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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 3, 121, 122, 128]

POLYCHLORINATED BIPHENYLS

Notice of Proposed Rule Making

The Commissioner of Food and Drugs is concerned about the problems of contamination of food with polychlorinated biphenyls (PCB's) arising indirectly from the use of PCB-contaminated animal feed, from industrial and environmental sources, and from the use of PCB-contaminated paper food-packaging materials. No authorization has been granted under the Federal Food, Drug, and Cosmetic Act for any use of PCB's which results, either directly or indirectly, in PCB's becoming a component or otherwise affecting the characteristics of food for man or other animals.

PCB's have been produced since 1929 and have been employed in a wide range of industrial uses including heat exchange liquids in pasteurization equipment; formulations in lubricants and hydraulic fluids; and ingredients of paints, plastics, resins, inks, waxes, adhesives, rubber, asphalt, and various building materials. PCB's are toxic substances which are very stable and highly persistent in the environment. Because of their widespread use, PCB's have been found in food as a result of avoidable industrial accidents and of environmental or industrial contamination.

Although it is not possible to remove PCB's from the environment, the Commissioner of Food and Drugs is taking all reasonable steps to limit the ways in which PCB's may otherwise contaminate food and to limit the level of PCB's in foods containing unavoidable PCB residues from environmental or industrial sources.

The Food and Drug Administration has been conducting a national survey to determine the extent and levels to which complete animal feeds are contaminated with PCB's. The survey results available to date show that less than 5 percent of the animal feeds sampled contain PCB's. Levels range from no detectable contamination to a maximum PCB level of 0.8 part per million. It appears that complete animal feeds are not a significant source of PCB's for food-producing animals and that PCB contamination of feeds for food-producing animals can generally be attributed to avoidable industrial accidents and practices. Investigations by FDA have revealed the use of PCB's in heat exchange fluids used in certain pasteurization equipment. Although heat exchange fluids in such equipment are considered to be in "closed systems," accidents have occurred that resulted in direct contamination of animal feed with PCB's and subsequently in contamination of food products such as poultry and eggs intended for human consumption. The use of PCB-containing coatings on the inner walls of silos has resulted in the contamination of silage which has in turn caused PCB residues in the milk of dairy cows. It is suspected that other industrial uses of PCB's have also resulted in the PCB contamination of animal feed and food for human consumption during processing and manufacturing.

Investigations have also revealed PCB migration to food resulting from the use of PCB-containing paper food-packaging material. This problem is being intensively studied by FDA and the paper and food industries. These studies show that paper for food-packaging materials, whether manufactured from recycled paper or virgin stock, may contain PCB's. The source of PCB's in recycled paper is attributed to the use of certain kinds of copying paper and printing ink. While the source of PCB's in virgin stock is not as well defined, it is generally attributed to the presence of PCB's in the equipment, machinery, and water used for the manufacturing of these materials and to environmental contamination.

The level of PCB contamination of foods from packaging materials is dependent upon many factors (e.g., levels of PCB's in food-packaging materials, type of food, length of storage). This is shown by the results of a national survey conducted by FDA, which revealed that even though 87 percent of the complete food packaging tested contained PCB's at levels as high as 338 parts per million, only 19 percent of the foods in these packages contained PCB's. The average PCB concentration in food was 0.1 part per million, and the maximum PCB level found was 5 parts per million. The survey further showed that 78 percent of the food product in packaged infant cereal samples contained PCB's. The average PCB concentration in the cereal was 0.3 part per million, and the maximum PCB level found was 1 part per million.

Other information which became available subsequent to the FDA survey shows a continuing and substantial reduction in the PCB concentrations of paper-packaging materials. For example, data on recycled paperboard currently being produced show that 95 percent of the samples examined contained less than 5 parts per million; data on the same type of material manufactured during 1970 and 1971 show that only 18 percent of the samples examined contained less than 5 parts per million.

Other investigations show the presence of PCB residues in fresh water fish and in some foods of animal origin. The source of these residues is attributed in part to environmental contamination such as discharges of PCB waste effluents into water and air.

Based on FDA total diet studies, the dietary intake of PCB's appears to be of a low order. The 900 food composites analyzed for PCB's in the total diet market basket samples for the past 2½ years showed 54 of the food composites to contain PCB residues. Calculated on the basis of dietary intake, the average PCB level found in the market baskets was less than 0.0001 milligram per kilogram of body weight per day. The market basket samples represent a high consumption diet which is approximately twice the normal diet.

