

(9) King-Seeley Thermos Co., Queen Products Division, Albert Lea, MN 56007 (PDE-139).

(10) L.E. Mason Co., Red Dot Division, Boston, MA 02136 (PDE-223).

(11) Minnesota Mining and Manufacturing Co., St. Paul, MN 55133 (PDE-157.3).

(12) National Association of Electrical Distributors, Stamford, CT 06901 (PDE-163).

(13) Royalite Co., Flint, MI 48502 (PDE-231).

(14) Sola Electric, Unit of General Signal, Elk Grove Village, IL 60007 (PDE-246).

(15) Transco, Inc., West Columbia, SC 29169 (PDE-276.1).

(16) Westinghouse Electric Corp., Pittsburgh, PA 15222 (PDE-298).

(c) The Administrator grants the following petitioners an exemption for one year to process PCB small capacitors and PCB equipment containing PCB small capacitors into other equipment and to distribute in commerce that equipment:

(1) Advance Transformer Co., Chicago, IL 60618 (PDE-4).

(2) Gould, Inc., Electric Motor Division, St. Louis, MO 63166 (PDE-103).

(3) GTE Products Corp., Danvers, MA 01923 (PDE-105).

(4) L.E. Mason Co., Red Dot Division, Boston, MA 02136 (PDE-223).

(5) Westinghouse Electric Corp., Pittsburgh, PA 15222 (PDE-298).

(d) The Administrator grants the following petitioners an exemption for one year to process and distribute in commerce PCB-contaminated fluid for purposes of servicing customers' transformers:

(1) Electrical Apparatus Service Association, St. Louis, MO 63132 (PDE-77), except for Ward Transformer Co., Inc.

(2) Ohio Transformer Corp., Louisville, OH 44641 (PDE-173).

(3) T & R Electric Supply Co., Inc., Colman, SD 57017 (PDE-265).

(4) Temco, Inc., Corpus Christi, TX 78410 (PDE-268).

(e) The Administrator grants the following petitioners an exemption for one year to process and distribute in commerce PCB-contaminated fluid in buying and selling used PCB-contaminated transformers:

(1) Electrical Apparatus Service Association, St. Louis, MO 63132 (PDE-77), except for Ward Transformer Co., Inc.

(2) Ohio Transformer Corp., Louisville, OH 44641 (PDE-173).

(3) Temco, Inc., Corpus Christi, TX 78410 (PDE-268).

(f) The Administrator grants the following petitioners an exemption for

one year to manufacture small quantities of PCBs for research and development:

(1) California Bionuclear Corp., Sun Valley, CA 91352 (ME-13).

(2) Foxboro Co., North Haven, CT 06473 (ME-6).

(3) ULTRA Scientific, Inc., Hope, RI 02831 (ME-99.1).

(g) The Administrator grants the following petitioners an exemption for one year to process and distribute in commerce small quantities of PCBs for research and development:

(1) California Bionuclear Corp., Sun Valley, CA 91352 (PDE-38.1).

(2) Chem Service, Inc., West Chester, PA 19380 (PDE-41).

(3) Foxboro Co., North Haven, CT 06473 (PDE-21.1).

(4) PolyScience Corp., Niles, IL 60648 (PDE-178).

(5) ULTRA Scientific, Inc., Hope, RI 02831 (PDE-282.1).

(h) The Administrator grants the following petitioners an exemption for one year to process and distribute in commerce PCBs for use as a mounting medium in microscopy for all purposes:

(1) McCrone Accessories & Components, Division of Walter C. McCrone Associates, Inc., Chicago, IL 60616 (PDE-149).

(2) R.P. Cargille Laboratories, Inc., Cedar Grove, NJ 07009 (PDE-181), provided that petitioner stores the PCBs it processes and distributes in commerce in accordance with the storage for disposal requirements of 40 CFR 761.65(b).

(i) The Administrator grants the following petitioners an exemption for one year to process and distribute in commerce PCBs for use as an immersion oil in low fluorescence microscopy (other than capillary microscopy):

(1) R.P. Cargille Laboratories, Inc., Cedar Grove, NJ 07009 (PDE-181), provided that petitioner stores the PCBs it processes and distributes in commerce in accordance with the storage for disposal requirements of 40 CFR 761.65(b).

(2) [Reserved]

(j) The Administrator grants the following petitioners an exemption for one year to process and distribute in commerce small quantities of PCBs for use as an optical liquid:

(1) R.P. Cargille Laboratories, Inc., Cedar Grove, NJ 07009 (PDE-181), provided that petitioner stores the PCBs it processes and distributes in commerce in accordance with the storage for disposal requirements of 40 CFR 761.65(b).

(2) [Reserved]

(k) The Administrator grants the following petitioners an exemption for

one year to distribute in commerce previously imported and repaired PCB equipment containing PCB small capacitors:

(1) Honeywell, Inc., Waltham, MA 02154 (PDE-119).

(2) [Reserved]

(l) The Administrator grants the following petitioners an exemption for one year to import samples of PCB-containing fluid taken from PCB transformers for purposes of testing and analysis:

(1) Dow Corning Corp., Midland, MI 48460 (ME-31.1).

(2) [Reserved]

(m) The Administrator grants the following petitioners an exemption for one year to process and export small quantities of PCBs for research and development:

(1) Chem Service, Inc., West Chester, PA 19380 (PDE-41).

(2) Foxboro Co., North Haven, CT 06473 (PDE-21.1).

(3) PolyScience Corp., Niles, IL 60648 (PDE-178).

(4) ULTRA Scientific, Inc., Hope, RI 02831 (PDE-282.1).

(n) The one-year exemption granted to petitioners in paragraphs (f), (g), (l) and (m) of this section shall be renewed automatically unless a petitioner notifies EPA of any increase in the amount of PCBs to be manufactured, imported, processed, distributed in commerce, or exported or any change in the manner of manufacture, processing, distribution in commerce, or export of PCBs. EPA will consider the submission of such information to be a renewed petition for exemption. EPA will evaluate the information in the renewed exemption petition, publish a proposed rule for public comments, and issue a final rule either granting or denying the exemption. Until EPA acts on the renewed exemption petition, the petitioner will be allowed to continue the activities for which it requests exemption.

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#### 40 CFR Part 761

[OFTS-62032A; TSH-FRL-2587-1]

**Toxic Substances Control Act; Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Exclusions, Exemptions, and Use Authorizations**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e), generally prohibits the manufacture, processing, distribution in commerce, and use of polychlorinated biphenyls (PCBs). EPA issued a final rule published in the *Federal Register* of October 21, 1982 (47 FR 46980), excluding PCBs generated in closed and controlled waste manufacturing processes from the TSCA prohibitions. This final rule amends the October 21, 1982 rule by excluding additional processes from regulation, based on EPA's determination that PCBs generated in these processes do not present an unreasonable risk of injury to health or the environment. In addition, this notice defers action on 49 exemption petitions to manufacture, process, and distribute PCBs in commerce; authorizes the use of PCBs in heat transfer and hydraulic systems at concentrations of less than 50 parts per million (ppm); and authorizes the use of PCBs in the compressors and in the liquid of natural gas pipelines at concentrations of less than 50 ppm.

**DATES:** These regulations shall be considered promulgated for purposes of judicial review at 1:00 p.m. eastern standard time on July 24, 1984. These regulations shall become effective on October 1, 1984.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404). Outside the USA: (Operator-202-554-1404).

**SUPPLEMENTARY INFORMATION:** OMB Control Number: 2070-0008.

**I. Overview of This Final Rule**

In today's rule, EPA is taking four actions concerning PCBs. These actions are: (1) An amendment of the October 21, 1982 Closed and Controlled Waste Manufacturing Processes Rule; (2) a deferral of action on 49 exemption petitions to manufacture, process, and distribute in commerce inadvertently generated PCBs; (3) a use authorization for PCBs in hydraulic and heat transfer fluid; and (4) a use authorization for PCBs in the compressors and liquid of natural gas pipeline systems. Units II, III, IV, and V, respectively, discuss these actions in detail.

**II. Amendment to the Closed and Controlled Waste Manufacturing Processes Rule****A. Overview of This Amendment**

This rule will permit the manufacture, processing, distribution in commerce, and use of inadvertently generated and recycled PCBs under limited circumstances. It is based on a determination that exposure to these PCBs would not present an unreasonable risk to health or the environment. This determination takes into account the effects from exposure to inadvertently generated and recycled PCBs, as well as the cost of controlling these PCBs. The regulatory history of this amendment and the no unreasonable risk determination are described in greater detail in the remainder of this Unit of the preamble.

EPA emphasizes that while today's rule sets certain limits on inadvertently generated and recycled PCBs released to air, water, products, and waste in certain processes, the Agency is not implying that these release limits represent an absolutely safe level. Rather, the Agency has decided that the risks associated with allowing the levels of PCBs in this regulation are not unreasonable. This means that EPA has set these levels based on a balancing of the costs associated with setting even lower limits (or removing PCBs entirely from the products in question) with the attendant reduction in risk that would result from stricter regulation. EPA has concluded that stricter regulation would result in great expense for a small increment in risk reduction.

