FINAL ENVIRONMENTAL IMPACT STATEMENT

RULE MAKING

ON POLYCHLORINATED BIPHENYLS

Food and Drug Administration

Department of Health, Education, and Welfare

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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.

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

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

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

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.

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.

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

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 anvironmental 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.

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

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

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

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

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

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

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.

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

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.

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

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.

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

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.

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

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

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

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

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

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.

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.

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.

SUPPLEMENT TO THE

FINAL ENVIRONMENTAL IMPACT STATEMENT

RULE MAKING

ON POLYCHLORINATED BIPHENYLS

Food and Drug Administration

Department of Health, Education, and Welfare

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CONTENTS

I. INTRODUCTION

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. Since it was interpreted that implementation of certain provisions of the proposed rule making may significantly affect the quality of the human environment, the Food and Drug Administration (FDA) prepared, in accordance with the National Environmental Policy Act of 1969, an environmental impact statement on the proposed rule making. Accordingly, FDA issued a Draft Environmental Impact Statement on the proposed rule making on May 11, 1972, and a Final Environmental Impact Statement on December 18, 1972. These statements addressed the following aspects of the PCB rule making: Background; description of rule making; environmental impact of rule making; alternatives to rule making; cumulative, long-term effects; and interagency review of rule making. In addition, the Final Statement included a summary of proposed rule making and evaluation of the comments received on the Draft Statement and notice of proposed rule making.

Subsequent to the issuance of the Final Statement, the Council on Environmental Quality advised FDA that the comments received on the Draft Statement should be appended to the

Final Statement. The Council on Environmental Quality also suggested that certain issues FDA intended to address in the final order of the PCB rule making are also appropriate considerations under the National Environmental Policy Act and as such should also be included in the Final Statement. Therefore, FDA has prepared this Supplement to the Final Environmental Impact Statement, which provides additional information relative to the PCB rule making. The Council on Environmental Quality further advised FDA that the provision in its guidelines promulgated under the National Environmental Policy Act, which requires that a final environmental impact statement be issued at least 30 days prior to the time the action it governs is taken, need not apply to this Supplement.

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 under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs issues this Supplement to the Final Environmental Impact Statement - Rule Making on Polychlorinated Biphenyls.

II. SUMMARY OF THE PROBLEM OF PCB's AS FOOD CONTAMINANTS; RULE MAKING ON PCB's AND RELATED ENVIRONMENTAL ISSUES

Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals, which are highly stable, heat resistant, and nonflammable. The industrial applications of PCB's include, or did include in the past, use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids and plasticizers; and use in formulations of lubricants, plasticizers, coatings, and inks. PCB's have been shown to occur as chemical contaminants in foods from the following sources:

A. Because of their unique chemical and physical properties and their widespread, uncontrolled industrial uses, PCB's have become a persistent and ubiquitous contaminant in the environment, resulting in the contamination of certain foods.

B. A number of incidents have occurred in which PCB's have directly contaminated animal feed as a result of industrial accidents i.e., leakage or spillage of PCB's from plant equipment.

C. PCB contaminated paper food-packaging materials made from recycled paper containing waste carbonless copy paper, in which 3-5 percent PCB's are used to encapsulate ink, has led to the contamination of foods as a result of migration of

PCB's from the packaging to the food contained in the package. The use of recycled paper is not, however, the only source of PCB's in paper food-packaging materials. Some paper made from virgin pulp has been shown to contain PCB's. The contamination probably occurred during processing.

The presence of PCB's in food and the sources by which PCB's may contaminate foods represent a potential hazard to public health. For this reason, FDA published a notice of proposed rule making in the FEDERAL REGISTER of March 18, 1972 (37 F.R. 5705) to limit human exposure to PCB's from dietary sources by dealing with known sources and causes of PCB contamination of food. The proposed rule making included the following provisions:

A. Restrictions on the industrial uses of PCB's in establishments manufacturing, handling, or storing animal feeds, food, or food-packaging materials, in order to preclude the direct, accidental PCB contamination of these articles.

B. Amendment of food additive regulation § 121.2546 to allow for food-packaging use of pulp from reclaimed fibers containing unavoidable poisonous or deleterious substances, providing these substances do not migrate to the food.

C. Establishment of temporary tolerances limiting the level of PCB's in animal feed, certain foods, and paper food-packaging materials as a result of unavoidable, environmental contamination.

On May 11, 1972, FDA made available its Draft Environmental Impact Statement which addressed the impact the proposed rule making on PCB's may have on the quality of the human environment. This impact included:

A. Potential adverse effects on the environment from improper disposal of PCB's as a result of requiring removal of PCB's from the FDA-regulated industry.

B. Potential adverse effects on racycled paper activities as a result of implementing the tolerance for paper food-packaging materials.

C. Beneficial affects on human health as a result of controlling the contamination of food with PCB's.

A 60-day period was provided for interested parties to comment on the Draft Environmental Impact Statement.