Knowledge of the toxicological effects of PCB's is limited at this time. Available information indicates that PCB's are classified as being of moderate acute toxicity. As a point of comparison, DDT has a higher acute toxicity than PCB's. In contrast to the recognized moderate acute toxicity of PCB's, the aspects of PCB-chronic toxicity, including mutagenicity and teratogenicity are at present not well defined and thus are potentially of greater concern. The chronic toxicity of PCB's is being extensively studied by the Government, industry, and the scientific community. Preliminary reports and observations indicate that it would be prudent to reduce and, wherever possible, eliminate long-term, low-level human exposure to PCB's.

On the basis of these investigations and other available information, including the report of the Interdepartmental PCB Task Force, the current dietary level of PCB's is not considered an immediate hazard to the public health. However, the Commissioner concludes that the sources and levels of PCB's in animal feeds, feed components, and food for human use can and should be significantly reduced or eliminated so as to minimize the overall long-term human exposure to PCB's. Accordingly, the Commissioner makes the following proposals:

1. Part 3 should be amended to (a) provide special provisions to preclude the direct accidental PCB contamination of animal feed, and (b) to provide special provisions to preclude the direct accidental PCB contamination of food-packaging materials.

2. Section 128.4 should be amended by adding special provisions to preclude the direct accidental PCB contamination of food.

3. Section 121.2546 should be amended to exclude pulp from reclaimed fibers

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containing poisonous and deleterious substances which may migrate to food from use in the manufacture of food packaging materials.

4. A temporary tolerance of 5 parts per million in paper food-packaging materials should be established permitting unavoidable PCB residues in these products for a sufficient period of time to provide an opportunity for the orderly elimination of PCB-containing raw materials used in the manufacture of food-packaging materials. There are no provisions for permissible uses of PCB's under 21 CFR 121.2536 or 121.2571. This temporary tolerance is not to provide for direct uses under the above regulations. Immediate elimination of all food packages containing PCB's would disrupt the nation's food packaging and distribution system and is not warranted by the hazard to human health.

5. It is recognized that nationwide controls in the uses of PCB's will reduce the unavoidable contamination of foods. Therefore, although a temporary tolerance cannot be established for all foods, regulations should be promulgated providing the following temporary tolerances permitting unavoidable residues for a sufficient period of time to permit elimination of such residues at the earliest practicable time:

	Parts per million
(a) Milk (fat basis)	2.5
(b) Dairy products (fat basis)	2.5
(c) Poultry (fat basis)	5.0
(d) Eggs	0.3
(e) Finished animal feed	0.5
(f) Animal feed components (including fishmeal)	5.0
(g) Fish (edible portion)	5.0
(h) Infant and junior foods	0.1
(i) Food-packaging material	5.0

Since PCB's are very stable and highly persistent in the environment, any disposal of PCB's should be accomplished by appropriate high temperature degradation or other appropriate means in order to avoid any environmental contamination which could affect food subject to the Federal Food, Drug, and Cosmetic Act or which could otherwise adversely affect the environment.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055-56 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785-86 as amended; 21 U.S.C. 342(a), 346, 348, 371) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Parts 2, 121, and 130 and to establish a new Part 122, as follows:

PART 2—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

1. By adding the following new sections to Part 2:

§ 2.... Use of polychlorinated biphenyls (PCB's) in the production and storage of animal feed.

(a) Investigations by the Food and Drug Administration have revealed use of PCB's in heat exchange fluids contained in certain pasteurization equipment used in processing animal feed. Although heat exchange fluids in such equipment are considered to be in "closed systems," accidents have occurred that resulted in direct contamination of animal feeds with PCB's and subsequently in PCB contamination of human food. The use of PCB-containing coatings on the inner walls of silos has resulted in the contamination of silage which has in turn caused PCB residues in the milk of dairy cows. Other industrial uses of PCB's include, or did include in the past, their use in formulations as lubricants and hydraulic fluids and their use as ingredients of paints, plastics, resins, inks, waxes, adhesives, rubber, asphalt, and various building materials.

