

§ 109.7

21 CFR Ch. I (4-1-04 Edition)

In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

[42 FR 52819, Sept. 30, 1977, as amended at 55 FR 20785, May 21, 1990]

§ 109.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances, regulatory limits, and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances, regulatory limits, or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

[42 FR 52819, Sept. 30, 1977, as amended at 55 FR 20785, May 21, 1990]

§ 109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in

formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of

PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (a) its toxicity; (b) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (c) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (d) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

§ 109.16 Ornamental and decorative ceramicware.

(a) Lead is a toxic metal that is used as a component of glazes and decorative decals on ceramics, including some ornamental and decorative ceramicware. The use of ornamental or decorative ceramicware to prepare, serve, or hold food may result in the leaching of lead from the glaze or decoration into the food. The provisions of paragraph (b) of this section are necessary to ensure that ornamental or decorative ceramicware bear adequate

indications that they are not to be used for food-handling purposes.

(b) Ornamental or decorative ceramicware initially introduced or initially delivered for introduction into interstate commerce on or after July 13, 1994 appears to be suitable for food use will be considered to be for food use unless:

(1) It bears:

(i) A conspicuous stick-on label on a surface clearly visible to consumers that states in legible script in letters at least 3.2 millimeters (0.125 inch) 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," 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.