Monsanto

FROM (NAME & LOCATION) W. B. PAPAGEORGE -ST.LOUIS

DATE JUNE 14, 1972 CC: K. W. EASLEY - 1920

SUBJECT FDA PROPOSED RULE MAKING - PCB

REFERENCE

TO :
H. S. BERGEN
W. R. COREY
T. L. GOSSAGE
P. S. PARK
~~W. PATON~~
J. F. STAPLETON
E. P. WHEELER

B.U. 7/6

We will meet Friday, June 16 in Room B-274 at 10:00 a.m. to review plans for commenting on the proposed FDA rule making relating to PCB's in food, food packaging and animal feeds.

Present plans include an informal discussion with appropriate FDA representatives on June 20-21 followed by a written statement submitted to the Hearing Clerk, HEW, before July 16.

Our objectives are:

1. Impress on FDA the impracticality of achieving zero detectable PCB's in converted heat transfer units.

2. Establish if we can continue to market replacement Therminols in food or food related processes.

3. Discuss the legal authority which enables the FDA to regulate PCB's as proposed.

I have attached the following:

1. Copy of Proposed Rule Making.

2. List of pertinent questions to be considered.

3. Summary of known comments submitted to the Hearing Clerk, HEW.

4. Summary of information relating to converted heat transfer systems.

5. Toxicity data - Therminal 55 and Therminol 66.

W. B. PAPAGEORGE

ms

the time prescribed in the notice of proposed rule making and who desire to present oral comments at such hearing should by May 12, 1972, submit an outline of the topics and the time they wish to devote to each topic. Such outlines should be submitted to the Commissioner of Internal Revenue, Attention: CC:LR:T, Washington, D.C. 20224.

Persons who desire a copy of such written comments or suggestions or outlines and who desire to be assured of their availability on or before the beginning of such hearing should notify the Commissioner, in writing, at the above address by May 17, 1972. In such a case, unless time and circumstances permit otherwise, the desired copies are deliverable only at the above address. The charge for copies is twenty-five cents ($0.25) per page, subject to a minimum charge of $1.

LEE H. HENKEL, JR.,
Acting Chief Counsel.

[FR Doc.72-4221 Filed 3-17-72;8:53 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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

POLYCHLORINATED BIPHENYLS

Notice of Proposed Rule Making

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

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

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

The Food and Drug Administration has been conducting a national survey to determine the extent and levels to which complete animal feeds are contaminated with PCB's. The survey results available to date show that less than 5 percent of the animal feeds sampled contain PCB's. Levels range from no detectable contamination to a maximum PCB level of 0.6 part per million. It appears that complete animal feeds are not a significant source of PCB's for food-producing animals and that PCB contamination of feeds for food-producing animals can generally be attributed to avoidable industrial accidents and practices. Investigations by FDA have revealed the use of PCB's in heat exchange fluids used in certain pasteurization equipment. Although heat exchange fluids in such equipment are considered to be in "closed systems," accidents have occurred that resulted in direct contamination of animal feed with PCB's and subsequently in contamination of food products such as poultry and eggs intended for human consumption. The use of PCB-containing coatings on the inner walls of silos has resulted in the contamination of silage which has in turn caused PCB residues in the milk of dairy cows. It is suspected that other industrial uses of PCB's have also resulted in the PCB contamination of animal feed and food for human consumption during processing and manufacturing.

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

The level of PCB contamination of foods from packaging materials is dependent upon many factors (e.g., levels of PCB's in food-packaging materials, type of food, length of storage). This is shown by the results of a national survey conducted by FDA, which revealed that even though 67 percent of the complete food packaging tested contained PCB's at levels as high as 338 parts per million, only 19 percent of the foods in these packages contained PCB's. The average PCB concentration in food was 0.1 part per million, and the maximum PCB level found was 5 parts per million. The survey further showed that 75 percent of the food product in packaged infant cereal samples contained PCB's. The average PCB concentration in the cereal was 0.3 part per million, and the maximum PCB level found was 1 part per million.

