

# CPG Sec. 580.100 Food Storage and Warehousing-Adulteration-Filth (Domestic and Import)

## REGULATORY ACTION GUIDANCE - DOMESTIC:

The following represents criteria for 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 of foods for human consumption if the foods are not reconditioned by sampling, when one of the following conditions is met:

NOTE: Refer to Sec. 690.600 (for CPG 7126.38) for guidance regarding rodent contamination of pet food. All animal food cases involving insect, rodent or bird 402(a)(3), or 402(a)(4) contamination should be referred to Division of Compliance, CVM (HFV-236) for concurrence.

### A. Rodent Contamination

#### 1. The storage facility is rodent infested and:

- a. Three or more of the bags in the lot are rodent gnawed;

or

- b. At least five of the bags in the lot bear either rodent urine stains at least 1/4 inch in diameter, or two or more rodent pellets;

or

- c. The food in at least one container in the lot contains rodent-gnawed material, or rodent excreta or urine.

#### 2. Whether or not the warehouse is rodent infested,

- a. At least three bags bear rodent urine stains of at least 1/4 inch diameter which penetrate to the product even though the product cannot be demonstrated to have been contaminated;

or

- b. At least two bags are rodent gnawed and at least five bags bear either rodent urine stains at least 1/4 inch in diameter, with or without penetration to the product, or two or more rodent pellets;

or

- c. The food in at least one bag in the lot contains rodent-gnawed material or rodent excreta or rodent urine, and at least five bags bear either rodent urine stains at least 1/4 inch in diameter or two or more rodent pellets.

B. Insect Contamination

C. NOTE: The criteria involving dead insects only should not be used to seize any food if the food will undergo further processing which will effectively remove all the dead insects present (For example: cocoa beans).

1. The product contains:

- a. One live insect in each of two or more immediate containers; or, one dead insect in each of three or more immediate containers; or, three live or dead insects in one immediate container;

plus

- b. Similar live or dead insect infestation present on, or in the immediate proximity of, the lot to clearly support a charge under Section 402(a)(4).

or

2. The product contains one or more live insects in each of three or more immediate containers.

or

3. The product contains two or more dead whole insects in at least five of the immediate containers. NOTE: This situation may follow fumigation and vacuuming of the exteriors of the bags of a lot.

or

4. The product is in cloth or burlap bags and two or more live or dead insects are present on at least five of the containers.
5. NOTE: Some live insects must be present. Product need not be shown to have become contaminated.

D. Bird Contamination

E. If product is in permeable containers (paper, cloth, burlap, etc.), and

1. The product contains bird excreta in one or more containers, and the insanitary storage conditions clearly support a charge under Section 402(a)(4);

or

2. Bird excreta is present on the exteriors of at least five of the containers, and the product contains bird excreta in one;

or

3. At least 30% of the number of the bags examined, but at least five bags, are contaminated with bird excreta; and at least three of the bags bear excreta stains which penetrate to the product, even though the product cannot be demonstrated by chemical analysis to have been contaminated.

NOTE: Bird excreta must in all instances be confirmed by positive test for uric acid.

**REMARKS:**

When the evidence clearly shows contamination after receipt in interstate commerce, and a 342(a)(4) charge is made, insert the following sentence at the end of the "Examination shows ..." paragraph:

"The evidence does not show article was adulterated when introduced into interstate commerce." If there is doubt whether the adulteration occurred before or after shipment, omit this sentence but still charge that the article was adulterated while held for sale after shipment in interstate commerce. If the evidence shows that rodents have gnawed through all layers of some of the bags and into the food, charge 342(a)(3), as shown in the attached specimen charge. If the gnawing is not shown to be all the way through the bags, then show in the Examination paragraph that the article is held in rodent-gnawed bags and charge under 342(a)(4) only. Likewise, if rodent urine, rodent excreta pellets, bird excreta or insects are observed in the food itself, charge 342(a)(3). If they are observed on the outsides of the bags but cannot be found in the food, show in the Examination paragraph that the article is held in bags contaminated with rodent urine, rodent pellets or bird excreta, or in insect-infested bags, and charge under 342(a)(4) only.

**SPECIMEN CHARGE:**

Article adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C., as follows:

- 342(a)(3) in that it consists in part of a filthy substance by reason of the presence therein of rodent urine and rodent excreta pellets;

and

- 342(a)(4) in that it has been held under insanitary conditions whereby it may have become contaminated with filth.

or

Article adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(4) in that it has been held under insanitary conditions whereby it may have become contaminated with filth.

#### CRITERIA FOR PROSECUTION:

NOTE: This authority is delegated to the appropriate Program Division Director or in his absence to the authorized Acting Director and may not be re-delegated.

1. The inspection or inspections on which the prosecution recommendation is based shows substantial insect, rodent or bird infestation of the warehouse;

and

2. Samples of lots from at least two different interstate shippers are found to contain insects, bird excreta, rodent gnawed food, rodent excreta, or rodent urine in the food itself. This does not mean one insect infested lot and one rodent infested lot. If the area is rodent infested there must be two rodent infested lots; if bird infested, two bird infested lots; or if insect infested, two insect infested lots. On insect infested lots, there must be insects of the same species in both lots;

and

3. At least one responsible individual is included in the prosecution recommendation;

and

4. There is substantial evidence to show that each individual included in the prosecution recommendation has authority to prevent or correct violative conditions found;

and

5. There is a background showing prior notification of the firm and all individuals included in the prosecution recommendation for similar insanitary conditions prior to the last inspection on which the prosecution is based.

#### REMARKS:

If the firm or any individual included in the prosecution recommendation has been previously prosecuted for violation of the Federal Food, Drug, and Cosmetic Act, a second offense must be charged (by indictment) if the case is referred directly to General Counsel. If the field office

thinks a second offense should not be charged the case should not be referred to General Counsel but should be forwarded to CFSAN/Office of \*Compliance\*/Division of Enforcement (HFS-605) in the usual manner.

There will, of course, be cases which do not meet the above criteria but which will warrant prosecution. In such cases, if the field office thinks prosecution is warranted, forward all information to CFSAN/Office of \*Compliance\*/Division of Enforcement (HFS-605) by the usual procedure for recommending prosecution.

#### REGULATORY ACTION GUIDANCE - IMPORT:

Detain import foods on the basis of the domestic criteria in this guideline only when associated with insanitary storage conditions on the dock, except for live insects.

NOTE: Mites, aphids, psocids, and thrips must be reported separately from usual storage insect contamination and are not applicable to this CPG.

#### *Live Insect Contamination*

Detain whether or not the present storage facility is insect infested if the product contains:

1. One live insect in each of two or more immediate containers;

or

2. Three live insects in one immediate container.

NOTE: Where there are insanitary storage conditions on the dock or live infestation in or on the product, disregard any existing DAL or other guidelines level for the product. When field insect filth (other than live insects) is found in a product, use the defect action levels (DALs) to determine whether or not to detain the shipment. If there is no applicable DAL for the specific product in question or the evidence suggests stored product insect filth, facsimile worksheets to CFSAN/Office of \*Compliance\*/Division of Enforcement (HFS-605) to determine if detention action should be taken.

\*Material between asterisks is new or revised\*

Issued: 10/1/80

Revised: 7/1/83, 3/1/86, 3/95, 8/96, 5/2005

Updated: 11/29/05