Comments on the Draft Statement were received from the U.S. Department of Agriculture, the Environmental Protection Agency, the U.S. Department of Commerce, and the American Paper Institute. Copies of these comments are included in the appendix to this Supplement. The Final Statement included FDA's evaluation of these comments. Further

discussion with respect to these comments, as well as other information on the PCB rule making, is provided in this Supplement.

III. BASIS FOR ESTABLISHING THE PCB TEMPORARY TOLERANCES

Section 406 of the Federal Food, Drug, and Cosmetic Act is the authority for establishing the temporary tolerances for PCB's in animal feeds, certain foods, and paper food-packaging materials. It states that where the addition of a poisonous or deleterious substance to food cannot be avoided the Secretary shall promulgate regulations "limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health," and also specifically states that the Secretary shall take into account the extent to which use of the substance "cannot be avoided." This same authority is also applicable to food-packaging materials. The fact that the tolerances for PCB's are termed "temporary" is recognition that in the future there should be less PCB contamination which "cannot be avoided," and the Commissioner is authorized to reduce the tolerance levels accordingly.

The temporary tolerances for PCB's are based on both an analysis of available data on the toxicological effects of PCB's and an analysis of reported levels of PCB's in the food supply.

A. Toxicological Effects of PCB's.

The toxicity of PCB's has been under study for the past several years. The Food and Drug Administration's evaluation of the significance of PCB's on human health and the development of allowable dietary intakes of PCB's was based on an analysis of both animal and human toxicological data and is summarized as follows:

1. Animal Toxicological Data. Available data from long-term animal studies shows that the no-effect level in rats and dogs (for PCB's with 42, 54, and 60 percent chlorination) is 10 ppm. Employing a 100 to 1 safety factor, the "no-effect" level for man based on data derived from dogs would be 2.5 microgram (mcg) per kilogram (kg) body weight per day, or from rats, 3 mcg per kg body weight per day. Therefore, based on long-term animal studies, the allowable level of PCB ingestion in man would be approximately 0.175 milligrams (mg) per day for a 70-kg individual.

2. Human Toxicological Data. Human intoxication with Kanachlor 400, a PCB that is manufactured in Japan and that contains 48 percent chlorine was noted in 1968 when a heat exchanger leaked fluid into rice oil and was consumed by Japanese families. About 1,000 people were eventually affected. Typical clinical findings included chloracne and increased pigmentation, visual impairment due to hypersecretion of the Meibomian glands, and systemic gastrointestinal symptoms that included abdominal pain and disturbances in liver function. A few babies were born with decreased birth weights and with skin discoloration which slowly regressed as the children grew in size. However, the growth rate of males appeared to be somewhat slower than normal. Adult patients had protracted clinical disease with very slow regression of symptoms and signs, suggesting slow metabolism and excretion of this PCB in humans, probably involving a long biological half-life. Exposure levels to the oil were calculated to approximate, on the average, 15,000 mg per day. The oil itself was reportedly contaminated at a level of about 2,000 ppm. This level was derived from the known organic chlorine content of Kanachlor 400. The average

total dose of PCB's causing an effect in the Japanese was reported to be 2,000 mg. The human data[2/] established that the lowest level of PCB that produced an effect in man (using a 50-kg man) was 500 mg consumed over a period of 50 days at a rate of approximately 200 mcg per kg body weight per day. The effect level was based on overt symptoms rather than sensitive biochemical tests that might have demonstrated some effects at even lower levels. Employing a safety factor of 10 to 1 to go from an effect level in man to a permissible no-effect level in man, allows for an ingestion of 20 mcg per kg body weight per day, or 1.4 mg per day for a 70-kg man, based on a total period of exposure of 50 days (equivalent to the Japanese incident). Since PCB's probably have a long biological half-life in man, an alternative toxicological analysis of the human data may be based on the assumption that ingested PCB's would continue to accumulate in tissues for a long period of time. Since 2,000 mg was reported to be the average total dose causing an effect in the Japanese, it is possible that 200 mg total dosage PCB's (applying a safety factor of 10 to 1 as above) may be tolerated over a much more protracted period of time without overt adverse effect if daily exposure is held to minimal levels. It

2/ Kanatsune, et. al., Fukuoka Acta. Med. 23:117 (1971)

would take 22 months of daily ingestion of 300 mcg of PCB's to arrive at a total ingestion of 200 mg. This would permit ingestion of 4 mcg per kg body weight per day in a 70-kg man. Since the lowest total dose producing an effect in man in the Japanese incident was 500 mg, a similar analysis leads to an allowable protracted ingestion of 1 mcg per kg body weight per day as derived from a 70-kg man.

