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Support Document/Voluntary Environmental Impact Statement

and

PCB Manufacturing, Processing, Distribution in Commerce, and Use Ban Regulation: Economic Impact Analysis



ENVIRONMENTAL PROTECTION AGENCY

SUPPORT DOCUMENT/

VOLUNTARY ENVIRONMENTAL IMPACT STATEMENT

for

Polychlorinated Biphenyls (PCBs)

Manufacturing, Processing, Distribution in Commerce, and

Use Ban Regulation (Section 6(e) of TSCA)

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VOLUNTARY ENVIRONMENTAL IMPACT STATEMENT

SUMMARY SHEET

(Check One)
( ) Draft.
(X) Final Environmental Statement.

Environmental Protection Agency

Office of Toxic Substances

1. Name of Action. (Check One)
(X) Administrative Action.
( ) Legislative Action.

2. Description of Action.

This rule implements §6(e) of the Toxic Substances Control Act (TSCA) which prohibits the manufacturing, processing, distribution in commerce, and use (unless the use is totally enclosed) of PCBs and requires regulations controlling marking and disposal of PCBs. It applies to any chemical substance or combination of substances that contain 50 ppm, or greater, PCB. The rule authorizes several limited exceptions to these general prohibitions in instances where activities do not present an unreasonable risk of injury to health and the environment. These exceptions are related to limited servicing and use activities involving the following: electrical transformers, railroad transformers, hydraulic systems, mining machinery, heat transfer systems, pigments, electromagnets, natural gas pipeline compressors, small quantities for research and development, microscopy, and carbonless copy paper. The use of PCBs has been extensive throughout the United States and, therefore, the rule has a nationwide impact.

3. Summary of Environmental Impact and Adverse Environmental Effects.

PCBs are a significant environmental pollutant occurring throughout the biosphere. They pose a significant risk to the health of man and numerous other living things. A number of adverse effects on living organisms have

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been demonstrated, including, but not limited to bioaccumulation, biomagnification, carcinogenicity, mutagenicity, teratogenicity, and fetotoxicity. PCBs are extremely persistent in the environment, circulating among the air, water, and land; and any additional release of PCBs in the environment will eventually result in widespread distribution of PCBs and, therefore, increase exposure and risks.

4. Alternatives Considered.

In developing these proposed rules, EPA considered whether there were other regulatory or nonregulatory options available as alternative approaches to implementing the §6(e) prohibitions against PCB activities and otherwise satisfy the purposes of §6(e) of TSCA. Below is a discussion of the three major options that the Agency considered.

a. No Action.

This alternative was rejected because Congress mandated in TSCA that the manufacturing, processing, distribution in commerce, and use of PCBs be prohibited according to a certain schedule. EPA's discretion with respect to these prohibitions is to establish and clarify certain definitions and to provide exceptions to the prohibitions if there is no unreasonable risk to health and the environment.

b. Action Through Other Statutes or Regulatory Bodies.

This alternative was rejected. It was determined that using other statutes administered by EPA (i.e., Clean Air Act, Clean Water Act, Safe Drinking Water Act, or Resource Conservation and Recovery Act) was inappropriate because they could not provide the comprehensive coverage necessary to implement §6(e). This is also true of statutes administered by other regulatory agencies or state governments. Furthermore, there is a strong case that EPA is required by TSCA to use §6(e) of TSCA to implement and grant exceptions, if appropriate, to the explicit prohibitions mandated by §6(e). Section6(e)(4) specifically exempts EPA from the requirements of §6(c)(1), including that of considering the use of other EPA-administered authorities as alternatives to rulemaking under §6 of TSCA. This indicates that Congress intended that EPA use TSCA to implement these prohibitions on PCBs.

The use of other authorities to resolve the PCB problem addressed by §6(e)(2) and (3) would be impractical, complex, time consuming, and in some cases impossible. No other Federal statute grants the kind of authority necessary to directly control the range of PCB activities covered by §6(e). Sections of several statutes might have to be invoked in separate actions for each aspect of each PCB activity. A number of indirect controls would be necessary to effectively prohibit PCB activities as required by TSCA except in those cases where risks were found to be reasonable.

The other relevant statutes, moreover, are often not designed to provide this comprehensive coverage, even when used in concert. For example, many sources of PCB air emissions are not included within the definition of sources subject to regulation under the Clean Air Act (CAA). The concepts of area-wide standards and controls in the Clean Water Act (CWA) and the CAA do not seem appropriate for implementing these prohibitions of PCBs and specific PCB Articles or activities of concern. There are final regulations under §307(a) of the CWA which complement this regulation and which set effluent standards prohibiting any discharge of PCBs, but only from PCB manufacturers, electrical capacitor manufacturers, and electrical transformer manufacturers. If the CWA, the Safe Drinking Water Act, or the Resource Conservation and Recovery Act were used in lieu of TSCA, many spills could be controlled, but other aspects of the PCB problem could not.

Some other Federal statutes not administered by EPA could also be utilized to control some types of exposure to PCBs. The National Institute for Occupational Safety and Health has set a workplace exposure criterion of 5 ppm for employee exposure and recommended that the Occupational Safety and Health Administration prepare regulations accordingly. But again, this only addresses a part of the problem. A few States have regulations on PCBs, but they are not sufficient to cover all activities addressed by TSCA nor, obviously, do they provide control of PCBs on a national scale.

c. Action Under Section 6(e) of TSCA.

Numerous alternatives were considered within the authority of §6(e) of TSCA. These alternatives were fully discussed in the Support Document/Voluntary Draft Environmental Impact Statement, the Preamble to proposed regulation, and the Preamble to this regulation.

5. Major Definitions.

"PCB" is defined to mean any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees or any combination of substances which contains such substances.

"Significant Exposure" is defined as any exposure of human beings or the environment to PCBs, as measured or detected by any scientifically acceptable analytical method.

6. Totally Enclosed Activities.

Congress mandated in §6(e)(2) of TSCA that all non-totally enclosed activities are banned as of January 1, 1978. Non-totally enclosed was defined by Congress to mean any manner that resulted in significant exposure as specified by EPA. Below are identified those activities that the Agency considers to be totally enclosed.

PCB Transformers (non-railroad) - Use, except servicing, of intact, non-leaking PCB transformers is considered totally enclosed.

PCB-Contaminated Transformers - Use, except servicing, of intact, non-leaking PCB-contaminated transformers is considered totally enclosed.

Electromagnets - Use, except servicing, of intact, non-leaking electromagnets is considered totally enclosed.

PCB Capacitors - Distribution and use of intact, non-leaking, PCB Capacitors are considered totally enclosed.

PCB Equipment - Processing, distribution in commerce, and use of PCB Equipment are considered totally enclosed.

7. Authorizations.

The Agency has found that the following activities do not present an unreasonble risk to health and the environment. In making these decisions the Agency considered (1) the health and environmental effects of PCBs, (2) the exposure to PCBs from these activities, (3) the availability of substitutes in these uses, and (4) the economic impact from restricting these uses. Unless otherwise noted, all authorizations expire on July 1, 1984; however, exemptions must be obtained if processing and distribution in commerce are to continue after July 1, 1979.

PCB Transformers (non-railroad) - Processing, distribution in commerce, and use are authorized. Servicing (except rebuilding) is authorized.

PCB-Contaminated Transformers - Processing, distribution in commerce, and use are authorized. Servicing (including rebuilding) is authorized.

Railroad Transformers - Processing, distribution in commerce, and use are authorized. Servicing (including rebuilding) is authorized.

Mining Equipment - Processing, distribution in commerce, and use (including servicing) are authorized until 1/1/82. After 1/1/80, rebuilding of continuous miner type motors is prohibited.

Heat Transfer Systems - Use is authorized.

Hydraulic Systems - Processing, distribution in commerce, and use are authorized.

Pigments - Processing and distribution in commerce are authorized. Use is authorized until 1/1/82.

Electromagnets - Processing, distribution in commerce, and use are authorized. Servicing (except rebuilding) is authorized.

Natural Gas Pipeline Compressors - Use is authorized until 5/1/80.

Small Quantities for Research and Development - Processing, distribution in commerce, and use are authorized.

Microscopy - Processing, distribution in commerce, and use are authorized.

Carbonless Copy Paper - Use is authorized indefinitely.

8. Federal Agencies That Participated on EPA's PCB Work Group:

Department of Commerce
Department of Defense
Department of Transportation
Department of Interior
Federal Railroad Administration
General Services Administration
National Institute for Occupational Safety and Health
Tennessee Valley Authority

9. On or about April 30, 1979 the Support Document/ Voluntary Environmental Impact Statement was officially filed with the Director, Office of Federal Activities, EPA. It is available to the public. Copies can be obtained by writing the Industry Assistance Office, Office of Toxic Substances (TS-793), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, or by calling (800) 424-9064, in Washington, D.C., call 554-1404. The official record of rulemaking, including both the draft and final Support Document/Voluntary Environmental Impact Statement, is located in room 709, East Tower, Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 755-6956. It will be available for viewing and copying from 9 a.m. to 4 p.m., Monday through Friday excluding holidays.

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I. INTRODUCTION

PCBs have been used in the United States since 1929 in such applications as transformer cooling liquids, capacitor dielectric fluids, heat transfer and hydraulic liquids, dye carriers in carbonless copy paper, plasticizers in paints, adhesives, and caulking compounds, fillers in investment casting wax, and dust control agents in road construction.

Monsanto was the major U.S. manufacturer of PCBs. Since 1972, Monsanto limited sales of PCBs to manufacturers of transformers and capacitors. Monsanto ceased manufacturing PCBs in mid-1977, and shipped the last remaining inventory by October 31, 1977.

Small quantities of PCBs may be produced currently, as unintentional byproducts of other chemical processes. Similarly, chlorination of water which contains appreciable concentrations of biphenyl can result in the unintentional formation of PCBs. No natural sources of PCBs have been identified.

Prior to the enactment of the Toxic Substances Control Act (TSCA), the authority of the EPA with respect to PCBs was limited to the regulation of contaminated water from point sources. EPA promulgated a rule under Section 307(a) of the Clean Water Act on February 2, 1977 (42 FR 6532-6556), which banned the discharge of PCBs into navigable waters by electrical transformer and capacitor manufacturers.

The enactment of TSCA in October 1976, placed additional restrictions on the use of PCBs and required that certain actions be taken by EPA. Section 6(e)(1) of TSCA required that EPA promulgate a disposal and marking rule for PCBs. This rule, promulgated by EPA on February 17, 1978 (43 FR 7150-7164), regulates the disposal of PCBs and requires that special warning labels be applied to large capacitors, transformers, and other PCB Items. The Disposal and Marking Rule covered liquid PCBs and all other material and equipment components containing or having contained PCBs in concentrations of greater than 500 ppm (0.050 percent). Clarifying amendments to this rule were published on August 2, 1978 (43 FR 33918).

On June 7, 1978 EPA published the proposed rules (43 FR 24802) implementing §§6(e)(2) and 6(e)(3) of TSCA. These rules proposed to prohibit or authorize certain PCB

activities that are not conducted in a totally enclosed manner. This rule also specified those activities that the Agency considered to be performed in a totally enclosed manner.

Concurrently with the proposed rule, the Agency also published a Support Document/Voluntary Draft Environmental Impact Statement (Draft Support Document). In that document, the Agency discussed the different alternatives it considered in regulating the various PCB activities.

The Agency held 10 days of public hearings in Washington, D.C. from August 21 to September 1 to solicit comments on the proposed rule. Over 50 oral presentations were made. On September 22, 1978 (43 FR 43048), EPA published a notice of the opportunity for cross-examination and extended the reply comment period to October 10, 1978. Two hearing participants conducted cross-examination on September 26, 1978. EPA received over 200 comments on the proposed rule.

Section 6(e)(3)(B) of TSCA also provides that persons may petition the Administrator for exemptions from the prohibition of the manufacture, processing, and distribution in commerce of PCBs or PCB Items. Interim rules establishing procedures for submitting petitions for exemptions from the prohibitions were published on November 1, 1978 (43 FR 50905). More than 70 petitions for

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exemptions have been received. On January 2, 1979 EPA announced (44 FR 108) that it would not enforce the PCB manufacturing and importation ban of §6(e)(3)(A) against persons who submitted petitions, until EPA had acted on their request for exemptions.

Concurrently with publication of the final manufacturing, processing, distribution in commerce, and use bans, the Agency has published its proposed disposition on the requests for exemptions from this Rule. Public hearing and publication of the final disposition will be forthcoming.

This Support Document/Voluntary Environmental Impact Statement (Final Support Document) has been prepared to address the major comments made during the rulemaking proceedings. Each of the major comments has been listed and assigned a number in parentheses in Appendix I to this document. For the convenience of readers, representative comments are referenced by number when they are addressed by the Agency in this document. EPA wishes to emphasize, however, that the comments listed may not represent all of the comments considered by EPA and which address the particular issue discussed. In some cases, discussion of issues raised by commentors will also be found in the Preamble to the final rule.

As noted, this document responds to comments received on the proposed rule. It contrasts with the Draft Support Document which discussed the options the Agency considered

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to control the various applications of PCBs. Two sections (Section I, Background and Section II, Alternatives to this Rule) in the Draft Support Document that are relevant to this phase of rulemaking have been revised and included in this Support Document in the Introduction and the Summary Sheet. Section III (Significance of Release of PCBs Into the Environment), and Section V (Substitutes) of the Draft Support Document are included as Sections II and III of this Final Support Document. Minor revisions have been made in these sections prior to their inclusion. The three remaining sections, Section IV (Definition of PCB Mixture), Section VI (Reasonable use Determinations), and Section VII (Waste Oil), although containing much of the same rationale used in the final rulemaking, have not been included in this document. However, those three sections describe (1) the regulatory options considered by EPA prior to proposal of this rule and (2) reflect the information that was then available to the Agency.

This Support Document/Voluntary Environmental Impact Statement contains the same information as would be prepared to meet the requirements of Section 6(c)(1) of TSCA. While not legally required to prepare an Environmental Impact Statement (EIS) by Section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, EPA has voluntarily prepared this Support Document/Voluntary Environmental

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Impact Statement in conformance with the spirit of its 1974 statement on voluntary EIS's (39 FR 37419, October 21, 1974). The voluntary preparation of this document in no way legally subjects the Agency to NEPA requirements.

Persons who are interested in the approximate costs to the various industries to comply with the requirements of the rule, are referred to the economic study entitled PCB Manufacturing, Processing, Distribution in Commerce, and Use Ban Regulation: Economic Impact Analysis (the Versar Report) found at the end of this document.

EPA wishes to emphasize that equality of PCB regulatory costs for the different affected industries described in the economic study is not the goal of this regulation. EPA is seeking to regulate as many PCBs as possible. The Agency recognizes, however, its inability to regulate some activities, such as disposel of many types of PCB Equipment, due to the broed ownership of such equipment at a vast number of sites. Although equality of regulatory costs for different affected industries has not been a goal, EPA has, where appropriate, taken costs into account by lengthening the compliance schedule or allowing disposal alternatives.

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II. SIGNIFICANCE OF THE RELEASE OF PCBs INTO THE ENVIRONMENT

Introduction

Section 6(e)(2)(A) of TSCA prohibits the manufacture, processing, distribution in commerce, and use of PCBs after January 1, 1978, in other than a totally enclosed manner. "Totally Enclosed Manner" is defined by TSCA to mean a manner which will ensure no significant exposure of human beings or the environment to PCBs, as determined by EPA by rule [Section 6(e)(2)(C)]. The final rule, in turn, provides that human or environmental exposure to any detectable quantities of PCBs shall be deemed significant. This provision is based on the finding that any release of PCBs into the environment will eventually result in widespread exposure of wildlife, including some of man's major food sources, and humans and that any such exposure may have adverse effects.