**B. Background**

Section 6(e) of TSCA generally prohibits the manufacture, processing, distribution in commerce, and use of PCBs. Section 6(e)(3)(B) of TSCA provides that any person may petition EPA for one-year exemptions from the prohibitions on manufacture, processing, and distribution in commerce of PCBs. EPA may grant such petitions, by rule, if the following two conditions are satisfied: (1) The exemption, if granted, would not present an unreasonable risk of injury to health or the environment; and (2) good faith efforts have been made to develop a PCB substitute which does not present an unreasonable risk of injury. In addition, section 6(e)(2) of TSCA permits EPA to exempt from the PCB ban totally enclosed uses of PCBs and authorizes EPA to allow continuation of non-totally enclosed uses of PCBs if the uses will not present an unreasonable risk of injury to health or the environment.

In the *Federal Register* on May 31, 1979 (44 FR 31514), EPA issued a regulation to implement the prohibitions of section 6(e) of TSCA. (This rule is hereafter referred to as the PCB Ban Rule.) Among other provisions, that rule: (1) Generally excluded from regulation materials containing PCBs in concentrations of less than 50 ppm; (2) designated all intact, non-leaking capacitors, electromagnets, and transformers (other than railroad transformers) as "totally enclosed," and permitted their use without specific conditions; and (3) authorized 11 non-totally enclosed uses of PCBs, based on the finding that they did not present unreasonable risks.

The Environmental Defense Fund (EDF) obtained judicial review of the PCB Ban Rule in the U.S. Court of Appeals for the District of Columbia Circuit in *EDF v. EPA*, 636 F.2d 1267 (D.C. Cir. 1980). On October 30, 1980, the court invalidated the regulatory exclusion of PCBs in concentrations of less than 50 ppm and EPA's determination that the use of PCBs in electrical equipment was "totally enclosed." However, the court upheld the use authorizations. This rule was remanded to EPA by the court for further action consistent with its opinion.

The issuance of the court's mandate without a stay would have adversely affected many industries throughout the United States, including both the electrical utility industry and certain segments of the chemical industry whose processes inadvertently generated PCBs as impurities or byproducts in concentrations below 50 ppm. Accordingly, on January 21, 1981, EPA, EDF, and certain industry intervenors in *EDF v. EPA* filed a joint motion with the court. The motion asked for a stay of that part of the court's mandate which set aside the designation of transformers, capacitors, and electromagnets as totally enclosed. During the period of the stay, EPA agreed to conduct a rulemaking on the use of PCBs in electrical equipment. On February 12, 1981, the court granted this joint motion. EPA subsequently addressed the use of certain electrical equipment containing PCBs in a rule, which was published in the *Federal Register* of August 25, 1982 (47 FR 37342). This will be referred to hereafter as the Electrical Equipment Rule.

The genesis of today's rule was another joint motion filed by the Chemical Manufacturers Association (CMA), EDF and other industry intervenors in *EDF v. EPA* on February 20, 1981. That motion sought a stay of

that part of the court's mandate overturning the 50 ppm cutoff established in the PCB Ban Rule. This motion also proposed that during the period of the stay: (1) EPA would conduct new rulemaking with respect to PCBs generated in low concentrations; and (2) industry groups would initiate studies to provide new information for subsequent rulemaking. A brief history of the events subsequent to the February 20, 1981 motion will explain how EPA arrived at today's rule.

Throughout the discussions leading to the February 20, 1981 joint motion, chemical industry representatives argued that some of their manufacturing processes inadvertently generate PCBs that present virtually no health or environmental risk because of limited PCB exposure potential. Industry representatives stated that some processes generating PCBs as byproducts are designed and operated so that no releases of PCBs occur or that the PCBs formed in the processes are disposed of in accordance with the PCB disposal regulations at 40 CFR 761.60. These processes were referred to as "closed manufacturing processes" and "controlled waste manufacturing processes," respectively. The joint motion proposed that EPA issue an ANPR to exclude these closed and controlled waste manufacturing processes from the prohibitions of section 6(e) of TSCA.

In addition to addressing the closed and controlled waste manufacturing processes, the February 20, 1981 joint motion also proposed the publication of an ANPR requesting information on all other manufacturing, processing, distribution in commerce, and use of PCBs in low concentrations. Such PCBs generated in and released from other than closed or controlled waste manufacturing processes are hereafter referred to as "uncontrolled PCBs" or "inadvertently generated PCBs." These PCBs which are not intentionally generated are also referred to as "non-Aroclor" PCBs. These non-Aroclor, inadvertently generated, PCBs are the principal subject of this rulemaking.

On April 13, 1981, the court entered an order in response to the February 20, 1981 joint motion. That order stayed the issuance of the court's mandate with respect to activities involving PCBs in concentrations of less than 50 ppm. Thus, the 50 ppm regulatory limit established in the PCB Ban Rule remains in effect for the duration of the stay, and persons who manufacture, process, distribute in commerce, and use PCBs in concentrations of less than 50 ppm may continue these activities during the stay.

However, once the stay is lifted, any activity involving any quantifiable level of PCBs (as discussed in this notice) is banned unless that activity is specifically excluded, exempted, or authorized by regulation.

The court order of April 13, 1981 required EPA to take three actions. EPA was required to: (1) Issue ANPRs covering PCBs in concentrations of less than 50 ppm; (2) promulgate a final rule by October 13, 1982 to exclude generation of PCBs in closed and controlled waste manufacturing processes from the prohibitions of sections 6(e)(3)(A) of TSCA; and (3) advise the court by March 13, 1982 of EPA's plans and schedule for further action on PCBs generated as uncontrolled PCBs in concentrations of less than 50 ppm.

EPA issued two ANPRs on the 50 ppm regulatory limit which were published in the *Federal Register* of May 20, 1981 (46 FR 17617 and 46 FR 17619). The ANPRs established two separate rulemaking proceedings with respect to PCBs in concentrations of less than 50 ppm. The first ANPR announced rulemaking activities on PCBs generated in closed and controlled waste manufacturing processes. The second ANPR announced the rulemaking activities for uncontrolled PCBs.

In accordance with the April 13, 1981 court order, EPA on March 11, 1982 submitted a report to the court that set forth EPA's plans for further regulation of uncontrolled PCBs. Since the number of processes generating uncontrolled PCBs is related to the number of closed and controlled waste manufacturing processes, EPA requested that the court allow EPA to report on its further plans for regulation of uncontrolled PCBs following the completion of the Closed and Controlled Waste Manufacturing Processes Rule. EPA also requested that the court extend its stay of mandate until December 1, 1982, to allow EPA time to develop detailed plans for regulating uncontrolled PCBs after issues were resolved in the Closed and Controlled Waste Manufacturing Processes Rule. On April 9, 1982, the court issued an order granting EPA's request.

The Closed and Controlled Waste Manufacturing Processes Rule was published in the *Federal Register* of October 21, 1982 (47 FR 46980). That rule provides an exclusion from the general ban on the manufacture, processing and distribution in commerce of PCBs for closed and controlled waste manufacturing processes. The Closed and Controlled Waste Manufacturing Processes Rule sets the limits for

inadvertently generated, non-Aroclor PCBs in products, air emissions and water discharges at the limit of quantitation (LOQ) and controls disposal of waste containing PCBs above the LOQ. These exclusions from the prohibitions of section 6(e) of TSCA were based on EPA's determination that risk would be *de minimis*, because there would be no measurable gain in protection of the environment or public health by attempting to regulate PCBs at levels that are nonquantifiable for all practical purposes. This environmentally conservative approach was taken because data were not available at that time to determine if higher concentration levels were appropriate.

### C. Background for Today's Amendment

After issuing the final Closed and Controlled Waste Manufacturing Processes Rule, EPA in accordance with the April 9, 1982 court order, submitted to the court a plan for regulating uncontrolled PCBs. EPA stated that it intended to propose a rule by December 1, 1983 and to issue a final rule for uncontrolled PCBs by July 1, 1984. EPA also requested an extension of the court's stay of mandate until October 1, 1984. In response to this request, the court on December 17, 1982 stayed the mandate until further order. In addition, the court ordered EPA to submit a progress report on March 31, 1983 and quarterly thereafter. In accordance with this December 17, 1982 order, EPA submitted progress reports at the end of March, June, September and December 1983; March and June 1984.

On April 13, 1983, CMA, EDF, and the Natural Resources Defense Council (NRDC) presented a document to EPA entitled "Recommendation of the Parties for a Final EPA Rule on Inadvertent Generation of PCBs." This document represents a consensus proposal of CMA, EDF, and NRDC and was the culmination of an independent negotiation effort between those parties that began in mid-1982.

The consensus proposal was designed to allow the manufacture of chemicals in processes that inadvertently generate PCBs if certain conditions are met. In the consensus proposal, EDF, NRDC, and CMA proposed five basic conditions that would have to be met in order to qualify for an exclusion from the TSCA section 6(e)(3)(A) prohibitions. These conditions were:

1. Concentrations of inadvertently generated PCBs in products are to be limited to a 25 ppm average per year and a maximum of 50 ppm at any given time.

2. Concentrations of inadvertently generated PCBs at the point where such PCBs are vented to the ambient air are to be less than 10 ppm.

3. Concentrations of inadvertently generated PCBs discharged from manufacturing sites to water are to be less than 0.1 ppm for any resolvable gas chromatographic peak.

4. The concentration of PCBs described in item 1 is to be calculated after dividing the concentration of monochlorinated and dichlorinated biphenyls by factors of 50 and 5, respectively.

5. Various certification, reporting, and record maintenance requirements must be met to qualify for this exclusion from the general ban on manufacture, processing, distribution in commerce, and use of PCBs.

Further, the consensus proposal included an "upset provision." This provision would have provided an affirmative defense for those manufacturing situations in which PCB levels released are higher than would be allowed by the rule, provided that such releases are due to factors beyond the control of the operator.

