

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 the residue. The

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temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with 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, February 1973" for determining compliance with the tolerances established in this section is available from the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[42 FR 52821, Sept. 30, 1977, as amended at 46 FR 8460, Jan. 27, 1981; 59 FR 14365, Mar. 28, 1994; 68 FR 24879, May 9, 2003; 88 FR 45066, July 14, 2023]

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****Subpart A—General Provisions****Sec.**

510.3 Definitions and interpretations.

510.4 Biologics; products subject to license control.

510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

510.95 [Reserved]

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- 510.105 Labeling of drugs for use in milk-producing animals.
- 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.
- 510.110 Antibiotics used in food-producing animals.
- 510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

Subpart C—Import Tolerances for Residues of Unapproved New Animal Drugs in Food

- 510.201 Scope.
- 510.202 Definitions.
- 510.203 Initiation of a proceeding to establish or amend an import tolerance.
- 510.205 Content and administration of a request.
- 510.206 Review of information supporting actions to establish or amend an import tolerance.
- 510.207 Disclosure of information submitted in a request.
- 510.209 Establishment, denial, or amendment of an import tolerance.
- 510.210 Revocation of an import tolerance.
- 510.212 Administrative reconsideration of action.
- 510.213 Administrative stay of action.

Subpart D—Records and Reports

- 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.
- 510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Subpart E—Requirements for Specific New Animal Drugs

- 510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.
- 510.440 Injectable iron preparations.
- 510.455 Requirements for free-choice medicated feeds.

Subpart F [Reserved]**Subpart G—Sponsors of Approved Applications**

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

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