REGULATORY ACTION GUIDANCE:

1. The following represents the 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*:

Whole Pepper

   a. Insect Filth and Mold

   The pepper contains an average of 1% or more insect infested and/or moldy pieces by weight.

   or

   b. Mammalian Excreta

   The pepper contains an average of 1 milligram or more of mammalian excreta per pound.

   or

   c. Foreign Matter

   The pepper contains an average of 1% or more pickings and siftings by weight.

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

Ground Pepper

   a. Insect Filth

   The ground pepper in six or more subsamples contains an average of 475 or more insect fragments per 50 grams.

   or

   b. Rodent Filth
The ground pepper in six or more subsamples contains an average of 2 or more rodent hair fragments per 50 grams.

REMARKS:

Since the majority of spices are imported, determine that the lot in question has not been previously examined and released by FDA as an import. If the lot has been examined and released previously, submit all available facts to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) for seizure consideration in the usual manner.

SPECIMEN CHARGE:

Article (whole/ground pepper) adulterated (when introduced into and while in interstate commerce) (while held for sale after shipment in interstate commerce), within meaning of 21 U.S.C. 342(a)(3), in that it consists wholly or in part of a filthy substance by reason of presence therein of (insects), (insect webbing), (insect excreta), (insect fragments), (insect damaged pepper), and (mammalian excreta), (rodent hairs); and that it consists in part of a decomposed substance by reason of presence therein of (moldy, decomposed pepper); and is unfit for food by reason of presence therein of (stones), (clay), and (sand); or 342(b)(2) in that (stones), (clay), and (sand) have been substituted wholly or in part for (whole/ground) pepper.

*Material between asterisks is new or revised.*

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