

Mycotoxin Control and Monitoring Program: All Hands on Deck

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- Views expressed in this presentation are those of the author and do not necessarily reflect the views or policies of the U.S. Food and Drug Administration

Overview

- FDA role in promoting and protecting consumer health
- FDA's mycotoxin compliance program
- FDA contribution to Codex mycotoxin activities
- Regulated industry role in fighting mycotoxins



FDA Authority:

Federal Food, Drug, and Cosmetic Act (FFDC Act)

- Section 201: Definitions
 - (f) the term food means (1) food or drink for man or animal (2) chewing gum (3) article used for components of (1) and (2)
- Section 301: Prohibited acts
 - (a) the introduction or delivery for introduction of any food, drug, device or cosmetic that is adulterated or misbranded in interstate commerce

FDA Authority

FFDC Act Section 402: A food shall be deemed to be adulterated

- (a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health
- (a)(2)(A) if it bears or contains **any added poisonous or added deleterious substance** (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe

21 CFR 109: Unavoidable Contaminants in Food

- Regulation issued under FFDC Act Section 406, 408 or 409
- 109.3(c) naturally occurring poisonous or deleterious substance
- 109.3(d) an added poisonous or deleterious substance
- 109.7: Unavoidability
 - (a) action levels based on unavoidability, do not established permissible level of contamination where it is avoidable
 - (b) Compliance with regulatory limits levels does not excuse failure to observe either the requirement that food may not be prepared, packed, or held under insanitary conditions (FFDC Act section 402(a)(4)) or that food manufacturers must observe current good manufacturing practices (21 CFR chapter 1)



FDA Office of Food and Veterinary Medicine

- Center for Food Safety and Applied Nutrition (CFSAN)
 - Responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.
- Center for Veterinary Medicine (CVM)
 - Responsible for protecting animal health by approving safe and effective products for animals and ensuring that animal foods are safe and wholesome

Strategic Plan to Control Mycotoxins

- Conducting science-based risk analysis
- Establishment of regulatory levels
- Monitoring susceptible commodities
- Taking appropriate enforcement action
- Working with other agencies on food safety
- Providing guidance to the food industry

FDA Regulatory Levels

- **Action Levels**

Informal guidelines for FDA field staff to determine when it may be necessary to take enforcement action against a product or establishment.

- **Advisory (Guidance) Levels**

Guidelines issued to food and feed industries to provide guidance concerning levels of a particular mycotoxin that is believed to provide an adequate margin of safety to protect human and animal health in the absence of definitive toxicological data.

Regulatory Levels Consideration

- Availability of analytical methodology
- Availability of occurrence data
- Availability of toxicological data
- The need to maintain an adequate food supply at reasonable cost
- Knowledge of legislation in other countries involved in international trade

FDA Mycotoxin Compliance Program

- Mycotoxins in Domestic and Imported Foods
 - <https://www.fda.gov/food/complianceenforcement/foodcomplianceprograms/default.htm>
- Objectives
 - To collect and analyze samples of food for mycotoxins of interest
 - To remove from interstate commerce those products that contain mycotoxins at levels judged to be of regulatory significance

Mycotoxins of Public Health Concern

Mycotoxin	Organism	Commodity
Aflatoxins	<i>aspergillus flavus</i>	Corn, peanuts, tree nuts, cottonseed, dairy products
Deoxynivalenol	<i>fusarium graminearum</i>	Corn
Fumonisin	<i>fusarium verticillioides</i>	Cereal grains
Patulin	<i>penicillium expansum</i>	Apples, apple products
Ochratoxin A	<i>aspergillus ochraceus</i>	Cereal grains, coffee and dried beans
Zearalenone	<i>fusarium graminearum</i>	Corn, wheat, barley, oats

Action Levels for Total Aflatoxins

Commodity	Level (ppb)
All products for humans, except milk	20
Aflatoxin M1 in fluid milk	0.5
Corn for immature animals, dairy cattle and all food for dairy animals	20
Corn and peanut products for breeding beef cattle, swine and mature poultry	100
Corn and peanut products for finishing swine	200
Corn and peanut products for finishing beef cattle and cottonseed meal (as an ingredient)	300