The following sections summarize the variety of adverse effects which PCBs have been found to have in humans, laboratory animals, and other organisms, and the extent to which PCBs released into the environment become distributed throughout the biosphere. The adverse effects have been described in greater detail in various documents, including EPA Report No. 440/9-77-021, Criteria Document for PCBs,

July 1976; Criteria for a Recommended Standard: Occupational Exposure to Polychlorinated Biphenyls (PCBs), National Institute for Occupational Safety and Health, September 1977; and "Environmental Health Criteria: Polychlorinated Biphenyls and Polychlorinated Terphenyls," World Health Organization, 1976. PCB-induced effects were also reviewed in detail in expert testimony at a public hearing before EPA and were acknowledged and described in a decision by the Administrator to promulgate toxic pollutant water effluent standards for PCBs (42 FR 6532-6556, February 2, 1977). These standards were affirmed in Environmental Defense Fund vs. Environmental Protection Agency, 12 E.R.C. 1353 (D.C. Cir. 1978).

Significance of Exposure to PCBs

A. Absorption and Storage

PCBs are absorbed through the lungs, the gastrointestinal tract, and the skin.[1] After absorption, PCBs are circulated throughout the body in the blood and are stored in adipose tissue and in a variety of organs and tissues, including the liver, kidneys, lungs, adrenal glands, brain, heart, and skin.[2]

B. Specific Adverse Health Effects of PCBs as Observed in Toxicology Tests and Epidemiological Studies

The view that human health risks resulting from exposure to chemicals may be determined experimentally by testing laboratory animals is one that is widely accepted in the

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scientitic community and has been adopted by EPA. Because experimentation on human beings raises ethical questions and because epidemiological studies often provide incomplete information, toxicology studies on laboratory animals are often necessary. However, because the extrapolation from animals to man is subject to some uncertainty, corroboration of laboratory test data with sound epidemiological information is desirable. The available toxicological and epidemiological data relating to the effects of PCBs are discussed below.

1. Oncogenicity

PCBs appear to have caused malignant and benign tumors in rats and mice in several experiments.[3] In one carefully conducted experiment, rats fed 100 ppm of Aroclor 1260 in the diet for 21 months developed a high incidence of carcinomas (26/184) and neoplastic nodules (144/184) in the liver. Only one of 173 control animals developed a carcinoma, and none developed neoplastic nodules. In another experiment, rats were fed Aroclors 1242, 1254, and 1260 for 24 months. Rats exposed to any of the three mixtures at 100 ppm in the diet developed liver tumors (hepatomas and cholangiohepatomas), whereas none was observed in the controls (3/20 for Aroclor 1242, 6/27 for Aroclor 1254, 7/27 for Aroclor 1260, and 0/20 for the controls). A high frequency of nodular hyperplasia in the liver, considered by some authorities to be precancerous,

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was observed in the rats fed 100 ppm of the three mixtures. A significant increase in frequency in comparison to controls was observed down to the 10 ppm dosage level.[4]

The results of the epidemiological data, although somewhat ambiguous, provide additional evidence that PCBs pose a carcinogenic risk to man. In 1968, at least 1,291 persons were afflicted with a disease known as Yusho as a consequence of eating rice oil contaminated with PCBs and relatively smaller amounts of polychlorinated dibenofurans (PCDFs). Although precise data are not yet available, a preliminary tabulation of the deaths among Yusho victims through 1975 showed an excess in the rate of cancer, particulary of the stomach and liver.[5] In another preliminary study, 92 workers considered likely to have been exposed to Aroclor 1254 at a New Jersey petrochemical facility between 1949 and 1957 indicated a significant excess of malignant melanoma and pancreatic cancer.[5a] In the third study, an examination of the death certificates of 50 employees formerly engaged in the manufacture of PCBs revealed seven cases of lung cancer, compared with an expected 2.5 cases. However, these results were not corrected for age or smoking habits and are only preliminary.[6]

2. Teratogenic, Fetotoxic, and Raproductive Effects

Beagle dogs fed Aroclor 1254 at the rate of 1.0 mg/kg/day had offspring with a significantly higher incidence of patent fontanelles than did controls but

exhibited no decrease in the number of offspring. In the same experiment, dogs fed 5.0 mg/kg/day had a fetal resorption rate of 45.5 percent (a fourfold increase over controls). Patent fontanelles were present in 50 percent of the offspring.[7]

Sows fed Aroclor 1254 at a dose of 1.0 mg/kg/day for 21 days before breeding and throughout gestation experienced a statistically significant rate of fetal resorption. Higher dosages further reduced fertility and caused a variety of defects in the offspring, including cleft palate, syndactyly, and patent fontanelles.[8]

Female rhesus monkey fed PCBs at 5 ppm and 2.5 ppm in the diet for 6 months before mating with untreated males demonstrated severe reproductive dysfunctions. Only one of the eight animals fed the higher dose gave birth, with five animals experiencing abortions and two not conceiving at all. Of the eight monkeys fed the lower dosage, five gave birth to extremely small infants, and three aborted.[9]

In another experiment, three of six infant rhesus monkeys born to mothers fed 2.5 ppm of PCB died within 6 months of birth. The surviving three infants exhibited behavioral and learning defects.[10]

Studies with mink have also demonstrated the adverse effects of PCBs on reproduction. Ranch mink fed coho salmon contaminated with 12 to 20 ppm of PCBs suffered reproductive failure and kit mortality. Female mink fed

dosages as low as 5 ppm of Aroclor 1254 and 2 ppm of Aroclor 1016 experienced substantial reductions in the number of live kits born.[11]

3. Enzyme Induction by PCBs

It has been demonstrated in several experiments that PCBs induce various microsomal enzymes of the liver, including mixed-function oxidases. Such induction has occurred after administration of Aroclors 1016, 1242, 1248, 1254, and 1260 to rats at dosages as low as 1 mg/kg/day for 21-28 days in the diet. Some of the enzymes induced by PCB mixtures and chlorobiphenyl isomers in rats and other animals are nitroreductases, dimethylases, diethylases, glucose-6-phosphatases, aryl hydrocarbon hydroxylases, cytochromes P-450 and P-448, NADPH cytochrome reductases, and delta-aminolevulinic acid synthetases.[12] In one study it was shown that humans exposed to PCBs showed elevated levels in the blood of the enzyme, gamma glutamyl transpeptidase, a sensitive indicator of liver dysfunction.[13]

The consequences of this enzyme induction may be quite significant. Some of the enzymes induced by PCBs, such as cytochrome P-450 and cytochrome P-450 dependent N-demethylase, are involved in the metabolism of therapeutic drugs. Induction of these enzymes would therefore be expected to alter the function of such drugs and interfere with the treatment of diseases in humans. This possibility has been clearly demonstrated in one experiment in which

workers occupationally exposed to Aroclor 1016 for the 2 years immediately before the experiment and to Aroclors 1242, 1254, and 1260 in earlier years were administered antipyrine, a prototype drug substrate. The half-life of the antipyrine in the plasma of the exposed workers was approximately two-thirds of that observed in control subjects.[14]

Another expected consequence of the induction of certain liver enzymes is an alteration of the incidence of human cancer. Although the mixed-function oxidases detoxify foreign chemicals in the body, they may also metabolize some of these substances into more toxic or carcinogenic forms.[15] However, it is difficult to predict whether induction of these enzymes would have a net effect of increasing or decreasing the incidence of cancer.

Induction of liver enzymes by PCBs could also result in a modification of the overall metabolism of the body by altering the metabolism of the steroid hormones.[16] In addition, stimulation of the production of the enzyme delta-amino-vulinic acid synthetase by PCBs has been demonstrated to cause porphyria and accumulation of porphyrins in the liver in rats, mice, and rabbits.[17]

4. Effects on the Immunological System

Several experiments have demonstrated that PCB mixtures produce immunosuppressive effects in laboratory animals. In

one study, guinea pigs were fed Aroclor 1260 at 10 ppm in the diet for 8 weeks and received injections of tetanus toxoid to stimulate antitoxin production by the lymphoid system. In comparison to controls, PCB-treated animals exhibited reduced numbers of gamma-globulin-containing cells in the lymph nodes as well as reduced serum gamma-globulin levels.[18] Infant rhesus monkeys dosed with 35 mg/kg of Aroclor 1248 for 4 weeks exhibited atrophy of the thymus. The same effect was observed in rhesus monkeys fed daily doses as low as 3 ppm of Aroclor 1242.[19] In addition, decreased weight and atrophy of the thymus and lymphoid system were observed in guinea pigs and rats administered oral doses of PCBs.[20]

5. Mutagenicity

Whydam and co-workers demonstrated that 4-chlorobiphenyl is a potent mutagen in the Ames test for bacterial mutagenesis.[21] These workers also found that the mutagenic activity of PCBs decreased with increasing chlorination and that the most highly chlorinated mixtures had almost no activity.

In several studies, various doses of Aroclor 1242 and Aroclor 1254 were administered to rats and the chromosomes of the bone marrow and testicular cells of these animals were then examined for abnormalities. No significant increases in chromosomal aberrations were observed in

comparison with controls. In another study, administration of these chemicals to rats did not appear to induce dominant lethal mutations.[22]

6. Effects on the Liver and Stomach

The induction of hepatic microsomal enzymes and the causing of malignant tumors of the liver by PCBs have already been discussed. Other adverse effects on the liver have also been observed and are described here.

In one study, weaning rats fed Aroclor 1254 at 1 ppm in the diet exhibited significantly increased liver weights.[23] In another experiment, rats fed Aroclors 1248, 1254, and 1260 at 1000 ppm in the diet for 6 weeks were found to have hypertrophied livers weighing four times as much as those controls. Abnormal ultra-structural changes within the liver cells of the PCB-treated animals included proliferation of smooth endoplasmic reticulum, development of large concentric arrays of membranes, atypical mitrochondria, and increases in lipid droplets.[24] One study performed by the National Cancer Institute observed proliferative changes in the liver cells of rats.[25] In guinea pigs, liver damage has been observed at dosages of Clophen A60 (a PCB mixture) as low as 250 ppm in the diet. Increased liver weight has been observed at doses down to 50 ppm.[26]

Low oral doses of PCBs have resulted in stomach lesions in several species. Dogs fed dietary levels of 1 ppm of Aroclors 1254 and 1260 and 10 ppm of Aroclor 1242 for 2 years suffered from stomach ulcers and nodules. Rhesus monkeys fed 2.5 ppm of Aroclor 1248 and 3 ppm of Aroclor 1242 in the diet developed stomach lesions which were severe in some cases. Sows also suffered from stomach lesions after being fed Aroclor 1242.[27]

7. Effects on Skin and Other Epidermal Tissues

Exposure to PCBs has resulted in various adverse effects on the skin and other epidermal tissues in humans. Chloracne, a specific type of acne caused by certain chlorinated hydrocarbon compounds, has developed among workers occupationally exposed to air containing PCBs at levels as low as 0.1 mg/m.[28] Skin lesions similar to chloracne have been one of the major clinical signs observed in victims of Yusho disease. In addition, Yusho victims have experienced eye discharges caused by hypersecretion of the meibomian glands, swelling of the upper eyelids and hyperpigmentation of the skin, nails, and mucous membranes. It has been estimated that Yusho disease has resulted from ingestion of PCBs in contaminated rice oil at a rate as low as 67 ug of PCB/kg of body weight per day for 3 months, although it should be noted that the Yusho incident involved exposure to high concentrations of chlorinated dibenzofurans and other chemicals which make it difficult to develop precise conclusions.[27]

8. Other Effects

Workers exposed to PCBs have been shown to have elevated levels of fat (triglycerides) in the blood.[30] The best current thinking in medicine is that such elevations constitute a serious risk for the development of heart diseases and strokes. Workers exposed to PCBs have experienced numerous other symptoms and adverse effects, including digestive disturbances, jaundice, impotence, dry or sore throat, and headache.[31] In addition, Yusho victims have suffered from abdominal pain, menstrual irregularity, fatigue, cough, and disorders of the peripheral nervous system.[32]

C. Effects on Wildlife

It is reasonble to expect that many of the adverse effects observed in laboratory animals could also occur in wild mammals exposed to PCBs. Since, as discussed below, PCBs have a tendency to collect in waterways and bioaccumulate in fish, fish-eating mammals such as otters, mink, and bears are particularly at risk. It has already been noted that mink fed PCB-contaminated fish suffered reproductive failure. Other effects observed in exposed mink include reduced weight gain, increased mortality, and enlargement of the liver, kidneys, and heart.[33]

Many wild birds are probably also highly susceptile to PCBs. Several fish-eating birds, including two bald eagles, have been found dead with lethal quantities of PCBs in the tissues.[34] Ring doves and American kistrels fed 10 ppm of PCBs suffered from severe reproductive failure. In addition, birds exposed to PCBs have also exhibited induction of hepatic microsomal enzymes, porphyria, changes in thyroid activity, abnormal behavior, and increased susceptibility to viral disease.[35]

The various PCB mixtures are highly toxic to several aquatic invertebrates and fish at extremely low concentrations. Aroclors 1248 and 1254 impair reproductivity of water fleas at concentrations as low as 0.48-1.0 ppb. Aroclor 1254 is toxic to several types of shrimp at levels of approximately 1 ppb. Substantially increased mortality of the fry of sheepshead minnows resulted from exposure to water containing 0.16 ppb of Aroclor 1254. It is thought that PCB levels of only a few parts per trillion in lake Michigan may be responsible for the reproductive failure of several species of fish in that body of water. There is also strong evidence that PCBs at concentrations below 1 ppb may adversely affect aquatic insects and crustaceans.[36]

Concentrations of Aroclors 1242, 1016, and 1254 as low as 0.1 ppb have been demonstrated to depress photosynthesis in phytoplankton and to reduce the rate of cell growth and

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division of these organisms. These effects are very significant since the productivity of the entire marine ecosystem may depend on the productivity of the phytoplankton within it.[37]

D. Toxicity of PCDFs

Polychlorinated dibenzofurans (PCDFs) are found in small but variable quantities as impurities in most PCB mixtures. In addition, PCDFs can be formed by photodegradation of PCBs in the environment. At present, it appears impossible to differentiate the toxic effects of PCBs from those of PCDFs. Consequently, it is necessary to regulate the commercial PCB mixtures with recognition that part of their toxicity may be attributable to unavoidable contaminants.[38]

E. Toxicity of PCB Metabolic Products

A number of studies have shown that PCBs are biodegraded into even more toxic metabolites. For example, it has been demonstrated that tetrachlorobiphenyl, which is a substantial component of several major commercial PCB mixtures, is transformed into toxic intermediate byproducts, including arene oxides and dihydrodiols. These substances have been found to cause cancer, mutations, and other toxic effects.[39]

F. Relative Toxicity of the PCB Mixture

PCBs are usually sold commercially as mixtures of biphenyl molecules with varying degrees of chlorination. Aroclors 1016 and 1242 have relatively low chlorine content, whereas the chlorine content of Aroclor 1254 is relatively

high. It has been argued (174) that the less highly chlorinated mixtures and components may be less toxic and hazardous than the more highly chlorinated mixtures, and therefore the regulation of the former should be less stringent. This argument was considered in great detail at public hearings before EPA on Toxic Pollutant Effluent Standards for PCBs and was rejected by the Administrator.[40] There were several bases for not establishing separate standards for the different PCB mixtures. It was determined that all PCB mixtures then in use, including the less chlorinated ones (e.g., Aroclor 1016), are capable of inducing severe toxic effects at low levels in mammals and aquatic organisms. In addition, the compositions of the different PCB mixtures change and may become more similar after release into the environment, so that it would make no sense to regulate the mixtures, under different standards. Furthermore, important components of all the mixtures, including the less chlorinated ones, are highly persistent. Finally, while the less chlorinated components of the PCB mixtures are not stored in tissues as efficiently as the more highly chlorinated molecules, even the less chlorinated commercial mixtures have substantial amounts of components that are subject to significant uptake and storage.[41]

G. Inability to Establish a "Safe" Level of Exposure for PCBs

The available data indicate the PCB may cause several adverse effects in humans, mammals, birds, and aquatic organisms at extremely low concentations. Therefore, for all practical purposes, exposure of humans and other animals to any level of PCBs should be deemed significant. This is especially true in light of the demonstrated carcinogenicity of PCBs. EPA has adopted the view that "safe" or "threshold" levels for carcinogens cannot be established given the present state of scientific knowledge.[42] This policy has been upheld by the Federal courts in several decisions.[43]

Environmental Exposure to PCBs

A. General

The purpose of this section is to discuss how PCBs released anywhere into the environment may eventually become widely distributed, with the result that many organisms, including man, may become exposed. This section also summarizes some of the data indicating that PCBs are already widely distributed throughout the physical environment and the biosphere and that this environmental burden is not likely to become reduced in the near future because of the persistence of these chemicals.

