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Compliance Policy Guide

Sec. 555.400 Aflatoxins in Human Food: Guidance for FDA Staff

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-0721 listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, contact the Center for Food Safety and Applied Nutrition (CFSAN), Office of Compliance at CFSANCompliancePolicy@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
and
Office of Regulatory Affairs**

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Sec. 555.400 Aflatoxins in Human Food:

Guidance for FDA Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

***I. Introduction**

The purpose of this document is to provide guidance for FDA staff on aflatoxins in human food. We revised this document to update the format and to include revisions for clarity, references to other aflatoxin Compliance Policy Guides (CPGs), and a reference to the Memorandum of Understanding between the Agricultural Marketing Service (AMS) of the United States Department of Agriculture (USDA) and FDA.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. Background

Aflatoxins (B1, B2, G1, and G2) are toxic metabolites produced by the molds *Aspergillus flavus*, *Aspergillus nomius*, and *Aspergillus parasiticus*. Toxicological manifestations of aflatoxins include teratogenicity, mutagenicity, and carcinogenicity in susceptible animal species. Consumption of food with high levels of aflatoxins is associated with liver cancer in humans. Aflatoxins may occur in food as a result of mold growth in susceptible raw agricultural commodities. The growth of molds that produce aflatoxins is influenced by environmental factors such as temperature, humidity, and extent of rainfall during the pre-harvesting, harvesting, or post-harvesting periods. Foods most susceptible to molds that produce aflatoxins include: peanuts, corn, some tree nuts including Brazil nuts and pistachios, and some small

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grains such as rice. Because aflatoxins are known carcinogens to humans, the presence of aflatoxins in foods should be reduced to the lowest levels attainable using modern agricultural and processing techniques.

III. Policy

Aflatoxins are poisonous or deleterious substances, which may render a food injurious to health. FDA may consider human food containing total aflatoxins greater than 20 micrograms per kilogram (mcg/kg) or parts per billion (ppb) to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1)).

IV. Regulatory Action Guidance

The following represents the criteria for submitting a recommendation for seizure or a recommendation that the article is subject to import refusal to CFSAN, Office of Compliance, Division of Enforcement (HFS-605), for aflatoxins in human food, except Brazil nuts, peanuts and peanut products, and pistachio nuts:

- Both original and check analyses show total aflatoxins (i.e., aflatoxins B1, B2, G1, G2) greater than 20 ppb, and
- Identity of any aflatoxin present (i.e., aflatoxins B1, B2, G1, G2) is confirmed.

Divisions should include a detention without physical examination (DWPE) request, if applicable, in the recommendation that the article is subject to import refusal.

CFSAN will evaluate such requests and recommendations on a case-by-case basis, based on the information specific to each regulatory package.

See the following CPGs for guidance on aflatoxins in Brazil nuts, peanuts and peanut products, and pistachio nuts:

- [CPG Sec. 570.200 Aflatoxins in Brazil Nuts](#)
- [CPG Sec. 570.375 Aflatoxins in Peanuts and Peanut Products](#)
- [CPG Sec. 570.500 Aflatoxins in Pistachio Nuts](#)

Coordination with USDA/AMS

See the Memorandum of Understanding ([MOU-225-19-031](#)) between USDA/AMS and FDA for information regarding working arrangements for sampling and analyzing raw peanuts, Brazil nuts, and pistachio nuts for aflatoxins.

V. Specimen Charges

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Domestic Seizure

The article of food was adulterated when introduced into, and while in interstate commerce, and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.*

Material between asterisks is new or revised

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