B. Dietary Sources of PCB's.

The results of FDA total diet studies for fiscal years 1970-72 show an intake of approximately 0.06 mcg per kg body weight per day (or 4.2 mcg per day for a 70-kg man). Because of the degree of sensitivity of the analytical methods used, PCB's may be present at levels too low to be detected. If lower levels could be quantitatively measured, the dietary intake of PCB's from the total diet studies would probably show an increase. It should be recognized, however, that in rare instances some people could have more systematic exposures to PCB's in foods than those expected by eating a moderately well balanced diet such as represented by the total diet samples. Hence, the need for minimizing potential human exposures. The total diet studies indicate that PCB's most frequently occur in the food composite consisting of meat, fish, and poultry (experience has shown that most of

the PCB residues in this composite are in fish and, to a lesser extent, poultry) and in the food composite consisting of grain and cereal products (experience has shown most of the PCB residues in this composite are derived from paper-packaging materials). FDA's food surveillance activities have shown that PCB's also may occur in dairy products, eggs, and packaged foods, in addition to packaged cereal products.

C. Temporary Tolerances for PCB's.

Using the human toxicological data described above, FDA concludes that for the short term, based on the lowest total dose producing an effect and estimated biological half-life of PCB's, current levels of PCB's in the diet represent no immediate hazard. This is also true for the average total dose causing an effect in the Japanese for long-term exposure. However, based on the most sensitive "Japanese patient" (i.e., lowest total dose producing an effect), the possibility of potential long-term hazards necessitates reduction of the levels of PCB's in food as soon as possible. In the interim, temporary tolerances are necessary to limit human exposure to those foods that may contain PCB's resulting from environmental contamination, which as a practical matter are presently unavoidable. Those foods for which temporary tolerances are being established include milk and dairy products, poultry, eggs, and fish. In addition, other information necessitates extending the temporary tolerances to other items, as described below:

1. Infants and young children consume a greater amount of food per kilogram body weight and thereby have a proportionately greater exposure than do adults. A separate temporary tolerance for PCB's in infant and junior food, therefore, reflects the possibility that undesirable exposures could result if combinations of certain PCB-contaminated foods comprise a major portion of this age group's diet.

2. PCB's in paper food-packaging materials represent a source of human exposure to PCB's in the diet. The FDA survey of the PCB food-packaging material problem showed that 67 percent of the packaging portions of the samples examined contained PCB's. The highest level was 338 ppm. Analysis also showed that 19 percent of the food portions of the samples contained PCB residues and that there was an average PCB concentration in the food portions of 0.1 ppm. The maximum level of PCB's found in food was 5 ppm. Either limiting the PCB level of paper food-packaging material to 10 ppm or requiring the use of a functional barrier which is impermeable to PCB migration provides the necessary means for limiting this source of PCB contamination of food.

3. Since PCB's are transmitted to and concentrated in edible portions of food-producing animals which ingest PCB-contaminated feed, animal feeds represent another source of PCB's in the human diet. Therefore, temporary tolerances for PCB's in animal feeds and animal feed components are necessary to minimize the frequency and magnitude of PCB residues in foods of animal origin.

FDA concludes that the temporary tolerances being established will protect the public health, but cautions that these temporary tolerances are not to be construed as guidelines permitting the consumption of foods containing these amounts of PCB's on a regular and consistent basis. Further, the temporary tolerances will be lowered as experience indicates that lower levels can be attained.

IV. ALTERNATIVES TO THE PCB TEMPORARY TOLERANCES

The Final Environmental Impact Statement included a discussion of the alternative courses of action available to FDA for each provision of the rule making. The following is a discussion of other alternatives which were suggested by consumer groups and by industry in their comments to the FDA on the notice of proposed rule making.

A. Enforce Zero Tolerances for PCB's in Animal Feeds, Certain Foods, and Paper Food-Packaging Materials.

Animal feeds, certain foods, and paper food-packaging materials contain PCB's, which under present conditions of environmental contamination are unavoidable. Current toxicological information does not support the necessity of establishing zero tolerances for these items in order to protect public health, since human exposure to dietary sources of PCB's is usually sporadic, nonsystematic, and occasional. The "finite" temporary tolerances being established by FDA will provide the assurance that significant PCB levels are not contained in food and that human exposure to PCB's from dietary sources will be maintained at safe and minimum levels. Zero tolerances, therefore, are unwarranted and would unnecessarily deprive the consumer of a portion of his food supply and would disrupt the Nation's food distribution system, because certain quantities of fish, poultry, eggs, milk, and food-packaging material would be violative.

B. Impose No Tolerances for the PCB Contamination of Animal Feeds, Certain Foods, and Paper Food-Packaging Materials.

This alternative was explored by FDA and rejected for the following reasons:

1. No authorization has been granted under the Federal Food, Drug, and Cosmetic Act permitting PCB's as components of food or as substances otherwise affecting the characteristics of food. The fact is, however, that PCB's are components of foods as a result of unavoidable, environmental contamination. Analysis of current toxicological data demonstrates a potential hazard to human health if dietary exposures to PCB's are not controlled. Therefore, as poisonous or deleterious substances, PCB's in animal feeds, foods, and paper food-packaging materials render such articles adulterated under the Federal Food, Drug, and Cosmetic Act. Failure to initiate positive action, i.e., establish limits on the PCB content of these articles and remove from consumer channels those articles containing PCB's in excess of the established limits, would be contrary to the interests of public health and contrary to congressional mandate.