DON Advisory Levels

Commodity	Level(ppm)
Finished wheat products for human food use	1.0
Grain and Grain by-products (88% dry matter basis)	
<ul style="list-style-type: none"> • Total ration for ruminating beef and feedlot cattle older than 4 months • For chicken ($\leq 50\%$ diet) • Total ration for dairy cattle older than 4 months ($\leq 50\%$ diet) 	10
<ul style="list-style-type: none"> • For swine ($\leq 20\%$ diet) • For all other animals ($\leq 40\%$ diet) 	5.0

*30 ppm in distillers grains, brewers grains, gluten feeds derived from grains, and gluten meals: not to exceed 10 ppm in total ration for ruminating beef and feedlot cattle older than 4 months, and 5 ppm in total ration for ruminating dairy cattle older than 4 months

FDA Compliance Policy Guide on Blending

- Compliance policy guide (CPG) section 555.200
 - <https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuideManual/ucm074551.htm>
- Blending or mixing of adulterated food with good food is generally not permitted and the final product resulting from blending is unlawful, regardless of the level of the contaminant
- Exception: CVM may permit “blending” under special provisions

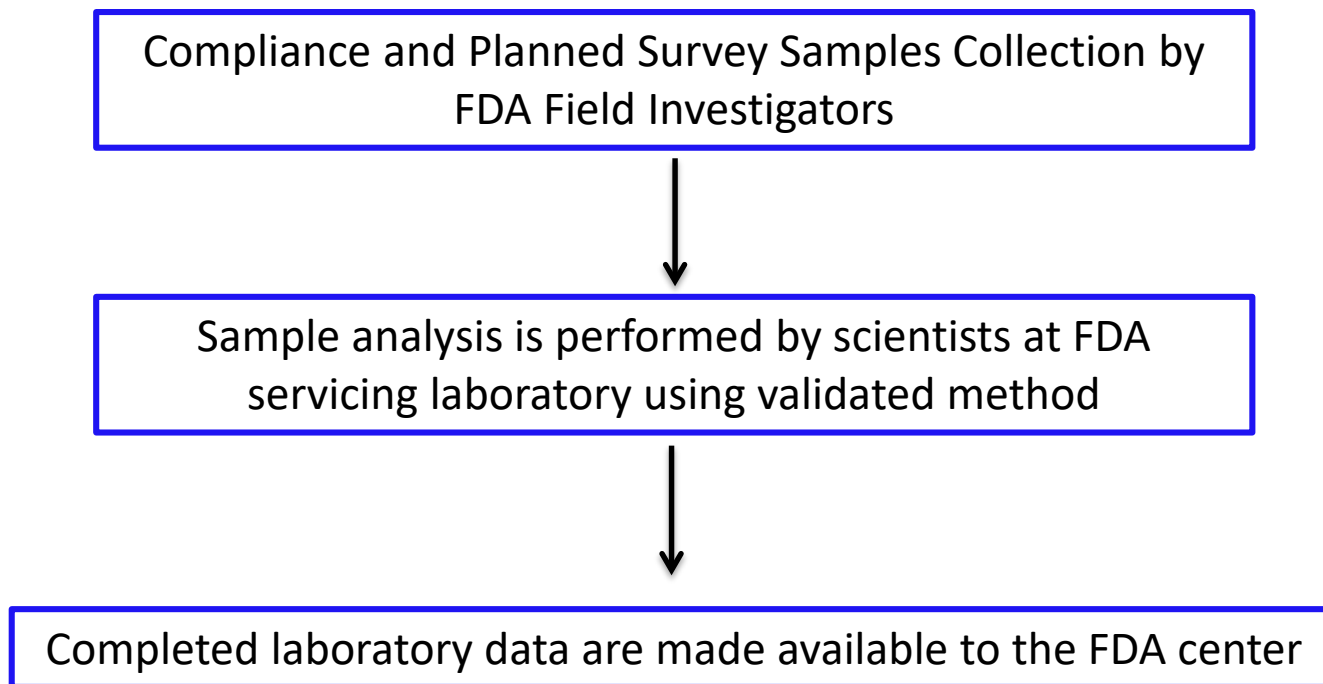
FDA Import Alerts for Mycotoxins

- IA-20-06: Detention Without Physical Examination of Apple Juice Products Due to Patulin
https://www.accessdata.fda.gov/cms_ia/importalert_57.html
- IA-23-14: Detention Without Physical Examination of Food Products due to the Presence of Aflatoxin
 - https://www.accessdata.fda.gov/cms_ia/importalert_581.html