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

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

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

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

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

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

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

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

MONS 098515

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

4. A temporary tolerance of 5 parts per million in paper food-packaging materials should be established permitting unavoidable PCB residues in these products for a sufficient period of time to provide an opportunity for the orderly elimination of PCB-containing raw materials used in the manufacture of food-packaging materials. There are no provisions for permissible uses of PCB's under 21 CFR 121.2520 or 121.2571. This temporary tolerance is not to provide for direct uses under the above regulations. Immediate elimination of all food packages containing PCB's would disrupt the nation's food packaging and distribution system and is not warranted by the hazard to human health.

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

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

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

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055–56 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785–88 as amended; 21 U.S.C. 342(a), 346, 348, 371) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Parts 3, 121, and 128 and to establish a new Part 122, as follows:

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

1. By adding the following new sections to Part 3:

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

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

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

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

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

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

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

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

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

(iv) Eliminate the use of any food-packaging materials that contain in excess of the 5 parts per million temporary tolerance for PCB's established in § 123.10 of this chapter.

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

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

(a) PCB contamination has been detected in paper food-packaging materials. Such contamination may have in some cases resulted from the use of PCB's in heat exchange fluids or other PCB-containing materials in the establishment manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

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

(2) Within 30 days following the effective date of this order, the management of establishments manufacturing food-packaging materials shall:

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

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

PART 121—FOOD ADDITIVES

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

§ 121.2546 Pulp from reclaimed fiber.

* * * * *

(b) * * *

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

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

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

Subpart A—Definitions and Procedural and Interpretative Regulations

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

§ 122.1 Definitions and interpretations.

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

MONS 098516

(b). Unavoidable natural, [redacted] iron-mental, or industrial contam[redacted]s include any poisonous or deleterious substance added to any food where such substance cannot be avoided by good manufacturing practice.

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

(a) Temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time, as follows:

	Parts per million
(1) Milk (fat basis)	2.5
(2) Dairy products (fat basis)	2.5
(3) Poultry (fat basis)	5.0
(4) Eggs	0.5
(5) Finished animal feeds	0.5
(6) Animal feed components (including fishmeal)	5.0
(7) Fish (edible portion)	5.0
(8) Infant and junior food	0.1
(9) Food-packaging material	5.0

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

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

§ 128.4 Equipment and utensils.

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

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

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

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

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

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

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

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

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

(Secs. 402(a), 406, 408, 701, 52 Stat. 1046 as amended, 1049, 1055–59 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785–88 as amended; 21 U.S.C. 342(a), 346, 348, 371)

Dated: March 16, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-4256 Filed 3-17-72;8:53 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 164]

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Proposed Advisory Committees and Rules of Practice Governing Hearings

Notice is hereby given that § 164.4(c) of Part 164 of Chapter I of Title 40 of the Code of Federal Regulations, issued pursuant to sections 4 and 6 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 135, 135d), is proposed to be revised to read as set forth below. This proposal to amend § 164.4(c) is independent of the proposal, published in the FEDERAL REGISTER on January 22, 1972 (37 F.R. 1059), to amend Part 164 in its entirety. In other words, this proposal signifies our intention to amend § 164.4(c) regardless of whether the previously proposed amendment is adopted in final form.

Any person may file comments on this proposal within 30 days from the date of publication of this notice in the FEDERAL REGISTER. Such comments should be filed in duplicate and addressed to the Hearing Clerk, Environmental Protection Agency, Room 3125, South Agriculture Building, 14th and Independence Avenue SW., Washington, DC. All written submissions filed pursuant to this notice will be available for public inspection.

Explanatory statement. This Agency anticipates that it may, in the immediate future, be called upon to consider suspending the registrations of a number of currently registered pesticide products and that its review may result in such suspension. While affected registrants will have the right to invoke on an expedited basis the full-scale administrative review procedures established by the FIFRA, those procedures, even on an expedited basis, necessarily consume a great deal of time. During that period, interstate shipment of the product is prohibited and, by virtue of doctrines reflected in the en banc decision of the U.S. Court of Appeals for the Seventh Circuit in Nor-Am Agricultural Products v. Hardin, 435 F. 2d 1151, no immediate remedy is available to the registrant. For, under those doctrines, judicial review of suspension orders is precluded until the registrant first exhausts the lengthy administrative review process.