2. In the absence of tolerances for PCB's in foods, FDA has used "action level guidelines" for determining the level of PCB contamination at which regulatory action is to be initiated. During the past 3 years, FDA, the U.S. Department of Agriculture, and State and local agencies have used these action levels as the basis for removing PCB-contaminated foods from commercial channels. The PCB temporary tolerances now being established are

generally comparable to these action levels both in terms of the level at which regulatory action is taken and the reason for taking regulatory action, i.e., protection of public health. The major distinction is that the tolerances are issued as a proposed regulation upon which all interested parties are invited to comment. Once established as a regulation, tolerances provide guidance to all regulatory agencies and to industry in order to assure efficient and equitable enforcement and consumer protection.

C. Establish Tolerances for Packaged Foods Rather Than Paper Food-Packaging Materials.

This alternative, which the paper industry recommended, was considered by FDA and rejected for the following reasons:

1. Since the transfer of PCB's from packaging material to the food is dependent on time and conditions of exposure, tolerances based solely on the packaged food would not provide adequate protection to the consumer. A packaged food analyzed at the time of packaging may be entirely free of PCB's, but by the time it reaches the consumer and is finally consumed it may have accumulated considerable quantities of PCB's if the packaging material is contaminated. A tolerance system in which analytical findings are so dependent on many variables such as time of sampling would not be reasonable or adequate.

2. In order to achieve compliance with a tolerance for packaged food, the level of PCB's in the packaging has to be taken into account and limited in order to preclude the potential transfer to the food of quantities of PCB's that would cause the food to exceed its tolerance level. Since the level of PCB's in packaged food is related to the level of PCB's in its packaging, tolerances for both the food and its packaging would be necessary. This amounts to an obvious redundancy.

3. Establishing a tolerance for packaged food alone would be inconsistent with the intent and meaning of Section 406 of the Federal Food, Drug, and Cosmetic Act. The packaged food by itself does not contain unavoidable PCB residues; the principal source of the PCB contamination of packaged food is the paper food-packaging material, which contains the unavoidable contamination. Accordingly, the tolerance should deal with this material. Therefore, this source of food contamination should be limited so as to minimise the levels of PCB's that may migrate to the packaged food.

4. Failure to limit the level of PCB's in paper food-packaging materials would perpetuate the use of a known, avoidable source of PCB contamination of food.

D. Exempt Aroclor 1242 from the PCB Temporary Tolerance for Paper Food-Packaging Materials.

This alternative, which FDA investigated and rejected, was also recommended by the paper industry. The paper industry comments state that the establishment of the PCB tolerance for paper food-packaging materials is unwarranted for public health reasons, because available scientific evidence shows that Aroclor 1242 (the predominant PCB found in paper) is not persistent and cumulative, and thus will not present a chronic toxicity problem. Although data indicates that some components of Aroclor 1242 are metabolized in biological systems more rapidly than the other higher chlorinated Aroclors, there is no information available which describes the composition, toxicity, and fate of the metabolic products. The absence of Aroclor 1242 residues in human and certain animal tissue and in the environment is not a sound basis from which to argue that no hazard exists from the ingestion of Aroclor 1242. The possibility exists that Aroclor 1242 is converted to alteration products which may be more toxic than the original compounds, but which are not detectable by current analytical methods. Further, available data from chronic feeding studies with rats and dogs fail to substantiate claims that Aroclor 1242 does not represent a toxic substance or that it differs in toxicity

from other Aroclors. Therefore, the Commissioner concludes that the temporary tolerance will apply to the term "PCB" irrespective of which Aroclor is present as the contaminant.

E. Postpone the PCB Tolerance for Paper Food-Packaging Materials Until Certain Information is Developed.

Comments received from industry and related trade associations argued that the temporary tolerance for PCB's in food-packaging materials should be deleted or postponed until: (1) quality control test procedures and adequate analytical methods are developed to regulate production and insure compliance, and (2) migration rates are established to take into account barrier effects, type of food, and the ratio of package weight to food weight. FDA considered these comments and concluded that the establishment of the tolerance should not be postponed for the following reasons:

1. Although a trade association submitted data which it claimed indicates a lack of reliability in analyses of paperboard material, the data failed to show that uniform test methods were employed by the participating laboratories or that these tests were performed by laboratories with demonstrated capabilities in trace residue analysis. Further, an interlaboratory study that was conducted under the auspices of another trade association and that utilized FDA analytical

methodology supports the conclusion that current methodology is adequately sensitive and reproducible from laboratory to laboratory to insure compliance with the tolerance.

