

CPG Sec. 570.375 Aflatoxin in Peanuts and Peanut Products

BACKGROUND:

The FDA program activity involving aflatoxin in domestic peanut products is directed toward products intended for direct consumption and not raw peanut products. The USDA has a comprehensive program involving raw peanuts which can be expected to result in proper processing or destruction of any high aflatoxin raw peanuts. The USDA will provide FDA with a copy of the certificate of analysis and the name of the applicant for each lot found to exceed 25 ppb aflatoxin *(MOU, FDA 225-96-2001)*.

Also, some *Field Offices within the Human and Animal Food Program* have been detaining shipments of U.S. raw peanuts returned from Canada because Canadian officials had found them to contain aflatoxin in excess of the Canadian limit.

POLICY:

The FDA offers no objection to the shipment of peanuts over the 25 ppb level for aflatoxin to processors if facilities are available to remove moldy or otherwise defective nuts from the lot before incorporation into the finished product.

Lots of raw peanuts which have been shipped to processors containing aflatoxin above 25 ppb level may be subject to appropriate action in cases where there is a lack of assurance that the finished product will comply with the current action level.

Raw peanuts, returned to the U.S. after export, should not be detained because of aflatoxin contamination. However, districts that learn of U.S. raw peanuts being returned should so inform Mr. J.S. Miller, Assistant Chief, Specialty Crops Branch, USDA/AMS, Independence Avenue, Washington, D.C. (202-447-5697) to make certain that USDA is aware of the return.

REGULATORY ACTION GUIDANCE:

The following represents the criteria for recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

Analyze nuts in accordance with applicable methods outlined in the current edition of the Official Methods of Analysis of the Association of the Official Analytical Chemists and supplements (at the time of this transmittal, Twelfth Edition sections 26.014-26.019 and 26.A17).

Recommend legal action where the following conditions are met:

1. Original and check analysis shows aflatoxin above 20 mcgs/kg;

and

2. Identity of aflatoxin B1 is confirmed by chemical derivative.

REMARKS:

Raw peanuts which have been sampled by USDA should not be sampled routinely on an objective basis. However, sampling and appropriate follow-up is indicated when lots of raw peanuts are reported by USDA certificate of analysis as exceeding 25 micrograms of aflatoxin per kilogram, and when such peanuts are destined for processors that do not have facilities and procedures to remove defective nuts, and there is no assurance that the finished products will be below the 20 mcgs/kg guideline.

The above guideline criteria do not preclude recommending action at lower than 20 mcgs/kg levels of aflatoxin in the finished product where there are inadequate control and sorting procedures, or deliberate attempts to dilute aflatoxin containing lots.

NOTE: The reserve sample must be of sufficient size to provide for the chick embryo test should it become necessary.

Material between asterisks is new or revised

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