The Congress apparently intends to change the governing statutory provisions and thereby overrule the Nor-Am result. Specifically, section 6(c)(3) of H.R. 10729, the proposed pesticides legislation which has been approved by the House of Representatives and is pending in the Senate, would permit immediate review of suspension orders in a district court. We believe that, in order to assure fairness to registrants and at the same time to comply with the spirit of the proposed legislation, this Agency should take whatever steps are available to it under current law to insure that registrants faced with suspension action are able to obtain immediate review of that action.

The procedure adopted today accomplishes that end. Under that procedure, the Agency is required to issue a notice of cancellation whenever suspension is ordered (the Agency rules proposed on January 22, 1972, and the pending legislation both contain similar requirements). Building on that requirement, other language in the rule expresses clearly that the considerations which control suspension decisions are somewhat different from those which govern ultimate cancellation.

MONS 098517

QUESTIONS RELATING TO PROPOSED FDA
PCB REGULATIONS

1. How were proposed levels in food, feed and packaging materials developed?

2. What sampling and analytical procedures are proposed? Samples range from heat transfer fluid to milk to stretch film packaging.

3. What corrective actions are permissable to reach acceptable PCB levels? Barriers in packaging, trimming of fat from poultry, skimming of milk, etc.?

4. How much PCB will be tolerated in converted units?

5. What is meant by "harmful and deleterious" as it applies to heat transfer fluids?

6. Is proposal intended to apply to capacitors or transformers?

MONS 098518

TOXICITY DATA

THERMINOL® 66 Heat Transfer Liquid
THERMINOL® 55 Heat Transfer Liquid

THERMINOL 66 (hydrogenated terphenyl) has an oral LD_{50} of 10.2 g/kg to albino rats and a dermal LD_{50} of approximately 6.8 g/kg to albino rabbits. This material is considered to be practically non-toxic by ingestion in single doses and by single dermal applications.

The undiluted product is a moderate irritant to rabbit skin (average score 3.1 on a scale of 8), but practically non-irritating to the rabbit eye (average score 6.4 on a scale of 110). Human patch tests on 200 subjects indicate that THERMINOL 66 is neither a primary irritant nor a sensitizer.

The product was fed to groups of albino rats, 15 males and 15 females per group, for 90 days at dietary concentrations of 100 ppm, 300 ppm, and 1,000 ppm. A similar group of 30 animals served as controls. There was no untoward behavior among these animals, and there were no deaths which could be attributed to ingestion of the product. Comparisons of final body weight and total weight gains revealed no statistically significant differences between test and control animals. There was a similar lack of outstanding differences between test and control rats in food consumption, blood parameters (hematocrit, hemoglobin, erythrocyte count, and total and differential leukocyte counts), clinical chemical values (blood urea nitrogen, blood glucose, and serum alkaline phosphatase and serum glutamic-pyruvic transaminase activities), and the results of urinalyses (pH, specific gravity, glucose and albumin concentrations, and microscopic examination).

At the end of the feeding period, all surviving animals were sacrificed and given a thorough gross autopsy during which the weights of liver, kidneys, spleen, gonads, heart, and brain were determined and recorded. Females fed 1,000 ppm of the product had statistically significant increases of absolute liver, kidney, and brain weights and the corresponding organ to body weight ratios. The 300-ppm group of females had a statistically significant increase of liver to body weight ratio, but the absolute liver weights were not sifnigicantly elevated. Although some statistically significant intergroup differences were noted in other groups, none of these differences could be related to ingestion of the product. Gross pathological examination did not reveal outstanding differences between test and control rats. Tissues and organs (approximately 30 per animal) from ten rats of each sex in both the control and 1,000 ppm group were examined microscopically. No lesions were observed which could be related to ingestion of THERMINOL 66.

