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DRAFT ENVIRONMENTAL IMPACT STATEMENT. NOTICE OF PROPOSED RULE MAKING POLYCHLORINATED BIPHENYLS

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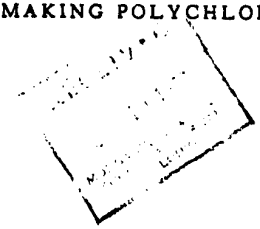

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MONS 059103

DRAFT

ENVIRONMENTAL IMPACT STATEMENT

NOTICE OF PROPOSED RULE MAKING

POLYCHLORINATED BIPHENYLS

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Office of the Associate Commissioner for Compliance

Food and Drug Administration

Department of Health, Education, and Welfare

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Draft - Environmental Impact Statement

ASSOCIATE COMMISSIONER FOR COMPLIANCE

FOOD AND DRUG ADMINISTRATION

Proposed Action

Notice of Proposed Rule Making, Polychlorinated Biphenyls (PCB's), 21 CFR Parts 3, 121, 122, 128; published in the FEDERAL REGISTER of March 18, 1972 (37 F.R. 5705).

BACKGROUND

PCB's are toxic substances having widespread industrial applications and have been shown to occur as contaminants in food. PCB's were first manufactured commercially in 1929, and, because of their chemical and physical properties, their industrial applications have become widespread. PCB's have been used principally in electrical capacitors and transformer fluids, plasticizers, hydraulic fluids and lubricants, and heat transfer fluids.

The identification of PCB's as a potential food contaminant was first reported in 1966 when they were discovered in fish from Swedish waters. Subsequent investigations established several sources by which foods may become contaminated with PCB's. The identifiable sources of PCB contamination of food are industrial accidents such as leakage, spillage, or other direct contact of PCB-containing materials with animal feeds or food; PCB migration

to food packaged in PCB-contaminated paper products; and the environmental contamination due to the presence of PCB's in water and air.

1. Industrial Accidents

Industrial accidents have resulted in a number of incidents involving the direct contamination of animal feeds which, in turn, have caused human food to become contaminated. Some of these incidents are cited below:

a. Poultry and eggs became contaminated as a result of the leakage of PCB heat transfer fluid during the pasteurization of fish meal. The contaminated fish meal was used as a poultry feed component.

b. PCB residues in milk have occurred because PCB-containing coatings were used as sealants on the inside walls of silos containing dairy feed silage. The PCB's migrated to the silage and the PCB-contaminated silage contaminated dairy herds.

c. The use of spent PCB transformer fluid as an herbicide spray vehicle was suspected to have contaminated dairy cattle grazing areas thereby causing PCB residues in milk from the cattle.

d. The grinding of bakery products (including wrappers that may have contained PCB's) for use as animal feed is suspected to have caused the contamination of poultry.

Other similar incidents during the past several years have resulted in the contamination of large quantities of food.

Extensive investigations failed, in some instances, to disclose the exact source or cause of the PCB contamination. However (on the basis of the excessive levels of PCB's found in the contaminated food or feed) leakage, spillage or other direct contact of PCB containing materials was implicated.

2. Food Packaging Materials

Food packaging materials were identified as a source of PCB contamination of foods in 1971. Investigations indicate a significant percentage of paper food-packaging materials contains PCB's that can result in the migration of low levels of PCB's to the packaged food. The origin of PCB's in packaging materials is not fully understood. Reclaimed pulp containing carbonless copy paper has been established as a primary source of PCB's in paper products. Carbonless copy paper contains 3-5 percent PCB's. Virgin paper products, however, have also been shown to contain PCB residues. The source of PCB's in virgin paper products is generally attributed to the use of PCB-containing equipment and machinery that is used in the paper mill or in the package manufacturing operation. Direct contamination from industrial accidents similar to those associated with animal feeds may occur in these establishments. Environmental sources of contamination, such as PCB's in water used in processing, may also be contributing to the contamination of virgin pulp.