Based on the data analyses EPA had completed when it received the consensus proposal, the Agency determined that it was appropriate to use the consensus proposal as a framework in this rulemaking. In a letter to CMA, EDF, and NRDC dated June 3, 1983, EPA stated that it would use the consensus proposal as a framework for regulation, although it intended to make modifications to that framework.

EPA also received information from a number of sources on PCBs that are recycled. Recycled PCBs are PCBs that were generated in the past and may enter certain limited manufacturing processes as PCB-contaminated raw materials. In general, these are intentionally generated PCBs (i.e., Aroclor) that are found in low concentrations.

On December 1, 1983, the Agency issued the proposed Uncontrolled PCBs Rule. Three actions were proposed in that notice: (1) An amendment to the Closed and Controlled Waste Manufacturing Processes Rule that would exclude additional activities from the TSCA section 6(e) PCB ban; (2) a deferral of action on 50 petitions previously filed under section 6(e)(3)(B) of TSCA for exemptions from the PCB regulations (see Unit II.B for an explanation of exemption petitions), and (3) a use authorization for PCBs in heat transfer and hydraulic systems.

In determining the legal basis for this Uncontrolled PCBs Rule, EPA decided to

adopt an approach under which the Agency will authorize those PCB activities which do not present unreasonable risks. This approach was suggested by CMA, EDF and NRDC in their consensus proposal. EPA's reason for adopting this approach is explained in the preamble to the proposed regulation at 48 FR 55079. The concept of unreasonable risk is explained further at 48 FR 55081.

To determine which processes would be affected by this rulemaking, EPA developed a list of approximately 200 chemical processes with a potential for generating PCBs. These chemical processes were then ranked as high, moderate, or low with respect to their potential to generate PCBs. EPA identified 70 chemical processes that were believed to have a high potential to inadvertently generate PCBs. Some of the processes included in this list were identified in petitions for exemption from the PCB Ban Rule that were previously submitted to EPA. The Agency focused on this group of 70 chemical processes in developing its assessments of environmental and human health exposures used to support this rulemaking.

The major difference between the criteria proposed by the Agency and the consensus proposal criteria is the addition of a concentration limit of 5 ppm for PCBs in consumer products with a high potential for exposure. These consumer products were deodorant bars and soaps, and plastic building materials and products. EPA also did not propose the "upset" provision suggested in the consensus proposal.

In response to the proposed rule, over thirty comments were submitted to the rulemaking record. No outside parties requested a public hearing in this rulemaking; therefore, no hearings were held.

#### *D. General Comments on the Proposed Amendment*

The majority of the comments received in this rulemaking generally agreed with the exclusions proposed in the December 8, 1983 Federal Register notice. However, many modifications to the rule and the supporting documents were suggested by the commenters. This Unit of the Preamble discusses many of the general comments made in response to the proposed rule. Unit F generally discusses the health effects and exposure assessment support documents and comments made with respect to these support documents. For further information concerning all of the comments made in response to the proposed rule, please refer to the support document "Response to

#### *Comments on the Proposed Uncontrolled PCBs Rule.*

A number of comments were made on the exclusion for consumer products with a high potential for exposure. Several commenters pointed out that deodorant bars are regulated by the Food and Drug Administration (FDA); therefore, these products may not be regulated under TSCA. FDA informed EPA that appropriate terminology for this type of product that is not controlled by FDA is "detergent bars." EPA agrees with these points. Accordingly, the wording "soap and deodorant bars" has been changed to read "detergent bars" as suggested by the FDA.

Similarly, several commenters suggested that EPA should delete from the "plastic building materials and products" designation the words "and products" because those words are redundant. Other commenters suggested that plastic building materials and products should be removed altogether from the category of "consumer products with a high potential for exposure." In response to these comments, the Agency reevaluated the relevant exposure assessment, and determined that the exposure is not as great as originally estimated. The modifications to the exposure assessment are explained in the "Response to Comments on the Proposed Uncontrolled PCBs Rule." Accordingly EPA has removed plastic building materials and products from the "consumer products with a high potential for exposure" category. The PCB concentration in plastic building products will be limited to an annual average of 25 ppm PCBs with a 50 ppm maximum.

A number of commenters were uncertain as to which Aroclor products were to be included under the definition of recycled PCBs. In today's rule, EPA clarifies this issue by stating that the only PCBs permitted to be recycled are those Aroclor PCBs that enter the paper or the asphalt roofing manufacturing process as PCB-contaminated raw materials. The discounting factors for monochlorinated and dichlorinated biphenyls are not to be used in quantifying the recycled PCBs. EPA chose these products because information submitted to the Agency showed that these were the only products in which raw materials contaminated with Aroclor PCBs were used in a manufacturing process.

EPA has received information on recycled PCBs from the American Paper Institute (API) and the Asphalt Roofing Manufacturers Association (ARMA). API stated that its members have

detected PCBs in paper, pulp, and paperboard products. It believes that ambient PCBs are the source of the PCBs found in its members' products. ARMA, which represents about 15 companies, stated that asphalt roofing manufacturers have detected PCBs in asphalt roofing waste streams as a result of PCBs found in the waste oil used to adjust the viscosity of the asphalt. The PCBs are present in the waste paper used in the production of roofing felt, and in the asphalt used for saturation of the felt. PCBs have not been detected in the final asphalt roofing product.

Two commenters stated that since the LOQ for Aroclor PCBs in water is much lower than the LOQ described for non-Aroclor PCBs, permissible discharges of recycled PCBs (Aroclor PCBs) should be set at this lower LOQ level. Setting this limit for recycled PCBs is appropriate based on the environmental risk assessment. EPA agrees with these comments concerning the LOQ for Aroclors. Therefore, the Agency is modifying the discharge limit to water (see Unit II.K.3). EPA is setting the discharge limit for recycled Aroclor PCBs at roughly 3 parts per billion (ppb). EPA's reasons for setting the limit are explained further in this rulemaking record. Unit VI.D of this preamble also explains the relationship of this Aroclor LOQ to EPA's activities under the Clean Water Act.

Several commenters questioned the designation of certain chemical processes as having a high potential to inadvertently generate PCBs. EPA agrees that not all of the processes included on that list in the proposed rule inadvertently generate PCBs. The Agency has also determined that several other processes which inadvertently generate PCBs are not on that list. The Agency intended that this list be used only as a guide in developing a regulatory strategy for PCBs. The act of inadvertently generating PCBs is the primary consideration in deciding if a process needs to be certified as an excluded manufacturing process, not the fact that the process does/does not appear on the list of chemical processes with a high potential to inadvertently generate PCBs.

#### E. Today's Final Rule

Based on the considerations mentioned above and other information available to the Agency, EPA is modifying the criteria for exclusion from the prohibitions of section 6(e) of TSCA that were proposed on December 8, 1983. Today's rule excludes those PCB activities (including manufacture, processing, distribution in commerce,

and use) that meet the criteria outlined below:

1. Inadvertently generated PCB concentrations in the components of detergent bars are limited to less than 5 ppm.

2. Inadvertently generated PCB concentrations present in all products except detergent bars are limited to an annual average of 25 ppm with a 50 ppm maximum. PCB concentrations in recycled paper are limited to an annual average of 25 ppm with a 50 ppm maximum.

3. Inadvertently generated and recycled PCB concentrations at the point where such PCBs are manufactured or processed and are vented to the ambient air are limited to less than 10 ppm.

4. Inadvertently generated PCB concentrations discharged from manufacturing or processing sites to water are limited to less than 0.1 ppm for any resolvable gas chromatographic peak. Recycled PCB concentrations discharged from manufacturing or processing sites to water are limited to less than 3 micrograms per liter ( $\mu\text{g}/\text{l}$ , roughly 3 ppb) total Aroclors.

5. All process wastes containing inadvertently generated or recycled PCBs at 50 ppm or greater PCBs are to be disposed of in accordance with the PCB disposal requirements of 40 CFR 761.60.

6. Quantitation of inadvertently generated PCBs to meet the criteria in items 1 through 5 is to be calculated after discounting the concentration of monochlorinated biphenyls by a factor of 50 and dichlorinated biphenyls by a factor of 5. These discounting factors do not apply to recycled PCBs.

7. The certification, reporting, and record maintenance requirements must be met.

#### F. Effects on Human Health and the Environment

CMA, EDF, and NRDC stated in the consensus proposal that while the parties to the consensus have different views on the toxicology of PCBs, they believe that their recommendation would assure an absence of unreasonable risk. According to the consensus proposal, the parties determined that it was not necessary to discuss the toxicology of PCBs in order to resolve this problem. The parties felt that a broad-based consideration of the health effects would only lead to further litigation.

To determine whether a risk is unreasonable section 6 of TSCA requires a balancing of the potential for harm from exposure as a result of manufacture, distribution in commerce, use, and disposal of the chemical under

consideration against the cost to society of placing restrictions on that chemical. Specifically, TSCA requires that the following factors be considered:

1. The effects of inadvertently generated and recycled PCBs on human health and the environment.

2. The magnitude of exposure of these PCBs to humans and the environment.

3. The benefits of using those products containing PCBs.

4. The economic impact of this rule upon the national economy, small business, technological innovation, the environment, and public health.

EPA has considered these factors in determining that there is no unreasonable risk from an excluded activity as well as the qualitative approach recommended in the consensus proposal. Based on this information, EPA is conditionally excluding from regulation under section 6(e) of TSCA the manufacture, processing, distribution in commerce, and use of certain inadvertently generated non-Aroclor PCBs and the processing, distribution in commerce, and use of recycled PCBs in certain processes. This decision is based on a finding that such PCBs present no unreasonable risk of injury to human health and the environment.

