

CPG Sec. 570.450 Tree Nuts - Adulteration with Filth, Involving the Presence of the Organism Escherichia coli

REGULATORY ACTION GUIDANCE:

1. The following represents the criteria for recommending direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFo) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

Nut Meats

When Escherichia coli MPN of at least 0.36 per gram (IMVIC confirmed) is found in 2 or more subsamples, if less than 10 samples examined, or in 20% or more of the subsamples if more than 10 subsamples examined, and no inspectional evidence is available to indicate the most probable source of the Escherichia coli.

SPECIMEN CHARGE:

The article was adulterated when introduced into, while in, and is adulterated while held for sale after shipment in interstate commerce, within the meaning of said Act 21 U.S.C. 342(a)(4) in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.

NOTES:

- a. If the evidence establishes that the article became adulterated after receipt in interstate commerce, then charge only that the article "is adulterated while held for sale after shipment in interstate commerce."
- b. If the evidence does not establish where the article became adulterated and the violation is such that it could have occurred anywhere, i.e. it is not a manufacturing defect, then also charge only that the article "is adulterated while held for sale after shipment in interstate commerce."
- c. Use direct citation authority only when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

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

Nut Meats

When *Escherichia coli* MPN of at least 0.36 per gram (IMVIC confirmed) is found in one or more subsamples, and inspectional evidence is available which would indicate the most probable source of the *Escherichia coli*.

Cases referred to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) will be reviewed to determine if a 21 U.S.C. 342(a)(3) charge can be supported.

Material between asterisks is new or revised.

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