

U.S. FDA Compliance Program for Mycotoxins in Foods

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Overview

- FDA statutory authority
- Mycotoxins of regulatory interest
- FDA mycotoxin compliance program
 - Sample collection
 - Sample analysis
- FDA mycotoxin compliance program results
- Mycotoxins activities at Codex

FDA Authority

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

Sec. 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

FDA Authority

FFDC Act Sec. 406: Tolerances for poisonous or deleterious substances in food regulations

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or **cannot be avoided by good manufacturing practice** shall be deemed to be unsafe for purposes of the application of clause 402 (a)(2)(A); but when such substance is so required or **cannot be so avoided**, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe

Mycotoxins

- Secondary metabolites produced by certain fungi during growth in the field, processing, transport or storage
- Two types
 - Saprophytic: prefers stored grains
 - Pathogenic: attacks the plant in the field
- Occur naturally
- Low molecular weight
- Many are stable to heat and food processing procedures
- Various toxicological effects

Mycotoxins of Public Health Interest Concern in Food	Associated Mold	Susceptible Food
Aflatoxin: (B1, B2, G1, G2 and M1)	<i>Aspergillus</i>	Corn, peanuts, tree nuts, dairy products (only M1)
Patulin	<i>Penicillium</i> <i>Aspergillus</i>	Apple juice, apple juice products
Ochratoxin A	<i>Penicillium</i> <i>Aspergillus</i>	Wheat, barley, grapes, coffee, corn
Deoxynivalenol,	<i>Fusarium</i>	<i>Cereal</i>
Fumonisin (B1, B2 and B3)	<i>Fusarium</i>	Corn

- Factors that affect mold growth:
 - Nutrients, i.e. carbohydrate, protein, lipid
 - Moisture
 - Temperature
 - Oxygen

Aflatoxins

- Name derived from: **A**spergillus (**A**), **fl**avus (fla), and **to**xin
- *Aspergillus (A), flavus & Aspergillus parasiticus*
- Affect mostly peanuts, tree nuts, corn, oil seeds, spices and dairy products (B1, B2, G1, G2). M1 only in milk
- Stable to heat and processing procedures
- unavoidable food contaminants; Low levels are allowed
- Reduce intake risk by avoiding moldy, discolored or shriveled nuts.
- Bio-accumulates and associated with human liver cancer

Regulatory Limits 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 Action Levels

- 20 ppb: total aflatoxins (B1, B2, G1, G2) in all products, except milk
- 0.5 ppb: aflatoxin M1 in fluid milk
- 50 ppb: patulin in apple juice, apple juice concentrates, apple juice products

Guidance Levels

- Deoxynivalenol
 - 1 ppm deoxynivalenol in finished wheat products, e.g., flour, bran, germ
- Fumonisin
 - 2 ppm degermed dry milled corn products
 - 4 ppm whole or partially degermed dry milled corn products
 - 4 ppm dry milled corn bran
 - 4 ppm cleaned corn for masa production
 - 3 ppm cleaned corn intended for popcorn

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 and feed for mycotoxins

 - To remove from interstate commerce those products that contain mycotoxins at levels judged to be of regulatory significance

FDA Compliance Program Procedures

- Each FDA Field Division Office is assigned list of commodities and quota of domestic and import samples to collect each year
 - <http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/cm272937.htm>
 - 2000 domestic and imported samples planned annually
- Collected samples are analyzed in FDA laboratories
- Analytical results are reviewed for compliance with FDA regulatory limits
- Enforcement procedures are initiated against firms with samples not in compliance on a case by case basis

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 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 mycotoxin analysis methods

- Currently mycotoxin are individually analyzed
- Several validated methods of analysis on different platforms
- Implementation of isotope dilution LC/MS/MS method

Future FDA mycotoxin analysis methods

- Multi-mycotoxins method
 - Based on isotope dilution
 - Allows for simultaneous analysis of currently regulated mycotoxins and others
 - Significant cost savings
 - Harmonization of platform