#### 1. Effects on Human Health

Toxicity and exposure are the two basic elements of risk. EPA considered both of these elements in determining the potential risks associated with PCBs and in deciding whether to grant an exclusion.

*a. Health effects.* The toxic effects of PCBs have been previously described in various documents that are part of the rulemaking record for the May 31, 1979 PCB Ban Rule and the August 25, 1982 Electrical Equipment Rule. EPA summarizes these findings here.

EPA has determined that PCBs are toxic and persistent. PCBs can enter the body through the lungs, gastrointestinal tract, and skin; circulate throughout the body; and be stored in the fatty tissue. In addition, EPA concludes that PCBs may cause chloracne, reproductive effects, developmental toxicity, and oncogenicity in humans exposed to PCBs. Available data show that some PCBs have the ability to alter reproductive processes in mammalian species, sometimes even at doses that do not cause other signs of toxicity. Data from studies using animals and limited available epidemiology data indicate that prenatal exposure to PCBs can result in various degrees of developmentally toxic effects. Postnatal effects have been demonstrated in

immature animals, following exposure to PCBs prenatally and via breast milk.

Available studies using animals indicate an oncogenic potential for PCBs. Available epidemiology data, however, are not adequate to confirm or negate oncogenic potential in humans at this time. Further epidemiology research would be needed to correlate data from humans and animals. However, when considered with all the other information, EPA finds no reason to suggest that the data from animals would not predict an oncogenic potential in humans.

In some cases chloracne has occurred in humans exposed to PCBs. Severe cases of chloracne are painful, disfiguring, and may persist for long time periods before the symptoms disappear. Although the effects of chloracne may be reversible, EPA considers these effects to be significant. Since the administration of PCBs to experimental animals results in tumor formation, reproductive effects and developmental toxicity, EPA finds that there is the potential to produce these effects in humans exposed to PCBs.

During the comment period on the proposed Uncontrolled PCBs Rule, a number of commenters presented additional information about the health effects. In particular, the National Electrical Manufacturers Association submitted a document prepared by Drill et al. A more detailed analysis of these comments is presented in EPA's support document "Response to Comments on the Proposed Uncontrolled PCBs Rule."

The health and environmental effects issues raised by these commenters have been considered by EPA throughout the long history of its rulemaking on PCBs under the Clean Water Act (42 FR 6532, February 2, 1977) and TSCA (44 FR 31514, May 31, 1979). Issues on the health effects of PCBs have been the subject of litigation in two cases before the United States Court of Appeals for the District of Columbia Circuit, 636 F.2d 1267 (1980); 598 F.2d 62 (1978). The administrative record in this proceeding contains well over one hundred documents discussing the effects of PCBs.

As EPA has stated numerous times, the health and environmental effects of PCBs are of concern to the Agency. However, the Agency has acknowledged conflicting interpretations of the scientific data and disagreements as to the weight to be assigned to particular data in making regulatory decisions. These conflicts have been noted by industry and environmental group commenters throughout the PCB rulemaking proceedings under both the Clean Water Act and TSCA. The

comments submitted in the proceeding on today's rule point out the same problems with conflicting interpretation of scientific evidence and disagreements over regulatory policymaking.

There is little value in revisiting these issues concerning the health and environmental effects of PCBs without substantial new information. While a number of new studies have been conducted on PCBs, those studies have not been sufficient to change any of EPA's findings with respect to the health and environmental effects of PCBs. Nevertheless, EPA has reviewed the data submitted by the commenters, which includes information previously submitted to the Agency, as well as new studies. EPA has determined that there is no reason to change its conclusions as to the hazards of PCBs.

*b. Exposure assessment.* Results of the National Human Adipose Tissue Survey conducted by EPA indicate that the estimated fraction of the national population having greater than 3 ppm of PCBs has decreased from 8 to 1 percent between 1977 and 1981, after increasing from 2.7 to 8 percent between 1972 and 1977. These data indicate that exposure of the U.S. population to PCBs is decreasing.

EPA conducted an exposure assessment to determine whether EPA could exclude materials containing PCBs at low concentrations from the statutory ban on PCBs without endangering human health or the environment. Few data were available to EPA regarding actual exposure to inadvertently generated and recycled PCBs. Therefore, for each potentially exposed population, EPA originally developed "maximum hypothetical exposures." EPA used the maximum hypothetical exposures as a screening device. Where the maximum hypothetical exposure level associated with a PCB concentration of 50 ppm was very low, no further work was done for this particular hypothetical exposure. Instead, the Agency concentrated on those situations where the estimated exposure levels were high. Assumptions for these hypothetical exposures were refined to obtain better and more reasonable worst-case estimates. Thus, for all of the estimated exposures presented in the support document, actual exposures are expected to be no more than the estimated exposures.

Included among the hypothetical exposure situations developed for this assessment are occupational, consumer, and general population exposures to PCBs through ingestion, inhalation, and dermal absorption. EPA also developed exposure assessments for recycled Aroclor PCBs. All of these exposure situations were designed to represent

high frequency or duration of use (maximum hypothetical exposures).

After the exposure assessment was conducted, EPA found that for the majority of hypothetical exposures were extremely low. In some instances, estimates showed higher exposure. In those instances where EPA calculated higher exposures, further evaluation of the assumptions showed that the estimated exposures overestimated the actual expected exposures.

Detailed descriptions of the hypothetical exposures and their findings are included in the support document entitled "Revised Exposure Assessment for Incidentally Produced Polychlorinated Biphenyls." This support document contains revisions made in response to the comments on the earlier draft exposure assessment. Examples of situations with the highest exposures, and EPA's findings concerning them are given below.

In occupational settings, dermal exposure was estimated assuming immediate and total absorption. Inhalation and dermal exposure situations assumed that workers were exposed to PCBs for 38.5 years. All of these hypothetical exposures assumed that workers do not wear protective clothing.

EPA estimated the exposure from ingestion of fish and water obtained from streams which receive industrial wastewater discharge containing 100 micrograms of PCBs per liter of wastewater ( $\mu\text{g}/\text{l}$ ). This is the LOQ for non-Aroclor PCBs. In this hypothetical exposure situation, the concentrations of PCBs in the drinking water and fish depend entirely on how much the PCB concentration is diluted by the receiving stream. Streams with low flow rates will have the highest concentrations of PCBs. If all of the fish and water in an individual's diet is obtained from a stream with a flow rate in the lower 50 percentile of streams receiving discharges from the chemical and plastics industries, exposure could be high.

EPA has determined that it could not practically measure non-Aroclor PCBs below 100  $\mu\text{g}/\text{l}$ . Therefore, there is no measurable reduction in exposure. For recycled Aroclor PCBs, because they can be measured at a lower level, EPA has reduced the discharge limit to 3  $\mu\text{g}/\text{l}$ , thereby reducing the exposure considerably. These discharge limits may be further reduced by more stringent regulations issued under EPA authorities, or any permits or pretreatment requirements issued by a state or local government.

EPA developed two hypothetical exposure situations to estimate maximum exposure resulting from the use of detergent bars. In both of these hypothetical exposures, EPA assumes that PCBs are present in the surfactant component of the detergent bars at 25 ppm. Comments submitted to the Agency in response to the proposed rule showed that some detergent bars may contain PCBs, although the levels are very low. If PCBs are not present in the components of detergent bars, then there will be no exposure to PCBs from these products.

The first hypothetical exposure assumes that all of the PCBs present in detergent bars are dermally absorbed. In actual use, most of the PCBs will be rinsed off before absorption. Thus, the estimated exposure overestimates the actual exposure. In a second hypothetical exposure, EPA assumes that only a detergent bar film is absorbed. Unlike all of the other hypothetical exposures that estimate dermal absorption of PCBs, this hypothetical exposure situation assumes that the absorption of PCBs is spread out over time and not instantaneous. The second hypothetical exposure is EPA's best estimate of maximum exposure to PCBs in detergent bars.

It is impossible to determine precisely whether the exposure estimated using the assumptions made in this second hypothetical exposure situation equal or exceed actual exposures. Since virtually all consumers come into contact with detergent bars which may contain PCBs on a daily basis, measures must be taken to minimize consumer exposure to PCBs in detergent bars. Therefore, EPA has set a 5 ppm concentration limit in the components of detergent bars. The surfactant is the component that is likely to contain PCBs; thus, PCB concentrations in the final detergent bar product will actually be well below 5 ppm.

EPA evaluated the exposure to PCBs from use of skin lotions and creams assuming that PCBs are present in the surfactant component of the skin lotions and creams at 25 ppm. This exposure assessment assumes daily usage, 100 percent immediate absorption, and generous application of the skin lotions and creams. Therefore, EPA believes that these exposure estimates overstate the actual exposures from skin lotions and creams. In fact, PCBs are only hypothesized to occur in skin lotions and creams. If PCBs do not occur in these products, there is no risk from PCB exposure in skin lotions and creams.

FDA is the Federal agency that regulates skin lotions and creams. EPA

has provided this information to the FDA for appropriate action.

*c. Magnitude of human exposure.* As CMA, EDF, and NRDC pointed out in the consensus proposal, the estimated total annual production of inadvertently generated PCBs approximates 100,000 pounds. This poundage is but a small percentage (1.0 percent) of the 10,000,000 pounds of Aroclor PCBs that the consensus proposal estimates to have entered the environment annually before PCB controls were instituted and less than 0.1% of the 150,000,000 pounds estimated to currently exist free in the environment.