B. Overview of PCB Transport in the Environment

Before presenting a detailed analysis of the manner in which humans and the general biota might be exposed to "free" PCBs (i.e., PCBs which have been released into the environment), it is first necessary to determine the processes by which free PCBs are distributed throughout the three compartments of the environment--air, land, and water. A number of processes affect the nature of this distribution. Once a PCB substance has entered a physical compartment, it may be dispersed throughout that compartment. In addition, each compartment may have sinks wherein free PCBs may be rendered physically unavailable to the biota or may be degraded by chemical or metabolic processes. Finally, a more or less continuous interchange of PCBs between the three compartments might be expected. The general nature of these processes is illustrated schematically in Figure 1,[44] and a summary of the possible sources, sinks, and exchange processes is given in Table 1.

It should be pointed out that the processes described in Figure 1 and enumerated in Table 1 are theoretical possibilities that apply to any environmental pollutant. Which of these processes play an important role in the environmental transport of PCBs is determined by the specific chemical and physical properties of the PCBs as well as the characteristics of each of the compartments. In

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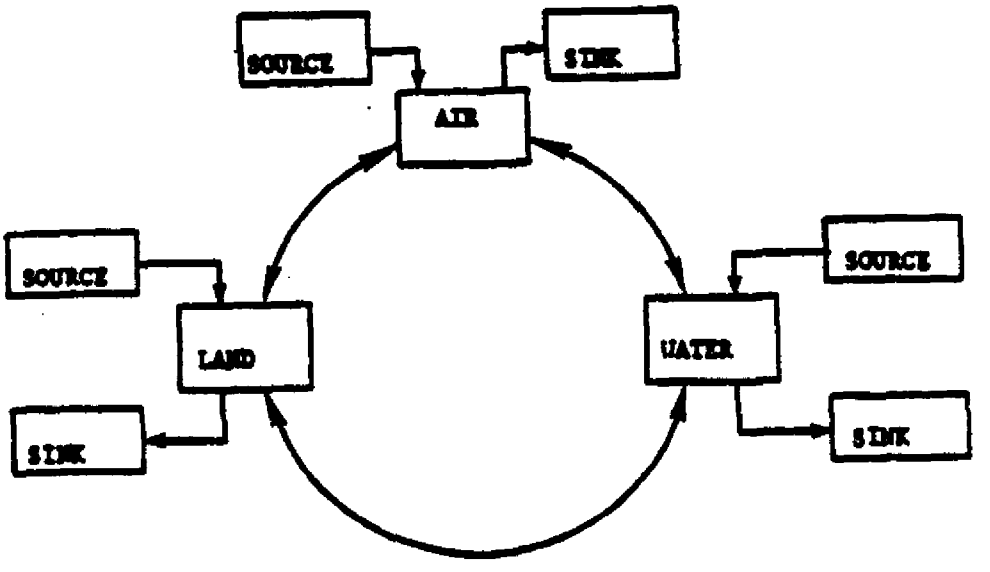

Figure 1

Schematic Representation of Transport Processes in the Environment

Table 1. Summary of Processes Involved in the Distribution of a Toxicant in the Environment

COMPARTMENT	SOURCES	EXCHANGE PROCESSES	SINKS
Atmosphere	Natural sources Gaseous residues from incineration of contaminated materials Evaporation during manufacturing processes Evaporation from consumer product uses Evaporation from accidental spills Degradation of other contaminants	Evaporation from terrestrial sources of free materials Coevaporation from contaminated water bodies	Photochemical reactions Oxidative reactions Reactions with other contaminants
Terrestrial	Degradation of discarded consumer products Industrial waste disposal by landfill Accidental spills Natural sources Degradation of other contaminants	Precipitation from contaminated air	Biodegradation - flora - fauna - microflora
Aqueous	Contaminated discharges Accidental spills Natural sources Degradation of other contaminants	Precipitation from contaminated air Runoff from contaminated soils Leachant processes from contaminated soils	Biodegradation - flora - fauna - microflora Chemical degradation - hydrolysis - photochemical - active chemical species reactions Sorption and entrapment onto fixed sediments

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view of this, the physical and chemical properties of PCBs are discussed next, in order to lay the proper framework for a more detailed discussion of the transport of PCBs.

C. Environmentally Relevant Properties of PCBs

PCBs are a group of compounds, some 209 in number, that are prepared by the partial chlorination of biphenyl to yield a complex mixture of chlorobiphenyls in the form of high boiling point liquids of moderate viscosity. The environmentally significant physical properties of several of the commercial mixtures (Aroclors) are presented in Table 2. The properties of PCBs that have made them so commercially attractive include low water solubility, low affinity for water (high lipid solubility), a high degree of chemical stability, and very low vapor pressure at ambient temperatures. A more detailed discussion of the relevance of these properties to the environmental hazard posed by PCBs is presented in the following sections.

1. Chemistry of Chlorobiphenyls

Chlorobiphenyls have been demonstrated to undergo a number of chemical reactions. Both oxidation and hydrolysis of these chemicals can be carried out, but only under conditions that are considerably more rigorous than would be found in an environmental situation.[45] Another class of reactions to which PCBs are susceptible is that of cyclization. Of particular interest is the cyclization of

Table 2. Environmentally Relevant Properties of PCB Formulations

PARAMETER	AROCLOR 1242	AROCLOR 1248	AROCLOR 1254	AROCLOR 1260
Chlorine content (percent)	42	48	54	48
Water content, max. (ppm)	50	50	50	50
Distillation range (°C)	325–366	340–375	365–390	385–420
Evaporation loss (percent at 100°C, 6 hr)	3.0–3.6	3.0–4.0	1.1–1.3	0.5–0.8
Viscosity (sec at 37.8°C)	82–92	185–240	1800–2500	1200–4500 (54.5°C)
Water solubility (mg/l at 25°C)	0.24	5.4×10^{-2}	1.2×10^{-2}	2.7×10^{-3}
Vapor pressure (mm Hg at 25°C)	4.06×10^{-4}	4.94×10^{-4}	7.71×10^{-5}	4.05×10^{-5}
Volatilization half-life[47a] (from 1-m water column)	5.96 hr	58.3 min	1.2 min	28.8 min
Solubility in CH_3OH at 25°C	42.5 g/100 ml	—	15 g/100 ml	—
Octanol/water partition coefficient (est.)	3.5×10^3	6.4×10^3	1.18×10^4	2.2×10^4

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2,2'dichlorobiphenyl, which yields the compound dichlorodibenzofuran.[46] The oral LD_{50} of the dibenzofuran for rats is approximately 250 mg/kg, whereas the LD_{50} for the chlorobiphenyl is in excess of 4000 mg/kg.[47]

As discussed below, it is thought that transport as a molecular species or as sorbed material on airborne particles is the major route of widespread transport of PCBs.[48] Since such processes would cause PCBs to be exposed to ultraviolet radiation from the sun, considerable attention has been directed to the photochemical stability of PCBs. A number of effects have been reported, including partial dechlorination and even, in some cases, the formation of very viscous semisolids apparently arising from some complex polymerization processes.[49] The environmental significance of these observations is difficult to assess since the solvents usually used in these studies were hydrocarbons rather than water.

The hydroxylation of the PCB molecule is the first step by which organisms metabolize this chemical.[50] Once the target chlorobiphenyl has been hydroxylated, there appears to be a wide variety of species-specific addition processes that can make use of the hydroxylated molecule. In this context, the failure to detect chlorodibenzofurans suggests that metabolic processes are not available to cyclize the PCBs. The further observation that the residual body burden

of PCBs usually consists of only the more highly chlorinated PCBs suggests that the higher the level of chlorination, the more resistant it is to metabolic processes.[51]

Several of the PCBs with relatively low chlorine content are readily metabolized by direct hydroxylation by both animals and microorganisms.[52] Consequently, di- and trichlorobiphenyls are not very persistent.[53] On the other hand, the highly chlorine-substituted PCB molecules are apparently not metabolized at all. In addition, these species of PCB are not easily excreted because of their very low aqueous solubility and high lipid solubility. As a result, these species tend to accumulate in exposed animals.[54]

2. Physical Properties of PCBs

As indicated in Table 2, PCBs and their technical mixtures are characterized by low water solubility, low vapor pressure at ambient temperatures, and very high octanol/water partition coefficients.[55] The significance of the combination of low water solubility and high octanol/water partition coefficient is that when organic matter is exposed to an aqueous solution of PCBs, there is a strong tendency for the PCBs in the aqueous solution to be preferentially taken up by the organic matter.[56] Consequently, when animals are exposed to aqueous solutions of PCBs, the lipids of these animals will preferentially

take up and store the PCBs. Since there is usually little metabolic activity in lipid bodies, the stored PCBs are, in some measure, protected from metabolic degradation. Therefore, larger and larger body burdens may be built up after continued exposure. It is this mechanism that accounts for the very large bioaccumulation factors that have been reported.[57]

In general, the volatility of a solute from a solution is governed by the vapor pressure of the (pure) solute at a given temperature and the mole fraction of the solute in the solution.[58] However, in those cases where there is either heat of mixing or change in volume when mixing the solvent and the solute (nonideal solutions), the volatility of the solute is not simply proportional to the molar concentration of the solute in the solution.[59] In those cases, it turns out that the lower the ultimate solubility, the greater the effective molar concentration. Thus, the volatility of the solute is significantly higher than would be expected for the given vapor pressure and the actual molar concentration. This phenomenon, which is known as codistillation, is responsible for the very short volatilization half-life of PCBs in water as illustrated by Table 2.[60] Codistillation from water is thought to be a major route of entry of PCBs into the atmospheric

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reservoir[61] and is believed to be responsible for the worldwide distribution of these substances.

D. Transport of PCBs in the Environment

This section discusses the mechanisms by which PCBs are transported from each compartment of the environment to the others.

1. Atmospheric Compartment

A number of investigators have determined that PCBs are very widespread in the atmosphere[62] both as molecular species and as adsorbed species on particulates and aerosols.[63] The mean air concentration of PCBs at several locations in Sweden was found to range from the detection limit of 0.8 to 3.9 ng/m^3. The highest detected level was 12.5 ng/m^3. In the United States, levels were found to range from 1 to 50 ng/m^3.[64] Over the Atlantic Ocean the airborne concentration was determined to range from 5 ng/m^3 near the northeast coast to 0.05 ng/m^3 at a distance of 2000 miles from the coast.[65] Numerous sources of airborne PCBs have been identified, including the incomplete incineration of PCB-containing materials (e.g., sewage sludge),[66] volatilization of PCBs from paints and plasticizers,[67] codistillation from surface waters that are PCB-contaminated,[68] and direct volatilization from PCB end uses and spills.[69]

Various writers have pointed out that the atmospheric reservoir of PCBs is the principal route by which the world-wide distribution of PCBs has occurred.[70] Thus the atmospheric reservoir serves as a mechanism for the dissemination of PCBs to the other compartments of the environment.

2. Terrestrial Compartment

The most significant sources of free PCBs in the terrestrial compartment of the environment include discarded consumer end use products that contain PCBs,[71] atmospheric fallout,[72] and spills associated with the use or the transport of PCBs.[73]

For that portion of the free PCBs that is confined to terrestrial sites, the primary mechanisms for dispersal are volatilization and solubilization by ground or surface waters. Since the vapor pressures of the typical PCB preparations (Aroclors) lie in the range of 10^{-2} to 10^{-4} mm Hg[74] at ambient temperatures, the loss rate by direct volatilization should be very small even in the absence of significant soil binding. It is possible, however, that under certain conditions heat produced by oxidation of organic materials in a landfill could raise temperatures significantly and thereby substantially increase the volatization of PCBs located in the fill.

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PCBs are soluble in water so that direct solubilization by percolating waters is a possible mechanism for the admission of these substances into the ground waters. As an example, the limiting solubility of Aroclor 1254 in water is about 54 ppb,[75] and the average rainfall on the continental United States is about 34.5 inches per year.[76] It therefore follows that, with the normal long percolation time, the losses into the local ground waters could be as high as 0.04 g/m^2/year in a region where PCBs have been landfilled.

In addition to solubilization, PCBs may be removed from land and enter the aquatic compartment by surface water runoff. This latter effect is of great concern in areas where contaminated oils have been used on highways or where land spills of PCBs are possible. There is no direct evidence that PCBs are degraded by soil microflora.[77]

3. Aquatic Compartment

Figure 2 illustrates the nature of the processes that are involved in the transport of PCBs to and from a body of water. It illustrates that the principal PCB inputs to a body of water are contaminated inflowing streams and the PCBs that precipitate from the atmospheric reservoir. An example of the significance of the inflowing streams is given in a recent report[78] which indicates that detectable PCB levels were found in some 40 percent of a total of 900

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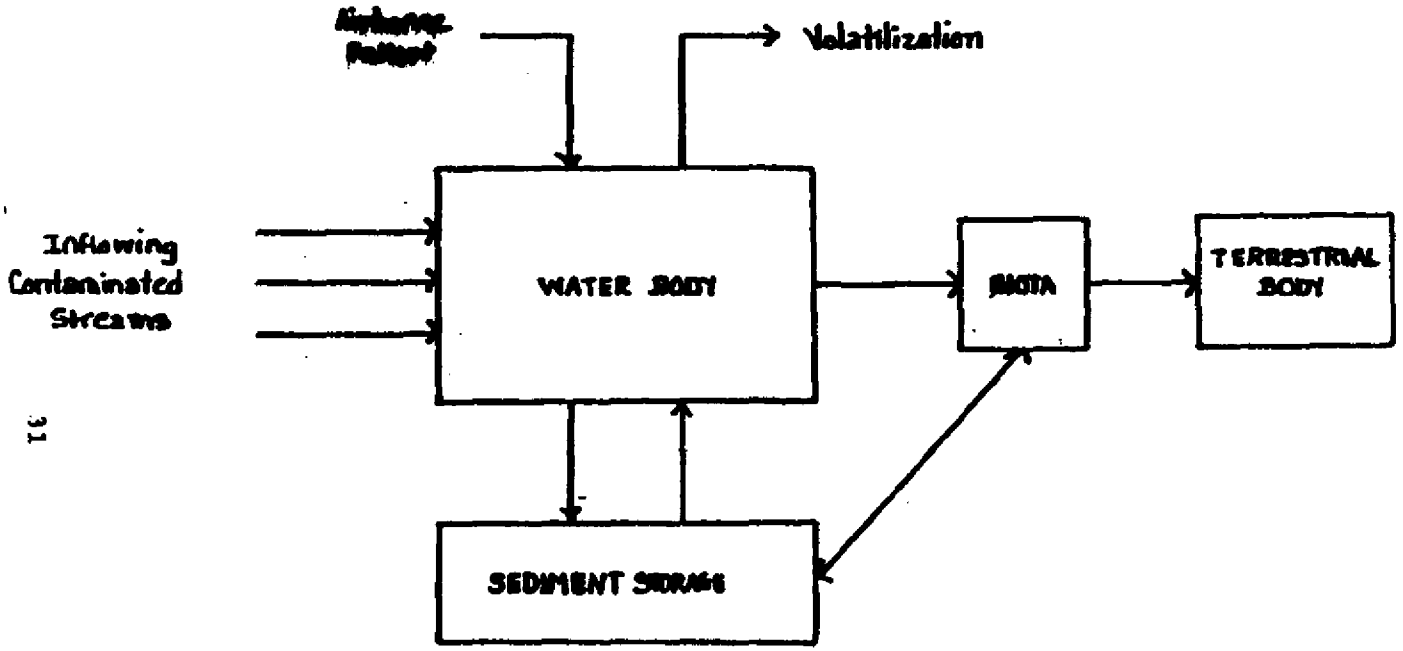

Figure 2

Model of Sources and Sinks for a Body of Water

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industrial effluent streams that were tested in Michigan. An earlier estimate[79] indicated that as much as 1 ton of PCBs was entering the Clyde River in Scotland per year as a component of crude sewage sludge from the Glasgow district. In addition, as noted above, PCBs on land may enter the aquatic reservoir as a result of solubilization and surface water runoff.