Limited studies indicate that THERMINOL 66 undergoes primary biodegradation and that it would not be a persistent aquatic pollutant if small amounts inadvertently entered waterways. Additional support for this view can be obtained from two published articles dealing with the environmental effects of HB-40. (An earlier designation for THERMINOL 66 was HB-40). The first is by J. E. Guthrie and O. E. Acres, Toxicity to Fish of Two Organic Reactor Coolants, Bull. Environ. Contam. & Toxicol. 5 (No. 2): 145-151 (1970). It states that ".... less than 25% of the fish (trout fry) died within 48 hours in HB-40 suspensions containing 100 mg/l or less....". The second is by J. L. Weeks, An Organic Cooled Nuclear Reactor and Its Environment, Arch. Environ. Health, 23: 123-128 (1971). This article has a general discussion of the environmental problem and concludes that HB-40 has not adversely affected the environment after 5½ years of use in a reactor in Manitoba, Canada.

THERMINOL 55 (alkylated benzene) has an oral LD_{50} of 15.8 g/kg to albino rats and a dermal LD_{50} of 7.94 g/kg to albino rabbits. This product is considered to be practically non-toxic by ingestion in single doses and by single dermal applications.

The undiluted product is a slight irritant to rabbit skin (average score of 1.0 on a scale of 8) but practically non-irritating to the rabbit eye (average score of 6.0 on a scale of 110). A group of male rats survived a six-hour exposure to air near saturation with vapor of this material at room temperature. They exhibited no adverse signs during the exposure and a subsequent 10-day observation period.

The biodegradability of THERMINOL 55 has not been studied. We believe its biodegradability would be similar to that of crude oil, and consequently recommend that the spent fluid be treated as such.

The preceding information was judged to be adequate for the safe use and handling of these two products when they were introduced. Subsequently, since the commercial possibilities for these fluids have increased, we have initiated additional toxicity tests which are currently underway.

THERMINOL 66. A rat feeding study has been designed to determine whether tissue residues occur when this material is ingested. In addition, reproduction studies with chickens have been initiated.

THERMINOL 55. A 90-day feeding to rats with a determination of whether tissue residues occur and chicken reproduction studies are in progress with this material. When these have been completed, we should have essentially the same amount of toxicity information on each of these products.

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
Society of Plastics Industry	Limitations on plastic packaging materials.	Plastics packaging industry will be in dilemma of proving compliance with no scientific means of doing so. No reason to believe PCB in food from plastics packaging material. Request plastics be excluded from coverage or at least delay for 180 days until studies are completed.
Environmental Defense Fund	Food tolerances.	Tolerances are insdequete to protect human health and welfare. Strongly urged FDA to revise tolerances downward by a factor 5-10.
Virginia Institute of Marine Sciences	Shellfish tolerances.	Zero tolerance for shellfish would be harmful to industry, unreasonable, unfounded. Should include shellfish with fish at 5 ppm or shellfish be specifically excluded from the proposal.
Container Corporation of America	Sampling, analysis and compliance	Requested extended period until appropriate sampling, testing procedure and compliance standards were proposed by FDA and were given reasonable opportunity to consider and comment. Regulation should be based on food content rather than package.
Clevepak Corporation	Non-paper packaging materials.	Requested extension of comment time to 4 months.
Reynolds Aluminum	Non-paper packaging materials.	Noted lack of testing procedures for non-paper materials, effectiveness of barrier materials and insufficient data on presence of PCB in materials other than paper. Requested 120 days extension of comment period.

MONS 098521

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
Diamond National Corporation	Food packaging materials.	Request section of packaging materials be withheld until studies on migration are completed.
John Strange Paperboard Division Menasha Corp.	Analytical procedures.	Analysis is complex and lengthy and results are erratic. Requests section on food packaging materials be withheld.
Can Manufacturers' Institute	Non-paper food packaging materials.	Requests change to refer specifically to paper food packaging materials where it is reasonable to expect the contained PCB to become a component of the packaged food.
Dow Chemical Company	Food packaging materials.	Sought clarification of types of materials covered and whether all materials were to be governed by the same limits. Asked that an accurate and commonly accepted methodology be provided for PCB determination. Offered method for plastics. Requested clarification of what is meant by "PCB". Questioned whether use of the classification "temporary" is realistic.
Mead Corporation	Limitations on food packaging materials.	Calls present proposal unworkable. Suggested set guidelines for all foods in FDA market basket survey and use these guidelines to establish levels in packaging materials depended on weigh ratios, barriers and expected migration.