2. It is recognised that migration rates (actual level of PCB's in food resulting from the use of contaminated packaging material) are affected by factors such as barriers, type of food, the ratio of package weight to food weight, and exposure time and conditions. Since FDA's primary concern is not the fact that paper food-packaging materials contain PCB's, but the fact that PCB's can migrate to the food from the packaging, then the use of barriers which prevent migration is an acceptable alternative to limiting the PCB content of paper food-packaging material. For this reason, the proposed rule making has been revised in the final order in § 122.10(a)(9) by exempting paper food-packaging materials from compliance with the temporary tolerance if the paper food-packaging material is separated from the food by a functional barrier impermeable to PCB migration. Metal cans and glass bottles are obvious examples of what constitues a functional barrier impermeable to PCB migration. Data from industry-sponsored studies have shown the materials such polyvinylidena-coated paper and glassine can, to varying degrees, prevent or reduce PCB migration under test conditions which would favor migration.

FDA would not object to the use of flexible materials and other materials as barriers, provided there is no evidence of migration of PCB's to the food. At this time, however, there is insufficient information for FDA to list as part of the regulation those materials that are considered functional barriers. The other factors mentioned above which affect migration rates may also be important considerations and should be thoroughly studied. In the interim, the temporary tolerance for paper food-packaging materials and the exemption to this temporary tolerance are considered necessary to assure the consumer that packaged food is not being contaminated with PCB's to an avoidable degree.

F. Establish a Higher Tolerance for Paper Food-Packaging Materials.

The notice of proposed PCB rule making included the proposal to establish the temporary tolerance for PCB's in paper food-packaging materials at 5 ppm. In exploring alternative courses of action regarding this regulation, FDA reevaluated the 5 ppm tolerance level. Data from the FDA survey of PCB's in foods and food-packaging material showed that the food portion of the samples with 5-10 ppm PCB's in paper food-packaging material contained the same range of PCB levels (0.1-0.6 ppm) as the food portion of the samples with 0-5 ppm in paper food-packaging material. Samples with more than 10 ppm in the

packaging contained higher levels in the food, ranging up to 3.7 ppm. On the basis of this information, the FDA concluded that the final order of the PCB rule making should be changed to incorporate a revision in the temporary tolerance for PCB's in paper food-packaging materials from 5 ppm to 10 ppm. This revision in the tolerance was also stated in the Final Environmental Impact Statement on the PCB rule making.

V. ENVIRONMENTAL IMPACT OF THE PCB RULE MAKING

Since the PCB rule making will reduce human exposure to dietary sources of a toxic, chemical contaminant, FDA concluded in its Final Environmental Impact Statement that the rule making will have a beneficial effect on the quality of the human environment.

The Final Statement also included a discussion concerning potential adverse effects the rule making may have on the quality of the human environment. The following is additional information relative to this matter:

A. Environmental Impact of PCB Replacement or Substitutes.

During the development of the provisions of the rule making, consideration was given to the possible adverse effects on the environment of those chemicals which may be used as replacements or substitutes for those industrial uses of PCB's prohibited by

the rule making. FDA was and continues to be concerned that the regulation could have the effect of causing the use of chemicals which would pose a threat to the environment and to human health. For this reason, a requirement in the final order of the rule making will call attention to this potential problem in order to reduce the likelihood of introducing a new "PCB-type problem." This requirement is as follows:

> "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: (1) its toxicity; (2) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account the fluid's color and odor; (3) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (4) 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."

Furthermore, the numerous PCB-associated "accidents" that have occurred in the past and the provisions of the rule making itself will serve as incentives to prevent future

problems from occurring. Industry should be more cognizant of the serious repercussions that can result from the indiscriminate use of toxic chemicals and from accidents of this type, such as adverse effects on human health and the environment, adverse publicity, criminal and civil penalties, and substantial financial losses. In addition to these considerations, there is information which indicates that less toxic, biodegradable PCB replacements have been developed and are being used for heat transfer systems and other industrial applications that have caused past environmental problems.

In conclusion, FDA can only speculate that some PCB replacements or substitutes may present future environmental problems. However, it is known with certainty that the continued use of PCB's by the regulated industries presents a definite hazard to man and his environment. Therefore, FDA's action to restrict the use of this contaminant in feed, food, and food-packaging material manufacturing establishments is clearly more beneficial to the quality of the human environment than allowing the continued use of PCB's.

B. Impact on Recycling Activities.

In commenting on the notice of proposed rule making, the paper industry and its trade associations have stated that the temporary tolerance for PCB's in paper food-packaging materials would be detrimental to the Nation's commitment to utilize recycling in solid waste disposal programs. This alleged

adverse environmental impact is based on the paper industry's contention that the tolerance would place severe economic hardships on recycling mills, as follows:

1. "Significant" quality control costs would be required to assure compliance with the tolerance; and

2. Financial losses would be incurred when products which contain PCB's in amounts above the tolerance are rejected.

The paper industry concludes that these increased costs in production would cause the closing of some recycling mills and thus result in the adverse environmental impact cited above.