It has been demonstrated that the PCBs have a high affinity for soils in soil-water systems[80] but that these hydrosoils may serve as a reservoir for resolution when the PCB concentration in the sediments become sufficiently high.[81] In addition, when contaminated sediments are disturbed (as, for example, in river scour), some of the PCBs may be resuspended. The processes associated with desorption from a sorbent may also tend to fractionate the components of the commercial PCB mixtures in favor of the more soluble components. In general, it is believed that the material that is adsorbed onto the sediments is eventually removed by migration to the ocean depths. Thus, the sediments constitute a sink and, most probably, the principal sink for the removal of PCBs from the environment.

Measurements of the PCB concentrations in the sediments in the Hudson River above the General Electric outfall

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indicated levels ranging from 0.0 to 16.8 ppm. At Thomson Island, about 1 mile downstream, typical sediment levels ranged up to 3700 ppm,[83] with the PCB levels in the overwaters ranging from 0.06 to 3.0 ppm. Fish collected within 1 mile of the General Electric outfall contained PCB levels ranging from 78 ppm in minnows to 350 ppm in rock bass.[84] Striped bass sampled near West Point (well over 100 miles downstream of the GE outfall) had PCB residuls of between 1.16 and 7.54 ppm.[85] The magnitude of the PCB losses through the process of volatilisation (codistillation) is not fully established, but there is general agreement, as noted above, that this process is of significance in the detailed mass balance for an aqueous system. Volatilisation from the air/water interface is a principel source of the atmospheric reservoir of PCBs.[86]

E. Exposure to PCBs

1. Current Environmental Load of PCBs

It has been estimated that between 300 and 400 million pounds of PCBs entered the general environment up to and including 1975. Of this total, it is estimated that some 25 to 30 percent is free material and thus constitutes the reservoir from which exposure of the biota might occur.[87] The remainder of the environmental load, mostly in the form

of industrial waste and discarded end use products, is believed to be in landfill sites and thus constitutes a potential source of new free PCBs. It is further estimated that, at any given time, approximately one-third of the non-terrestrial free PCBs are in the atmospheric reservoir, while the remaining two-thirds are in the aquatic reservoir.[88]

2. Exposure of Organisms to the Terrestrial Reservoir of PCBs

As pointed out above, the largest portion of the terrestrial reservoir of PCBs remains in the discarded PCB-containing products that are contained in landfills.[89] The average soil concentration of PCBs taken in non-landfill areas has been found to be below detection level.[90] A recent report[91] indicates that only 0.1 percent of the soil samples analyzed showed detectable PCB levels. Sixty-three percent of the contaminated sample were from urban areas.[92] It is not clear whether any substantial exposure of the biota to the terrestrial reservoir of PCBs occurs.

3. Exposure of Organisms to the Atmospheric Reservoir of PCBs

Inhalation and dermal contact by humans and other animals are two possible modes of exposure to the atmospheric reservoir of PCBs. Although measurements taken at widely separated points have shown that there is a detectable level of PCBs in most air samples, the observed

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levels are close to the limits of detection except in the vicinity of PCB sources.[93] If the estimated atmospheric load noted above were uniformly distributed throughout the atmosphere, the concentration of PCBs in the air would be approximately 5 ng/m^3.

4. Exposure of Organisms to the Aquatic Reservoir of PCBs

The rather complex relationship between the aqueous phase, the biota, and the sediments is illustrated in Figure 2 by the interconnecting lines in the figure. The biota-incorporate PCBs either by direct sorption from the contaminated waters or through the food chain relationship between the benthic organisms living within the contaminated sediments and the free-swimming organisms. There can be little doubt that the direct pickup of PCBs from the surrounding waters is a major route by which these compounds enter the biota. A large number of marine and freshwater species have been demonstrated to take up PCBs selectively from surrounding water and concentrate these compounds at levels many timea higher than those in the water. The phenomenon is known as bioconcentration. A typical example[94] is the reported bioconcentration of PCBs by the fathead minnow by a factor of 230,000.

Currently, there is considerable disagreement as to the role played by the process of bioaccumulation in the

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contamination of aquatic organisms. However, this process is apparently the major source of PCB contamination of terrestrial animals that feed upon aquatic organisms. This relationship is illustrated by the right-hand side of Figure 2. It should be noted that terrestrial animals may have significantly higher concentrations of PCBs in their tissues than the aquatic forms they feed on. For example, while cod and pike have been found with PCB levels on the order of 10 mg/kg of extractable fat, fish-eating birds such as herring gulls and cormorants have been found with levels of 600-700 mg/kg and 400 mg/kg of extractable fat, respectively.

However, the impact of this route of exposure is not limited to aquatic species. Man as well as fish-eating terrestrial animals and birds also may be adversely affected. Fish constitute a substantial part of man's diet. Therefore, the concentration of PCBs in fish gives man the choice of either giving up an important food source or subjecting himself to the adverse effects of PCBs. In addition, man may be exposed to lower levels of PCBs by drinking contaminated water.

F. Present Distribution of PCBs in the Environment

This document has shown that the additional release of PCBs into any of the environmental compartments may be

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expected to result in widespread distribution into all these compartments and will eventually expose large populations of wildlife and man to PCBs. This conclusion is further supported by the fact that PCBs are already widespread in the physical environment and in the biosphere.

Since the earliest identification of PCBs in fish samples,[95] literally thousands of environmental and ecological samples from all over the world have been analyzed and reported to contain PCB. For example, PCBs have been identified in Antarctic ice samples from depths as great as 5.5-6 meters.[96] Sea and air samples taken in the Sargasso Sea showed PCB levels on the order of 1 ng/m^3 in the air samples and up to 10 ng/l in the sea samples. Approximately 75% of human adipose tissue samples taken from 31 persons in the United States in 1973, showed PCB levels ranging from 1 to greater than 3 ppm.[98] Polar bears, sampled as indicators of the top trophic level in arctic and subarctic food chains, have been shown to have PCB levels of up to 8 ppm (wet weight in fat).[99] Seals taken from a variety of Canadian waters show levels of from a few ppm to a high of 52 ppm.[100] In addition, PCBs have been detected, frequently at high levels, in a large number of fish and bird species inhabiting widely separated geographic areas.[101] These samples, which are by no means all-inclusive, indicate that PCBs are a global problem.

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G. Conclusions

PCBs have been demonstrated to cause a number of severe adverse effects on many living organisms at very low concentrations. As a practical matter, it is not possible to determine a "safe" level of exposure to these chemicals. Because PCBs are already widely distributed throughout the biosphere, they currently pose a significant risk to the health of man as well as that of numerous other living things. As a consequence, any further increase in levels of PCBs in the biosphere is deemed undesirable by EPA. It has also been demonstrated that PCBs released anywhere into the environment will eventually enter the biosphere. Therefore, as a corollary, EPA has determined that any such release of PCBs must be considered "significant."

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III. PCB SUBSTITUTES*

The following is a discussion of substitutes available or in the process of development for PCB dielectric fluid used in capacitors and transformers. This discussion of substitutes is intended as a brief summary. Inclusion or omission of any substance in this discussion should not be construed as an indication of EPA approval or disapproval of its use.

A. Capacitors

1. Phthalate Ester[1]

Dioctyl Phthalate (DOP) has been used in capacitors manufactured in Japan since 1974. It is presently being used in most of the capacitors manufactured in the United States.

*The information on substitutes for PCB Capacitors and Transformers was primarily based on data contained in the Versar study, PCBs in the United States: Industrial Use and Environmental Distribution. Some of the facts in that study were updated based on a review by Versar of this discussion of substitutes prior to issuance of the Draft Support Document. Information on Uniroyal PAO-20E was provided by the Uniroyal Chemical Company prior to preparation of the Draft Support Document.

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Advantages of DOP are: (1) the cost is approximately one-half that of PCBs; (2) DOP is available as a substitute since it is currently used as a plasticizer for polyvinyl chloride; and (3) its dielectric constant is 5.3, similar to that of PCB.

Disadvantages of DOP are: (1) the maximum service temperature of capacitors containing DOP is 85°C, as opposed to 95°C for PCB; and (2) the corona inception voltage is lower than that of PCB but can be raised by the addition of trichlorobenzene to the mixture.

Diisononyl phthalate is a potential substitute for PCB. It is manufactured by Exxon under the tradename Enjoy 2065 and is not available in large quantities. Diisononyl phthalate is similar to DOP, although it is more stable chemically.

The flash points for DOP and diisononyl phthalate are relatively high (220° for DOP), yet both of these phthalate esters are more flammable than PCBs. It should be noted that a particular class of phthalate esters, the alkyl phthalates, were recommended for testing by the TSCA Interagency Testing Committee[2].

2. Alkylated Chlorodiphenyl Oxide[3]

Butylated monochlorodiphenyl oxide is marketed by Dow Chemical Company under the tradename XFS-4169L.

Based on four years of testing, McGraw-Edison, a capacitor manufacturer, has found this material (which they tradenamed EDISOL) to be a "viable substitute" for PCBs in high voltage power capacitors. Although the dielectric constant of EDISOL is somewhat lower than that of PCB (4.5 versus 5.85), the size of EDISOL capacitors marketed by McGraw-Edison is the same as PCB capacitors at equal KVAR ratings.

Advantages of butylated monochlorodiphenyl oxides are: (1) a lower loss-tangent; (2) a higher corona inception voltage than PCB by 20 to 30 percent; (3) a higher flash point (174°C). Advantages of this substitute vis-a-vis toxicity are that it (1) is more biodegradable than trichlorobiphenyl; (2) has been shown to be nonmutagenic in an Ames test; (3) has a lower bioconcentration factor than PCB; (4) has a lower adipose concentration than PCB; and (5) does not show chloracnegenicity.

Disadvantages of butylated monochlorodiphenyl oxide are: (1) the higher material costs; and (2) a lower fire point (199°C) than that of PCB.

B. Transformers

1. Fluorocarbons[4]

Certain fluorocarbon compounds have properties similar to PCBs. Fluorocarbons are highly volatile in

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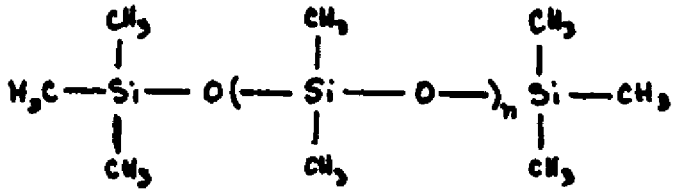
comparison to PCB, and they are about six times as expensive. Perfluoroethane is extensively used as a dielectric gas in totally enclosed gas filled transformers, which can be used to replace PCB Transformers in certain hazardous locations.

2. Silicones[5]

Low viscosity silicone fluids, on the order of 50 centistokes, are possible substitutes for PCBs in transformers. They are produced by General Electric, Dow Corning, Union Carbide, and SWS Silicones. Polydimethyl siloxane, a potential substitute, has the molecular structure:



Silicone fluids have the special advantage of a relatively temperature-independent viscosity. The silicone fluids have somewhat poorer heat transfer characteristics than askarel but can be substituted directly for askarel in existing transformers, resulting in only a small decrease in the transformer rating.

Electrical Properties:

Dielectric Constant	2.72
Dielectric Strength	200 volt/mil
Resistivity	7.1×10^{14} ohm-cm
Dissipation Factor	1.8×10^{-5} at 100 Hz, 23°C

Polydimethyl siloxane has a higher flash point than conventional, non-PCB transformer coolants: 280°C for mineral oil (PCBs have no true flash point.) The heat of combustion of 50 centistoke polydimethyl siloxane is lower than that of mineral oil--7.67 kcal/gm versus 11.0 kcal/gm--and since the silicones burn more slowly, they are considered poor fuel.

On the Underwriters Laboratories' fire hazard classification (in which water is rated as 0 and ether as 100) polydimethyl siloxane is classified as 4 to 5, which is slightly higher than the 2 to 3 rating given to PCBs, but is considerably less than the mineral oil rating of 10 to 20.

These compounds do not biodegrade, as measured by sewage sludge breakdown to CO_2. However, there is evidence that they partly depolymerize to low molecular weight compounds upon contact with soil and water. Since ultraviolet light decomposes methyl silicones, sunlight exposure may be the mechanism for environmental degradation.

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No tendency for bioaccumulation or bioconcentration has occurred in experiments. In mammals, the compound is not absorbed through the gastrointestinal tract or the skin.

The PCB substitute developed by Dow Corning for transformers is called DC561. This is a mixture of polydimethyl siloxanes of various chain lengths which have a viscosity of 50CS. The literature on environmental and health characteristics of silicones makes reference to at least six fluids, most of which are probably similar to the DC561, but some of which could be other mixtures with certain additives. By necessity, the usefulness of published toxicological data depends on the validity of the assumption that all of these compounds have identical persistence, bioaccumulation, and toxicity properties.

A review of toxicological studies of silicones reported the following results:

Dietary Toxicity:

LD_{50} (rats) >28 gm/kg

Extended Feeding Tests:

Guinea pigs--47 gm/kg/day for extended period--no toxic effect.

Mallard ducklings and bobwhite quail--5000 ppm for 5 days--no effect.

Rats--20 gm/kg/day for 28 days--no effect.

Rats--190 mg/kg/day for 90 days--no effect.

Beagle dogs--300 mg/kg/day for 120 days--no effect.

Mice--3 percent in diet for 80 weeks--no effect.

Man--FDA allows silicones as food additives at up to 10 ppm.

The major deficiency in knowledge of the silicones appears to be in their fate in the environment and the toxicity of their breakdown products.

The silicone transformer fluids currently cost up to twice as much as PCBs on a volume basis.

Dow Corning has completed evaluation of polydimethyl siloxane as a high voltage insulating fluid. They report, though, that a near term 100 percent replacement of PCBs in transformers by this fluid is not possible. If a transformer market were to develop for polydimethyl siloxane, the present domestic capacity could be adequate to supply new transformers. The time lag for a 100 percent replacement of PCBs in transformers by polydimethyl siloxane would be on the order of 5 to 10 years.

3. Mineral Oils[6]

Mineral oils are widely used in transformers. The flash point of mineral oils is a function of its molecular weight. Since crude petroleum can be refined to have any required molecular weight over a wide range, it is possible to specify any particular flash point that is desired for the minimal oil transformer liquid. This approach has been taken by RTE Corporation in the development of their proprietary transformer liquid, which has the tradename RTEmp.

RTEmp is a highly refined paraffinic mineral oil that has a flash point of 285°C, approximately the same as the 50CS silicone liquid proposed by Dow Corning as a PCB substitute. To achieve this higher flash point, the oil is refined to have a higher molecular weight and consequently a higher viscosity, which reduces its effectiveness in convective cooling.

The major current advantage of the high flash point mineral oils is their low price relative to silicone and askarel and their inherent biodegradability and low toxicity.

4. Synthetic Hydrocarbons[7]

Certain mixtures of synthetic hydrocarbons may result in a liquid having the high flash point characteristics of RTEmp or silicone combined with the

relatively low viscosity and satisfactory heat transfer characteristics. Examples of synthetic hydrocarbons being tested as PCB substitutes include FR Dielectric Fluid manufactured by Gulf Oil Chemical Company and PAO-20E produced by Uniroyal Chemical.

PAO-20E[8] was designed for use in transformers. Its dielectric strength (KV/0.25 cm) is 50, and its dielectric constant is 2.15, as compared with 40 and 4.3, respectively, for PCB. It has a flash point of 276°C and a fire point of 307°C. Its acute oral LD_{50} (rats) is over 40 mg/kg.

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IV. SIGNIFICANT EXPOSURE/TOTALLY ENCLOSED MANNER

A number of persons commented on the Agency's proposed definition of the term "significant exposure". This term was defined as any exposure of human beings or the environment to PCB chemical substances or PCB mixtures as measured or detected by any scientifically acceptable analytical method. The majority of the persons who commented objected to the proposed definition (6, 31, 35, 38, 42, 46, 70, 81, 86, 94, 97, 116, 139, 140, 151, 167, 174, 208, 215, 216). Some persons stated that there was a lack of adequate health and environmental effects data to justify such a stringent position (31, 46, 140, 138, 215, 216). Some of these persons stated that the Agency's zero exposure limit was unfounded particularly in light of the Center for Disease Control (CDC) epidemiological study* on the exposure of PCBs in Bloomington, Indiana. They also contended that a National Cancer Institute (NCI) bioassay** of Aroclor 1254 for possible carcinogenicity refuted earlier data on the carcinogenicity of PCBs (82, 46).