MUNS 098522

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
Ralston Purina Company	PCB concentrations in food and animal feed.	Objected to use of concentration in fat content of food. Suggested tolerances be on "as is" basis. Suggested 0.6 ppm as an "as is" tolerance. Asked for mention of difference between "complete" animal feeds and "concentrates". Recommended 5 ppm PCB in pet foods.
American Feed Manufacturers Association	Animal feed.	Proposes reference to "finished" feed be changed to "complete" animal feed. Supplements and concentrates be allowed 0.5 ppm on a complete feed basis. Recommended 1 ppm for ingredients not of animal or marine origin. Noted use of the phrase "harmful or deleterious" and claimed it a practical impossibility to eliminate all substances that could conceivably be harmful. Notes important use of PCB transformers in plants.
Acco Feeds	Animal feed.	Endorsed American Feed Manufacturers Assoc. comments.
Certified Ballast Manufacturers Association	Lamp ballasts	Sought confirmation that proposal does not apply to fluorescent lamp ballasts.
General Electric Company	Capacitors and transformers	Called for distinction in equipment in physical contact with food, feed or packaging material and the equipment relating to power supply.
Aerovox Corporation	Capacitors	Emphasized that capacitor failure is obvious and corrective actions can be quickly implemented.

MONS 098523

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
The Boxboard Research and Development Association	Paper packaging material.	Cited that lower chlorinated PCB's degrade and have no harmful effects on warm blooded animals even at extreme feed levels.
Fibreboard Corporation	Paper packaging material.	Suggested that 15 ppm be set for maximum PCB in food packaging.
Anaconda Aluminum Company	Non-paper packaging material.	Requested an additional 90 days of comment.
Brown Company	Paper packaging materials.	Calls the proposal an unenforceable law, therefore, an embarrassment to the Government and can harm the recycling industry.
Stone Container Corporation	No details available	
Lowe Paper Company	No details available	
Milprint	No details available	

MONS 098524

COMPANY - LOCATION	TSR NO.	CONV DATE	CONV FLUID	FR CONT %	SYST VOL GAL	OPR TEMP OF	CONVERSION SCHEME DRAIN	FLUSH/ FLUID	CHEM CLEAN	TOP UP	SOLIDS	APPLICATION	REMARKS
Ledgerbe Prod. Milwaukee, Wisc.	22/72	8-71	T-55	39 FR-1	900	350°	Yes	No	No	No	0.3% (Rust)	Rendering Plant	A.S.P Thermo Disc Processor - Not fully drainable - Vertical Hairpin Tube Heater - Kerosene & water caustic wash to reduce Hi FR content
Ralston Purina Corp. St. Louis, Mo.	25/72	12-70	T-66	3.9 FR-1	1200	525°	Yes	No	No	No	--	2 Fish Fryers	Initial system - electric - on FR - Second larger system on T-66. FR drained at time of start up of larger system which heats both fryers
Industrial Grain & Elvie Flour Thunder Bay, Ont.	29/72		T-66	0.18 FR-2 2nd Fill	350		Yes	Yes/ T-55	No	No	Yes	Dextrine Starch Unit	First change to T-66 without flush - sludge problem resulting in flush with T-55, refill with T-66
Murphy Oil Minelander, Wisc	31/72	3-72	T-55	FR-0	3000	350°	Yes	No	No	No	-	Heavy Oil Heating	Only 1800 gal FR-0 drained from system - leakage before conversion was high so 1400 gal T-55 on hand after fill
Sherwin Williams Hayward, Calif.	33/72	2-72	T-66	FR-1	500	500°	Yes	Yes/ T-66	No	No	Yes Iron Salts	Resin kettle in paint manufacturing	Vapor 5m BTU/hr heater
Reed Senderu Co. Detroit, Mich	12/72	1971	T-66	15.6 FR-1			Yes		No			RemoTherm Donut Fryer	
Chevron Oil Co. Harvey, La.	18/72	3-72	T-66	14.3 FR-1	2000	525°	Yes	T-55	No	No	-	Offshore Platform	
New Era Foods (f.k.a. Evon) Detroit, Mich.	19/72	Fall 1971	T-55	18.3 FR-1	700	475°	Yes		No	No	-	Potato Chip Fryer	IBW heater - cooking oil runs in shell/tube exchanger

