by monitoring the food supply by collecting and analyzing domestic and import foods.”

##### **Regulatory Activity**

FDA says its “approach under the Food, Drug & Cosmetic Act is to handle instances of DON contamination on a case-by-case basis. If DON levels exceeding the agency’s guidance level are detected in a food, FDA will review the relevant information to determine whether the DON levels found in that food may pose a health hazard such that it would be deemed adulterated and subject to enforcement actions under the FD&C Act.”

NAMA food safety counsel advises that “FDA’s conclusion that finished products with DON levels above 1 ppm are adulterated has no legal standing. In any individual case, FDA would have to support that position with scientific evidence, and not merely rely on the statement in the field assignment.”

In Canada, the Canada Food Inspection Agency (CFIA) has stepped up sampling of raw grain and milled grain products. Canada’s maximum DON level is 2 ppm in uncleaned soft wheat for human consumption, and 1 ppm in uncleaned soft wheat for use in baby foods.

CFIA has proposed these Ochratoxin A (OTA) maximum limits: raw grains 5 ppb, flour 3 ppb, bran 7 ppb, breakfast cereals 3 ppb, and baby cereals 0.5 ppb. Even though these OTA levels are merely proposed, CFIA has been aggressive in asserting compliance and enforcement based on its interpretation of Canadian law. The FDA has not proposed limits for OTA. This has the potential to create a non-tariff trade barrier.

Internationally, the Codex Alimentarius (Latin, for *Book of Food*) Commission, a body of the United Nations, develops and coordinates food standards. Codex standards are heavily influenced by the European Union.

The government of Canada chairs the committee of Codex (UN body which drafts model food laws) discussing establishing maximum limits for DON. Prior to the March 2012 Codex meeting, NAMA met with the FDA officials comprising the U.S. delegation, as well as with the Grocery Manufacturers Association, and explained the logic and value of the U.S. approach, i.e., using guidelines and not action levels, and not setting a guideline on raw grain. As a result, the U.S. delegation did not support the Codex proposal and the issue has been put off for another year. Canada's government prepared a discussion document to address the comments raised, including NAMA's, which will inform the debate at the 2013 Codex meetings.

### **Need for Harmonization of U.S./Canada Food Safety Statutes**

There is a fundamental lack of regulatory harmonization caused by differences in U.S. and Canadian law. Section 4 of the Canada Food & Drugs Act says: "No person shall sell an article of food that has in or on it any poisonous or harmful substance." On its face, this standard appears to be inflexible, and not allowing for consideration of health effects.

In contrast, the U.S. law provides much more discretion to manage contaminants in a more realistic fashion. The U.S. Food, Drug and Cosmetic Act says: "A food shall be deemed adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated... if the quantity of such substance does not ordinarily render it injurious to health."

NAMA supports the harmonization of the Canadian and U.S. food safety laws and regulations whenever possible. A key harmonization step would be to align the two food safety laws.

Parliament missed opportunities in 2012 to amend the Canada Food and Drugs Act and include language to align the two food safety laws. NAMA and the Canadian National Millers Association will continue to seek opportunities to achieve alignment.

In presentations in Canada, NAMA has communicated its position that:

- The zero tolerance implied by Canada's Food & Drugs Act is not achievable
- Government guidance and industry-led monitoring are effective (FDA guidelines enforced as commercial contract terms)

- Its preference for best practices to manage health and commercial risk (eg. operating characteristic curves to describe performance of sampling and testing programs)
- There are huge trade implications and harmonization of Canadian regulations with those in the U.S. is essential.

## **Research**

In 2004 the FDA requested the wheat milling and food processing industries gather data and conduct a study on the effects of processing on DON levels in wheat-based foods. The goal was to give a better estimate of exposure to DON via wheat foods as well as help establish acceptable levels of DON in foods in international trade.

A coalition was formed to complete the work, including NAMA, Grocery Manufacturers Association, American Institute of Baking, General Mills and Frito-Lay. The scientific analysis was conducted at the USDA Toxicology and Mycotoxin Research Unit in Athens, GA.

Foods studied were bread, cookies, crackers, pretzels, donuts, and flaked cereal.

The study results were presented in a scientific paper published December 3, 2010 in the *Food Additives and Contaminants* journal.

The findings show that DON is generally stable during the production of flour-based foods. DON concentration in finished foods was reduced 50 percent or more only in donuts and bread.

Prepared by Jim Bair, Vice President, 202.484.2200, ext. 14, [jbair@namamillers.org](mailto:jbair@namamillers.org).

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