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*USDHEW, Center for Disease Control. Exposure to Polychlorinated Biphenyls in Bloomington, Indiana. Atlanta: Public Health Service, EPI-77-35-2, (May 26, 1978).

**USDHEW, PHS, NIH, NCI. Bioassay of Aroclor 1254 for Possible Carcinogenicity. Washington: National Cancer Institutes, Tech. Report Series No. 38, (1978).

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Two persons, however, agreed with the Agency's decision to define "significant exposure" as any exposure (85, 182). One person pointed out that the NCI and CDC studies do not invalidate any of the results of previous studies indicating that PCBs pose a carcinogenic risk to man. This person also pointed out that scientists have observed other adverse health effects from exposure to PCBs.

After reviewing all these comments and the CDC and NCI studies, the Agency concludes that no change in its evaluation of the health hazards of PCBs is warranted or appropriate. The CDC study was not designed to determine the carcinogenicity ot PCBs; therefore, that study is not relevant for purposes of evaluating the carcinogenic risk posed by PCBs. Furthermore, the study established that humans exposed to PCBs had elevated serum levels of gamma glutamyl transpeptidase (a liver enzyme) and triglycerides. These effects indicate that PCBs cause enzyme induction and may damage the liver in humans. The elevation of serum triglyceride levels has additional significance in that such elevations have been associated with atherosclerotic cardiovascular disease. In sum, it is apparent that the CDC study, rather than undermining the Agency's conclusions about the hazards of PCBs, supports these conclusions.

The NCI study cannot be considered to establish non-carcinogenicity. The study showed certain trends which raise concern about the carcinogenicity of Aroclor 1254.

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For example, liver and gastrointestinal tumors were found in rats treated with Aroclor 1254 but not in controls. The incidence of these tumors was not statistically significant. However, lack of statistical significance may be a result of insufficient numbers of animals used in the experiment.

In conclusion, the comments submitted and the CDC and NCI studies do not warrant any change in the Agency's evaluation of the adverse health and environmental effects caused by PCBs. In particular, no acceptable reason has been provided for rejecting the results of several studies which indicate that Aroclor 1254 and other PCB mixtures are carcinogens and cause numerous other adverse effects. Therefore, the Agency adheres to its conclusion that the release of any quantity of PCBs into the environment is significant.

Further objections to the definition of "significant exposure" were that the proposed definition makes compliance difficult and could deter clean-up of existing contamination (31, 46, 70, 16, 139, 140, 151, 167, 208, 216). Persons stated that any housekeeping or maintenance operation will necessitate some human or environmental exposure to PCBs. To alleviate this problem some persons suggested that the Agency take into consideration, when defining "significant exposure", such factors as (1) industry's existing safe

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handling practices, (2) Occupational Safety and Health Administration (OSHA) regulations which control a substantial portion of the potential worker exposure from maintenance and housekeeping operations, and (3) the distinction between existing and newly introduced PCBs.

These comments indicate a misunderstanding of the Agency's criteria for defining "totally enclosed manner." The Administrator is required by §6(e)(2)(B) to define by rule the term "totally enclosed manner" as the manner which will ensure that any exposure of human beings or the environment to a PCB will be insignificant. This language clearly indicates that the Agency's definition of "totally enclosed manner" is to be based strictly upon health and environmental factors. Nowhere does TSCA state that in defining "totally enclosed manner", the Agency is to consider technological feasibility, economic impact, or current industry practices. It is the Agency's understanding that this same rationale can be applied to defining "significant exposure". As General Electric (58) commented, the term "significant exposure" is different from the definition of "unreasonable risk" and is used solely for the purposes of defining "totally enclosed manner".

Thus although such factors as technological feasibility, economic impact, or current industry practices are not considered in determining "significant exposure", they are

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considered, among other factors, by the Agency in deciding whether or not an activity presents an "unreasonable risk" to health and the environment. If an activity is found not to present an "unreasonable risk", an authorisation and an exemption for such an activity to take place in a non-totally enclosed manner may be granted.

V. PCB DEFINITION: 50 PPM

A large number of persons representing industry and environmental action groups commented on the Agency's decision to lower the definition of "PCB Mixture" from 500 ppm to 50 ppm PCB. Some persons were concerned that 50 ppm was too high (53, 84, 92, 126, 211, VIII TR, p. 172-178) because there existed a health and environmental risk from PCBs even at levels below 50 ppm. The majority of these persons suggested that EPA lower the level at which PCBs would be regulated.

Three persons agreed with the Agency's decision and reasons, as stated in the proposed rule, for lowering the level defining a "PCB Mixture" to 50 ppm (57, 85, 101). One person stated that lowering the definition to 50 ppm would not have a detrimental effect on his industry (158).

The majority of persons commenting on this action disagreed with the Agency's proposal to lower the definition of "PCB Mixture" to 50 ppm. Their first objection was based upon what they perceived to be either the lack of sufficient economic information to determine the impact or the substantially greater economic impact that would be incurred by industry and the national economy by lowering the definition from 500 to 50 ppm. This impact, they thought, was unreasonable and, therefore, contrary to Congress' intent (3, 4, 6, 11, 15, 17, 20, 25, 31, 35, 36, 37, 46, 49,

55, 58, 62, 69, 70, 71, 72, 75, 80, 87, 89, 90, 91, 93, 94, 95, 96, 97, 99, 100, 104, 106, 109, 116, 122, 123, 133, 134, 137, 138, 139, 140, 145, 146, 147, 150, 151, 152, 156, 161, 165, 167, 170, 174, 178, 189, 190, 191, 201, 202, 208, 216, IV TR, p. 7, V TR, p. 41).

These persons attributed the impact to a variety of reasons. First, they thought that lowering the concentration for regulating PCBs would require the affected industries to spend more money on the additional requirements for recordkeeping, testing, draining and flushing, specialized storage and containers. Second, they thought the affected businesses would incur a loss as a result of the premature disposal of PCB Articles and PCB-contaminated fluids. Third, they thought the restrictions on allowable repair may cause some industries to reduce their maintenance force. Lastly, they felt that industry would incur a loss from shut down of certain PCB Articles while these articles were being replaced or were being serviced in order to bring the article into compliance with the rule. These impacts, they believed, would affect all sectors of the economy including industries, consumers, and workers.

A substantial number of comments were received indicating that the Agency was lacking prudence in lowering the definition of "PCB Mixture" to 50 ppm. They felt that by banning the current industry practice of burning of PCB

contaminated fuels and by indirectly causing an increased demand for fuel needed to transport PCBs to approved incinerators, the Agency was aggravating energy problems in the U.S. (11, 29, 36, 47, 49, 55, 134, 150, 198).

The Agency has reviewed all the comments and the accompanying economic data that was submitted in regard to this 50 ppm vs. 500 ppm issue. None of these comments provide evidence that changes the Agency's finding that 50 ppm is the most reasonable concentration at which to regulate PCBs. (For a thorough discussion of the Agency's rationale for regulating PCB above 50 ppm see section II.B in the Preamble to the final rule.)

The Agency, however, has modified the rule to reduce the economic consequences to industry of the restrictions on PCBs and PCB Articles containing greater than 50 ppm PCB to the extent possible without compromising necessary protection to health and the environment. (For a discussion of the Agency's justification for reaching these conclusions, see section III, Changes in Subpart B: Disposal of PCBs and PCB Items, as found in the Preamble to the rule). First, the Agency is allowing persons to dispose of PCB-contaminated fluids between 50 and 500 ppm PCB, in high efficiency boilers. Second, for those industries who do not have access to high efficiency boilers or who prefer landfill disposal, the Agency is permitting the use of

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chemical waste landfills for the disposal of such PCB-contaminated fluids, subject to certain conditions. Third, the Agency is permitting the recycling of mineral oil. Lastly, the Agency has decided to allow persons to drain mineral oil transformer fluids contaminated with PCBs in the range of 50 to 500 ppm into collection tanks and test the batched mineral oil instead of requiring them to test each individual transformer. These practices will substantially reduce the cost of disposal and testing.

The Agency believes that the changes that have been made in the rule, particularly the changes in testing and disposal requirements for PCB liquids, will permit the use of PCB-contaminated mineral oil dielectric fluid as a fuel and will therefore alleviate some of the cost to the consumer and the power industry for energy. In addition, by permitting other methods of disposal that may be more conveniently located, the Agency is also reducing the demand for fuel needed to transport PCBs and PCB Items to disposal facilities.

Some persons objected to the proposed definition because they did not believe that the Agency had sufficient health and environmental justification for regulating PCB at 50 ppm particularly in light of the economic impact. These persons, in general, felt that the economic impact far outweighed the adverse health and environmental effects

(11, 15, 31, 36, 69, 70, 71, 81, 89, 91, 93, 94, 95, 100, 109, 140, 145, 146, 147, 148, 150, 156, 165, 198, IV TR, p. 7). In some cases these persons felt that there was no data that suggested that there was any health and environmental hazard from PCBs (6, 29, 59, 96, 97, 116, 199, 122, 123, 132, 172, 191).

The Agency disagrees that there are insufficient adverse health effects data to warrant regulations below 500 ppm. PCBs at levels below 500 ppm have been shown to cause a variety of adverse health effects in animals including malignant and benign tumors, enzyme induction, immunological suppression, and fetotoxic, mutagenic, and reproductive effects. (A more detailed discussion of these health effects is discussed in Section II of this document.)

Some persons objected to the proposed 50 ppm definition for reasons of inadequate analytical chemistry capability. These persons contended that relieble analytical results were unobtainable because either the methods were invalid or because they were unable to find a laboratory that was able to supply reliable results (18, 29, 95, 97, 202). Other persons objected because there were not enough laboratories to perform these tests (31, 95) or because the already existing laboratories would become overburdened with work thus aggravating the delay in receipt of results (88).

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They felt that unless there was a valid method for analyzing PCBs at low levels in oils and chemical products such as pigments, industry could not be expected to comply with the rule.

The Agency disagrees with these comments. A variety of accepted analytical methods for measuring the concentration of PCBs in several media are currently available. A number of these methods are described in the Preamble to the rule in Section III. In addition, commercial and industrial laboratories are capable of using these methods to produce valid analytical results for PCBs. Industries with specialized analytical expertise for their product, e.g., pigments, will be expected to adopt appropriate PCB analytical methods to determine PCB concentrations in their processes or products.

Some commentors thought that because 1) EPA was increasing the amount of PCBs that had to be handled by lowering the applicable PCB concentration from 500 to 50 ppm and 2) the distances to EPA approved incinerator or disposal facilities may be far, EPA was actually increasing the chances that this material might be accidentally released to the environment (36, 81, 90, 146, 152, 172, 198, IV TR, p. 7).

As a result of the Agency's decision to permit certain PCBs and PCB Items to be disposed of in chemical waste landfills and high efficiency boilers in addition to high temperature incinerators, the number of approved facilities

will be expanded. This should reduce the likelihood of environmental contamination from spills as the distance over which these materials must be transported is reduced. In addition, the Agency is also requiring persons who possess PCBs to comply with certain spill prevention practices (see Preamble section V.C.3).

One person stated that the proposed 50 ppm definition would have a disproportionate impact on small businesses because in most cases small businesses are unable to perform their own testing. They must therefore rely on independent organisations and would need substantially more time to test for PCBs than would be needed by large businesses who could perform their own testing. The commentor suggested that the delay in receipt of the results for transformer testing could increase the time that the transformer is out of service (87).

The Agency is aware that small businesses have to rely on outside testing laboratories to a greater extent than large businesses. However, the final rules greatly reduce the need for testing by allowing persons to make certain assumptions about the transformer, based upon its history. This alternative benefits small and large businesses equally.

A variety of alternative regulatory techniques other than the ones adopted by the Agency were suggested. A number of persons recommended that EPA raise the lower level at which the Agency is regulating PCBs and PCB Articles to

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levels above 50 ppm and/or postpone the effective date by which persons must comply with this level. (500 ppm was the most frequently recommended level.) (31, 34, 36, 37, 49, 54, 59, 72, 75, 81, 87, 89, 91, 94, 95, 102, 104, 116, 119, 122, 123, 132, 133, 137, 139, 146, 150, 156, 161, 174, 188, 189, 190, 191, V TR p. 139) Others suggested that EPA apply the restrictions on the disposal of articles that contain greater than 50 ppm only if the total amount of PCBs in the articles exceeds a specified amount (15, 49, V TR, p. 21).

The Agency considered these suggested alternatives and believes that the approach that it has taken in the final rule is the best method for both controlling the risks from PCB and minimizing the economic impact.

The Agency believes that the first alternative is unacceptable because it would allow a substantial amount of PCB to escape to the environment since many activities involving PCB-contaminated materials would go unregulated. For the most frequently mentioned cut-off level, 500 ppm, the Agency has predicted that at least 1 million pounds of existing PCBs (using data developed by Versar) and 100,000 to 500,000 pounds per year of newly manufactured PCBs (using data from manufacturing petitions) could escape to the environment. The later numbers are based upon the assumption that the 60,000 or so pounds that industry suggested is an underestimate. The Agency believes that

chere are some pigment manufacturers that have not submitted an exemption request because they have assumed, erroneously, that they do not need to do so.

The second alternative is a more complicated approach to implement because of the difficulty with using poundage instead of concentration limits as a trigger for requiring compliance with restricted disposal procedures. The problem becomes particularly pronounced when a volume of PCB liquid is in someway combined with other PCB liquids changing the pounds of PCB per container. The Agency believes that its use of concentrations to define applicability is much simpler, more easily implemented, and achieves the same goal of defining a reasonable level at which to regulate PCBs. As discussed above, alternative methods of disposal such as high efficiency boilers, chemical waste landfills, and the use of batch testing should substantially reduce the cost of this rule.

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VI. DILUTION

One pigment manufacturer stated that some persons in the pigment industry would have difficulty complying with the anti-dilution clause in the proposed rule (VII TR, p. 9). He stated that some pigment manufacturers produce pigments in batches and then blend the batches to insure uniformity. Two persons stated that because, as they believed, the dilution constraint was aimed at persons who might consider diluting in order to avoid complying with EPA's disposal procedures, EPA should qualify the rule by stating that normal manufacturing operations such as blending do not constitute "dilution" (174 VII TR, p. 9,).

The Agency agrees that the blending and subsequent use of chemicals such as pigments was not the type of dilution that EPA wanted to control. Person's who, for operational reasons, dilute their PCBs in a manner not specifically authorized by EPA, may request an exemption from the prohibitions on dilution. These exemptions will be dealt with on a case-by-case basis. See section II.C of the Preamble for a discussion of the dilution provisions.

One person asked that reduction of PCB concentration that occurs during an authorized activity, such as refilling hydraulic systems, not be subject to the prohibitions on dilution (101).

One person also objected to the restrictions against unintentional dilution as contained in the definition of PCB mixture (29). He stated that EPA needs to distinguish more adequately between dilution to avoid disposal compliance and dilution from unintentional contamination. He also recommended that EPA exclude non-PCB contaminated fluids from the definition of PCB mixture when the PCB concentration is less than 50 ppm (29).

The Agency agrees with this comment and again has accordingly modified the final rule by deleting the defined term "PCB Mixture" and by explaining in the Preamble (see sections II.C.4.a and III.E of the Preamble) the circumstances under which intentional and unintentional dilution resulting in improper disposal of PCBs or PCB Articles, constitutes a violation of the rule. As part of these changes, the final rule no longer restricts the disposal of PCBs that contain less than 50 ppm PCB as long as the PCB concentration was the result of activities permitted by an authorization. The Agency, however, is restricting the disposal of PCB-contaminated fluid above 50 ppm whether or not the PCBs are present as a result of unintentional contamination. The Agency believes that whether or not PCBs are the result of intentional or unintentional action, PCBs above 50 ppm pose a health

and environmental risk. (See section II.B of the Preamble for a more explicit discussion of the Agency's reasons for choosing 50 ppm as the cut-off concentration.)