FDA Compliance Program Procedures

- Objectives: Each FDA district assigned list of commodities and quota of domestic and import samples to collect each year
 - <http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm272937.htm>
 - 2000 domestic and imported samples planned annually
- Collected samples are analyzed in FDA laboratories
- Analytical results are reviewed for compliance with FDA regulation
- Enforcement procedures are initiated against firms with samples not in compliance

FDA Sampling Process



Uses of Compliance Program Data

- Estimates of the incidence and levels of mycotoxin contamination
- Dietary exposure data for conducting risk assessments
- Occurrence data for establishing action or guidance levels
- Information needed to support U.S. positions in international standard setting (e.g., Codex Alimentarius)

FDA Mycotoxin Analysis Methods

- Currently several validated methods of analysis for mycotoxins of interest on different platforms
- Implementation of multi-mycotoxins LC/MS/MS method
 - Based on isotope dilution
 - Allows for simultaneous analysis of currently regulated mycotoxins and others
 - Significant cost savings
 - Harmonization of platform

Codex Activities

- FDA heads U.S. Delegation to Codex Committee for Contaminants in Food (CCCF)
- Member of CCCF electronic working groups responsible for developing:
 - maximum levels for various contaminants including mycotoxins in foods
 - Code of practices for prevention and reduction of contaminants including mycotoxins in various food commodities
- FDA provides occurrence data upon request for Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluation

Codex Recommended Practices for Prevention and Reduction of Mycotoxin Contamination in Cereals

- Awareness of regional differences in fungi species and strains
- Understanding of correlation between weather condition and fungi growth
- Good agricultural practices
- Good manufacturing practices
- Analytical testing throughout the supply chain
- Use of seed free of toxigenic fungi

Codex Maximum Levels for DON in Foods

Commodity/Product Name	Maximum Level (ML) $\mu\text{g/g}$ (ppm)	Notes/Remarks
Cereal-based foods for infants and young children	0.2	All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months)
Flour, meal, semolina and flakes derived from wheat, maize or barley	1.0	
Cereal grains (wheat, maize and barley) destined for further processing	2.0	“Destined for further processing”: undergo an additional processing/treatment that has proven to reduce levels of DON

Regulated Industry Role in Mycotoxins Prevention

- Implementation of Good Agricultural Practices and Good Manufacturing Practices
- Sampling and testing throughout the value chain
- Awareness of FDA guidance and regulation
- Awareness of and participation in Codex activities

Prevention and Reduction of Mycotoxin Contamination in Cereals

Codex observation/recommendation	USWBSI Activities
Use of toxigenic fungi free seed	Release of resistance cultivars; avoidance of highly susceptible cultivars
Regional variation in weather condition	Multistate disease forecasting
Commitment to Don testing	Establishment and support for DON testing laboratories
Fungicides treatment	Development of a 14-State uniform fungicide evaluation network

US Wheat and Barley Scab Research Areas

- Fusarium head blight (FHB) Management
 - Research focusing on disease and mycotoxins management
- Food Safety and Toxicology
 - Focusing on obtaining better toxicology and analytical data
- Gene Discovery and Engineering Resistance
 - Working on improving current cultivar to avoid diseases
- Pathogen Biology and Genetics
 - Better understanding of pathogenic fungi

Conclusion

- FDA utilizes compliance programs in carrying out its responsibility of promoting and protecting the public health
- FDA continues to participate and provide data in support of mycotoxin activities at Codex
- Industry group such as US Wheat and Barley Scab Initiative continue to make contribution in combating food plant diseases
- Degree or potential for mycotoxin contamination remains unpredictable and therefore, all hands should remain on deck



Thank you