Sampling Process

Compliance and Planned Survey Samples Collection by
FDA Field Investigators

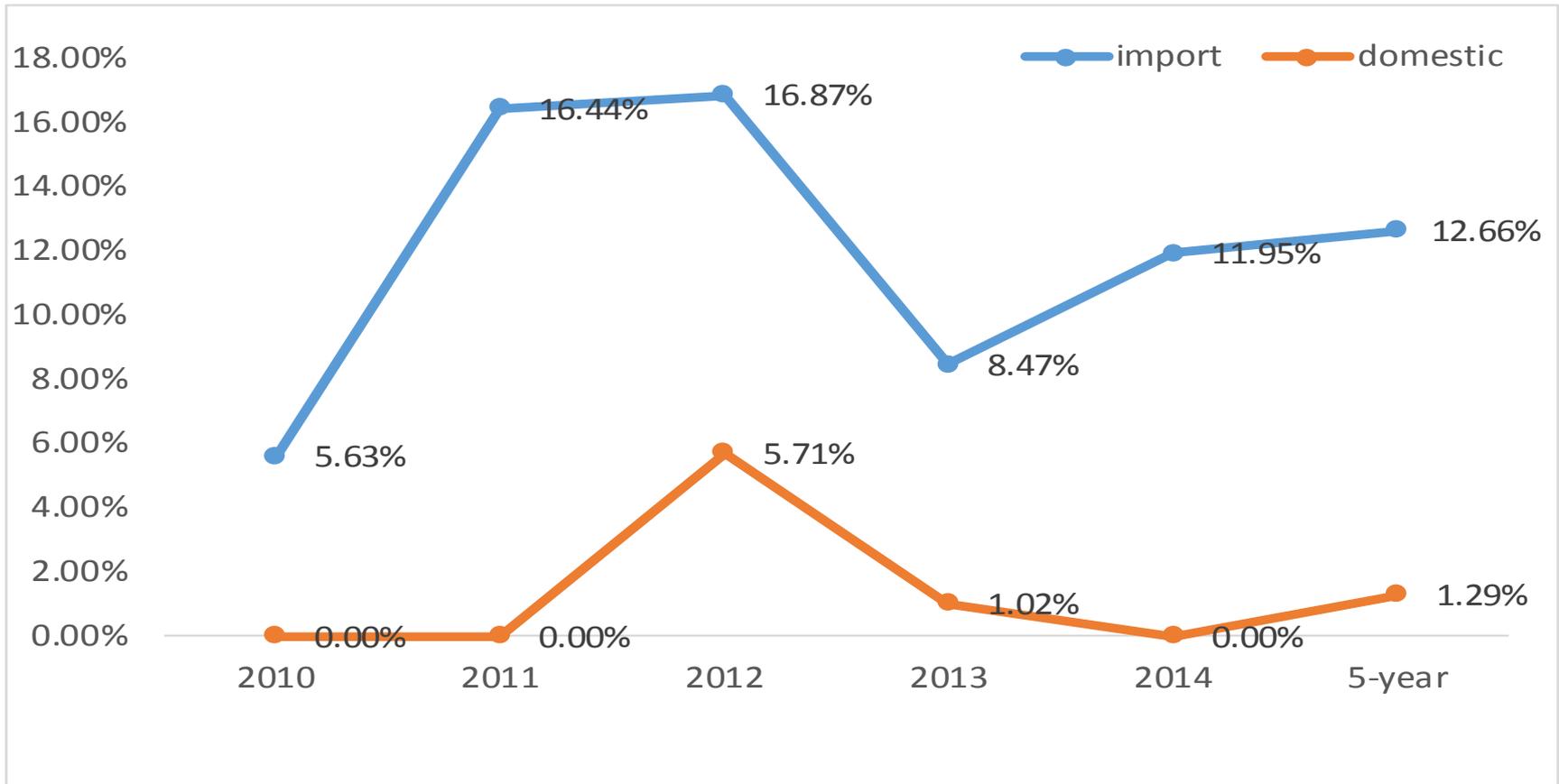


Sample analysis is performed by scientists at FDA serving
laboratory using validated method