This aspect of the rule making was addressed in the Final Environmental Impact Statement. FDA concluded that the revision in the tolerance level and allowing an exemption to the tolerance would reduce or eliminate the alleged adverse effects on recycling programs. First, increasing the tolerance for paper food-packaging materials from 5 ppm to 10 ppm is expected to result in only a low percentage of paper products being excluded from use for food-packaging purposes. This conclusion was based on industry survey data which showed that 20 percent or more of paperboard samples tested contained PCB levels in excess of 5 ppm, while about 7 percent exceeded the tolerance level of 10 ppm. Second, the exemption from the tolerance when a functional barrier is used will serve to further reduce the percentage of paperboard that would be unacceptable (i.e., containing PCB's in an amount above the tolerance level) for food-packaging use.

In addition, the Final Statement stated that recycled paper products are not being singled out as objects of this tolerance. Virgin paper products have been shown to contain PCB's and, for this reason, the entire paper industry will have to bear added costs of implementing quality control procedures. In this respect, recycling mills are not being placed at a competitive disadvantage. Furthermore, these added costs are fully warranted and justified because of the public health benefits that will be derived from regulating this source of food contamination.

As a possible means of reducing the incidence of food-packaging materials that exceed the tolerance level for PCB's, the Environmental Protection Agency stated in its comments on the Draft Environmental Impact Statement that consideration should be given to removing from existing inventories carbonless copy paper that contains PCB's. In the Final Statement, FDA responded to the EPA comment by stating that it lacks jurisdiction to implement this action. This continues to be the reason FDA does not consider this approach an effective and realistic alternative to the temporary tolerance for PCB's in paper food-packaging materials. However, FDA does recognize that it may be feasible to some degree to control the flow of PCB-containing carbonless copy paper into waste paper channels, and thus lessen any impact the PCB rule making may have on recycled

paper programs. In this regard, FDA has contacted the Environmental Protection Agency and requested its assistance in exploring possible procedures for implementing the Environmental Protection Agency's suggestion.

C. Economic Considerations.

The U.S. Department of Commerce, in its comments on the Draft Statement, stated that a cost/benefit analysis relative to the PCB rule making should be conducted. The Final Statement responded to this comment by stating that since a cost/benefit analysis is an economic consideration, it is not a proper subject of an environmental impact statement. The Counsel on Environmental Quality advised FDA that economic considerations should be addressed along with the environmental considerations under the National Environmental Policy Act. FDA is in agreement and retracts its previously stated position on this matter for the following reasons:

1. The position is contrary to the National Environmental Policy Act.

2. The position is not an accurate reflection of the considerations given by FDA to the economic impact of the PCB problem.

FDA recognized that because PCB's are widely used and important industrial chemicals and ubiquitous environmental contaminants, any action taken would have adverse economic consequences. FDA also recognized that because PCB's are toxic substances, not taking action with respect to the sources of PCB contamination of the food supply would have adverse consequences on human health. In the development of the PCB rule making, FDA fully considered consequences in terms of both the cost of compliance and the health benefits derived from minimizing human exposure to PCB's. The rule making reflects a balance between these consequences, i.e., the regulations are not more restrictive than is necessary to protect public health. This fact is exemplified in the proposed rule making, wherein it was stated: "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." The Draft and Final Environmental Impact Statements on the PCB rule making contained similar examples of FDA's considerations relative to the cost/benefit aspects of the rule making. In addition, this Supplement responds to industry comments that the rule making will cause a severe economic impact on the recycling industry.

Therefore, although not explicitly stated in the above Statements and proposed rule making, FDA conducted a form of a cost/benefit analysis. After full consideration of alternative courses of action, the toxicological effects of PCB's on human health, and other related information, FDA concluded that each provision of the rule making is necessary in order to minimize human exposure to PCB's from all dietary sources and that the health benefits derived outweigh any adverse economic consequences that may result.

COMMENTS RECEIVED ON

DRAFT ENVIRONMENTAL IMPACT

STATEMENT

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

October 18, 1972

Dr. L. L. Ramsey
Assoc. Director, Regulatory Programs
Office of Compliance
Bureau of Foods, FDA
Washington, D.C. 20204

Dear Dr. Ramsey:

We have reviewed the document "Draft Environmental Impact Statement, Notice of Proposed Rule Making, Polychlorinated Biphenyls, May 8, 1972."

The Department of Agriculture participated in the Interdepartmental Task Force on PCBs, which also received copies of the draft notice of proposed rule making on February 29. As indicated on page 20, the Task Force, including the USDA representatives, found no objection to the FDA proposal.

In addition, the Department formed its own ad hoc group on PCBs which has prepared a report on "Agriculture's Responsibility Concerning PCBs" (enclosed). This group also supports the FDA notice of proposed rule making.

