

# CPG Sec. 545.500 Silver-Plated Hollowware - Lead Contamination

## BACKGROUND:

Imported and domestic silver-plated hollowware have been found to contain significant quantities of leachable lead. The metal is extractable by acid foods and could cause chronic heavy metal poisoning under continued food use.

## REGULATORY ACTION GUIDANCE:

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

## IMPORTS:

The article:

1. (Unless exempted as defined below) is normally used to hold liquid or liquid type foods for storage or is used repeatedly to hold such foods;

and

2. If intended for use by adults, it releases in 6 units examined an average of seven or more micrograms lead/ml. of leaching solution.

or

3. If intended exclusively for use by infants and children, it releases in one or more of 6 units examined 0.5 or more micrograms lead/ml of leaching solution as determined 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).

Liquid type foods include viscous foods some examples of which are applesauce, ketchup, gelatin and puddings, and solid foods in liquid medium some examples of which are peas, sauerkraut and fruits.

NOTE: The article is not subject to the guideline if:

1. It is made or rendered unsuitable for holding liquid or liquid type foods by some means such as bored holes;

or

2. It bears a label, incapable of obliteration, permanently affixed to the article's potential food contact surface; and such a label states that the article is "not for food use" along with a statement of the hazard associated with the article if used for food purposes.

#### SPECIMEN CHARGE:

The article was adulterated when introduced into, while in, and is adulterated while held for sale after shipment in interstate commerce within the meaning of said Act 21 U.S.C. 342 (a)(2)(C) in that it contains a food additive, namely lead, which is unsafe within the meaning of 21 U.S.C. 348 because its use and intended use are not in conformity with a regulation or exemption established pursuant to 21 U.S.C. 348.

#### REMARKS:

If all lots in an import entry were sampled using an invoice on a line by line basis, detain only those lots meeting the above criteria. If one sample (line item) meets the above criteria, the entire entry may be detained without further analysis.

If articles are of domestic manufacture, regulatory action may include all lots from a single batch.

#### 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 based on labeling of the article as for other than food use where:

1. The article is rendered unsuitable for food use;

or

2. A label is placed on the potential food contact surface that is incapable of obliteration or removal and states the article is "Not for Food Use" along with the statement "Article May Poison Food."

Items that are not used to hold liquid or liquid type foods for repeated use or storage but are components of articles under detention may be released upon separation by the importer. For example, although all items in a silver plated hollowware coffee serving set consisting of a tray, coffee pot, creamer and sugar bowl may be detained because one item of the set (e.g., creamer) is found to contain levels of lead in excess of the guideline, those articles in the set that are not used to hold liquids or liquid type foods (e.g., sugar bowl and tray) may be separated by the importer and upon request may be released without examination. Release based on any other conditions

must have prior clearance of CFSAN/Office of \*Compliance\*/Division of Enforcement (HFS-605).

**EXEMPTION:**

Nonfood service silver-plated hollowware will not be required to meet the guidelines for leachable lead. Nonfood service silver-plated hollowware includes, but is not necessarily limited to, the following types of articles manufactured solely for ornamental display purposes: commemorative articles (pots, plates, cups, etc.), souvenir articles and other highly ornamented silver-plated hollowware articles. This exemption applies provided the articles do not come in place settings for the table and further provided that there is a permanent label on the back of the article stating "Not for Food Use - Article May Poison Food. For Decorative Purposes Only."

\*Material between asterisks is new or revised.\*

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