In addition, the consensus proposal states that fewer than 11,000 pounds of inadvertently generated PCBs were estimated to enter products annually. Further, many products that contain inadvertently generated PCBs are chemical intermediates. In the consumer end-use products, the PCBs would in many instances be bound in tight matrices. CMA, EDF, and NRDC estimate that fewer than 1,000 pounds annually are likely to enter the environment. Based on these facts, EPA agrees with the consensus proposal that releases of inadvertently generated PCBs are unlikely to have a measurable effect on the public health or the environment. Also, as noted above, exposures from the non-Aroclor and recycled PCBs are estimated to be low.

*d. Quantitative risk assessments.* At the time of the proposed rule, EPA had prepared quantitative carcinogenicity and reproductive/developmental risk assessments. The Agency has reviewed the range of quantitative risks and determined that the risks presented by the activities excluded in this rulemaking are not unreasonable. Therefore, after evaluating all of the information, EPA has concluded that the qualitative evaluation of health and environmental effects suggested in the consensus proposal is a reasonable approach to risk assessment.

In support of the proposed rule, EPA also developed a reproductive/developmental effects risk assessment for PCBs entitled "Quantitative Risk Assessment of Reproductive Risk Associated with PCB Exposure." This assessment included quantitative risk models without threshold levels, as well as a more traditional "No Observable Effects Level" (NOEL) approach to risk assessment. The Agency specifically requested comments on this preliminary reproductive/developmental effects risk assessment in the proposed rule.

The comments received identified two areas of concern for the Agency: (1) These were scientific and policy issues

dealing with quantitative risk assessment for reproductive/developmental effects risk assessments in general, and (2) those associated with PCBs in particular. After evaluating these comments, EPA has decided that additional time is needed to resolve the scientific and policy issues surrounding quantitative risk assessment for reproductive/developmental effects. Therefore, EPA is not using this risk assessment to support this rulemaking.

## 2. Effects on the Environment

In previous PCB rulemaking, EPA concluded that PCBs can be concentrated in freshwater and marine organisms. The transfer of PCBs up the food chain from phytoplankton to invertebrates, fish, and mammals can result ultimately in human exposure through consumption of PCB-containing food sources. Available data show that PCBs affect the productivity of phytoplankton communities; cause deleterious effects on environmentally important freshwater invertebrates; and impair reproductive success in birds and mammals.

PCBs also are toxic to fish at very low exposure levels. The survival rate and the reproductive success of fish can be adversely affected in the presence of PCBs. Various sublethal physiological effects attributed to PCBs have been recorded in the literature. Abnormalities in bone development and reproductive organs also have been demonstrated.

EPA conducted a quantitative environmental risk assessment of PCBs for this rulemaking, including a review of available environmental data. This assessment can be found in the support document entitled "Environmental Risk and Hazard Assessments of Polychlorinated Biphenyls." EPA concluded that ambient concentrations and food chain transport of PCBs may impair the reproductive potential of commercially valuable fish and certain wild mammals. PCB residues are strongly correlated with reductions in natural populations of marine mammals and may be correlated with declines in river otter populations. High PCB residues have been found in various birds, especially gulls and carnivorous birds, but no resulting effects have been demonstrated.

In addition, EPA estimated the toxicity for the monochlorinated through hexachlorinated biphenyls and for decachlorinated biphenyl. These estimates show that as the number of chlorine atoms on the biphenyl molecule increases, the no observable effect concentration (NOEC) for fish decreases. These estimates were

partially based upon data obtained using the most sensitive fish species.

According to the consensus proposal, the total annual production of inadvertently generated PCBs approximates 100,000 pounds, most of which are never released to the environment. CMA, EDF, and NRDC estimate that fewer than 1,000 pounds annually are likely to enter the environment. This annual production is only 0.01 percent of the 10 million pounds of Aroclor PCBs that are estimated to have entered the environment annually before PCB controls were instituted. This production is only 0.0007 percent of the total 180 million pounds of Aroclor PCBs estimated to have entered the environment prior to institution of PCB controls. In addition, the consensus proposal states that various monitoring studies have documented the declining load of PCBs in the environment. Based on these facts, EPA agrees with the conclusion stated in the consensus proposal that releases of PCBs from inadvertent generation, even at a level of 10,000 pounds of PCBs released annually, would have no measurable effect on the declining environmental load.

EPA is setting the non-Aroclor PCB concentration limit for water discharges below 0.1 ppm, the LOQ for these PCBs. This is the level below which non-Aroclor PCBs cannot practically and reliably be measured. Setting the concentration limit for PCBs below this level will in effect be equivalent to a total ban on PCBs in water discharges. Likewise, the Agency is setting the PCB concentration limit for water discharges from processes that are recycling PCBs below 3 ppb, the LOQ for Aroclor PCBs. This limit for Aroclor PCBs in water discharges is the result of several comments submitted on the proposed Uncontrolled PCBs Rule.

### 3. Discounting Factors for Monochlorinated and Dichlorinated Biphenyls

The consensus proposal provided discounting factors for monochlorinated biphenyls and dichlorinated biphenyls of 50 and 5, respectively. As stated in the consensus proposal, despite the manufacture in the United States of approximately 10 million pounds of monochlorinated biphenyls and more than 100 million pounds of dichlorinated biphenyls (as part of commercial PCB mixtures) from 1930 to 1978, no monochlorinated biphenyls and few, if any, dichlorinated biphenyls have been detected in humans or the environment. The consensus proposal attributes these monitoring results to several factors that

distinguish between monochlorinated and dichlorinated biphenyls and the higher chlorinated biphenyls.

In contrast to the more highly chlorinated biphenyls, the monochlorinated and dichlorinated biphenyls are: (1) Less likely to adsorb to solids; (2) more likely to dissolve in water; (3) more likely to move from natural bodies of water to air; (4) more likely to biodegrade; and (5) less likely to bioaccumulate. Thus, CMA, EDF, and NRDC concluded that monochlorinated and dichlorinated biphenyls are less persistent in the environment and less likely to magnify or accumulate than the more highly chlorinated biphenyls.

In support of these discounting factors, CMA, EDF, and NRDC considered data by Moolenaar (1982) as well as information provided by Dow Chemical Company in a May 13, 1982 citizen's petition to amend 40 CFR Part 761. In general, this information demonstrates that monochlorinated and dichlorinated biphenyls are less persistent than more highly chlorinated biphenyls. The information included environmental variables such as environmental persistence, residence time in water, and fish bioconcentration. Adipose and plasma levels in capacitor workers and levels in human milk samples were also considered. A chart is presented in the consensus proposal that compares persistence data for monochlorinated and dichlorinated biphenyls with persistence data for trichlorinated biphenyls, demonstrating that monochlorinated and dichlorinated biphenyls are less persistent than trichlorinated biphenyls.

These discounting factors encompass all activities involving inadvertently generated monochlorinated and dichlorinated PCBs, but do not apply to any other PCBs subject to EPA regulation. This position is consistent with previous EPA PCB regulatory policy. The Agency has a long history, in regulations under both the Clean Water Act and TSCA, of covering the lesser chlorinated PCBs in the same manner as the higher chlorinated PCBs. The decision to affect this policy under Clean Water Act regulations was upheld by the United States Court of Appeals of the District of Columbia Circuit in *EDF v. EPA*, 598 F.2d 62 (1978). EPA has continued this policy under TSCA regulations. The definition of PCBs under 40 CFR 761.3 states that PCBs consist of any chemical substance "that is limited to the biphenyl molecule that has been chlorinated to varying degrees."

Today's rule is making a small exception to this long-standing policy.

While EPA is continuing to regulate the lesser chlorinated PCBs for all intentionally generated PCBs, the Agency has determined that discounting inadvertently generated monochlorinated and dichlorinated biphenyls will not present an unreasonable risk. EPA has arrived at this decision based on the very small amounts of monochlorinated and dichlorinated biphenyls that will be generated and released as a result of this rule, the fact that these PCB homologs are generally less persistent and less likely to bioaccumulate than the higher chlorinated PCB homologs and the high cost of preventing the generation of the monochlorinated and dichlorinated biphenyls in manufacturing processes. Accordingly, EPA has determined that the incremental risk reduction that would result from more stringent regulation of the monochlorinated and dichlorinated biphenyls in the limited circumstances of this regulation is outweighed by the costs that would be incurred.

To illustrate how these discounting factors would work, assume a product is analyzed and found to have a PCB concentration of 510 ppm PCBs. After further analysis it is determined that the product contains 10 ppm of decachlorinated biphenyl and 500 ppm of monochlorinated biphenyl. Since the discounting factor for monochlorinated biphenyl is 50, this product, for purposes of this regulation, contains only 10 ppm of monochlorinated biphenyl (500 ppm monochlorinated biphenyl  $\div$  50 discounting factor = 10 ppm PCBs). This product would be found in compliance since, for purposes of this regulation, it would be considered to contain only 20 ppm PCBs (10 ppm attributed to monochlorinated biphenyl and 10 ppm attributed to decachlorinated biphenyl). Although the PCB limits for detergent bars are lower, calculation of total PCBs in the components of detergent bars would be discounted similarly.