MONS 098525

COMPANY - LOCATION	TSR NO.	CONV DATE	CONV FLUID	FR CONT %	SYST VOL GAL	OPR TEMP °F	CONVERSION SCHEME DRAIN	FLUSH/ FLUID	CHEM CLEAN	TOP UP	SOLIDS	APPLICATION	REMARKS
H. H. Evon Chicago, Ill.	9/72	8-71	T-55	49.9 FR-2 1248	1250 (2 syst	425	Yes	No	No	No	--	Food Preparation	No inert blanket
Warm Crest Bak. Detroit, Mich	8/72	8-71	T-55	4.05 FR-1	76ea (2 syst	520	Yes	No	No	No	--	Donut Fryer	No inert gas. Sludge in drain FR fluid - Hot Exp. tank
Tasty Fry Foods Crookston,Minn	7/72 & 39/71	7-71	T-66	8.1 ExTK 5.9 Fryer FR-1	4500 FR-1	525	Yes	No	No	No	Yes Exp. Tank	Heaters & Fryers Potatoes	2 Cleaver Brooks - 10M BTU/Hr each - caustic contamination of fluid - 2nd change recommended & make up added. 12.7% FR-1 on orig. conversion Jan (39/71) T-66 drained, filtered & recharged.
Mrs. Pauls Kitchens, Inc. Haddock, N.J.	6/72		T-66	0.14 FR-1	1000	500°		?				Fish & Onion Ring Fryers 3 Fryers	Vapor Corp. Heaters Hot Exp. tanks - Fire in heater after conversion to T-6
Philadelphia,Pa.		8/71	T-66	37.7 FR-1	500	550°		No					
Princisfield, Md.		8/71	T-66	12.9 FR-1	500			No					
Charleston, Md.		9/71	T-66	2.24 9.31 FR-1	500			?		Yes		3 Fryers	
Glycol Chem. Jamesville, Ohio	36/71	10/71	T-66	3.26 FR-1			Yes	No	No	No	-		Horizontal Helical Coil Heater
Wolfe's Best Foods Sacramento, Cal.	23/71	10/71	T-55	1.6 FR-1	475	510°	Yes	Yes T-55	No	No	No	French Fry Potato Processing	Full volume flush with T-55 (Conversion work done by Boutin & Roush) - Sid Parker Heater - Cooking oil heated by T-55 in S-T exchanger

MONS 098526

COMPANY - LOCATION	TSR NO.	CONV DATE	CONV FLUID	FR CONT %	SYST VOL GAL	OPR TEMP OF	CONVERSION SCHEME DRAIN	FLUSH/ FLUID	CHEM CLEAN	TOP UP	SOLIDS	APPLICATION	REMARKS
Ocato Products Grandview, Mo.	33/71	9/71	T-55	9.67 FR-1	1000		Yes		No	No	No	Processing Food Additives (bakery prods.)	Solids appear at leakage points, seal
Honeywell Prods. Mankato, Minn.	32/71		T-66	10.3 FR-1		550°	Yes		No	No	Yes 0.01%		Carbonaceous material blocks strainer. First change to T without flush. 2nd change used Oakite 18 flush followed by Oakite 77, then "to fill with T-66.

MONS 098527

TOXICITY DATA

THERMINOL® 66 Heat Transfer Liquid
THERMINOL® 55 Heat Transfer Liquid

THERMINOL 66 (hydrogenated terphenyl) has an oral LD_{50} of 10.2 g/kg to albino rats and a dermal LD_{50} of approximately 6.8 g/kg to albino rabbits. This material is considered to be practically non-toxic by ingestion in single doses and by single dermal applications.

