

§ 109.30

Food Use May Result in Lead Poisoning," and "Not for Food Use—Food Consumed from this Vessel May be Harmful," and

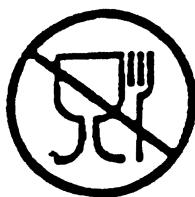
(ii) A conspicuous and legible permanent statement of the message selected from paragraph (b)(1)(i) of this section molded or fired onto the exterior surface of the base or, when the ceramicware is not fired after decoration, permanently painted onto the exterior surface of the base. This permanent statement shall be in letters at least 3.2 millimeters (0.125 inch) in height, except that if insufficient space exists for the permanent statement in letters of such height, the statement shall be in the largest letters that will allow it to fit on the base of the piece, provided that the letters are at least 1.6 millimeters (0.062 inch) in height; or

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

(c) In addition to steps required under paragraphs (b)(1) and (b)(2) of this section, the following optional information may be provided on the ware:

(1) A further explanatory statement concerning the decorative nature of the piece, such as "Decorative" or "For Decorative Purposes Only," may be used; however, such additional statement shall be placed after the required statement.

(2) A symbol may be used to advise that a piece of ornamental or decorative ceramicware is not to be used with food, as illustrated below.



The circle of the above symbol should be at least 2.54 centimeters (1 inch) in diameter. The symbol may be used on the temporary label or applied to the base of the piece in the same manner as the permanent statement.

[59 FR 1641, Jan. 12, 1994]

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Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 109.30 Tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food-producing animals ingesting PCB-contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

- (1) 1.5 parts per million in milk (fat basis).
- (2) 1.5 parts per million in manufactured dairy products (fat basis).
- (3) 3 parts per million in poultry (fat basis).
- (4) 0.3 parts per million in eggs.
- (5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).
- (6) 2 parts per million in animal feed components of animal origin, including

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fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 2 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, June 1979" for determining compliance with the tolerances established in this section is available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(c) A barrier is functional for purposes of paragraph (a)(9) of this section if the barrier limits migration of PCB's from the packaging material to food to a level not exceeding the migration which occurs under the same test conditions from packaging material containing 10 parts per million PCB without the use of a barrier. A class of barrier material is functional for purposes of paragraph (a)(9) of this section if a representative barrier of the class limits migration of PCB's from the packaging material to food to a level not exceeding the migration which occurs under the same test conditions from packaging material containing 10 parts per million PCB without the use of a barrier. Migration levels shall be determined for purpose of this paragraph solely by use of testing conditions described in "Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983", which is incorporated by reference. Copies are available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or available

for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. A class of barrier material shall be deemed functional only if the definition of the class and the designation of one or more representative barriers has been approved by the Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration. In the event that the Director, Center for Food Safety and Applied Nutrition, does not approve a proposal made to the Center regarding the definition of a class of barrier material or the designation of representative barriers, the Director shall advise the person making the proposal of the reasons for the Center's disapproval within 90 days of receipt of the proposal. All proposals for definition of classes and determinations of the Food and Drug Administration regarding such proposals shall be on file with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(d) Any person who asserts that a barrier or class of barriers is functional shall submit the results of tests conducted to determine the functionality of the barrier or class of barriers to Center for Food Safety and Applied Nutrition (HFS-308), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. All barriers or classes of barriers shall be tested with the four solid food receptors specified in "Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983", which is incorporated by reference. The availability of this reference is given in paragraph (c) of this section. The test results as to each barrier shall be accompanied by (1) a description of the barrier's composition adequate to enable identification; and (2) a specific definition of the barrier by relevant technical characteristics. The Center for Food Safety and Applied Nutrition shall review submitted test results promptly. Within 60 days of the receipt of test results, the Director,

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Center for Food Safety and Applied Nutrition, shall notify the person submitting the test results whether the tests were conducted in accordance with the "Analytical Methodology for Polychlorinated Biphenyls; June 1979", which is incorporated by reference, or the "Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983" and whether, therefore, the barrier or class of barriers is deemed functional within the meaning of paragraph (c) of this section. The test results and any response of the Food and Drug Administration shall be placed on file with the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[42 FR 52819, Sept. 30, 1977, as amended at 44 FR 38340, June 29, 1979; 46 FR 8459, Jan. 27, 1981; 48 FR 10811, Mar. 15, 1983; 48 FR 37021, Aug. 16, 1983; 54 FR 24892, June 12, 1989; 59 FR 14364, Mar. 28, 1994; 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

EFFECTIVE DATE NOTE: At 38 FR 22794, Aug. 24, 1973, the following appeared concerning §109.30(a)(9) (formerly 122.10(a)(9)):

* * * §109.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by §109.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]

Subpart D—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Subpart A—General Provisions

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Subpart D [Reserved]

Subpart E—Production and Process Controls

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Subpart F [Reserved]

Subpart G—Defect Action Levels

110.110 Natural or unavoidable defects in food for human use that present no health hazard.

AUTHORITY: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

SOURCE: 51 FR 22475, June 19, 1986, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 110 appear at 81 FR 49896, July 29, 2016.

Subpart A—General Provisions

§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Acid foods or acidified foods* means foods that have an equilibrium pH of 4.6 or below.

(b) *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) *Blanching*, except for tree nuts and peanuts, means a prepackaging