### G. Regulatory Impact Analysis, Benefits, and Availability of Substitutes

#### 1. Benefits of PCBs and Availability of Substitutes

CMA has stated that any chemical process involving carbon, chlorine, and elevated temperatures is likely to inadvertently generate some PCBs. Chlorine and carbon are two of the most abundant elements on Earth. Thus, both are present in many chemical processes. In fact, as mentioned in Unit I.C of this preamble, EPA originally developed a list of approximately 200 chemical processes with a potential to

inadvertently generate PCBs. These 200 chemical processes are of major importance to the organic chemical industry. For example, many of these processes produce high volume chlorinated solvents.

A wide variety of other products are known or believed to contain inadvertently generated PCBs. Among these products are paints, printing inks, agricultural chemicals, plastic materials, and detergent bars. These products are widespread and products, such as detergent bars and paint, are considered essential, non-luxury items in our society. Thus, many of the products that contain inadvertently generated PCBs have great societal value.

Industry commented in response to the Closed and Controlled Waste Manufacturing Processes Rule that, in general, cost-competitive substitutes are not available for products contaminated with low level PCBs. In general, industry has not been successful in modifying processes to prevent the incidental formation of any PCBs. Furthermore, CMA has commented that research programs to study ways of reducing incidental PCB formation are very costly and have met with limited success.

EPA estimated the cost of controlling the level of inadvertently generated PCBs, considering that if exclusions were not provided by this rule, these processes would be banned. Estimates of the benefit to producers of a 25 ppm cutoff range from approximately \$77 million to \$451 million if plants continue operations for 10 years. The estimated benefits to producers, distributors, and commercial users who remain in business for 10 years range from \$950 million to \$5.59 billion.

EPA believes that most of the chemical processes with unknown PCB concentrations that are analyzed in the RIA are produced in low volumes. In addition, a number of interested parties commented that PCBs have not been detected in products whose manufacture was suspected to involve inadvertent generation of PCBs. Based on this information, EPA believes that the majority of products are already below the 25 ppm limit (5 ppm for detergent bars).

## 2. Economic Consequences

EPA evaluated several options for dealing with the uncontrolled PCBs. One of these options was to allow the total ban of section 6(e) to take effect. EPA also had the option to set permissible levels of PCBs either higher or lower than the levels set in this rule.

Had EPA allowed the ban to become effective, companies could: (1) Modify the processes that inadvertently

generate PCBs so that they would not generate PCBs, (2) substitute PCB-containing products with non-PCB-containing products, or (3) apply for annual exemptions under section 6(e)(3)(B) of TSCA. Industry has commented that substituting products or substituting processes to eliminate inadvertently generated PCBs is not generally feasible. Thus, the selection of this regulatory option could result in a major disruption in commerce.

The Regulatory Impact Analysis (RIA) prepared for this rulemaking estimates that if no exclusion were provided by this rule, the total costs of the exemption petition process for producers, distributors, and commercial users over the next 10 years would range from \$950 million to \$5.6 billion. These costs are extremely high and would present a significant economic burden to industry while the amount of PCBs eliminated by such regulation would be small. However, EPA believes that in the majority of cases PCB concentration levels are currently below the levels excluded by this rule.

If EPA set the PCB concentration limits at a higher level, the result will be much lower costs. However, higher PCB concentration limits would result in significantly higher risks of injury to health and the environment. Conversely, if EPA set the PCB concentration limits at a lower level, the result would be lower risks of injury to health and the environment. The costs associated with lowering these concentration limits, however, would be much greater, approaching the total costs estimated for the exemption petition process.

The only identifiable costs of this rule with respect to uncontrolled PCBs result from the certification, recordkeeping, and reporting requirements. These costs were estimated in the RIA to range from \$10 million to \$59 million over a 10-year period. Thus, this rule presents very low costs in comparison with more restrictive approaches.

EPA estimates that this rule will not result in a disruption of commerce. A disruption of commerce is likely if the total ban or more restrictive concentration limit options were chosen. EPA also believes that this rule will not stifle new technology. EPA estimates that the discounting factors for monochlorinated and dichlorinated biphenyls are likely to save industry \$800 thousand to \$4.7 million each year based on the avoidance of exemption costs.

EPA analyzed the distribution of benefits of this rule across companies of various sizes and employment. According to the RIA, many small businesses will benefit from the

exclusions provided by this rule in avoiding the expense associated with filing annual exemption petitions. Thus, the Agency concludes that small businesses generating inadvertent PCBs will benefit from the provisions of this rule.

With respect to technological innovation, it is reasonable to assume that at least some portion of the money that industry will save by not being subjected to a total PCB ban will go to research and development activities. No negative comments were made on the RIA completed for the proposed Uncontrolled PCBs Rule. Therefore, no major changes have been made in the final RIA. For further details, see the support document "Regulatory Impact Analysis of the Final Rule Regulating Inadvertent PCB Generation from Uncontrolled Sources."

## H. Unreasonable Risk Determination

EPA concludes that the risks associated with the manufacture, processing, distribution in commerce and use of those inadvertently generated and recycled PCBs excluded from the prohibitions of section 6(e) of TSCA by this rule are outweighed by the costs that would be incurred if these PCBs were to be banned. The high costs of eliminating the low risks that might be attributed to the inadvertent generation of low level concentrations of PCBs would place an unwarranted burden on society, with only a minimal reduction in public health risks. Therefore, EPA concludes that the exclusions provided for in this rule do not present an unreasonable risk of injury to health or the environment. The following facts support this conclusion.

1. Although the number of processes that inadvertently generated PCBs may be large, the total quantity of such PCBs is estimated to be less than 100,000 pounds per year. Of this estimated total, only 1,000 pounds are expected to enter the environment yearly. In contrast, it is estimated that 10 million pounds entered the environment annually before PCB controls were instituted. It is also estimated that there are currently 150,000,000 pounds of PCBs that are currently present in the environment as free PCBs.

2. This rule will save society the enormous costs of instituting a ban on low level concentrations of inadvertently generated PCBs. The rule does impose recordkeeping and reporting burdens; however, the larger burdens imposed on industry by the prohibitions of section 6(e)(3), in particular the annual exemption process with its uncertainties, are avoided.

3. Monochlorinated and dichlorinated biphenyls are not as persistent in the environment as other PCBs. A measure of persistence in humans is the level of a substance found in adipose tissue; monochlorinated and dichlorinated biphenyls have not been found in adipose tissue. Further, EPA estimates that these discounting factors are likely to save industry \$800 thousand to \$4.7 million yearly. Therefore, the discounting factors established in this rule will not present unreasonable risks to human health or the environment.

4. EPA determined that none of the realistic hypothetical exposures were significant, especially when compared to the 150,000,000 pounds of PCBs already existing in the environment. When those hypothetical situations showing a high exposure were reviewed, EPA found that these hypothetical exposures overstate the actually expected exposures. Therefore, EPA concludes that the risks associated with these exposure situations are not unreasonable.

EPA is setting a lower, more protective concentration limit of 5 ppm PCBs in the components of detergent bars based on the high exposure potential of these products. This limit is more protective of consumers who are often unaware of potential hazards from exposure to chemicals in consumer use products.

5. EPA has also determined that exposure to recycled PCBs at the levels excluded by this rule are of minimal significance; therefore, the risks associated with these exposures are not unreasonable.

6. The recordkeeping and reporting requirements set in this rule provide EPA with a means of accounting for major releases of inadvertent PCBs, and for reassessing the findings in this rule, if necessary.

7. In general, substitutes are not reasonably available for products contaminated with low level PCBs and the processes that generate these PCBs cannot be cost-effectively modified to prevent the formation of any PCBs.

8. Small companies would benefit from this rule and the rule could provide some impetus to technological innovation in the chemical industry.

#### *1. Disposal Requirements*

In the May 1979 PCB Ban Rule, EPA concluded generally that PCBs at levels of 50 ppm or greater must be disposed of in accordance with the requirements of 40 CFR Part 761. The 50 ppm cutoff was a practical level which would allow EPA to reasonably administer TSCA and attain the objectives of section 6(e) of TSCA (44 FR 31516). Today's rule does

not deal with the regulatory cutoff for disposal of PCBs established in the PCB Ban Rule except for authorizing discounting factors for inadvertently generated monochlorinated and dichlorinated biphenyls. The discounting factors do not apply to any other PCBs regulated under TSCA.

Suggestion has been made that EPA take regulatory action to resolve issues relating to disposal regulations. Concern has been expressed with the 50 ppm cutoff for PCB disposal, including the fact that waste oil containing less than 50 ppm PCBs may be burned as fuel. EPA notes that, while legitimate concerns may be raised about the disposal regulations, this proceeding is not the proper forum to deal with those issues. In this proceeding, EPA is dealing only with issues arising from the *EDF v. EPA* lawsuit. These issues did not relate to the disposal regulations.

#### *J. Recordkeeping, Certification, and Reporting*

The consensus proposal would have required manufacturers to meet certain recordkeeping, certification, and reporting requirements. In the proposed rule, EPA adopted these requirements with minor modifications. Today's rule adopts the requirements proposed in the December 8, 1983, Federal Register notice.

Today's rule requires manufacturers who intend to take advantage of this exclusion, to notify EPA of products leaving the manufacturing site or imported products that contain greater than 2 micrograms of PCBs per gram of product ( $\mu\text{g/g}$ ) for any resolvable gas chromatographic peak (roughly 2 ppm). These reports must include the number, type, and location of excluded manufacturing processes. In addition, these reports must include a certification, signed by an appropriate corporate official, that: (1) The manufacturer is in compliance with all requirements of the regulation, including requirements for products, air, and water releases, and process waste disposal; (2) the determination of compliance is based on actual monitoring or on a theoretical assessment; and (3) monitoring data or the theoretical assessment is maintained. EPA intends to use the information required under this rule in developing an enforcement strategy and compliance monitoring program. These reports must be filed with EPA by October 1, 1984 or within 90 days of starting up a process or commencing importation of PCBs. These reports must be repeated whenever chemical process conditions are significantly modified to make the previous reports invalid.