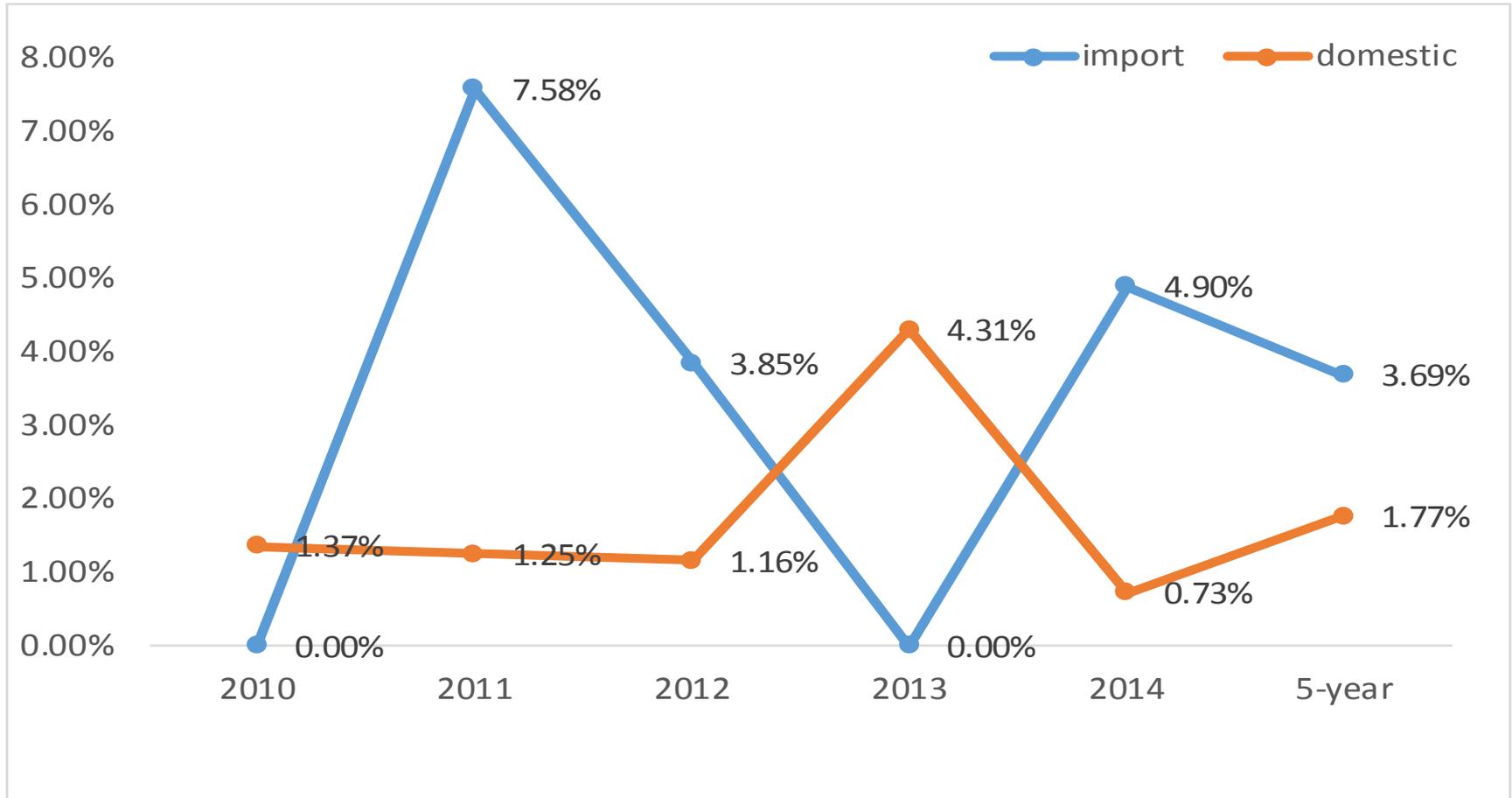
Completed laboratory data is made available to the FDA Center Offices

Aflatoxins in peanuts



- Violation rate for domestic peanut products is generally lower than import peanut products
- Higher violation rate for domestic peanut products in 2012
- Higher violation rate for import peanut products in 2011, 2012 and 2014 (violation greater than 10%)

Aflatoxins in Corn



- Total violation rate is higher for import corn products
- Higher violation rate domestic corn products in 2013
- Higher violation rate for import corn products in 2011

Codex Activities

- FDA actively participates in the activities of 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 mycotoxins in various food commodities
- FDA provides occurrence data upon request for Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluation

Conclusion

- FDA utilizes compliance programs in carrying out its responsibility of promoting and protecting the public health
- Steps are being taken to update mycotoxins methods of analysis
- Import products continue to have higher rate of violation than domestic products
- Degree or potential for mycotoxin contamination remains unpredictable
- FDA continues to participate and provide data in support of Codex activities

Acknowledgement

Special Thank You To

- FDA Field Investigators and Scientists
 - CFSAN Office of Compliance
 - CFSAN Office of Regulatory Science
- CFSAN Office of Analytics and Outreach

For supporting the mycotoxin compliance program



Thank you for your interest.

Any questions?