It is believed that these proposed actions will considerably reduce the accidental contamination and long-term exposure of man to PCBs in the U.S. The widespread occurrence of PCBs in the environment already makes it highly desirable to set temporary tolerances for PCBs as proposed, until the background levels are reduced.

This Department wishes, therefore, to support this environmental impact statement. Appreciation is expressed for the opportunity to review it.

Sincerely,

Gerald F. Combs

GERALD F. COMBS
Nutrition & Food Safety Coordinator
Science and Education

MONS 042838

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 14 1972

Hearing Clerk
Department of Health, Education, and Welfare
Room 6-88, Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

We apologize for the delay in responding to the draft Environmental Impact Statement and to the Proposed Rule Making on Polychlorinated Biphenyls (PCB) of May 8, 1972. I hope it is not too late to make use of our comments.

The Environmental Protection Agency has no objection to the intent of or principle behind the proposed rule making. We do feel, however, that until a consistent dependable analytical method for PCB quantification is developed that FDA sampling procedures be carefully structured to avoid any condemnation of packaging material that is based on only one or two samples.

The proposed rule making and the draft environmental impact statement should emphasize the concern over the ultimate PCB content of packaging material rather than the level in the source material. The EIS gives the impression that contaminated pulp can only come from recycling. For example, item 4 on page 7 of the EIS describes an amendment to the regulation which prohibits "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," (emphasize ours). A restructuring of this language would alleviate any potential discrimination against recycling.

The data on migration of PCB's from packaging to food in quantities needs further exploration in the use of barriers. Procedures for sampling and enforcement of this regulation should take into consideration the difficulties in accurately measuring PCB content. Moreover, no support is given in the statement or in the report of the Task Force for the 5 ppm tolerance level for food packaging. The statement should detail whatever justification was used for this figure.

An additional method towards the reduction of PCB levels in food packaging which might merit examination is the removal of carbonless copy paper containing PCB's from existing inventories. If this is

found economically feasible it would aid in eliminating the reappearance of PCB's in paperstock used for manufacturing paper board.

We appreciate the opportunity to comment on the draft environmental impact statement and the proposed rule making. We look forward to receiving a copy of the final impact statement. Please contact us if we can be of any further assistance.

Sincerely yours,

Sheldon Meyers

Sheldon Meyers
Director
Office of Federal Activities

THE ASSISTANT SECRETARY OF COMMERCE
Washington, D.C. 20230

September 15, 1972

Mr. Robert C. Brandenburg
Acting Deputy Associate Commissioner
for Compliance
Department of Health, Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Maryland 20852

Dear Mr. Brandenburg:

The draft environmental impact statement, Notice of Proposed Rule Making, Polychlorinated Biphenyls which accompanied your letter of August 21, 1972 has been received by the Department of Commerce for review and comment.

The Department of Commerce has reviewed the draft environmental statement and has the following comments to offer for your consideration. We believe this statement should be redrafted and recirculated.

General Comments

1. Little or no discussion of the toxicological effects of PCB's on human health or the effects of PCB's on biota is included in the statement, making it very difficult to appraise the relevance of and basis for the PCB levels proposed. Information on these subjects should be added to the statement.

2. The rules as stated in the statement are incomplete. The time required for compliance, the testing to determine the presence of PCB's and the verification of the absence of PCB's has been omitted and should be included for comment. The 30 day period for compliance as stated in the Federal Register, Volume 37, No. 54 of March 18, 1972, will pose

hardships to industry, especially if new equipment is required within this period. Further, it is unlikely that testing facilities and instrumentation are adequate to perform the work required by the rules in the necessary 30 day period.

3. While the general intent of the rules is clear, the ommission of coatings and paints from food-packaging material establishments and food establishments may make the interpretation and enforcement of "the elimination of any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's" difficult. The same circumstances may also occur because the rules do not clearly cover machinery for manufacturing, processing, storing and handling consistantly for all three categories of establishments. Similarly, the statement does not address handling and storage for transportation and in-transit storage facilities or equipment.

4. While the environmental impact of the removal and disposal of PCB-containing materials is discussed, no indication of the need for or existence of rules controling removal and disposal is made in the statement. This issue should be addressed irrespective of FDA's jurisdiction of it.

5. The statement indicates that some materials which would replace PCB-containing materials would have similar characteristics to those of PCB's because of the use conditions. If it is implied that those replacement materials be subject to the Environmental Impact Statement review process this statement should clearly affirm or deny that implication.

6. In our judgment, this impact statement does not meet the NEPA requirement for "a detailed statement by the responsible official"; nor does it follow the format provided by NEPA. In particular, a cost/benefit analysis has been omitted. Not only is one required, but in this case, it is of

special importance because the impact statement contains no other economic or social information and the control of PCB's has potentially a considerable economic impact. Also, the health benefits have not yet been clearly established. A thorough and comprehensive cost/benefit rational and analysis should be included in the statement.

