has submitted a petition, may publish a proposal to issue, amend, or revoke, under this part, a regulation prescribing a common or usual name for a food, pursuant to part 10 of this chapter.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative, e.g., a smaller type size. A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted pursuant to part 10 of this chapter.

Subpart A—General Provisions

§ 509.3 Definitions and interpretations.


(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A naturally occurring poisonous or deleterious substance is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An added poisonous or deleterious substance is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) Food includes pet food, animal feed, and substances migrating to food from food-contact articles.

§ 509.4 Establishment of tolerances, regulatory limits, and action levels.

(a) When appropriate under the criteria of §509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b) When appropriate under the criteria of §509.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c)(1) When appropriate under the criteria of §509.6, an action level for an
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added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the Federal Register as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.

(d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.


§ 509.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under sections 406, 408, or 409 of the act by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request the EPA to recommend such an action level pursuant to the criteria established in paragraph (d) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent of which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) A regulatory limit for an added poisonous or deleterious substance in any food may be established when each of the following criteria is met:

(1) The substance cannot be avoided by current good manufacturing practices.

(2) There is no tolerance established for the substance in the particular food under sections 406, 408, or 409 of the act.

(3) There is insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may
§ 509.15 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
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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.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 509.30 Temporary 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
Subpart B—Specific Administrative Rulings and Decisions

§ 510.3 Definitions and interpretations.

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

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

PART 510—NEW ANIMAL DRUGS

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§ 510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.

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510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Subpart G—Sponsors of Approved Applications

510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.


Source: 40 FR 13807, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 510.3 Definitions and interpretations.

As used in this part: