FINAL ENVIRONMENTAL IMPACT STATEMENT

RULE MAKING

ON POLYCHLORINATED BIPHENYLS

Food and Drug Administration

Department of Health, Education, and Welfare

Sam D. Fine
Associate Commissioner for Compliance

December 18, 1972

DSW 282492

STLCOPCB4063821

CONTENTS

	Title	Page
I.	Summary of Proposed Rule Making and Evaluation of Comments on Draft Environmental Impact Statement and Notice of Proposed Rule Making	1
II.	Background	7
III.	Description of Rule Making	12
IV.	Environmental Impact of Rule Making	18
V.	Alternatives to Rule Making	22
VI.	Cumulative, Long-Term Effects	28
VII.	Interagency Review of Rule Making	29

DSW 282493

STLCOPCB4063822

FINAL ENVIRONMENTAL IMPACT STATEMENT

RULE MAKING

ON POLYCHLORINATED BIPHENYLS

I. SUMMARY OF PROPOSED RULE MAKING AND EVALUATION OF COMMENTS ON DRAFT ENVIRONMENTAL IMPACT STATEMENT AND NOTICE OF PROPOSED RULE MAKING

The Commissioner of Food and Drugs published in the FEDERAL REGISTER of March 18, 1972 (37 F.R. 5705) a notice of proposed rule making to limit human exposure to polychlorinated biphenyls (PCB's) from dietary sources. The proposed rule making would: (1) Prohibit the use of certain PCB-containing materials and equipment in animal feed, in food, and in food-packaging material manufacturing, handling and storage establishments to preclude direct accidental PCB contamination of animal feed, food, and food-packaging materials; (2) exclude from food-packaging materials the use of pulp from reclaimed fibers containing poisonous and deleterious substances which may migrate to food; and (3) establish temporary tolerances for unavoidable PCB residues in food-packaging materials and for unavoidable PCB residues in certain foods as a result of environmental contamination.

DSW 282494

STLCOPCB4063823

In the FEDERAL REGISTER of May 11, 1972 (37 F.R. 9503), the Commissioner published a notice of availability of the draft environmental impact statement issued by the agency on this notice of proposed rule making.

Comments from the public, consumer interest groups, industry, trade associations, and State and Federal agencies were received concerning both the notice of proposed rule making and the draft environmental impact statement. The comments received on the draft environmental impact statement and those received on the notice of proposed rule making which deal with the environmental issues are considered together for the purposes of this final environmental impact statement.

The Department of Agriculture supported the environmental impact statement, commenting that the proposed rule making will considerably reduce accidental contamination and long-term exposure of man to PCB's in the United States, and that widespread occurrence of PCB's in the environment makes it highly desirable to set temporary tolerances for PCB's as proposed until the unavoidable background levels are reduced.

The Environmental Protection Agency recommended that the environmental impact statement emphasize concern over the ultimate PCB content of packaging material rather than the

DSW 282495

STLCOPCB4063824

level in the source material in order to alleviate any potential impression that contaminated pulp can only come from recycling. The agency further recommended that the impact statement should detail the justification for the tolerance level of 5 parts per million (ppm) for food-packaging material. The agency also recommended that the impact statement should include consideration of the removal from existing inventories of carbonless copy paper containing PCB's as an additional method to reduce the level of PCB's in food packaging. It also recommended that the impact statement should include an examination of data on use of barriers with respect to migration of PCB's to food from food packaging.

The Department of Commerce recommended that discussion of the following be included in the impact statement: Toxicological effects of PCB's on human health; the 30-day time period required for compliance with the regulations; a statement as to whether materials which would replace PCB-containing materials will be the subject matter of an environmental impact statement; the need for or existence of rules controlling removal and disposal of PCB-containing materials, regardless of FDA's jurisdiction over this issue; the effect of the regulations on recycling programs; a cost-benefit analysis; the expected duration of the tolerances, considering an

DSW 282496

STLCOPCB4063825

adjustment of the limits once the toxicological effects of PCB's have been adequately determined.

Comments from the paper industry and related trade associations which were received on the notice of proposed rule making reflected industry's concern that the proposed temporary tolerance of 5 ppm PCB's for food-packaging materials would be detrimental to the paper recycling industry and to solid waste disposal programs. Industry commented that the proposal is contrary to sound national objectives on resources recovery, particularly to the recycling of residential, commercial, and industrial solid waste. It stated that the major impact of compliance with this proposal would fall on combination paperboard mills which perform vital environmental functions of recycling waste paper. The comments maintained that these recycling mills would suffer losses resulting from their inability to sell for nonfood purposes paperboard that is custom-made to food-packaging specifications and that is rejected as exceeding the tolerance. It added that the use of food-packaging materials made from recycled waste paper would be curtailed because sharply higher costs arising from compliance with the tolerance would stimulate demand for alternative materials. Industry anticipates that a number

DSW 282497

STLCOPCB4063826

of the recycling mills would close if the 5 ppm tolerance is implemented and that such closing would entail adverse environmental consequences.

The American Paper Institute recommended against simultaneous publication of the final environmental impact statement and the final rule making order.

The Commissioner, having considered the comments received and other relevant material, concludes as follows:

A. The regulations will have a beneficial effect on the quality of human environment in that they are designed to minimize and eliminate human exposure to PCB's from dietary sources by regulating identified sources or causes of PCB contamination of food.

B. Information on the toxicity of PCB's, which is included in the final environmental impact statement, supports the need to limit the level of PCB's in certain food-packaging materials that may migrate to packaged food.

C. The final order establishes the temporary tolerance for paper food-packaging materials as 10 ppm, rather than the proposed temporary tolerance of 5 ppm. It includes an exemption from this tolerance of paper food-packaging material which is separated from the packaged food by a functional barrier impermeable to PCB migration.

DSW 282498

STLCOPCB4063827

D. These revisions of the proposed tolerance for paper food-packaging material will reduce or eliminate the alleged adverse effects on recycling programs.

E. While establishing the 10 ppm tolerance for PCB's in paper food-packaging material to reduce the PCB level in paper food-packaging material, the Food and Drug Administration lacks jurisdiction to require removal from existing inventories of carbonless copy paper containing PCB's.

F. The 30-day time period for compliance and the recommended cost-benefit analysis are economic considerations. They are not the proper subject of an environmental impact statement under the National Environmental Policy Act.

G. A decision as to whether extensive disposal of animal feed, food, and paper food-packaging material containing excessive amounts of PCB's should be the subject of an environmental impact statement will be made should the agency receive data indicating the existence of such extensive disposal.

H. A decision as to whether the use of non-PCB replacement materials will be covered by an environmental impact statement is relevant neither to the PCB final environmental impact statement nor to the PCB rule making order.

STLCOPCB4063828

I. The toxicological information and other related information on PCB's supports the need to set, for certain foods containing unavoidable PCB residues, temporary tolerances that are as low as practicable. The FDA does not expect nor intend for these foods to normally reach the established tolerance levels. The tolerance levels are to serve as limiting values to prevent foods containing excessive levels of PCB's from reaching consumer channels.

J. The final rule making order shall be published in the FEDERAL REGISTER no sooner than 30 days after this final environmental impact statement is made available to the public.

Therefore, pursuant to provisions of the National Environmental Policy Act of 1969 (sec. 102(2)(c), 83 Stat. 853; 42 U.S.C. 4332(2)(c)) and the guidelines of the Council on Environmental Policy published in the FEDERAL REGISTER of April 23, 1971 (36 F.R. 7724), and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs issues this Final Environmental Impact Statement relating to the notice of rule making on polychlorinated biphenyls.

II. BACKGROUND

Polychlorinated biphenyls (PCB's) are toxic chemical substances which have been shown to occur as contaminants in food. They were first manufactured commercially in 1929

STLCOPCB4063829

and, because of their chemical and physical properties, their industrial applications have become widespread. PCB's have been used principally in electrical capacitors, transformer fluids, plasticizers, hydraulic fluids and lubricants, and heat transfer fluids.

The identification of PCB's as potential food contaminants 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 as follows: 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 environmental contamination due to the presence of PCB's in water and air.

A. Industrial Accidents.

A number of industrial accidents have occurred involving the direct PCB contamination of animal feeds which, in turn, have caused human food to become contaminated. Some of these are as follows:

1. 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 component of poultry feed.

STLCOPCB4063830

2. 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 PCB-contaminated silage contaminated dairy herds.

3. 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 these cattle.

4. 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, there was a likelihood that leakage, spillage, or other direct contact with PCB-containing materials had taken place.

B. Paper Food-Packaging Material.

In 1971, food-packaging material was identified as a source of PCB contamination of foods. Investigations indicate

STLCOPCB4063831

that a significant percentage of paper food-packaging material contains PCB's and that this can result in the migration of low levels of PCB's to the packaged food. The origin of PCB's in such paper material is not fully understood. Reclaimed pulp containing carbonless copy paper has been identified as a primary source of PCB's in paper products. Carbonless copy paper contains between 3 and 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 establishment where the package is manufactured. 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.

In the fall of 1971, the FDA initiated a nationwide survey to determine the extent of the PCB food-packaging problem. The survey included analysis for PCB's in all the paper food-packaging components and the packaged food portions of 15 selected food categories. The survey showed that 67 percent of the packaging portions of the samples examined contained

DSW 282503

STLCOPCB4063832

PCB residues. The highest level encountered was 338 ppm. 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 ppm. The maximum PCB level found in food was 5 ppm.

C. 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 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 the following: open burning or incomplete incineration of municipal and industrial solid waste; 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 the FDA's total diet studies for the past 2 1/2 years, is of a low order (less than 0.0001 milligram per kilogram of body

STLCOPCB4063833

weight per day in a high consumption diet). There is, however, limited knowledge of the effects of PCB's on human health even at low levels.

Toxicological information available indicates that the acceptable daily intake of PCB's, applying appropriate safety factors, ranges from 0.175 to 1.4 milligrams/day for an adult. The lower level is based on animal data; the upper level is based on human data which based the effect level on occurrence of overt symptoms. The lower level could be exceeded if a combination of chicken, milk, eggs, other dairy products, and fish containing the maximum allowable tolerance levels is regularly ingested. FDA concludes that in no case should the daily PCB intake from all food sources exceed 1.4 milligrams.

III. DESCRIPTION OF RULE MAKING

The notice of rule making provides for 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. It includes provisions to preclude direct, accidental PCB contamination of animal feed, food, and food-packaging materials; to amend an existing regulation

STLCOPCB4063834

governing the use of pulp from reclaimed fiber for food-packaging use; and to establish temporary tolerances for unavoidable PCB residues in paper food-packaging material and in certain foods.

On the basis of the FDA's review and evaluation of the comments received and other information pertaining to the draft environmental impact statement and the notice of proposed rule making, revisions have been made in these provisions and in the temporary tolerances. The description of the rule making reflects these revisions as follows:

A. Animal feed establishments.

Under 21 CFR Part 3, the rule making includes the following provisions:

1. Coatings or paints for use on the contact surfaces of feed storage areas shall not contain PCB's.

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

3. The management of establishments producing animal feed shall eliminate to the fullest extent possible commensurate with current good manufacturing practice the following: heat exchange fluids formulated with PCB's, any PCB-containing feed contact surfaces and lubricants, and any

DSW 282506

STLCOPCB4063835

other PCB-containing materials that reasonably could be expected to cause animal feed to become contaminated with PCB's. The management of such establishments shall eliminate the use of any feed-packaging material containing PCB's in excess of 10 ppm. Paper feed-packaging material containing PCB's in excess of 10 ppm can be used, provided this material is separated from the packaged feed by a functional barrier impermeable to PCB migration.

4. The use in these establishments of electrical transformers and capacitors that contain PCB's are not expected to cause the contamination of animal feed in these establishments and are exempt from the above-mentioned provisions.

B. Food-packaging material establishments.

Under 21 CFR Part 3, the rule making includes the following provisions:

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

2. The management of establishments manufacturing food-packaging material shall eliminate to the fullest extent possible commensurate with good manufacturing practice the following: heat exchange fluids formulated with PCB's and any other PCB-containing materials that reasonably could be

STLCOPCB4063836

expected to cause food-packaging material to become contaminated with PCB's.

3. Electrical transformers and capacitors that contain PCB's are not expected to cause the contamination of food-packaging material in these establishments and are exempt from the above-mentioned provisions.

C. Food establishments.

Under 21 CFR Part 128, the rule making includes the following provisions:

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

2. The management of food plants shall eliminate to the fullest extent possible commensurate with good manufacturing practice the following: heat exchange fluids formulated with PCB's, any PCB-containing food-contact surfaces and lubricants, and any other PCB-containing materials that reasonably could be expected to cause food to become contaminated with PCB's. The management of such establishments shall eliminate the use of any paper food-packaging material containing PCB's in excess of 10 ppm. Paper food-packaging material containing PCB's in excess of 10 ppm can be used, provided this material is separated from the packaged food by a functional barrier impermeable to PCB migration.

DSW 282508

STLCOPCB4063837

3. Electrical transformers and capacitors that contain PCB's are not expected to cause the contamination of food in these establishments and are exempt from the above-mentioned provisions.

D. The amendment to food additive regulation 121.2546 does not allow the use in food-packaging material of pulp from industrial waste or salvage that bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food.

E. Temporary tolerances are established under the authority of section 406 of the Federal Food, Drug, and Cosmetic Act the establishment of temporary tolerances for PCB's would permit unavoidable PCB residues in paper food-packaging material and in certain foods. These temporary tolerances are established for a sufficient period of time to permit the elimination of such contaminants at the earliest practicable time and are based on currently available information regarding the toxicity and the analytical behavior of PCB's, and the background levels of PCB's in these products. Where appropriate and necessary, new or additional information on PCB toxicity, analytical behavior, and background levels may serve as the basis for changing the temporary tolerances. These tolerances are

STLCOPCB4063838

established because the 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, expressed as parts per million, to be included in a new Part 122 are as follows:

(1)	Milk (fat basis)	2.5
(2)	Dairy products (fat basis)	2.5
(3)	Poultry (fat basis)	5.0
(4)	Eggs	0.5
(5)	Complete and finished animal feeds	0.2
(6)	Animal feed components	2.0
(7)	Fish and shellfish (edible portion)	5.0
(8)	Infant and junior food	0.2
(9)	Paper food-packaging material	10.0

The tolerance for paper food-packaging material shall not apply to such material separated from the packaged food by a functional barrier impermeable to PCB migration.

The Food and Drug Administration will provide upon request the analytical methods it will use for enforcing the temporary tolerances.

DSW 282510

IV. ENVIRONMENTAL IMPACT OF RULE MAKING

All available information indicates that the rule making for dealing with PCB's in food will have a beneficial effect on the quality of the human environment. The rule making consists of a series of individual actions aimed at limiting the ways in which avoidable industrial sources cause PCB contamination of food and animal feed and at limiting the level of PCB's in food, in feed, and in paper food packaging from unavoidable environmental sources. These 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 establishment of temporary tolerances for certain foods and for paper food-packaging material is directed toward FDA-regulated industries. However, the FDA asserts that, in order to reduce and eliminate the causes of unavoidable and indirect environmental contamination of food, nationwide controls and preventive measures concerning the uses, handling, and disposal of PCB's and PCB-containing materials, other than regulatory actions by the Administration, must be instituted by parties other than the FDA. This is the basis for establishing tolerances for a sufficient period

DSW 282511

STLCOPCB4063840

of time to permit elimination of PCB residues at the earliest practicable time. If nationwide controls are instituted and implemented, this will result in 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 rule making will not be without potential adverse effects on the quality of the human environment. However, a clear understanding of the purpose and intent of the rule making, combined with an exercise of caution and judgment, will avoid these potential adverse effects. Important considerations are as follows:

A. The provisions of the rule making require the elimination of most 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 by high-temperature incineration (2,000° F. or above for 2 sec.) or other means whereby the PCB's are destroyed or degraded to chemical compounds of harmless composition and nonpolluting properties.

STLCOPCB4063841

B. The physical properties of PCB's, such as their being stable at high temperatures and being nonflammable, 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 comparable to PCB's. Otherwise, potential fire or explosion hazards may be possible in equipment operated at high temperatures and under other severe conditions.

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

D. Industry opposed the proposed amendment to food additive regulation 121.2546 and the proposed temporary tolerance for PCB's in paper food-packaging material as being detrimental to the concept, purpose, and practice of the recycling waste programs. The Commissioner finds that the amendment and tolerance would not be detrimental to the recycling waste programs. The amendment will prohibit the inclusion in the recycling process of pulp that contains any poisonous or deleterious substance which may migrate to food

DSW 282513

STLCOPCB4063842

from use in food-packaging. The FDA anticipates that the effect of this 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, the FDA is establishing a temporary tolerance in paper food-packaging material for a sufficient period of time in order to allow for the orderly elimination of PCB-containing raw materials used in the manufacture of food-packaging material. The temporary tolerance applies equally to virgin paper products, which also have been found to contain PCB's, and to recycled paper products. Therefore, recycled paper products are not being singled out as objects of this rule making; they should not be rejected as a form of food-packaging material. Any paper food-packaging material not in compliance with the tolerance of 10 ppm PCB's will be usable for all other forms of packaging; it may also be used for food packaging when the material is separated from the packaged food by a functional barrier impermeable to PCB migration.

DSW 282514

STLCOPCB4063843

V. ALTERNATIVES TO RULE MAKING

The FDA is responsible for 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 components of food or otherwise affecting the characteristics of food. For the 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 would be contrary to the interests of public health. The rule making represents positive action that the FDA concludes is appropriate and necessary for minimizing long-term human exposure to PCB's; the rule making notifies the regulated industries of the actions that the FDA will require for reducing and eliminating PCB's in dietary sources. For each provision of the rule making alternative courses of action are possible. These alternatives are as follows:

A. Alternatives to eliminating industrial uses of PCB's in regulated establishments.

As described in Part II. BACKGROUND, the FDA has encountered numerous incidents of direct, accidental PCB contamination of animal feed and human food. The FDA learned of these incidents through its food inspection and surveillance activities and through information received from other

STLCOPCB4063844

government agencies and from industry. In response to these incidents, the 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 rule making has provisions to preclude this type of direct, accidental PCB contamination in those establishments involved in the handling and processing of animal feed, food, and food-packaging material. 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. As in the past, the FDA would exercise regulatory controls only when PCB accidents involving feed and food occur. This alternative would not prevent the accidental PCB contamination of food; it would present a formidable task requiring large expenditures of resources to locate, test, and take regulatory action for the removal of food implicated in these accidents; and it would not provide the assurance that all such accidents could be identified prior to distribution and consumption of the contaminated food. This alternative would not only expose

DSW 282516

STLCOPCB4063845

the public to an unwarranted risk, but also it would not provide equitable regulatory control of an industrywide problem.

B. Alternatives to amendment to food additive regulation 121.2546.

The FDA investigations showed that PCB's in paper food-packaging material are a source of PCB residues in packaged food. The presence of these residues results from the use of food-packaging material made of both recycled paper and of virgin paper. As described in Part III. DESCRIPTION OF RULE MAKING, the FDA's rule making provides two separate but related provisions concerning the subject, namely, an amendment of an existing regulation on the use of pulp from reclaimed fiber and the establishment of a temporary tolerance for unavoidable PCB residues in paper food-packaging material.