The undiluted product is a moderate irritant to rabbit skin (average score 3.1 on a scale of 8), but practically non-irritating to the rabbit eye (average score 6.4 on a scale of 110). Human patch tests on 200 subjects indicate that THERMINOL 66 is neither a primary irritant nor a sensitizer.

The product was fed to groups of albino rats, 15 males and 15 females per group, for 90 days at dietary concentrations of 100 ppm, 300 ppm, and 1,000 ppm. A similar group of 30 animals served as controls. There was no untoward behavior among these animals, and there were no deaths which could be attributed to ingestion of the product. Comparisons of final body weight and total weight gains revealed no statistically significant differences between test and control animals. There was a similar lack of outstanding differences between test and control rats in food consumption, blood parameters (hematocrit, hemoglobin, erythrocyte count, and total and differential leukocyte counts), clinical chemical values (blood urea nitrogen, blood glucose, and serum alkaline phosphatase and serum glutamic-pyruvic transaminase activities), and the results of urinalyses (pH, specific gravity, glucose and albumin concentrations, and microscopic examination).

At the end of the feeding period, all surviving animals were sacrificed and given a thorough gross autopsy during which the weights of liver, kidneys, spleen, gonads, heart, and brain were determined and recorded. Females fed 1,000 ppm of the product had statistically significant increases of absolute liver, kidney, and brain weights and the corresponding organ to body weight ratios. The 300-ppm group of females had a statistically significant increase of liver to body weight ratio, but the absolute liver weights were not sifnigicantly elevated. Although some statistically significant intergroup differences were noted in other groups, none of these differences could be related to ingestion of the product. Gross pathological examination did not reveal outstanding differences between test and control rats. Tissues and organs (approximately 30 per animal) from ten rats of each sex in both the control and 1,000 ppm group were examined microscopically. No lesions were observed which could be related to ingestion of THERMINOL 66.

Limited studies indicate that THERMINOL 66 undergoes primary biodegradation and that it would not be a persistent aquatic pollutant if small amounts inadvertently entered waterways. Additional support for this view can be obtained from two published articles dealing with the environmental effects of HB-40. (An earlier designation for THERMINOL 66 was HB-40). The first is by J. E. Guthrie and O. E. Acres, Toxicity to Fish of Two Organic Reactor Coolants, Bull. Environ. Contam. & Toxicol. 5 (No. 2): 145-151 (1970). It states that ".... less than 25% of the fish (trout fry) died within 48 hours in HB-40 suspensions containing 100 mg/l or less....". The second is by J. L. Weeks, An Organic Cooled Nuclear Reactor and Its Environment, Arch. Environ. Health, 23: 123-128 (1971). This article has a general discussion of the environmental problem and concludes that HB-40 has not adversely affected the environment after 5½ years of use in a reactor in Manitoba, Canada.

THERMINOL 55 (alkylated benzene) has an oral LD_{50} of 15.8 g/kg to albino rats and a dermal LD_{50} of 7.94 g/kg to albino rabbits. This product is considered to be practically non-toxic by ingestion in single doses and by single dermal applications.

The undiluted product is a slight irritant to rabbit skin (average score of 1.0 on a scale of 8) but practically non-irritating to the rabbit eye (average score of 6.0 on a scale of 110). A group of male rats survived a six-hour exposure to air near saturation with vapor of this material at room temperature. They exhibited no adverse signs during the exposure and a subsequent 10-day observation period.

The biodegradability of THERMINOL 55 has not been studied. We believe its biodegradability would be similar to that of crude oil, and consequently recommend that the spent fluid be treated as such.

The preceding information was judged to be adequate for the safe use and handling of these two products when they were introduced. Subsequently, since the commercial possibilities for these fluids have increased, we have initiated additional toxicity tests which are currently underway.

THERMINOL 66. A rat feeding study has been designed to determine whether tissue residues occur when this material is ingested. In addition, reproduction studies with chickens have been initiated.

THERMINOL 55. A 90-day feeding to rats with a determination of whether tissue residues occur and chicken reproduction studies are in progress with this material. When these have been completed, we should have essentially the same amount of toxicity information on each of these products.