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VII. TRANSFORMERS

The Agency's proposal to regulate mineral oil transformers that are contaminated with PCBs resulted in a large number of comments, especially from electric utilities and transformer servicing and manufacturing companies. A few comments argued that the rule, as it related to PCB and mineral oil transformers, went beyond the intent of the TSCA (46, 49, 97, 156, 169, III TR, p. 124, IV TR, p. 5).

The Agency believes TSCA is clear in giving EPA authority to regulate the manufacturing, processing, distribution in commerce, and use of PCBs in transformers. Transformers, inasmuch as they contain PCBs or PCB contamination, are subject to control under the authority of TSCA. (See Section XII of this Support Document for a discussion of the justification for regulating PCB Articles and PCB Equipment.) The extent of controls on transformers has been determined by a process of considering both the clear benefits resulting from transformer activities and the potential environmental and human hazards that can result from those activities.

Many of those commenting expressed the belief that the environmental, economic, and energy trade-offs had not been fully and properly weighed (11, 35, 44, 46,

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48, 49, 53, 55, 57, 60, 70, 71, 82, 83, 91, 96, 97, 100, 109, 110, 121, 129, 131, 134, 137, 140, 150, 156, 167, 170, 189, 190, 196, 208, 210, 216, 218, I TR, p. 22, I TR, p. 118, II TR, p. 6-7, II TR, p. 60, III TR, p. 138, VII TR, p. 45-48).

In proposing the PCB regulation as it applies to transformers, the Agency weighed all environmental, health, and economic (including energy) factors available to it at the time. In the Preamble to the proposed regulation, the Agency noted a number of areas in which more information relating to these factors would be particularly useful. Largely as a result of data submitted in response to the Agency's request for additional information, a number of modifications to the proposed regulation have been made. These changes include allowing PCB Transformers to be reclassified as PCB-Contaminated Transformers under certain conditions and changing disposal and testing requirements for PCB-contaminated mineral oil. (An extensive discussion of the Agency's rationale is found in the Preamble to the final rule in section II.C, Classification of Transformers Under This Rule.)

Several comments requested that EPA impose a moratorium on adopting the prohibition rule pending further study of economics and acceptable levels of

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PCBs in the environment (48, 49, 91, 93, 210, I TR, p. 15).

The Agency is directed by TSCA to implement the bans on PCB activities in keeping with the designated timetables that are contained in the Act. In setting specific dates for the prohibition of PCB activities, Congress intended to give the Agency limited discretion in the timing for implementing the PCB bans.

The proposed five year authorization period for servicing PCB Transformers was strongly objected to by many persons as being too short and therefore unreasonable (11, 17, 20, 31, 32, 35, 37, 42, 53, 58, 71, 85, 88, 104, 156, 199, 210, I TR, p. 17). One comment endorsed the servicing authorization of five years provided the authorization was subject to further renewal (89). One comment recommended shortening the five year authorization period since the criteria in §6(e)(3)(B) of TSCA called for annual exemptions (83). Many comments suggested an authorization should be granted for the useful life of the transformer (17, 36, 37, 54, 70, 82, 98, 156, 178, 189, I TR, p. 17).

The proposed five year authorization for servicing transformers was not intended to signify Agency intent to end those activities after five years. Its purpose was to require a reassessment of the servicing

limitation prior to the end of the five year period so that factors such as new servicing technology could be considered in deciding the need for authorizations beyond the initial five year period. Due to the Agency's desire to have exemptions and authorizations expire at the same time, the Agency has changed the five year authorization so that it will expire on July 1, 1984. (This issue is discussed in sections VIII.B and IX.A of the Preamble).

Two persons objected to the differentiation made between exemption requirements for servicing by owners and non-owners (11, 156).

Under §6(e)(3) of TSCA, processing and distribution in commerce of PCBs after July 1, 1979 are not permitted unless an exemption has been granted by EPA. If a person services his own transformer with his own PCBs, processing and distribution in commerce do not occur. However, if one is servicing another's transformer and adds PCBs to that transformer so that title to those PCBs is changed, processing and distribution in commerce occurs. Because TSCA requires an exemption for distribution in commerce after July 1, 1979, the Agency must require a person who adds PCBs to another's transformer to have an exemption after that date.

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One person commented that the proposed rule would have a greater impact on small businesses whose sole income comes from the repair of PCB Transformers than it would have on companies such as General Electric and Westinghouse who, in addition to repairing PCB Transformers, also manufacture other electrical articles and equipment (49).

The Agency acknowledges that this regulation could have a greater impact on businesses who have smaller profit margins and less diversified sources of income. However, as one trade association noted, the restriction on the rebuilding of PCB Transformers would affect around only 10% of the total business for small repair companies (VI TR, p. 79). Further, it is reasonable to assume that the loss of this repair activity can be compensated for by expansion into other repair activities.

A large number of persons commenting objected to the prohibition against rebuilding of PCB Transformers (30, 57, 58, 89, 91, 93, 94, 123, 131, 137, 156, III TR, p. 87-88, III TR, p. 124, VI TR, p. 8). A number of comments contended that rebuilding presented no risk to man or the environment (9, 46, 49, 91, 93, 137, 210, I TR, p. 18, III TR, p. 127, IV TR, p. 5, VII TR, p.

53-55). Two comments were received expressing concern for the exposure to workers during the rebuilding of PCB Transformers (53, 74). Three comments recommended that rebuilding be allowed at EPA-approved transformer facilities using EPA standards for the rebuilding activities (17, 48, 74). Three comments stated that they had no serious objections to the restrictions on rebuilding of PCB Transformers (46, 71, VII TR, p. 29).

None of the comments the Agency received presented data that would change EPA's finding that continued rebuilding of PCB Transformers would present an unreasonable risk of injury to human health or the environment. EPA decided to not develop rebuilding standards because they would probably have an unacceptably high economic impact. This issue is discussed further in section IX.A.1, General Discussion of Transformer Servicing, in the Preamble to the rule.

Several persons recommended that EPA either require or at least permit PCB Transformers to be drained, flushed, and refilled with non-PCB fluid, or, on a voluntary basis, be permitted to perform such actions (39, 53, 58, 77, 82, 85, 94, 104, 123, 144, 190, 204, VI TR, p. 162). Three persons stated that acceptable substitutes for PCBs were available for both topping-off and refilling (38, 58, 121). Some comments

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expressed apprehension about the availability of acceptable substitutes (31, 35, 44, 71, 91, 104, 144, VI TR, p. 59, VII TR, p. 51-52). Others objected to the suggestion that PCB Transformers must be refilled with non-PCB fluid (31, 153). One comment objected to refilling and topping off with non-PCB fluid because it would only add to the amount of material to be disposed of (43).

EPA wishes to note that the use of substitutes for topping off or refilling PCB Transformers is optional. Owners or operators are not precluded from adding a dielectric fluid with greater than 500 ppm PCB to a PCB Transformer. Routine servicing and topping off of PCB Transformers with additional PCBs is not considered a potentially hazardous operation and is consistent with the authorization of continued use of PCB Transformers.

Many of the comments received regarding mineral oil transformers expressed concern that the restrictions on the recycling of PCB-contaminated mineral oil and transformer casings would result in the waste of oil, valuable metals and other natural resources (3, 11, 36, 46, 49, 55, 77, 82, 88, 97, 103, 107, 122, 137, 150, 151, 153, 156, 188, 210). The majority of comments advocated permitting a disposal

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method, other than high temperature incineration for mineral oil contaminated between 50 and 500 ppm PCB (41, 46, 70, 71, 90, 93, 94, 102, 119).

Most of the persons commenting recommended the use of contaminated mineral oil (mineral oil containing between 50 and 500 ppm of PCBs) as a fuel in electric utility boilers. They argued that this method of disposal had two very positive effects; one, it would reduce the economic costs of disposal, and, two, it would utilize the fuel value of the oil thus reducing the waste of natural resources (4, 28, 36, 37, 46, 58, 72, 88, 97, 100, 103, 111, 134, 144, 145, 147, 151, 156, 172, 190, 198, I TR, p. 142-143, I TR, p. 116, II TR, p. 60, VI TR, p. 46). In addition, several comments were made stating that the scarcity of suitable disposal facilities makes disposal burdensome and costly (11, 37, 46, 77, 82, 87, 88, 102, 156, 165, 172, 188, 201, I TR, p. 156, II TR, p. 60-61). Others argued that the lack of disposal facilities would increase the hazard of environmental contamination created by transporting PCBs long distances to approved facilities and would increase the length of storage time (33, 77, 82, 144, 151, 198, 210). A few comments suggested that contaminated mineral oil should be permitted for reuse as recycled oil or used as a

solvent for successive flushings of transformers. This would further reduce the total amount of contaminated mineral oil that will be disposed of, decrease the demand for new mineral oil, and reduce the economic impact of the rule (5, 27, 40, 42, 82, 156, I TR, p. 16). Several comments endorsed the EPA proposal which did not place restrictions on the salvaging of mineral oil transformers once the fluid had been drained from them (40, 94, IV TR, p. 22).

The final rule represents a significant change from the proposal on the disposal requirements for mineral oils contaminated between 50 and 500 ppm PCB. As noted above, a number of comments, particularly from utilities, favored continuation of the existing practice of burning waste mineral oil in power generation boilers. On the basis of our analysis of these comments, the rule has been changed to allow the burning of such oil in high efficiency boilers. A complete discussion on this change is contained in section III.A, Mineral Oil Dielectric Fluid with 50 to 500 ppm PCB, in the Preamble to the rule.

In addition, the final rule allows the disposal of PCB-contaminated mineral oil dielectric fluid and other low concentration PCB liquid wastes in chemical waste landfills. Chemical waste landfills have been shown to

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be an acceptable technique for disposing of low concentration liquid wastes. These two alternatives will reduce mineral oil disposal costs and lessen the burden on incinerators.

Another area of concern to many of the persons commenting were the testing requirements for mineral oil. The costs of testing were cited as extremely burdensome (31, 35, 37, 49, 80, 83, 90, 91, 94, 100, 103, 108, 111, 113, 122, 137, 144, 145, 146, 147, 165, 176, 189, 201, I TR, p. 136, II TR, p. 51, II TR, p. 5-6). Several alternatives were suggested for dealing with the problems associated with testing mineral oil transformers. The most commonly advocated suggestion was to permit bulk storage and testing of mineral oil for PCB contamination. This method would be preferable because it would substantially reduce the economic burden associated with testing, reduce the likelihood of long delays in obtaining results, and reduce interference in day to day business operation (4, 27, 37, 65, 87, 100, 103, 183, I TR, p. 15-16, I TR, p. 107, I TR, p. 131-132, I TR, p. 138).

Several comments recommended that the requirements for testing of PCBs in non-PCB Transformers be deleted because of high cost (123, 188, VI TR, p. 20). One alternative suggested that EPA exempt mineral oil

filled distribution transformers from sampling and analysis for the purpose of labeling and disposal, if the unit was originally a mineral oil transformer and there had been no servicing that would have made contamination possible (88, 108).

Some comments stated that there are not sufficient laboratories qualified to analyze PCBs to meet the demand created in the proposal. They also expressed concern about the divergent results reported by different laboratories analyzing identical samples, and they feared that increased demand would result in the establishment of many unqualified laboratories because EPA has not established testing standards for PCBs (31, 46, 88, 95, 144, 172, 190, 210, II TR, p. 57, I TR, p. 139-140).

The Agency is addressing the issue of testing burdens and costs by allowing persons to assume that mineral oil from mineral oil transformers is contaminated with PCBs between 50 and 500 ppm PCB. This assumption therefore permits these persons to dispose of their mineral oil in high efficiency boilers or chemical waste landfills in addition to the proposed method of disposal in high temperature incinerators. This greatly reduces the need to test mineral oil for PCB concentration. Testing may be desired to determine

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if the PCB concentration is below 50 ppm in order to use or dispose of the oil with fewer restrictions.

In instances where testing is to be performed, batch testing of the mineral oil is allowable, rather than requiring testing of the oil from each individual transformer. As indicated in comments, batching of mineral oil is common industry practice and the Agency sees little environmental advantage to requiring individual transformer testing. In addition, batch testing will result in additional testing cost savings. (A more complete discussion on transformer testing and batch testing is provided in the Preamble to the rule in section II.C.4.a, Determining Appropriate (Transformer) Categories, and in section III.E, Batch Testing of Mineral Oil Dielectric Fluid, respectively.)

The Agency has responded to the concerns about testing methods and consistent results by adding a new section to the Preamble of the rule, section XII, Test Procedures for PCB, that describes the approach for improving testing results for PCBs.

The disposal and salvage of drained mineral oil transformers are essentially not controlled by this rule, which is unchanged from the proposal.

Several persons requested that EPA revise the rule

to deal with mineral oil transformers and equipment under a less restrictive set of rules (46, 97, 134). Others desired that all mineral oil filled transformers be exempted from the rule (4, 87, 147, 189, VI TR, p. 17-18). A few comments recommended that transformers containing mineral oil with less than 500 ppm PCB be excluded from the rule (110, 129, 134, 139, I TR, p. 15). Several comments advocated the partial or total exclusion of certain types of transformers containing less than a certain number of gallons of fluid (83, 147, 156), and one comment was received suggesting that only mineral oil transformers past a certain age should be subject to regulation (11).

No evidence has been presented that would convince EPA to be less restrictive or to exclude certain classes of mineral oil transformers from control under this regulation on the basis of size, age, or manufacturer. None of the comments were able to disprove the Agency's belief that PCB contamination results both from previous manufacturing practices and past and present service practices.

A few comments were received advocating a requirement that all transformers manufactured after January 1, 1979 be labeled "No PCBs" (4, 102, 109, 144). Other comments were received that stated

existing marking requirements were sufficient (46, 91, 93, 94).

The marking requirements for PCBs have been modified to reflect EPA's lowering of the applicable PCB concentration to 50 ppm. All containers of PCB-contaminated mineral oil that have 50 ppm or greater of PCBs are required to be marked, but PCB-Contaminated Transformers are not required to be marked since all transformers are either marked as PCB Transformers or are assumed to be PCB-Contaminated Transformers. A more complete discussion of marking changes is contained in the Preamble to the rule; section IV, Changes in Subpart C: Marking of PCBs and PCB Items.

The Agency does not agree with the recommendation to place "No PCBs" labels on transformers manufactured after January 1, 1979 because of the continuing potential to contaminate transformers with PCBs during servicing operations.

One person objected to the proposed 50 ppm cut-off concentration because he thought that regulation of PCB-Contaminated Transformers would create an increased demand for naphthenic oil, a replacement transformer fluid that is in short supply. He thought that the rule would worsen an already critical situation and make it difficult to maintain equipment (88).

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The Agency wishes to clarify that this comment presumes that EPA was prohibiting recycling transformer oils containing more than 50 ppm PCB. This is not the case. The Agency, in its authorization for servicing PCB-Contaminated Transformers, permits the recycling of dielectric fluid with less than 500 ppm PCB for use in PCB-Contaminated Transformers. The Agency, aware that the proposal could have been more direct, has made this point more explicitly in the final rule in §761.31(a)(3).

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VIII. RAILROADS

A number of comments were made by affected parties that were critical of the Agency's proposal. The Agency proposed that railroad transformers that use PCB dielectric fluid, reduce the PCB concentration in the dielectric fluid to less than 40,000 ppm PCB at the end of 15 months and to 1,000 ppm at the end of three years. Two commentors indicated that due to the availability of substitutes, the requirements for draining and refilling PCBs for use in this application should be more stringent (53, 85). Other commentors stated that the schedule was too stringent because analysis has not yet been completed on the technical and safety aspects of refilling railroad transformers with non-PCB fluid. Therefore, these persons thought that requirements for refilling transformers in 15 months and restrictions on the allowable residual PCB levels in those transformers should be delayed until that analysis is completed (12, 13, 33, 128, 149, 197). Comments were also submitted which expressed concern that 40,000 ppm PCB (4% on dry weight basis) would be difficult to achieve using standard refilling practices. They recommended a slightly higher level of 6% PCB (33, IX TR, p. 125).