FDA initiated a nationwide survey in the Fall of 1971 to determine the extent of the PCB-food-packaging problem. The survey included analysis for PCB's in all the paper packaging components and the packaged food portions of 15 selected food categories. The survey was completed in December of 1971, and, in general, it showed that 67 percent of the packaging portions of the samples examined contained PCB residues. The highest level encountered was 338 parts per million. Analysis also showed that 19 percent of the food portions of the samples contained PCB residues and there was an average PCB concentration of 0.1 parts per million. The maximum PCB level found in food was 5 parts per million.

3. Environmental Contamination

Environmental contamination of lakes, streams, and air as a result of effluent PCB waste discharges and various industrial uses of PCB materials directly exposed to the environment has resulted in the indirect, widespread PCB contamination of most fresh water fish. In some instances foods of animal origin, such as meat, poultry, eggs, and milk contain low background levels of PCB's that may also be attributable to environmental sources of contamination. PCB's reach the environment from several sources, such as open burning or incomplete incineration of municipal and industrial solid wastes; municipal and industrial

sewage; vaporization from paints, coatings and plastics; and accidental spills or improper waste disposal practices.

The dietary intake of PCB's, as shown in FDA's total diet studies for the past two and a half years, is of a low order (less than 0.0001 milligrams per kilogram of body weight per day in a high consumption diet). There is, however, limited knowledge of the effects on human health even at low levels. Based on available toxicological data, including human data, FDA has concluded that it is necessary to minimize and, wherever possible, eliminate long-term, low-level human exposure to PCB's.

DESCRIPTION

The notice of proposed rule making represents comprehensive regulations designed to limit human exposure to PCB's from dietary sources by dealing with known sources and causes of PCB contamination of food. Specifically, the proposed action provides special provisions to preclude direct, accidental PCB contamination in those establishments involved in the handling and processing of animal feeds, food, and food-packaging materials; amendment of an existing regulation governing the use of pulp from reclaimed fiber for food-packaging use; and temporary tolerances for unavoidable PCB residues in food-packaging materials and in foods.

1. Animal feed establishments--under 21 CFR Part 3 the proposed regulations include the following special provisions:

a. 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.

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

c. The management of establishments producing animal feed shall eliminate heat exchange fluids formulated with PCB's, any PCB-containing feed contact surfaces and lubricants, any other PCB-containing materials that could reasonably be expected to cause animal feed to become contaminated, and the use of any feed packaging materials that contain PCB's in excess of 5 parts per million.

2. Food-packaging material establishments--under 21 CFR Part 3 the proposed regulations include the following special provisions:

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

b. The management of establishments manufacturing food-packaging materials shall eliminate heat exchange fluids formulated with PCB's and any other PCB-containing materials that could be reasonably expected to cause food-packaging materials to become contaminated with PCB's.

3. Food establishments--under 21 CFR Part 128 the proposed regulations include the following special provisions:

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

b. The management of food plants shall eliminate any PCB-containing food-contact surfaces, lubricants for equipment, or machinery that is used for handling or processing food; any other PCB-containing materials that could be reasonably expected to cause food to become contaminated with PCB's; and use of any food-packaging materials that contain PCB's in excess of the 5 parts per million.

4. The amendment of food additive regulation § 121.2546 (21 CFR 121.2546) would not allow reclaimed and salvaged fibers which would be used in food-packaging materials to include pulp that contains poisonous and deleterious substances which may migrate to food.

5. Temporary tolerances would be established under the authority of section 406 of the Federal Food, Drug, and Cosmetic Act and would permit unavoidable PCB residues for a sufficient period of time in food-packaging materials and in certain foods. These tolerances are established because FDA recognizes that total, immediate elimination of PCB's in these articles is not possible and that controls in uses of PCB's will reduce unavoidable contamination of foods. The temporary tolerances being proposed for a new Part 122 in 21 CFR include:

		Parts Per Million
(1)	Milk (fat basis)	2.5
(2)	Dairy Products (fat basis)	2.5
(3)	Poultry (fat basis)	5.0
(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

ENVIRONMENTAL IMPACT

All available information indicates that the action proposed by FDA for dealing with PCB's in food will have a beneficial affect on the quality of the human environment. The proposed action consists of a series of individual actions aimed at limiting the ways in which avoidable industrial sources cause PCB-contamination in food and limiting the level of PCB's in food and food packaging from unavoidable environmental and industrial sources. Individually or in the aggregate, the actions will significantly minimize or eliminate the overall long-term human exposure to PCB's from dietary sources and will significantly reduce the potential for any possible chronic toxicological effects of PCB's on human health.

