

CPG Sec. 570.425 Tree Nuts - Adulteration Involving Rejects (Insect Infestation, Moldy, Rancid, Otherwise Decomposed, Blanks, and Shriveled)

This guidance document represents the Agency's current thinking on its enforcement process concerning the adulteration of tree nuts involving rejects (insect infestation, moldy, rancid, otherwise decomposed, blanks, and shriveled). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

REGULATORY ACTION GUIDANCE:

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*:

1. Nuts in-shell and shelled nuts

	Percentage Rejects	
	In-shell	Shelled
Almonds	5	5
Brazils	10	5
Cashews	--	5
Green chestnuts	15	--
Baked chestnuts	10	--
Dried chestnuts	--	5
Filberts	10	5
Pecans	10	5

	Percentage Rejects	
	In-shell	Shelled
Pistachios	10	5
Walnuts	10	5
Lichee nuts	15	--
Pili nuts	15	10

2. Mixed nuts in-shell

Separate each variety and recommend seizure of lot if the percentage of rejects for any variety is greater than the action level for that individual variety.

Where insect infestation is involved, the above action levels are for orchard type infestation.

Determination of reject in-shell and shelled nuts is done using the appropriate sequential sampling plans in Macroanalytical Procedures Manual 10.A.(4)a and b, and 10.A.(5)a and b.

REMARKS:

Seizure based on reject findings involving these products must be discussed with the U.S. Department of Agriculture. Therefore, submit the following information *by e-mail* or FAX to the CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number

Date of Shipment

Article Involved

Dealer

Amount of Lot

Shipper

Codes

Analytical Conclusions

SPECIMEN CHARGES:

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)(3) in that it consists in part of a filthy substance by reason of the presence therein of insects; of a decomposed substance by reason of the presence therein of moldy, rancid, or otherwise decomposed nuts; and in that it is otherwise unfit for food by reason of the presence therein of blanks or shriveled nuts.

NOTES:

1. 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."
2. 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."
3. 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.

Material between asterisks is new or revised.

Issued: 11/07/79

Reissued: 10/1/80

Revised: 12/2/88, 3/95, 5/2005

Updated: 11/29/05