

Issue Brief: Mycotoxins

Mycotoxins are toxic secondary metabolites produced by fungi (commonly known as molds) that can develop in certain agricultural commodities pre-harvest or post-harvest while in storage. Common mycotoxins include aflatoxins, fumonisins, deoxynivalenol (DON or vomitoxin), and patulin. Mycotoxin contamination varies year to year and by geographic region depending on weather conditions that stress crops and contribute to mold growth. Mycotoxins are harmful to humans and animals. They resist decomposition or being broken down by digestion, so they can remain in the food chain (becoming components of meat, milk, and eggs intended for human consumption). Many mycotoxins can survive processing grains into flours and meals and patulin can survive pasteurization.

Legal Framework

There are no Food and Drug Administration (FDA) regulations addressing mycotoxins in human foods. Nonetheless, a food that contains a mycotoxin will be adulterated under Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) if it contains any “poisonous or deleterious substance which may render it injurious to health” or, in the case of naturally occurring substances, the substance is in a quantity that “ordinarily render[s] it injurious to health.” Food facilities may not ship or introduce into commerce any adulterated product.

Although there are no regulations setting thresholds for mycotoxins, FDA has issued either “advisory” levels or “regulatory action” levels for several common mycotoxins. “Advisory” levels provide guidance to industry on the maximum levels 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. “Regulatory action” levels are those levels at which FDA will consider whether to take legal action against a product. Neither is considered legally binding, but will be taken into account when determining whether a product is adulterated. Current levels for certain foods are detailed below.

Mycotoxin	Commodity ¹	Level	Level Type
Patulin	Apple juice, apple juice concentrate, apple juice component of a food that contains apple juice as an ingredient	50 ppb	Regulatory action guidance (See CPG 510.150)

¹ Animal feed levels are not provided. For more information regarding mycotoxins in animal feed, contact AFFI.

Aflatoxin	Food except milk	20 ppb	Regulatory action guidance (CPGs 555.400; 570.375; 570.500; 570.200)
Aflatoxin	Milk	.5 ppb	Regulatory action guidance (CPG 527.400)
Fumonisin	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	Advisory ²
Fumonisin	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); Dry milled corn bran; Cleaned corn intended for masa production	4 ppm	Advisory
Fumonisin	Cleaned corn intended for popcorn	3 ppm	Advisory
Deoxynivalenol (DON or vomitoxin)	Finished wheat products for human consumption	1 ppm	Advisory ³

It is important to keep in mind that FDA's current good manufacturing practice regulations (GMPs) prohibit blending a lot of food that is contaminated with another lot in order to bring down the level of contamination in the product.⁴ Such an action renders the food adulterated regardless of the level of contamination in the final food. Nonetheless, in rare circumstances, FDA has not objected to state-controlled blending under specific conditions.⁵

With the recent passage of the FDA Food Safety Modernization Act (FSMA), FDA has several additional tools at its disposal for addressing mycotoxin contamination. First, registered food facilities will need to implement food safety plans, based on a

² Food and Drug Administration, *Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds; Final Guidance* (2001),

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm109231.htm>.

³ Food and Drug Administration, *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* (2010),

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120184.htm>.

⁴ 21 C.F.R. § 110.110(d).

⁵ *Review of the U.S. Department of Agriculture's Crop Disaster Assistance and 1993 Crop Quality Issues: Hearing Before the Subcommittee on General Farm Commodities of the House Committee on Agriculture, 103rd Congress 87-93 (1994)* (statement of John Wessel, Contaminants Policy Coordination Staff, Office of Regulatory Affairs, Food and Drug Administration).

through hazard analysis. This hazard analysis must consider the potential for chemical hazards and mycotoxins fall within the definition of chemical hazards. We suspect FDA would expect food establishments that receive raw materials that have the potential for mycotoxin contamination to consider mycotoxins in their hazard analysis. Food establishments will need to assess raw materials on a case-by-case basis to determine whether mycotoxin contamination is a "significant hazard" and if so, the preventive controls that are advisable to address the hazard. These requirements will apply to both human and animal food manufacturers.

In addition, importers and registered food facilities will need to implement supplier verification programs to ensure that the materials they receive are produced in compliance with applicable regulatory requirements and are not adulterated. Third, FDA has the authority under the Act to establish "performance standards" for the most significant foodborne contaminants (it is unclear whether mycotoxins would be considered a significant foodborne contaminant, but the Act provides FDA with this authority). As FDA implements FSMA, the agency could issue guidance regarding mycotoxins and identify the type of preventive controls the agency considers appropriate to address mycotoxin levels.