Manufacturers who wish to take advantage of the exclusion must also report to the Agency if they are releasing more than 10 pounds of PCBs to air or water annually. Furthermore, manufacturers must report the total quantity of PCBs in products leaving the site of an excluded manufacturing process in any calendar year when the total production quantity exceeds 0.0025 percent of that site's rated capacity for such manufacturing processes. Importers must report to EPA whenever the quantity of PCBs imported in any calendar year exceeds 0.0025 percent of the average total quantity of product containing PCBs imported by the importer between 1978 and 1982.

Reports of theoretical analyses or actual monitoring must be kept for seven years or three years after the process ceases, whichever is shorter. Reports of theoretical assessments must include a description of the reactions generating PCBs, levels generated, and levels released. The basis for these estimates, as well as the names and qualifications of personnel preparing the assessment, must be included in the report. Monitoring reports must include the data, the method of analysis, quality assurance plan, name of analysts, the date and time of the analysis, the identification of the sample matrix, and the lot numbers for the sample.

A report to EPA will not be required for those PCBs in air, waste, and products below to LOQ, as established under the Closed and Controlled Waste Processes Manufacturing Rule. Generally, a report will not be required for those PCBs in water below the LOQ. However, under certain conditions PCBs could be released at concentration levels below the practical LOQ, but still result in elevated levels of total PCBs. This would occur if the discharges containing the low level PCBs are released at very high volumes. In light of the fact, theoretical assessments that predict a plant will release more than 10 pounds of PCBs annually in the water discharges must be submitted to EPA, even if PCBs are not quantitated in the discharges during monitoring.

Since CMA, EDF, and NRDC jointly recommended the basic recordkeeping, certification, and reporting requirements in this rule, EPA believes that these reporting requirements do not present an unreasonable burden on the regulated industry. The recordkeeping, certification, and reporting requirements have been incorporated in §§ 761.185, 761.187, and 761.193 of this rule.

Substances that are covered by this rule and are exported or imported are also subject to the exporting and

importing requirements of TSCA sections 12(b) and 13. EPA regulations interpreting section 12(b) requirements appear at 40 CFR Part 707. Imported products are covered by TSCA section 13 certification requirements at 19 CFR 12.118 through 12.127 and 127.8 (amended), (48 FR 34734, August 1, 1983). EPA's policy in support of these requirements appears at 40 CFR Part 707 (48 FR 55462, December 13, 1983).

#### K. Quantitation of PCB Concentration Levels

##### 1. Analytical Chemistry Methodology

The consensus proposal recommends that the analytical chemistry methods developed for the Closed and Controlled Waste Manufacturing Processes Rule by used in determining the non-Aroclor PCB concentration level in particular media. EPA agrees with CMA, EDF, and NRDC that the analytical chemistry methodology developed for the Closed and Controlled Waste Manufacturing Processes Rule is appropriate under this rule. Thus, the PCB analytical chemistry methodology that will be used for non-Aroclor PCBs in determining compliance with today's rule will be the Closed and Controlled Waste Manufacturing Processes Rule guidance that was set forth in the document entitled "Analytical Methods for By-Product PCBs—Preliminary Validation and Interim Methods."

The analytical chemistry guidance document presents methods for chemically analyzing inadvertently generated PCBs in commercial products, product waste streams, water dischargers, and air. These analytical chemistry methods are based on a determination of quantities of PCBs using capillary gas chromatography/electron impact mass spectrometry (CGC/EIMS). This analytical chemistry methodology for commercial products and product waste streams relies heavily on a strong quality assurance program.

Several comments on the use of different, more Aroclor-sensitive analytical chemistry methods in water were submitted in response to the proposed Uncontrolled PCBs Rule. EPA recognizes that there is a specific analytical chemistry methodology to determine Aroclor PCB concentrations in water. This analytical chemistry methodology is a test method published by the EPA for Organochlorine Pesticides and PCBs, referred to as Method 608. This method uses gas chromatography/electron capture (GC/EC) to analyze for Aroclor PCBs while the method for non-Aroclor PCBs uses CGC/EIMS.

GC/EC is the more sensitive method. It establishes chemists to measure at very low levels specific quantities of a limited number of PCB compounds with a highly recognizable pattern (Aroclor PCBs). On the other hand, CGC/EIMS is a more specific method. Using CGC/EIMS, a chemist can confirm the actual presence of a great number of different PCB compounds, but cannot specify quantities at the very low concentrations possible by using Method 608. Since Aroclor PCBs have more easily recognizable patterns than non-Aroclor PCBs, the issue of specificity is not as crucial as with non-Aroclor PCBs. Therefore, the Agency believes that it is appropriate to utilize GC/EC in the chemical analysis of Aroclor PCBs.

##### 2. Sampling Scheme

EPA has developed a sampling technique for non-Aroclor PCBs that will be used by the Agency when it monitors for compliance during an enforcement inspection. This sequential sampling protocol bases the decision to take a further sample of the results on previous analyses. The advantage of sequential sampling is that early results will, in some cases, provide adequate evidence for a decision of compliance or noncompliance, and the expense of further testing can be avoided. Under this sampling protocol, only a few chemical analyses would be required to confirm non-Aroclor PCB levels in product, air, and water samples which are strongly compliant (very low PCB levels) or strongly noncompliant (very high PCB levels). Given this protocol, no more than seven samples would need to be analyzed.

This sampling scheme has been developed for non-Aroclor PCBs and will not be used for sampling Aroclor PCBs. Further information about the sequential sampling protocol is included in the support document entitled "Guidance Document on Sampling and Sample Selection for Uncontrolled PCBs."

##### 3. Establishing a Baseline for Measurement of PCBs

The lowest concentration of a substance that an analytical process can detect is referred to as the limit of detection (LOD). The lowest concentration of a substance that an analytical process can quantify with a known level of precision and which can be reproduced in repeated analyses is referred to as the limit of quantitation (LOQ). Thus, the baseline level for quantifying the total PCB concentration could be established at the LOD, the

LOQ, or at an arbitrary level between these values.

In the Closed and Controlled Waste Manufacturing Processes Rule, EPA selected the LOQ in establishing the numerical cutoffs instead of the LOD. At that time, EPA concluded that it may be impossible to confirm the identity of non-Aroclor PCBs at the LOD. EPA concluded that a PCB concentration at or near the LOQ is needed to confirm the identity of the chlorinated biphenyls for compliance monitoring purposes (47 FR 46984). EPA reaffirms these conclusions reached in the Closed and Controlled Waste Manufacturing Processes Rules. Therefore, EPA is establishing the baseline for quantitating PCBs at the LOQ.

EPA has considered the appropriate baseline to use for measuring Aroclor PCBs. The Agency has decided that for purposes of this regulation, the appropriate baseline for measuring Aroclor PCBs is also the LOQ, rather than the LOD.

In light of the need to select a single LOQ level which can be widely achieved, even in difficult matrices, these data lead EPA to conclude that a practical LOQ for all wastewaters is 3 µg/L. This level is reasonably within the range of levels demonstrated in interlaboratory validations on different kinds of wastewaters, and, in fact, allows for some increase in the method LOQ for less efficiently removed interferences. EPA also notes that, on a case-by-case basis, it will often be possible to achieve far lower LOQs for specific wastewaters. Such determinations would, however, be more appropriate for specific wastewaters and permit authorities than for this general PCB rule. For further information concerning this LOQ, refer to the support document "Practical Limit of Quantitation of EPA Method 608 for Use in Aroclor Analysis of All Wastewaters" (memo from J. Smith to S. Sterling).

##### III. Notice of Deferral of Action on PCB Exemption Petitions

In the Federal Register of November 1, 1983 (48 FR 50486), EPA proposed to grant 49 exemption petitions, deny 73 exemption petitions, and defer action on 50 exemption petitions that had been previously submitted to the Agency. The exemption petitions on which EPA proposed to defer action are to manufacture, process, or distribute in commerce substances or mixtures inadvertently contaminated with 50 ppm or greater PCBs.

EPA was aware that the ongoing PCB rulemaking described in Unit II of this

preamble would affect the disposition of certain exemption petitions. Some of the petitioners are engaged in activities that, because of the discounting for monochlorinated and dichlorinated biphenyls, involve concentrations of PCBs at levels below the new limits and, therefore, will no longer require exemptions. Other petitioners are engaged in activities that involve concentrations of PCBs at levels above the new limits and, therefore, will still require exemptions to continue their activities.

In the December 8, 1983 Federal Register notice on uncontrolled PCBs (48 FR 55076), EPA gave notice that it intended to defer action on 50 exemption petitions that may be affected by the Uncontrolled PCBs Rule. No comments were received on the proposed deferral of action for certain exemption petitions that may be affected by the Uncontrolled PCBs Rule. The Agency is hereby giving notice that it has deferred action on these exemption petitions.

After proposing the Uncontrolled PCBs Rule, EPA discovered that one of the petitions listed in the proposed rule did not deal with inadvertently generated PCBs. Since the disposition of that petition would not be affected by the exclusion for inadvertently generated and recycled PCBs, EPA has not included the petition (Honeywell, Inc., ME-51) in the listing of those petitions on which EPA is deferring action. Therefore, in today's notice, the Agency is deferring action on 49 exemption petitions.