An alternative to the amendment of food additive regulation 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 reasonably may be expected to be retained in the recovered pulp. The FDA's recent national survey on the occurrence of PCB's in food-packaging material indicates that most salvaged

STLCOPCB4063846

paper and paperboard could be expected to contain PCB's and, therefore, these materials would not be in compliance with the present regulation. The FDA enforcement of the present regulation may have the effect of prohibiting the manufacture of food-packaging material from salvaged or reclaimed paper. The FDA believes that this alternative course of action would not be in the interests of the public. The intent of the rule making is to reduce and avoid, insofar as is possible, the dietary intake of PCB's. The primary concern is not with low levels of PCB's in paper food-packaging material which do not increase unavoidable PCB levels currently in some food products; therefore, prohibiting all PCB-containing paper food-packaging material regardless of 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 the beneficial effects, if any, that could be gained by a complete prohibition on the use of salvaged or reclaimed paper that contains low levels of PCB's.

For these reasons, the FDA intends to amend food additive regulation 121.2546 as a means of dealing with this problem. The amendment will prohibit inclusion of pulp from salvaged or reclaimed fibers containing PCB's

DSW 282518

STLCOPCB4063847

which may migrate to food. The temporary tolerance of 10 ppm PCB's for paper food-packaging material or the functional barrier exemption will serve as the mechanism for industrywide compliance with the amendment. This 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.

C. Alternatives to the 10 ppm temporary tolerance for paper food-packaging material.

An alternative to the 10 ppm temporary tolerance for paper food-packaging material 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.

Investigations indicate that levels of PCB's in paper food-packaging material have diminished during the past year to the point that 93 percent or more of paper packaging material intended for food use contains less than 10 ppm PCB's. The remaining 7 percent can be used either for nonfood

DSW 282519

STLCOPCB4063848

purposes or for food-packaging material that is separated from the packaged food by a functional barrier impermeable to PCB migration. As a result of industry controls and the FDA's rule making, it is expected that the levels will continue to be reduced so that, in time, the problem of PCB's in paper food-packaging material may be nonexistent. In the interim, the 10 ppm temporary tolerance for food-packaging materials provides necessary control for this source of food contamination.

D. Alternatives to the temporary tolerances for PCB's in foods.

Section 406 of the Federal Food, Drug, and Cosmetic Act provides authority for promulgation of regulations limiting the quantity of unavoidable poisonous or deleterious substances in food. Acting on this authority, the FDA is establishing temporary tolerances for unavoidable PCB residues in certain foods.

One alternative would be to refrain from promulgating a regulation governing the levels of unavoidable PCB residues in food. As a result, food found to contain unavoidable PCB contamination would have to 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.

DSW 282520

STLCOPCB4063849

These alternatives would serve no useful purpose. The promulgation of tolerances for foods that have been shown to contain PCB residues provides guidance to industry and to other Federal and State regulatory agencies concerned with the safety of food; such promulgation notifies these agencies of levels of PCB contamination which will cause the FDA to remove foods from interstate commerce. It will also provide the means for a uniform and equitable treatment of a national problem and will provide direction for minimizing the entry of PCB-contaminated food into consumer channels.

VI. CUMULATIVE, LONG-TERM EFFECTS

PCB's are highly stable and persistent chemical compounds. PCB residues can be found in many forms of wildlife, in fish and other marine life and in other environmental substrates including man. They are cumulative in animals; the exact biological effect of long-term exposure and accumulation of PCB's in living organisms is generally unknown. The rule making 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.

STLCOPCB4063850

VII. INTERAGENCY REVIEW OF RULE MAKING

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 report of the Task Force, entitled "Polychlorinated Biphenyls and the Environment," was made public in May 1972. The findings, conclusions, and recommendations of the report supported the FDA rule making.

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.

DSW 282522