(b) The following special provisions are necessary to preclude accidental PCB contamination of animal feed:

(1) Coatings or paints for use on the contact surfaces of feed storage areas may not contain PCB's or any other harmful or deleterious substances likely to contaminate feed.

(2) New equipment or machinery for handling or processing feed in or around an animal feed producing establishment shall not contain PCB's.

(3) Within 30 days following the effective date of this order, the management of establishments producing animal feed shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling and processing feed sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. Within the 30 days specified above, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's or any other harmful or deleterious substances.

(ii) Eliminate from the animal feed producing establishment any PCB-containing feed-contact surfaces of equipment and utensils and any PCB-containing lubricants for equipment or machinery that are used for handling or processing animal feed.

(iii) Eliminate from the animal feed producing establishment any other PCB-containing materials, whenever there is a reasonable expectation that such materials could cause animal feed to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) Eliminate the use of any feed-packaging materials that contain in excess of the 5 parts per million temporary tolerance for PCB's established in § 122.10 of this chapter.

(c) For the purpose of this section, the term "animal feed" includes all articles used for food or drink for animals other than man.

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

(a) PCB contamination has been detected in paper food-packaging materials. Such contamination may have in some cases resulted from the use of PCB's in heat exchange fluids or other PCB-containing materials used in the establishment 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) Within 30 days following the effective date of this order, 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. Within the 30 days specified above, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's or any other harmful or deleterious substance.

(ii) Eliminate from the establishment any other PCB-containing materials wherever there is a reasonable expectation that such materials 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.

PART 121—FOOD ADDITIVES

2. In Part 121 by revising § 121.2546 (b) in subparagraphs (1) and (2), as follows:

§ 121.2546 Pulp from reclaimed fiber.

* * * * * *

(b) * * *

(1) Industrial waste from the manufacture of paper and paperboard products excluding that which bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food.

(2) Salvage from used paper and paperboard excluding that which (i) bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and migrates to the food or (ii) has been used for shipping or handling any such substance.

PART 122—UNAVOIDABLE NATURAL, ENVIRONMENTAL, OR INDUSTRIAL CONTAMINANTS IN FOOD AND FOOD-PACKAGING MATERIAL

Subpart A—Definitions and Procedural and Interpretative Regulations

3. By adding a new Part 122 consisting initially of two sections, as follows:

§ 122.1 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in this part.

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(b) Unavoidable natural, environmental, or industrial contaminants include any poisonous or deleterious substance added to any food where such substance cannot be avoided by good manufacturing practice.

122.2-122.9 [reserved]

§ 122.10 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) 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, as follows:

	Parts per million
(1) Milk (fat basis)	3.5
(2) Dairy products (fat basis)	3.5
(3) Poultry (fat basis)	3.0
(4) Eggs	0.5
(5) Finished animal feeds	0.5
(6) Animal feed components (including fishmeal)	5.0
(7) Fish (edible portion)	5.0
(8) Infant and junior food	0.1
(9) Food-packaging material	5.0

PART 128—HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURE, PROCESSING, PACKING, OR HOLDING

4. In Part 128, by designating the existing text of § 128.4 as paragraph (a) and by adding a new paragraph (b) as follows:

§ 128.4 Equipment and utensils.

(a) *General.* All plant equipment and utensils should be (1) suitable for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design; construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(b) *Use of polychlorinated biphenyls (PCB's) in food plants.* Polychlorinated biphenyl (PCB's) contamination has been detected in food and in food-packaging materials. Such contamination may have, in some cases, resulted from the use of PCB-containing equipment and utensils or from the use of PCB-contaminated food-packaging materials. PCB's are toxic substances which are very stable and highly persistent in the environment and have been employed in a wide range of industrial uses including heat exchange liquids in certain pasteurization equipment; additives in lubricants and hydraulic fluids; and ingredients of paints, plastics, resins, inks, waxes, adhesives, rubber, asphalt, and various building materials. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) Within 30 days following the effective date of this paragraph, the management of food plants shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. Within the 30 days specified above, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's or any other harmful or deleterious substances.

(ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.

(iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) Eliminate the use of any food-packaging materials that contain in excess of the 5 parts per million temporary tolerance for PCB's established in § 122.10 of this chapter.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

(Secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055-56 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785-86 as amended; 21 U.S.C. 342(a), 346, 348, 371)

Dated: March 16, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

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