CPG Sec. 570.200 Brazil Nuts - Adulteration with Aflatoxin

REGULATORY ACTION GUIDANCE:

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

The entire sample of nuts (20-60 lbs.) is cracked out and the obviously inedible nuts discarded. The remaining moldy and non-moldy nuts are composited and the well-mixed sample analyzed in accordance with applicable methods of the current Official Methods of Analysis of the Association of Official Analytical Chemists, (at the time of this transmittal) Thirteenth Edition, sections 26.026-26.031 or 26.032-26.036 and 26.083.

Recommend legal action where the following analytical conditions are met:

1. Original and check analysis show aflatoxin above 20 mcg/kg

and

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

REMARKS:

The Department of Agriculture, importers of Brazil nuts, and FDA carry out a total coverage analysis program on imported Brazil nuts *(MOU, FDA 225-96-2002).* This program should preclude sampling by the Field Offices on an objective basis.

RECONDITIONING OF BRAZIL NUTS:

Collect sample from the lot using the same sampling scheme used for the original sample collection. Crack-out 1000 nuts drawn representatively from the sample. Discard obviously inedible nuts. Combine the moldy and non-moldy nuts into a single composite and analyze for aflatoxins. Release reconditioned lot when the aflatoxin content of the composited nuts does not exceed 5 mcgs/kg, currently the limit of detectability of the methodology. For a reconditioned lot found to contain aflatoxin above 20 mcgs/kg, the analytical conditions specified above for recommending legal action are to be met. When the aflatoxin content falls between 5 and 20 mcgs/kg, contact CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) for further guidance.

*Material between asterisks is new or revised*
Issued: 8/1/83
Revised: 3/95, 5/2005
Updated: 11/29/05