The Agency agrees that additional data on the technical feasibility and safety of potential substitutes used in a refilling program would be extremely useful and has,

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therefore, postponed the date by which a 1,000 ppm level must be achieved. This delay will allow the railroad industry a reasonable amount of time to complete the study and to reduce their PCB concentrations to a level that will not present an unreasonable risk to health and the environment. In addition, the Agency agrees that routine refilling is not likely to reduce PCB concentrations to 4% PCB and has, therefore, raised the allowable concentration of PCB from four percent to six percent. The rationale for these decisions is discussed in depth in section IX.B of the Preamble.

Some comments were also made urging that the rule not apply to equipment that will be retired as a result of the Northeast corridor power conversion (VIII TR, p. 196, IX TR, p. 159, IX TR, p. 177).

In response to the railroad industry's concern about completing and reviewing the safety study on non-PCB substitution, EPA postponed, as explained above, the date by which the initial refilling was to be completed to January 1, 1982. Originally this coincided with the schedule for the Northeast power conversion. However, recently the Department of Transportation announced that the project will not be completed until the Fall of 1983. Although the date for this initial refilling does not coincide with the new DOT schedule for power conversion, EPA has decided not to

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again postpone the date because the economic impact of the proposed rule has already been significantly reduced by postponing to January 1, 1982, the date of initial refilling to achieve a 60,000 ppm PCB residual. The PCB concentration in all PCB railroad transformers will have to be further reduced to 1,000 ppm by January 1, 1984.

Since the DOT change-over will not occur until late 1983, almost 90 percent of the time period authorized for operation at 60,000 ppm will be available for the older locomotives before the change-over forces them out of service. This means that the railroads will not have to spend large amounts of capital for PCB reduction and then shortly thereafter phase out the use of the older railroad transformers.

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IX. MINING

Few comments were made regarding the proposed authorization for PCB use and servicing in underground coal mining. One commentor essentially supported the proposal (I TR, p. 6-34). Another commentor briefly criticized the proposal as placing too much emphasis on economic factors (53). The Agency disagrees with this latter comment inasmuch as the schedule for removal of PCB motors and loaders is based on the rate at which this equipment can be substituted with non-PCB Equipment or can be modified to accomodate non-PCB fluids without disrupting the U.S.'s coal production.

The Agency believes that the phased removal approach it has taken will substantially reduce the cost of immediate removal while not creating an unreasonable risk to health and the environment. For a more detailed discussion of this use of PCBs, see section IX.C of the Preamble.

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X. HYDRAULIC SYSTEMS

The proposed rule authorized the use and regulated the removal of PCBs from hydraulic die casting systems which are machines used to cast metals under high pressure and are a major source of PCB-contaminated hydraulic fluid. During the comment period the agency received comments explaining that there are other types of similar hydraulic equipment that are not classified as "die casting" hydraulic equipment but which should logically be treated the same as hydraulic die casting equipment for purposes of this regulation (15, 59, 101).

The Agency agrees with this comment and has, therefore, broadened the applicability of the authorization to cover all hydraulic systems that use PCB-contaminated hydraulic fluid.

Some comments stated that the proposed semi-annual requirements for testing of hydraulic systems and replacement of the fluid were impractical due to testing difficulties and production disruptions (15, 59, 101).

The Agency has taken note of this concern and is now requiring that the system be tested within six months from the effective date of the rule and then only annually thereafter until the PCB concentration is below 50 ppm. Refilling, if required, must take place within six months after testing. This change from semi-annual to annual testing and refilling will be less disruptive as most

systems undergo repair or overhaul at least once annually (see section IX.E of the Preamble).

Comments from industry also noted difficulties in reducing the PCB level in a hydraulic system's fluid to less than 50 ppm (15, 101). One non-industrial commentor was critical of the Agency for not requiring reduction of the concentration of PCBs to undetectable levels (V TR, p. 163).

The Agency agrees with this first comment that it would be difficult to reduce PCB levels in hydraulic systems to levels below 50 ppm. Reducing PCB concentrations to 50 ppm would require relatively few flushings; whereas, to achieve and maintain levels substantially below 50 ppm is likely to require a large number of flushings. This is due to the residual levels of PCBs that are found in most systems that ever used or that were ever contaminated with PCBs and which are likely to recontaminate the purified fluid with minute amounts of PCBs. These residual PCBs are not likely to raise the fluid's PCB concentration to levels above 50 ppm but may raise the PCB concentration from undetectable levels to detectable levels. (For a more extensive discussion of this 50 ppm subject as it relates to all uses of PCBs, see the Preamble to the rule section I.B)

A comment was made that once a hydraulic system is tested and found to contain less than 50 ppm PCB, the Agency's proposed requirement that testing be performed

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again after at least three months is unnecessary (15). The Agency agrees with this comment and has deleted that requirement.

One comment was received that suggested hydraulic systems of less than 55 gallons not be covered by the rule (15). The commentor stated that since the capacity of systems which hold less than a 55 gallons is small, they have tended to be easier to top and refill in the past and thus are less likely to contain high PCB levels.

The Agency feels that testing is necessary in order that owners of all hydraulic systems that ever contained PCBs accurately determine the PCB levels contained in all their hydraulic systems. In addition, the Agency has no reason to assume that all small hydraulic systems are better maintained than larger systems. The one comment EPA received may not necessarily be representative of all owners of such hydraulic systems.

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XI. HEAT TRANSFER SYSTEMS

In the proposed rule, the Agency did not authorize the use or servicing of heat transfer systems contaminated with 50 ppm or greater PCBs. At the time of the proposal, the Agency did not have adequate data on the use of heat transfer systems to propose an authorization. The Agency received very few comments on this use of PCBs.

Two commentors were critical of the Agency's lack of a proposed authorization (81, 116). One commentor, a manufacturer of heat transfer fluids, said that as many as 450 heat transfer systems may have been contaminated with PCBs but that the potential for exposure to PCBs from these systems is low. He said that the pump seal, which is the highest risk area for leakage, is monitored and inspected so that a leak would be rapidly detected (81). The other commentor addressed the need for a servicing authorization for heat transfer systems, noting that the environmental risks presented by continued use and servicing are no greater than for other PCB activities that EPA proposed authorizing (116).

The Agency understands the need for a use and servicing authorization for owners of heat transfer systems. (See section IX.D of the Preamble for a discussion of the Agency's reasons for authorizing this use.) These

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activities are authorised until July 1, 1984 under the condition that all systems that have ever contained PCBs are tested to determine their current PCB levels. Any system found to contain more than 50 ppm PCB must be drained within six months and refilled with fluid containing less than 50 ppm PCBs. Topping off a heat transfer system with non-PCB fluids can also be conducted to reduce PCB concentrations below 50 ppm. Annual testing will be required until a 50 ppm or less PCB concentration is achieved. The first testing must be by October 1, 1979. This date was chosen on the basis of a commentor's suggestion that considerably more than the 30 days that was proposed would be needed for testing of a hydraulic or heat transfer system (15).

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XII. PCB ARTICLES AND PCB EQUIPMENT

A number of commentors (1, 2, 7, 16, 46, 52, 53, 58, 66, 86, 115, 120, 130, 156, 157) contended that the legislative history of §6(e) of TSCA demonstrates that this provision does not give the Agency authority to regulate PCB Articles and PCB Equipment. However, another commentor (182) noted that the legislative history for §6(e) does support such regulation by the Agency.

EPA has reviewed the legislative history of §6(e) in light of the various comments received concerning regulation of PCB Articles and Equipment. The legislative history indicates (1) that the words "polychlorinated biphenyls" as used in §6(e) are intended to include PCB Articles and PCB Equipment and (2) that comprehensive and direct regulation of PCB Articles and Equipment was contemplated. Illustrative material from the legislative history, which has led the Agency to the above conclusions, is given in the following paragraphs.

Although commentors (46, 50) have cited Congressman Gude, they have not cited the following statements by the Congressman. These statements indicate that direct regulation of PCB Articles and Equipment was contemplated under §6(e). Mr. Gude said:

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> ...our amendment [on PCB's] does not affect small business except in the handling of articles that have PCBs in them;...
>
> * * *
>
> For example, an electric company must show that continued use of PCB's in transformers is necessary to guarantee safety from fire and that they are making a good faith effort to find substitutes.

122 Cong. Rec. H8830-31 (daily ed., August 23, 1976).

Similarly, Senator Nelson (the Senate sponsor of the PCB amendment) assumed there would be direct regulation of PCB Articles and Equipment under his amendment. He stated:

> ...this [PCB] amendment provides over a period of time the elimination of the use in open or closed systems of PCB's, polychlorinated biphenyls, unless the EPA administrator finds that there is not a serious health hazard.
>
> * * *
>
> Second. The manufacture of all PCBs would be banned effective two years from the date of enactment; and the processing and distribution of all PCBs would be banned six months after that - 2 1/2 years after enactment - unless the administrator finds that no reasonable risk of injury to health or the environment

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> is presented by PCBs. This would effectively ban all PCB use, including closed uses, such as in electrical capacitors and transformers.

122 Cong. Rec. S4408 (daily ed., March 26, 1976 with emphasis added). These remarks by Senator Nelson clearly indicate that direct regulation of PCB Articles and Equipment was contemplated.

Senator Nelson's discussion of the labeling and disposal provisions of §6(e) also establishes that regulation of PCB Articles and Equipment was intended. He stated:

> Within 6 months after enactment, EPA is required to issue regulations for the first [requirement], disposal of PCB's and second, labeling with warnings and instructions of all products containing PCB's with respect to their use and disposal.

122 Cong. Rec. S4408 (daily ed., March 26, 1976 with emphasis added). The reference to "products containing PCB's" indicates that PCB Articles and Equipment are to be regulated.

In summary, the legislative history of §6(e) supports and requires direct regulation by the Agency of PCB Articles and PCB Equipment.

XIII. PIGMENTS

In the proposed rule, the Agency redefined the lower concentration of PCB which constitutes a "PCB Mixture" from 500 to 50 ppm. In effect, this would result in a ban on the manufacture, processing, distribution in commerce, and use of PCBs as they appear at 50 ppm or greater. This prohibition includes even those processes which inadvertently produce PCBs in excess of 50 ppm at any step in the manufacturing process.

A number of persons objected to the proposal of lowering the concentration of PCB regulated under this rule because it would cause many pigment manufacturers and processors to close down until process changes could be made. They felt that no one would be able to reduce their concentrations to less than 50 ppm by the effective date of the rule (14, 39, 43, 63, 177, VIII TR, p. 6, p. 106-107, p. 121, p. 125, p. 136, pp. 151). These persons further stated that there currently is no valid method available for determining the concentration of PCBs in certain pigments (14, 43, 118, VIII TR, p. 10, p. 14, p. 105, p. 125, p. 135, p. 150-151) and, therefore, no way of knowing conclusively whether or not they are in conflict with the rule.

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To circumvent these problems, a number of persons requested that either the Agency maintain the 500 ppm definition of PCB for the next two years or authorize the pigment industries to manufacture and process PCB contaminated mixtures containing over 50 ppm PCB for the next two years (14, 39, 63, 118, VIII TR, p. 6, p. 44-45, p. 124, p. 137, p. 151). It was thought that this alternative, in comparison to the formal exemption rulemaking process, would be less demanding of administrative resources (VIII TR, p. 21, p. 151). One person (63) suggested that the Agency grant a six month exemption from the ban on distribution in commerce in order to allow suppliers to sell their inventory. In either case they thought that they would need from six months to three years to both develop a valid analytical method for quantifying PCB in pigments and to convert to new technology to reduce or eliminate PCBs from pigments (118, VIII TR, p. 6).

The Agency does not believe that a 500 ppm cut-off concentration is an acceptable alternative because (1) there would be a substantial amount of PCBs between 50 and 500 ppm that would go unregulated and (2) the pigment industry has indicated that it is possible to reduce PCB concentrations in pigments to less than 50 ppm. The Agency believes that the authorization and exemption processes are the most

effective way to deal with any difficulties. The authorization and exemption processes allow the Agency to tailor the compliance requirements and to be informed as to which companies are having problems and how they are disposing of their waste streams. (See section IX of the Preamble.)

In this final rule, the Agency has authorized the processing, distribution in commerce, and use of pigments containing PCBs until January 1, 1982. However, persons who manufacture these pigments must petition for an exemption if they want to manufacture pigments containing 50 ppm or more of PCBs after the effective date of this rule. Similarly, persons must file exemption petitions if they wish to process or distribute in commerce pigments which contain 50 ppm or more of PCBs after July 1, 1979.

XIV. PROCESS CONTAMINATION

In the proposed rule, the Agency banned the manufacture of chemicals inadvertently contaminated with PCBs in excess of 50 ppm, including those chemicals that are manufactured for site-limited use. Some persons objected to this ban because (in the absense of exemptions) th[illegible]ould cause some industries to shut down their operations (136, 161, 39) and would unfairly favor foreign products (136). These persons suggested that as alternatives, EPA consider raising the level for controlling PCBs to 500 ppm or specifically exclude unintentionally produced PCBs from the rule (136, 161).

None of these persons provided the Agency with any economic data that allows EPA to determine the magnitude of economic impact of this rule on persons who manufacture chemicals contaminated with PCBs. Because of the substantial amounts of PCBs that are produced in chemicals that contain between 50 and 500 ppm PCB (EPA estimates 100,000 to 500,000 pounds of PCB per year based on data included in exemption petitions), the Agency believes that excluding these chemicals from the rule is not an appropriate alternative. In some cases, more careful quality control of the production operations can reduce or eliminate these PCB impurities. Persons may, however, request an exemption from the January 1, 1979

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manufacturing bans and the July 1, 1979 processing and distribution in commerce bans on PCBs. Information submitted in these requests should adequately provide the Agency with the information it needs to determine whether or not such exemption would present an unreasonable risk. (See section VI.C.1 of the Preamble for additional discussion of this process contamination issue).

Two persons (124, 136) commented that the Agency should consider the use of authorities within TSCA other than §6(e) to control inadvertently manufactured PCBs. It was indicated that §6(b) of TSCA was intended to be the appropriate authority to control chemical processes.

The broad coverage of §6(e) indicates that EPA has the authority to control inadvertently manufactured PCBs. Further, although §6(e)(5) gives EPA the prerogative to use other authorities, EPA is not required to use these other authorities. The Agency has reviewed the various regulatory alternatives including TSCA §6(b) and believes that §6(e) is a less cumbersome and more expedient way in which to control inadvertently manufactured PCBs than regulation under other TSCA or EPA authorities.

One person (174) commented that the Agency was improperly using the term "manufacture" by applying it to

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chemicals manufactured for use as an intermediate. The commentor suggested that the regulation's application be limited to the manufacture of PCBs for distribution in commerce and not for on-site use. This person asserted that the Agency was overextending the accepted definition of an intermediate as established in the inventory rules which defines an intermediate as a chemical substance that is removed from the equipment in which it is manufactured. In addition, this person thought that site-limited intermediates present little, if any, threat to either health or the environment.

The Agency disagrees with this comment. For the purposes of the inventory rule, §710.4(d) excludes certain chemicals from the requirements for reporting, including intermediates which are not removed from the equipment in which they were manufactured. However, such intermediates are still specifically considered to be "manufactured and processed for a commercial purpose" for the purposes of §8 and §6 of TSCA.

The manufacture and processing of chemicals at a site could present exposure problems to workers and the environment. Because of the risks associated with such exposure to PCBs, the rule prohibits all manufacturing and processing and does not exempt "site limited" activities. This is in keeping with the inventory rule which requires persons to identify those intermediates which have site-limited use.

XV. ELECTROMAGNETS

The Agency has become aware that PCBs have also been used in large electromagnets that are designed to remove tramp iron from non-magnetic commodities such as coal and grain. One person stated that he did not see any significant difference between the environmental threat of an electromagnet and an askarel transformer and suggested that they be handled similarly (X TR, p. 165). Other persons stated that their electromagnets are enclosed in a solid steel casing and have never experienced failure in their many years of use (137, 31).

