

CPG Sec. 545.450 Pottery (Ceramics); Import and Domestic - Lead Contamination

BACKGROUND:

Some ceramic foodwares have been found to leach significant quantities of lead from potential food contact surfaces. The metal is extractable by foods and can cause a wide variety of adverse health effects including the traditional effects of chronic lead poisoning under continued food use.

REGULATORY ACTION GUIDANCE:

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

The article:

1. Is suitable for use with foods, and
2. Contains upon examination of 6 units a level of lead per mL of leaching solution exceeding the guideline by 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	3.0
Small Hollowware other than cups and mugs	any one of 6 units	2.0
Cups/mugs	any one of 6 units	0.5
Large Hollowware other than pitchers	any one of 6 units	1.0
Pitchers	any one of 6 units	0.5

The categories of ceramic articles 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 which have an internal depth 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.

Cups and mugs: small ceramic hollowware vessels commonly used for consumption of beverages, for example, coffee or tea at above room temperature. Cups and mugs normally, but not exclusively, have a capacity of about 240 mL or 8 fl. oz. and are manufactured with a handle. Cups normally have a base and curved sides while a mug has cylindrical sides.

Pitchers: large ceramic hollowware vessels (sometimes known as jugs) commonly used for the storage and dispensing of fruit and vegetable juices or other acidic beverages at or below room temperature which are normally manufactured without a lid but with a handle and lip spout. For the purpose of this guideline, creamers, coffeepots, and teapots are not considered to be pitchers. Depending on capacity, creamers, coffeepots and teapots will be considered small or large hollowware.

NOTE: In accordance with 21 CFR 109.16(b), the article will be considered unsuitable for food use if:

1. It bears:
 - a. A conspicuous stick-on label on a surface clearly visible to consumers that states in legible script in letters at least 3.2 mm (0.125 inches) in height one of the following messages: "Not for Food Use. May Poison Food," "Not for Food-Use. Glaze contains lead. Food Use May Result in Lead Poisoning," or "Not for Food Use -Food Consumed from this Vessel [Plate] May be Harmful," and
 - b. A conspicuous and legible permanent statement of the message selected from the above paragraph molded or fired onto the exterior surface of the base or, when the ceramicware is not fired after decoration, permanently painted onto the exterior surface of the base. This permanent statement is in letters at least 3.2 mm (0.125 inches) in height;

or

2. A hole is bored through the potential food-contact surface.

SPECIMEN CHARGE:

Article (Flatware) (Hollowware) (Cups and Mugs) (Pitchers) 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 lead, 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 the article for other than food use in compliance with 21 CFR 109.16(b).

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 guidelines for dinnerware. These include, but are not necessarily limited to, the following types of articles manufactured solely for ornamental display purposes: commemorative plates, souvenir plates, hand-painted plates, and other highly decorated plates, provided the article is in compliance with 21 CFR 109.16(b).

*Material between asterisks is new or revised *

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