The proposed action for the establishment of temporary tolerances for certain foods and food-packaging materials is directed towards FDA-regulated industries. FDA, however, fully recognizes that PCB's are environmental contaminants and asserts that nationwide controls and preventive measures beyond the agency's statutory authorities concerning the uses, handling, and disposal of PCB's are necessary in order to reduce and eliminate the causes of unavoidable and indirect environmental contamination of food. This is the basis for proposing temporary tolerances for a sufficient period of time to permit elimination of PCB residues at the earliest practicable time. If this expectation materializes, it will indicate a lower concentration of PCB's in the ecological system and will reflect a diminishing exposure of humans, wildlife and fish and other marine life to all sources of PCB's.

Compliance with the proposed action is not without potential adverse effects on the quality of the human environment. The exercise of caution, judgment, and a clear understanding of the purpose and intent of the proposed action will, however, avoid these potential adverse effects:

1. The special provisions of the proposed action will require the elimination of PCB-containing materials from animal feed, food, and food-packaging material establishments.

The improper removal and disposal of the PCB-containing materials from these establishments could cause further environmental contamination. This potential adverse effect can be avoided by appropriate disposal, such as high temperature incineration (2000°F or above for 2 seconds) or other means whereby the PCB's are destroyed or degraded to chemical compounds of harmless composition and non-polluting properties.

2. PCB's have certain physical properties, such as being stable at high temperature as well as relatively nonflammable, which have contributed to their widespread industrial uses. Substitute or replacement chemicals for those uses of PCB's that are to be eliminated in the regulated establishments may need to possess physical properties relatively comparable to PCB's. Otherwise, potential fire or explosion hazard is possible in equipment operated at high temperatures and under other conditions.

3. An exception to the proposed special provisions eliminating certain industrial uses of PCB's will permit the continued use of electrical power equipment containing PCB's in regulated establishments. This use of PCB's is considered essential and presents only a minimal risk of accidental contamination of food and the environment.

4. The proposed amendment to food additive regulation § 121.2546 (21 CFR 121.2546) and the temporary tolerance for PCB's in food-packaging materials could be construed as detrimental to the concept, purpose, and practice of the recycling waste programs. This is not the intent of FDA and is not the effect of the proposed amendment. The proposed amendment would prohibit the deliberate or avoidable and continued inclusion in the recycling process of pulp that contains any poisonous or deleterious substances which may migrate to food from use in food packaging. Regarding PCB's, FDA anticipates that the primary effect of the amendment will be the exclusion of PCB-containing carbonless copy papers from reclaimed and salvaged fibers. The paper industry is currently following this practice without any obvious detrimental effects on recycling programs. It is recognized that some reclaimed paper will continue to contain unavoidable residues of PCB's. For this reason, FDA has further proposed to establish a temporary tolerance in food-packaging materials for a sufficient period of time to allow for the orderly elimination of PCB-containing raw materials used in the manufacture of food-packaging materials. Since the proposed temporary tolerance equally applies to virgin paper products, which also have been found to contain PCB's, recycled paper products are not being singled out as objects of this regulation, nor should they be

rejected as a form of food-packaging materials. Any food-packaging material not in compliance with the tolarance of 5 parts per million PCB's will be usable for all other forms of packaging except food.

ALTERNATIVES

FDA has the responsibility of administering the Federal Food, Drug, and Cosmetic Act. No authorization has been granted under this act for any use of PCB's which results, either directly or indirectly, in PCB's becoming a component of food or otherwise affecting the characteristics of food. For FDA not to take any positive action regarding the PCB contamination of food would be in violation of the Federal Food, Drug, and Cosmetic Act and contrary to the interests of public health. The proposed regulations represent positive action that FDA concludes appropriate and necessary for minimizing long-term human exposure to PCB's and notifies the regulated industries of the controls and steps that FDA will require for reducing and eliminating PCB's in dietary sources. For each provision of the proposed action, alternative courses of action are possible. These alternatives are discussed below:

1. Alternatives to Eliminating Industrial Uses of PCB's in Regulated Establishments

As previously described, FDA has encountered numerous incidents of direct, accidental PCB contamination of animal feed and human food

FDA learned of these incidents through its food inspection and surveillance activities and through information received from other government agencies and from industry. In response to these incidents, FDA took appropriate steps by exercising necessary controls and legal sanctions to minimize distribution and consumption of the contaminated feed and food. As a result, substantial quantities of PCB-contaminated animal feed and human food were seized, recalled from the market, or held under State embargo.