The Agency agrees that use of PCBs in intact, non-leaking electromagnets are like transformers that are used in a totally enclosed manner. Electromagnets are constructed such that the PCBs are enclosed in completely welded structures and, historically, have been subject to few leakages. Therefore, use of these electromagnets is permitted; however, like transformers, rebuildings of electromagnets is not permitted. (See section IX.H of the Preamble for additional discussion.)

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XVI. MICROSCOPY

Historically, there have been three uses for PCBs in the field of microscopy. The first application is the use of PCBs as an immersion oil. The second microscopic application is the use of PCBs as a refractive index oil. The third application is the use of PCBs as a mounting medium. This technique is particularly important to scientists who need to preserve, for future reference, a microscopic sized particle. According to one person (76), it is also used in air pollution and criminology labs for particle identification. In the mounting medium method, PCBs are used as the medium in which the particle is placed and covered with a glass slip usually for permanent reference.

During the PCB Ban Hearing representatives from the field of microscopy agreed that of the three microsopic uses, use as a mounting medium is the only application for which PCBs are essential (X TR, p. 13, p. 50-51, p. 65-66, p. 69-70). All the microscopists indicated that suitable substitutes for PCBs as an immersion oil and as a

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refractive index oil exist (10, X TR, p. 18, p. 74, p. 76). However, there are currently no substitutes for PCBs as a mounting medium with the desirable physical properties that characterize PCBs (10, X TR, p. 18, p. 87). In addition, these persons stated or implied that extremely small quantities of PCBs are used for each application and, over time, the total quantities used are also small (127, X TR, p. 5, p. 46-47). Some persons recommended that EPA require special protective garments, vapor hoods, and instructions and training in handling and disposal for these PCB uses (23, X TR, p. 26-28; p. 90). These recommendations however were challenged by other participants at the hearing. At least one person pointed out that the use of a fume hood would create a problem because of the likelihood that the air movement may cause the loss of the particle being studied (X TR, p. 46). It was also pointed out that a substantial amount of exposure to PCBs has been minimized because of the extremely high viscosity of Aroclor 5442 which aids in preventing spillage (X TR, p. 28) and the extremely small amounts of PCBs which are used (76, X TR, p. 46, p. 60). Further, it appears from the comments at the hearings that meticulous and careful procedures are typical because of the nature of laboratory work (X TR, p. 27, p. 46, p. 59).

The Agency believes that exposure to PCBs used as a mounting medium will be minimal because of the small amounts that are used at any one time and the careful nature of the work. For these reasons and because no one presented any convincing evidence indicating that the risk from the use of PCBs as a mounting medium outweighs the benefits, the Agency has decided to authorize this processing, distribution in commerce, and use until July 1, 1984; however, after July 1, 1979 persons will have to obtain an exemption to process and distribute in commerce PCBs for microscopy.

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XVII. WASTE OIL

The Agency proposed prohibiting the use of used ("waste") oil containing any detectable amount of PCB as a sealant, coating, or dust control agent. It was understood that the use of waste oil as a dust control agent is widespread on unpaved roadways. Few comments were received on the proposal and its impact on road oiling.

One environmental group commented favorably upon the proposed ban of this activity, citing potential widespread environmental and human exposure to PCBs resulting from this use ot waste oil (85). Another commentor cited a lack of substitutes for waste oil on uncovered roadways other than paving, which he characterized as expensive, or watering, which he said is less efficient (15). One manufacturer of a substitute for waste oil that is used to control dust commented about the advantages of his product over waste oil with respect to both cost and performance (217).

The Agency agrees that use of PCBs as sealants, coatings, and dust control agents provides a direct route for entry of PCBs into the environment. Further, it is the Agency's understanding that substitutes for PCBa as a dust control agents are available. In the absence of any convincing data to the contrary, the Agency has decided to maintain its ban on these uses. For a more detailed discussion of this determination, see section VI.A.1 of the Preamble.

XVIII. NATURAL GAS COMPRESSORS

The proposed rule contained no authorization for the use or servicing of PCB-containing natural gas compressors since, at the time of proposal, the Agency had virtually no knowledge of this application of PCBs. During the comment period, a few persons submitted comments indicating that PCBs were used in compressors in natural gas pipelines. One of the commentors cautioned EPA that the implementation of the 50 ppm cut-off concentration for the regulation of most uses of PCBs could impact the nation's ability (1) to maintain its productive capacity and (2) to assure an adequate, clean fossil energy supply at a reasonable cost (29). Because natural gas systems are not designed with backup compressors, any unscheduled or extended loss of compression decreases the capacity of the system, exacerbating the present natural gas shortage. This person noted that the economic impact of reduced gas quantities was not evaluated in the economic study entitled Microeconomic Impacts of the Proposed PCB Ban Regulation.

Another person indicated that the ban on the use of articles contaminated with 50 ppm PCB or greater, although originally appearing to be burdensome, will now cause him little economic impact (138). He stated that, by the

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effective date of the regulation, his company will be able to achieve a sufficiently low concentration of PCBs in the lubricants by flushing the system one additional time.

The Agency has considered these comments and the potential energy and economic impacts of an immediate ban on the use and servicing of PCB-containing natural gas compressors. The final rule authorizes the use of PCBs above 50 ppm in natural gas compressors until May 1, 1980. The Agency believes that by this date owners and operators will have had sufficient time to drain, flush, and replace the compressors' fluid so that the fluid will contain PCBs below 50 ppm. A more in-depth discussion of the Agency's rationale for this use is found in section IX.I of the Preamble.

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XIX. REVISED VERSAR REPORT

The study entitled Microeconomic Impacts of the Proposed PCB Ban Regulations (the proposed Versar Report) was made available in May 1978 as part of EPA's Draft Support Document for the proposed PCB ban regulation. As a part of the Final Support Document for the final regulation, EPA requested Versar to revise the Versar Report to reflect data submitted in comments and at the informal hearing on the proposed PCB rule.

By letter dated September 1, 1978, Electronic Industries Association (EIA) sought to reopen the comment period for comment on the then unwritten Revised Versar Report. EPA, however, did not reopen the comment period. The Agency responded to the EIA request by letter dated December 13, 1978, stating (1) that EPA had already extended the comment period from September 15, 1978 to October 10, 1978 and (2) that the PCB rulemaking had to be brought to a close in view of the deadlines imposed by §6(e) of TSCA for the regulation of PCBs. The Agency also noted that the nature of the Revised Versar Report does not require reopening of the comment period. EPA stated:

> The purpose of the revised Versar Report is to determine the economic impact of the expected PCB ban regulation in light of the facts submitted at the informal

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hearing (including the prior Versar Report) and in comments. This does not constitute an action which would call for reopening of the record. See e.g., International Harvester Company v. Ruckelshaus, 478 F.2d 615, 632 n. 51 (D.C. Cir. 1973).

The letter was from Peter P. Principe, Chairman of PCB Hearing Panel to Steven S. Rosenthal, attorney for Electronic Industries Association dated December 13, 1978.

EIA renewed its request for an extension of the comment period by letter from Mr. Rosenthal dated December 19, 1978. EPA is treating this letter as a comment and reiterates its response made to EIA by letter on December 13, 1978. As earlier stated, the purpose of the Revised Versar Report is to incorporate economic data supplied in written comments and at the informal hearing into the Versar Report which was previously prepared for the proposed rule. Revisions of this nature by a contractor do not require reopening of the comment period. Accordingly, EPA has not reopened the comment period.

The National Acadamy of Sciences has developed a draft report entitled, Polychlorinated Biphenyls, which includes sections on economic analysis of PCB control strategies. This draft report was not used by the Agency in the development of the final PCB rule because the report was only in draft form and not available for citation. Since the EPA was under a statutory deadline to promulgate the PCB rules, the Agency chose not to wait for an opportunity to consider the final report.

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Appendix I: LIST OF MAJOR COMMENTS

Main Comments

1. Advance Transformer Co.
2. Air-Conditioning and Refrigeration Institute
3. Alabama Power Co.
4. Allegheny Power Service Corp.
5. Allied Chemical Corp.
6. The Aluminum Association, Inc.
7. Amana Refrigeration, Inc.
8. AMAX Environmental Services, Inc.
9. American Electric Apparatus Repair Corp.
10. American Institute for Conservation of Historic and Artistic Works
11. American Public Power Association
12. American Public Transit Association
13. AMTRAK
14. Apollo Colors, Inc.
15. Armco Steel Corp.
16. Association of Home Appliances Manufacturers
17. Atlantic City Electric Co.
18. Baltimore Gas and Electric Co.
19. Bartlett, Louise
20. Bethlehem Steel Corp.
21. Boston Edison Co.

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22. Brown Co.
23. Center for Occupational Hazards, Inc.
24. Central Vermont Public Service Corp.
25. Chemetron Pigments Corp.
26. Chemical Waste Management Limited
27. Cincinnati Gas and Electric Co.
28. Clavaland Electric Illuminating Co.
29. Columbia Gas System Service Corp.
30. Columbus and Southern Ohio Electric Co.
31. Commonwealth Edison Co.
32. Consolidated Edison Company of New York, Inc.
33. Consolidated Rail Corp.
34. Consumers Power Co.
35. Dayton Power and Light Co.
36. Department of Water and Power of the City of Los Angeles
37. Detroit Edison
38. Dow Corning Corp.
39. Dry Color Manufacturers Association
40. Duke Power Co.
41. E.I. DuPont de Nemours and Co.
42. Duquesne Light Co.
43. Dyes Environmental and Toxicology Organization, Inc.
44. Eastern Iowa Light and Power Corp.
45. Eastern Utilities Associates

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46. Edison Electric Institute
47. Edison Sault Electric Co.
48. Electric Equipment Co.
49. Electrical Apparatus Service Association, Inc.
50. Electronics Industries Association
51. Ellish, Andrew
52. Emerson Quiet Kool Co.
53. Environmental Defense Fund
54. EUA Service Corp.
55. Florida Public Utilities Co.
56. Ford Motor Co.
57. Fort Howard Paper Co.
58. General Electric Co.
59. Ganeral Motors Corp.
60. GPU Service Corp.
61. A.P. Green Refractories Co.
62. Gulf Power Co.
63. Harmon Colors Corp.
64. Hartzler, Emma
65. Hawaiian Electric Co., Inc.
66. Honeywell Information System Inc.
67. Iliff, George W.
68. International Business Machines
69. Interstate Power Co.
70. Iowa-Illinois Gas and Electric Co.

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71. Iowa Power and Light Co.

72. Iowa Public Service Co.

73. Joy Manufacturing Co.

74. Kiggans, Michael

75. Loup Power District

76. Walter C. McCrone Associates, Inc.

77. Mead Corp.

78. Middle South Services Inc.

79. Minnesota Pollution Control Agency

80. Minnkota Power Cooperative, Inc.

81. Monsanto Co.

82. National Electrical Manufacturers Association

83. National Rural Electric Corporative Association

84. National Wildlife Federation

85. Natural Resources Defense Council, Inc.

86. NCR Corp.

87. Nebraska Power Industry Committee

88. Nebraska Public Power District

89. NEGEA Service Corp.

90. New England Power Co.

91. New York Power Pool

92. New York State Department of Environmental Conservation

93. Niagara Mohawk Power Corp.

94. Northeast Utilities

95. Northern States Power Co.

96. Ohio Edison Co.

97. Ohio Transformer Corp.

98. Olin Corp.

99. Omaha Public Power District

100. Otter Tail Power Co.

101. Outboard Marine Corp.

102. Pacific Gas and Electric Co.

103. Penelec-GPU

104. Phillips Petroleum Co.

105. Phthalchem Inc.

106. Pope Chemical Corp.

107. Port Authority of New York and New Jersey

108. Public Service Company of Colorado

109. Public Service Company of New Hampshire

110. Public Service Electric and Gas Co.

111. Public Service of Indiana

112. Public Utility District No. 1 of Okanogan County

113. Puget Sound Power and Light Co.

114. RADCO Industries, Inc.

115. RCA Corp.

116. Reynolds Aluminum

117. Reynolds Tobacco Co.

118. Ridgeway Color and Chemical Co.

119. Rochester Gas and Electric Corp.

120. Rockwell International

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121. RTE Corp.

122. Salt River Project

123. San Antonio, Texas, City of Public Service Board of

124. SCA Services, Inc.

125. Sierra Club

126. Sierra Club's Task Force (Thomas Murphy)

127. Smithsonian Institution

128. Southeastern Pennsylvania Transit Authority

129. Southern California Edison Co.

130. Sprague Electic Co.

131. Springfield, Missouri, City Utilities of

132. Stauffer Chemical Co.

133. Sun Chemical Corp.

134. T&R Electric Supply Co., Inc.

135. Tenneco, Inc.

136. Tennessee Eastman Co.

137. Tennessee Valley Authority

138. Texas Eastern Transmission Corp.

139. Texas Electric Service Co.

140. Texas Power and Light Co.

141. Tivian Laboratories, Inc.

142. Transformer Sales Co.

143. Union Carbide Corp.

144. Union Electric Co.

145. United Illuminating Co.

146. United Power Association

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147. U.S. Department of Agriculture, Rural Electrification Administration

148. U.S. Department of Health Education and Welfare, Public Health Service, Center for Disease Control

149. United States Department of Transportation, Federal Railroad Administration

150. Vermont Electric Power Co., Inc.

151. Virginia Electric and Power Co., Inc.

152. Virginia Fibre Corp.

153. Wallingford, Connecticut, Town of

154. Waste Management, Inc.

155. Water and Wastewater Equipment Manufacturers Association, Inc.

156. Westinghouse Electric Corp.

157. Xerox Corp.

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Reply Comments

158. AEROVOX Industries, Inc.

159. Air-Conditioning and Refrigeration Institute

160. Alleghany Power Services Corp.

161. Aluminum Company of America

162. American Institue for Conservation of Historic and Artistic Works

163. AMTRAK

164. Arizona Public Service Co.

165. Arkansas Power and Light Co.

166. Associaition of Home Appliance Manufacturers

167. Burleson, Rep. Omar

168. Canadian Embassy

169. Carolina Power and Light Co.

170. Collins, Rep. James M.

171. Consumers Power Company

172. Crown Zellerbach Environmental Services

173. Dayton Power and Light Co.

174. Dow Corning Corp.

175. Dry Colors Manufacturers Association

176. Duke Power Co.

177. E.I. DuPont de Nemours and Co.

178. Eastern Iowa Light and Power Cooperative

179. Edison Electric Institute

180. Electronic Industries Association

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181. Emerson Quiet Kool Co.

182. Environmental Defense Fund

183. Environmental Research Group, Inc.

184. Florida Power and Light Co.

185. Forging Industry Association

186. General Electric Co.

187. General Motors Corp.

188. GPU Service Corp.

189. GTE Service Corp.

190. International Minerals and Chemical Corp.

191. Iowa Electric Light and Power Co.

192. Joy Manufacturing Co.

193. Kiggans, Michael

194. Walter C. McCrone Associates, Inc.

195. McCrone Research Institute

196. McGovern, Sen. George

197. Metropolitan Transportation Authority

198. Minnesota Power and Light Co.

199. National Electrical Manufacturers Association

200. Northern States Power Company

201. Orange and Rockland Utilities, Inc.

202. Philadelphia Electric Co.

203. Phillips Petroleum Co.

204. RTE Corp.

205. Society of Die Casting Engineers, Inc.

206. Smithsonian Institution

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207. T&R Electric Supply Co., Inc.

208. Teague, Rep. Olin E.

209. Tennessee Eastman Co.

210. Transformer Consultants

211. U.S., Department of the Interior

212. U.S., Department of Health Education and Welfare, Public Health Service, Center for Disease Control

213. U.S., Department of Transportation, Federal Railroad Administration

214. VERSAR, Inc.

215. Westinghouse Electric Corp.

216. Wilson, Rep. Charles

217. Witco Chemical Corp.

218. Wright, Rep. James

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Hearing Transcripts

I TR	August 21, 1978
II TR	August 22, 1978
III TR	August 23, 1978
IV TR	August 24, 1978
V TR	August 25, 1978
VI TR	August 28, 1978
VII TR	August 29, 1978
VIII TR	August 30, 1978
IX TR	August 31, 1978
X TR	September 1, 1978
Cross-Examination	September 26, 1978

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