

CPG Sec. 545.400 Pottery (Ceramics); Import and Domestic - Cadmium Contamination

BACKGROUND:

Imported and domestic ceramic ware has been found to have significant quantities of extractable cadmium. The metal is extractable by acid foods and could cause chronic cadmium poisoning under continued food use.

REGULATORY ACTION GUIDANCE:

The following criteria should be considered when deciding to recommend legal action or to detain imports to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

The article:

1. Is suitable to be used for liquid foods,

and

2. Contains upon examination of 6 units a level of cadmium per mL of leaching solution exceeding the guideline for the category specified as examined by the current editions of ASTM method C738 (volume 15.02, Annual Book of ASTM Standards, American Society for Testing and Materials), AOAC methods 973.32 and 973.82 (Official Methods of Analysis, AOAC International), or FDA Laboratory Information Bulletin Numbers 4123 and 4126 (US Food and Drug Administration, *Office of Regulatory Science*, Rockville, MD 20857).

Category	Criteria	Guidelines micrograms/mL
Flatware	Average of 6 units	0.5
Small Hollowware	any one of 6 units	0.5
Large Hollowware	any one of 6 units	0.25

The categories of ceramic articles, flatware and hollowware used in the preparation, serving or storage of food, are defined as follows:

Flatware: ceramic articles which have an internal depth, as measured from the lowest point to the horizontal plane passing through the upper rim, that does not exceed 25 mm.

Hollowware: ceramic articles having an internal depth, as measured from the lowest point to the horizontal plane passing through the upper rim, greater than 25 mm.

Small hollowware: a capacity of less than 1.1 liter.

Large hollowware: a capacity of 1.1 liter or more.

NOTE: The article may be considered unsuitable for food use if:

1. It is rendered unsuitable by some method such as boring holes through the potential food contact surface;

or

2. A label, incapable of obliteration, is permanently affixed to the back or base of the article; and such label states: "Not for Food Use - Article May Poison Food."

SPECIMEN CHARGE:

Article (Flatware)(Hollowware) adulterated (when introduced into and while in interstate commerce)(while held for sale after shipment in interstate commerce), within meaning of Section 402(a)(2)(C) of the Federal Food, Drug and Cosmetic Act in that it contains a food additive, namely cadmium, which is unsafe within the meaning of Section 409(a) because its use and intended use are not in conformity with a regulation or exemption established pursuant to Section 409.

REMARKS:

If all lots in an entry were sampled using an invoice on a line by line basis, detain only those lots meeting the above criteria.

If only one lot (line item) was sampled and meets the above criteria, the entire entry may be detained without further analysis.

RELEASE OF IMPORT DETENTIONS:

Upon analysis or other examination by the importer to demonstrate suitability for release, the articles may be released on a lot by lot basis with checks by the appropriate ORA laboratory to

determine compliance.

Release may be based on labeling of the article as for other than food use when:

1. The article is rendered unsuitable for food use;

or

2. A label is permanently affixed to the back or base of the article that is incapable of obliteration or removal and states: "Not for Food Use - Article May Poison Food."

Release based on any other labeling conditions must have prior clearance of the CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605).

EXEMPTION:

Non-food service plates will not be required to meet the guideline for dinnerware. These include, but are not necessarily limited to, the following types of plates manufactured solely for ornamental display purposes: commemorative plates, souvenir plates, hand-painted plates, and other highly decorated plates, provided that they do not come in place settings for the table and provided further that there is a permanent label on the back or base of the plate stating, "Not for Food Use - Article May Poison Food," or a hole is bored through the food contact surface.

Material between asterisks is new or revised.

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