The proposed action has special provisions to preclude this type of direct, accidental PCB contamination in those establishments involved in the handling and processing of animal feeds, foods, and food-packaging materials. An alternative to these provisions would be to inform industry of the potential, serious problem of PCB accidents and to permit the continued use of PCB materials in regulated industries. FDA would, as in the past, exercise appropriate regulatory controls only when PCB accidents involving feed and food occur. This alternative would not prevent the accidental PCB contamination of food; would present a formidable task with large expenditures of resources in order to locate, test, and take regulatory action for the removal of food implicated in these accidents; and would not provide the assurance that all such accidnats could be identified prior to distribution and consumption of the contaminated

food. This alternative would not only expose the public to an unwarranted risk, but also would not provide equitable regulatory control of an industry-wide problem.

2. Alternatives to the Proposed Amendment to Food Additive Regulation § 121.2546 (21 CFR 121.2546)

FDA investigations showed that PCB's in packaging material are a source of PCB residues in food packaged in paper products. These residues arise from the use of food-packaging material made of both recycled paper and virgin paper. As previously described, FDA's proposed action for dealing with this problem provides two separate but related provisions, namely an amendment of an existing regulation on the use of pulp from recycled fiber and the establishment of a temporary tolerance for food-packaging materials.

An alternative to the proposed amendment of food additive regulation § 121.2546 (21 CFR 121.2546) would be the enforcement of the existing regulation. This regulation permits salvage from used paper and paperboard excluding that which bears or contains any poisonous or deleterious substance (including PCB's) which may reasonably be expected to be retained in the recovered pulp. FDA's recent national survey on the occurrence of PCB's in food-packaging materials indicates that most salvaged paper and paperboard could be expected to contain PCB's, and, therefore, these materials would not be in compliance with the present regulation. FDA

enforcement of the present regulation would have the effect of prohibiting the manufacture of food-packaging materials from salvaged or reclaimed paper. FDA believes that this alternative course of action would not be in the interests of the public. The intent of actions taken or being proposed by FDA is to reduce and avoid, insofar as is possible, the dietary intake of PCB's. Since the primary concern is not with the low levels of PCB's in food-packaging materials which do not increase the unavoidable levels currently in some food products, prohibiting all PCB-containing food-packaging materials regardless of the level of PCB contamination would be an unreasonable solution to the problem and would serve no useful purpose. Such action would also have an adverse impact on recycling programs that would outweigh beneficial effects, if any, that could be gained by a complete prohibition on the use of low level PCB-containing salvaged or reclaimed paper.

For these reasons, FDA proposed to amend the food additive regulation § 121.2546 (21 CFR 121.2546) as a means of dealing with this problem.

The amendment will prohibit the avoidable and deliberate inclusion of pulp from salvaged or reclaimed fibers containing PCB's which may migrate to food and cause an increase in the levels of PCB's currently in some food products. In part, the

proposed temporary tolerance of 5 parts per million PCB's for food-packaging materials will serve as the mechanism for industry-wide compliance with the amendment. The tolerance will permit the continued use of most salvaged or reclaimed fiber while providing the assurance that foods will not become contaminated with significant levels of PCB's, because they are packaged in paper products with 5 parts per million PCB's or less.

3. Alternatives to Proposed Temporary Tolerance for Food-Packaging Materials

An alternative to the proposed temporary tolerance for food-packaging materials would be the establishment of PCB tolerances for the packaged food. Toxicological information on the chronic effects of PCB's is not sufficient to serve as the basis for setting tolerances for all packaged foods. Furthermore, this alternative course of action would perpetrate the use of a known, avoidable source of PCB contamination of food and would thus violate the Federal Food, Drug, and Cosmetic Act.