Recent Developments

- This summer, the Codex Alimentarius Commission approved a new work proposal for a "Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals" as well as a "Maximum Level for Total Aflatoxins in Ready-to-Eat Peanuts and Associate Sampling Plan."
- The Commission also adopted a standard for maximum levels for fumonisins in corn and corn products at Step 8 and 5/8 in the eight-step Codex approval process.
- The Codex Committee on Contaminants in Foods (CCCF) put on hold its work on a new maximum limit (ML) for deoxynivalenol (DON) in raw cereal grains and infant formula. U.S. bakery, grains, and food processing groups expressed concerns about three potential standards: a 2 parts per million (ppm) ML for raw cereals prior to sorting and removal of damaged kernels; 0.2 ppm for cereal-based foods fed to infants and young children; and 1 ppm for the flour, semolina, meal and flakes. In addition, the CCCF has an electronic working group developing a code of practice for mycotoxins in spices.
- The Food and Agriculture Organization (FAO) recently developed a Mycotoxin Sampling Tool (<http://bit.ly/19zN8c3>) that can help a user develop sampling plans and quantify mycotoxin contamination in a range of food commodities.
- In July, USDA's Agricultural Marketing Service issued a final rule permitting the use of mechanical samplers ("auto-samplers") to obtain samples from pistachio lots for aflatoxin analysis as part of the agency's marketing order that regulates the handling of pistachios grown in California, Arizona, and

New Mexico. The use of auto samplers is expected to significantly reduce costs to growers.

Issues to Watch

- AFFI members should re-evaluate their food safety plans and consider whether they need to implement preventive controls or verification activities to address mycotoxins. In particular, AFFI members should consider whether any additional actions are needed for human food by-products rejected by the facility due to mycotoxin contamination that may be diverted to animal feed. Further, AFFI members should monitor FDA developments for any additional information or guidance from FDA regarding mycotoxins.
- AFFI members also should be alert to potential new performance standards addressing mycotoxin contamination.

International Perspective

- European Union (EU). Mycotoxins are regulated in the EU as food contaminants. Commission Regulation (EC) No 1881/2006 sets maximum levels for certain contaminants in foodstuffs (the "EU Contaminants Regulation") in the Annex to the Regulation.⁶ In particular, the maximum levels for various mycotoxins are found in Section 2 of the Annex to the EU Contaminants Regulation. It is unlawful to introduce into commerce foods that exceed the maximum contaminant levels.⁷
- Currently, the European Food Safety Authority (EFSA) is preparing the opinions on human and animal health risks related to the following mycotoxins: beauvericin and enniatins; moniliformin; and diacetoxyscirpenol. Should EFSA conclude that the scientific evidence available requires establishment of maximum levels for these mycotoxins, it will provide the European Commission with the relevant recommendation and the commission will then, most probably, follow up with a proposal for regulatory measures. Recent evaluation by EFSA of the scientific data on T-2 and HT-2 toxin, Alternaria toxins, Nivalenol, Citrinin, Sterigmatocystin and Phomopsins did not lead to establishment of maximum levels.
- Codex Alimentarius (Codex). Codex via the General Standard for Contaminants and Toxins in Food and Feed (Codex Standard 193-1995 as amended) currently provides recommendations regarding the maximum level and methods of sampling and control for aflatoxins, ochratoxin, and patulin. Codex also has issued several standards regarding the prevention of mycotoxins, which are gathered in a thematic compilation issued in 2012

⁶ See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1881:20121203:EN:PDF>

⁷ Provisions for methods of sampling and analysis for the official control of mycotoxins were introduced in Regulation (EC) 401/2006. See <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R0401-20100313&rid=1>.

entitled "Prevention and Reduction of Food and Feed Contamination."⁸ More recently, at the end of 2013, Codex adopted standards for the prevention and reduction of Ochratoxin A in Cocoa (CAC/RCP 72-2013) and of Hydrocyanic Acid in Cassava (CAC/RCP 73-2013).

AFFI Action Items

- Monitor FDA and Codex developments regarding levels for mycotoxins and measures to prevent contamination.

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