7. While the actions necessary to remove PCB's from equipment according to the proposed rules are reasonably clear, the discussion of the removal of PCB-containing materials from the waste recycling program is not clear or complete enough to appraise the effects of the proposed rules on industry. Some "carbonless" carbon paper may be being removed from the recycling process now, but the extent of that practice throughout that industry is not stated, nor is the effectiveness of that practice in reaching the temporary tolerance limit stated. Because such a very small quantity of carbonless carbon paper per ton of waste paper when recycled exceeds the proposed tolerances, it is unlikely that the tolerance limit can be met without significant additional costs to the recycling industry thus reducing its competitiveness in the market and its chances of survival. When carbonless carbon paper is combined with unknown materials containing PCB's the problem is further compounded, making the tolerance limits even more difficult to achieve. The actions by the recycling industry necessary to meet the proposed rules are in the main different from and more difficult than those the virgin paper industry must take. While the intent of FDA is not to propose rules detrimental to the waste recycling program, that in fact may very well be the effect. The impact statement should address recycling in depth to protect against any economic and hence function dislocation of this important conservation effort.

8. The statement does not discuss the temporal aspects of the temporary tolerances, nor the ways by which a "sufficient period of time to permit elimination of such (PCB) residues at the earliest practical time" is to be determined. These issues are components of the economic impact of the rules and information about the expected duration of the temporary tolerances and some definition of "sufficient" and "earliest practical time" should be included in the statement.

9. The rational for not establishing the PCB tolerance of the food itself described under Alternatives on page 16 is only valid because present information about the chronic toxicological effects of PCB's is not sufficient.

This alternative is highly desirable, because it would provide the necessary incentives to the food packaging and processing industry to research and develop alternative solutions to the control of PCB's in food from any source. It would further the development of not only new products but the development of new and improved tests and instrumentation as well as produce a better understanding of the chemical and physical composition and behavior of PCB's. Conversely, prescriptive restrictions on products ancillary to the real purpose of the proposed rules serve only to discourage the type of technological invention that a rule on the PCB tolerance of food would foster. A part of the rational for not setting food tolerances should be amended in the statement so that once toxicological effects are adequately determined, limits could be adjusted accordingly.

In summary, we believe the impact statement is not adequate for the type of balanced factual consideration expedited under NEPA and suggest that it be rewritten with more information and redistributed for comment.

Sincerely,

Sidney R. Galler

Sidney R. Galler
Deputy Assistant Secretary
for Environmental Affairs

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October 6, 1972

Miss Beryl McCullar
Hearing Clerk
Department of Health, Education and Welfare
Food and Drug Administration
Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Re: In the Matter of
POLYCHLORINATED BIPHENYLS
Proposal to Amend 21 C.F.R.
Parts 3, 121, 122, 128

Dear Miss McCullar:

When FDA's final environmental impact statement relating to the proposed PCB regulations is issued, it is likely that the American Paper Institute (API) will file comments during the thirty day period provided for this purpose by the Guidelines of the Council on Environmental Quality (CEQ). See 36 Fed. Reg. 7724, 7726 (April 23, 1971). It is API's position that both legal and policy considerations require a period of at least thirty days for comment on the final environmental impact statement before the final regulation issues.

The National Environmental Protection Act provides that both the final statement and the comments of interested parties shall "accompany the proposal through the existing agency review processes ... ." NEPA §102(2)(C), 42 U.S.C. §4332(2)(C). The purpose of this provision is to assure agency consideration of all environmental factors in the formulation of regulations. This would be impossible if final regulations were issued in advance of the opportunity for comment on the environmental statement.

Moreover, the CEQ Guidelines and the published procedures of the Department of Health, Education and Welfare (36 Fed. Reg. 23676-23679 (Dec. 11, 1971)) spell out a precise timetable to facilitate agency consideration of the statement and public comments. Both Section 10(b) of the CEQ Guidelines and Section 20-15-80(B)(3) of the HEW procedures, which are applicable to FDA, require an agency to issue its final environmental impact statement "at least thirty days before acting." "Acting" in this context can have no meaning other than the affirmative step by which the proposal is formally enacted -- a Section 701(e)(1) order. This language clearly precludes contemporaneous release of the statement and the order, even if the effective date of the regulations is postponed for thirty days. After the thirtieth day, the regulations would automatically become effective without the need for further FDA action.

These procedural requirements are designed to afford a meaningful opportunity for interested parties, including industry and other governmental agencies, to comment on the completed environmental statement, and for the agency to consider these comments before it finally commits itself. The opportunity would be seriously undermined if, as has been suggested, FDA issues the impact statement and PCB regulations simultaneously.

Sincerely yours,

Selma M. Levine
Counsel for American Paper Institute, Inc.

SML/gw
cc: Mr. Fine
Mr. Brandenburg
Mr. Wessel

MONS 042846