

SECTION 555.425 -Foods - Adulteration Involving Hard or Sharp Foreign Objects

BACKGROUND:

Hard or sharp foreign objects in food may cause traumatic injury including laceration and perforation of tissues of the mouth, tongue, throat, stomach and intestine as well as damage to the teeth and gums. From 1972 through 1997, the FDA Health Hazard Evaluation Board evaluated approximately 190 cases of hard or sharp foreign objects in food. These include cases of both injury and non-injury reported to FDA. The Board found that foreign objects that are less than 7 mm, maximum dimension, rarely cause trauma or serious injury except in special risk groups such as infants, surgery patients, and the elderly. The scientific and clinical literature supports this conclusion.

Hard or sharp natural components of a food (e.g. bones in seafood, shell in nut products) are unlikely to cause injury because of awareness on the part of the consumer that the component is a natural and intrinsic component of a particular product. The exception occurs when the food="s" label represents that the hard or sharp component has been removed from the food, e.g., pitted olives. The presence of the naturally occurring hard or sharp object in those situations (e.g., pit fragments in pitted olives) is unexpected and may cause injury. FDA has established Defect Action Levels for many of these types of unavoidable defects in other Compliance Policy Guides and therefore they are not subject to the guidance in this document.

REGULATORY ACTION GUIDANCE:

The following represent the criteria for direct reference seizure to the Division of Compliance Management and Operations (HFC-210) and direct reference import detention to the districts.

- a. The product contains a hard or sharp foreign object that measures 7 mm to 25 mm, in length.

and

- b. The product is ready-to-eat, or according to instructions or other guidance or requirements, it requires only minimal preparation steps, e.g., heating, that would not eliminate, invalidate, or neutralize the hazard prior to consumption.

Samples found to contain foreign objects that meet criteria a. and b., above should be considered adulterated within the meaning of 21 U.S.C. 342(a)(1).

The following represent the criteria for recommending legal action to CFSAN Office of *Compliance, Division of Enforcement* (HFS-605).

- c. The product contains a hard or sharp foreign object that measures 7 mm to 25 mm in length, and the product requires additional preparation or processing that may have an effect on the presence of the foreign objects in the finished food. For

example, additional sifting of a product may or may not remove foreign objects, depending on the measurements of the objects and the mesh aperture of the sifter. In these situations, the preparation or processing of the food must be described in the recommendation submitted by the District.

or

- d. The product contains a hard or sharp foreign object less than 7 mm in length and if a special-risk group, as defined in the background section, is among the intended consumers of the product.

or

- e. The product contains a hard or sharp foreign object over 25 mm in length.

A sample found to contain a foreign object that meets criterion c., d., or e., above should be considered adulterated within the meaning of 21 U.S.C. 342(a)(1) if a health hazard is established by CFSAN review. The CFSAN health hazard review in this case will consider various factors including the intended use of the product, subsequent processing steps, official guidance and requirements concerning unavoidable natural defects, and other mitigating factors that could eliminate, invalidate or neutralize the hazard prior to consumption of the food product.