Another alternative to the proposed temporary tolerance for food-packaging materials would be to require a functional barrier that would prohibit the potential migration of PCB's to the food contents of the package. This alternative would meet FDA objectives regarding the elimination of a source of PCB's in food, and if there is such a barrier, the paperboard

need not meet the temporary tolerance. There is, however, no available information clearly indicating that such a barrier would be a feasible or a practical solution to this problem. Neither is there research on the types of materials that would prevent PCB migration. As shown in FDA's food-packaging survey, inner wrappers of various composition that were used as barriers for different types of packaged foods either contained PCB's or failed to completely prevent migration. There is the additional problem of converting existing food industry processing equipment and machinery to include the functional barrier in the production of packaged food. The food industry would most likely demand PCB-free packaging materials from their suppliers. This would be a reasonable demand and would require the paper industry to test and supply packaging materials intended for food use at levels substantially less than FDA's proposed temporary tolerance of 5 parts per million PCB's. This would also have the effect of eliminating recycled paper as a source of food-packaging materials. Furthermore, investigations indicate that levels of PCB's in food-packaging materials have diminished during the past several months so that 80 percent or more of packaging materials intended for food use contain less than 5 parts per million PCB's. The remaining 20 percent can be used for non-food purposes. As a result of industry

controls and FDA's proposed regulations, it is expected that the levels will continue to be reduced so that, in time, the problem of PCB's in food-packaging materials may be non-existent. In the interim, the proposed temporary tolerance for food packaging materials appears to be a more reasonable and realistic alternative to this specific problem.

4. Alternatives to the Proposed Temporary Tolerances for PCB's in Foods

Section 406 of the Federal Food, Drug, and Cosmetic Act provides the authority for the promulgation of regulations limiting the quantity of unavoidable poisonous or deleterious substances in food. Acting on this authority, FDA has proposed to establish temporary tolerances for unavoidable PCB residues in certain foods. One alternative to this action would be to refrain from promulgating a regulation governing the presence of unavoidable PCB residues in food. As a result, each lot of food found to contain unavoidable PCB contamination could be regulated on a case-by-case basis regarding its acceptability for human and animal consumption. Another alternative would be to declare any food containing unavoidable PCB residues illegal. These alternatives serve no useful purpose. The promulgation of tolerances for foods that have been shown to contain PCB residues as a result of environmental contamination provides guidance to industry and other Federal and State

enforcement agencies concerned with the safety of food by notifying them of the levels of PCB contamination which will cause FDA to remove foods from interstate commerce. It will also provide the means for a uniform and equitable treatment of a potentially national problem and will provide direction for the most efficient and effective way of minimizing the entry of PCB-contaminated food into consumer channels.

CUMULATIVE AND LONG-TERM EFFECTS

PCB's are highly stable and persistent chemical compounds. PCB residues can be found in many forms of wildlife, fish and other marine life, and other environmental substrates including man. PCB's are accumulative in animals, and the exact biological effect of long-term exposure and accumulation of PCB's in living organisms is generally unknown. The proposed action will have the short-term effect of directly reducing and, in some instances, eliminating the dietary sources of PCB's and the long-term effect of indirectly reducing the levels of PCB's currently in the environment. As a result, this should enhance the quality of the human environment for succeeding generations.

REVIEW AND DISCUSSION OF PROPOSED ACTION

On February 29, 1972, the Interdepartmental Task Force on PCB's, which was established in September 1971 to coordinate a government-wide investigation into PCB contamination of food and food products, received copies of the draft notice of proposed rule making on PCB's and was briefed on the exact purpose and content of the proposed action. The Task Force had no objections to the FDA proposal. The following organizations are represented on the Task Force: Office of Science and Technology, Council on Environmental Quality, Department of Agriculture, Department of Commerce (National Bureau of Standards and National Oceanic and Atmospheric Administration), Environmental Protection Agency, Department of Health, Education, and Welfare (Food and Drug Administration and National Institute of Environmental Health Sciences), and Department of Interior.