Elsewhere in today's Federal Register, EPA is requesting additional comments on the 49 exemption petitions that would be affected by the Uncontrolled PCBs Rule. The 49 petitioners whose exemption petitions are affected by the Uncontrolled PCBs Rule are listed in that notice. As stated in that notice, the 49 petitioners must evaluate the Uncontrolled PCBs Rule and decide whether they still need exemptions to continue their activities.

If a petitioner still needs an exemption, it must submit written comments renewing its exemption petition to continue the activity. These comments must be submitted no later than October 1, 1984. If an exemption petition is renewed, EPA will allow the petitioner to continue the activity for which it requests exemption until EPA has acted to grant or deny the exemption. If the exemption petition is not renewed, EPA will dismiss the exemption petition.

#### IV. Amendment to the 1979 Use Authorizations for PCBs in Hydraulic and Heat Transfer Fluid

##### A. Background

PCBs were manufactured for use in hydraulic and heat transfer systems in a variety of industries until 1972. The aluminum, copper, iron and steel forming industries used hydraulic systems with commercial Aroclor PCB fluid. PCBs in heat transfer systems were used in the inorganic chemical, organic chemical, plastics and synthetics, and petroleum refining industries. High PCB levels apparently remained in some systems until at least 1979. In addition, some unknown quantity of unused PCB fluids was probably kept by facilities after production ceased in 1972 and used for topping-off hydraulic and heat transfer systems.

Under section 6(e)(2) of TSCA, EPA may authorize the use of PCBs if the Agency finds that the use will not present an unreasonable risk of injury to health or the environment. In the PCB Ban Rule, EPA determined that the continued use of PCBs in hydraulic systems and heat transfer systems under certain conditions did not present an unreasonable risk. Therefore, in 1979, EPA authorized the non-totally enclosed use of PCBs at concentrations of 50 ppm or greater in hydraulic systems and in heat transfer systems (40 CFR 761.30 (d) and (e)). These use authorizations expire on July 1, 1984. In promulgating these use authorizations, EPA assumed that the conditions of those authorizations, which required refilling with non-PCB fluids, would reduce the PCB concentration levels in those systems to below 50 ppm by July 1, 1984.

With the overturning of the 50 ppm regulatory cutoff as a consequence of *EDF v. EPA*, the status of heat transfer systems and hydraulic systems with less than 50 ppm PCBs will be placed in doubt after July 1, 1984. EPA is clarifying the status of these systems in today's rule by authorizing the use of PCBs in these systems at concentrations of less than 50 ppm for their remaining useful lives. Systems with more than 50 ppm PCBs are unlawful after July 1, 1984. Under this rule, hydraulic and heat transfer systems cannot be filled (i.e., "topped off") with fluids containing 50 ppm or greater of PCBs. In addition, EPA is requiring that workers wear protective gloves under circumstances which would most likely lead to dermal exposure.

To determine whether a risk from PCB use is unreasonable, EPA balances the probability that harm will occur from the use against the benefits to society of

the authorized use. In determining whether these uses of PCBs at concentrations of less than 50 ppm presented unreasonable risks, EPA considered the effects of PCBs on health and the environment, including the magnitude of PCB exposure to humans and the environment; the benefits of using PCBs; the availability of substitutes for PCB uses; and the economic impact resulting from the rule's effect upon the national economy, small business, technological innovation, the environment, and human health. EPA proposed that the use of PCBs at levels of less than 50 ppm be continued for heat transfer and hydraulic systems.

EPA has determined that the use of PCBs in hydraulic and heat transfer fluid at concentrations of less than 50 ppm under certain circumstances does not present an unreasonable risk of injury to human health or the environment. Therefore, EPA is amending the PCB Ban Rule to authorize for the remaining useful lives of these systems the use of PCBs in hydraulic and heat transfer fluid at concentrations of less than 50 ppm provided that workers wear protective gloves whenever performing certain high exposure tasks.

##### B. Human Health and Environmental Risks

In determining whether to amend § 761.30 (d) and (e), EPA generated exposure and risk assessments for these uses of PCBs. A review of the general methodology for exposure and risk assessments, and a general analysis of the health and environmental effects of PCBs, are included under Unit II of this preamble. Information related specifically to the use of PCB fluids in hydraulic and heat transfer systems is described below. Further details concerning the exposure assessment for these uses are included in Volume IV of the support document entitled "Exposure Assessment for Incidentally Produced Polychlorinated Biphenyls."

Two categories of factors are particularly important to the evaluation of risk for these uses of PCBs: (1) The estimated contamination level, number, and size of PCB-contaminated hydraulic and heat transfer systems at the expiration deadline for these uses of PCBs under the PCB Ban Rule; and (2) the estimated number of workers potentially exposed to PCBs from contaminated systems during a period of exposure assumed to be 38.5 years. EPA inspection data were primarily used for developing estimates for these key factors.

Worker exposure to leaked PCBs from heat transfer and hydraulic systems may occur through both inhalation and dermal absorption during machine operation and during maintenance and repair operations. EPA has estimated the maximum inhalation exposure to PCBs that volatilize from the leaked hydraulic or heat transfer fluid. The exposure assessment of PCB fluid that has volatilized from these systems includes considerations of evaporation rates, emission rates, "downwind" concentrations, and annual inhalation. These annual inhalation estimates have been developed for worker exposure during 40 hours per week and 48 weeks per year.

Occupational dermal exposure from these uses of PCBs has been calculated from several variables. These variables include annual PCB dermal exposure, the duration of exposure, the frequency of exposure, the PCB exposure level, the skin area exposed, the absorption rate of PCBs through the skin, liquid thickness on skin, the density of liquid, and the PCB concentration in the liquid.

Using these exposure calculations for machine operations, and maintenance and repair workers, EPA determined that the carcinogenic risk from the long-term dermal and inhalation exposure to PCBs in hydraulic and heat transfer systems is very low. However, the hypothetical dermal absorption situations may have a higher risk because of higher exposures. In evaluating the risks from exposure to PCBs in hydraulic and heat transfer systems, EPA assumed a constant 50 ppm exposure each workday for a period of 38.5 years. These assumptions represent a worst-case; therefore, the estimated exposures are probably overstated.

EPA believes that it is necessary to protect workers from the higher dermal exposures presented in this assessment. EPA believes that the highest occupational dermal exposures result from actual maintenance of the heat transfer and hydraulic systems. To mitigate these exposures, EPA has added a requirement to this use authorization that workers are provided with and wear protective gloves whenever performing certain high exposure tasks. EPA has reviewed information on protective materials. Based on PCB break-through times for different materials, EPA has determined that viton elastomer is the only material that will adequately protect workers.

These use authorizations for heat transfer and hydraulic systems require owners to provide and workers to wear viton elastomer gloves whenever doing work on these systems that present a

high potential exposure to PCBs. EPA believes that maintenance work on these systems presents a high potential exposure.

### C. Regulatory Impact Analysis

EPA has developed a regulatory impact analysis for the reauthorization of these uses of PCBs. In this analysis EPA has evaluated the various regulatory options by comparing the total and incremental costs for achieving different PCB concentration levels with the total and incremental pounds of PCBs removed in order to comply with each concentration level. Cost estimates were determined for average hydraulic and heat transfer systems attaining compliance with the various draining, fluid replacement, testing, and disposal requirements in the current PCB regulations in § 761.30 (d) and (e) at each concentration level. In addition, EPA has prepared cost estimates for requiring the use of protective gloves.

In its Regulatory Impact Analysis (RIA), EPA considered three regulatory options: (1) Reauthorizing the use of PCBs in these systems at a 25 ppm concentration level; (2) reauthorizing the use of PCBs in these systems at PCB levels greater than 50 ppm; and (3) reauthorizing the use of PCBs in these systems at a 50 ppm concentration level.

In evaluating these regulatory options, EPA considered the costs involved in a mandatory removal of PCBs from hydraulic and heat transfer systems to concentration levels of less than 25 ppm. Mandatory immediate removal of PCBs in these systems to levels of less than 25 ppm would severely affect significant segments of the metal forming, die-casting, chemical, plastics and synthetics, and petroleum refining industries. In addition, technological factors may prevent an undetermined percentage of hydraulic and heat transfer systems from achieving an elimination of PCB residues below a 25 ppm concentration level. For reasons related to the internal geometry as well as operating and design characteristics of hydraulic and heat transfer systems, PCB residues tend to persist despite complete draining and refilling. Finally, EPA has concluded that an immediate removal of contaminated systems is not necessary to safeguard human health or the environment from high level risks arising from these uses of PCBs.

EPA has determined that tightening the standard from 50 ppm to 25 ppm would result in approximately 2,300 pounds of PCBs removed from the environment at an estimated cost of approximately \$103 million. EPA also has determined that relaxing the standard from 50 ppm to 100 ppm would

result in an estimated additional 4,000 pounds of PCBs in the environment. The 50 ppm standard would not impose an additional cost over the 1979 PCB Ban since that rule established a requirement that all heat transfer and hydraulic systems reduce PCB levels below 50 ppm by July 1, 1984.

EPA has balanced the cost of these options with the risks from exposure to humans and the environment. While the 100 ppm option is less costly than either the 25 or 50 ppm option, it is less protective of human health and the environment. Conversely, the 25 ppm option results in a lower risk to human health and the environment at a high cost.

EPA received a number of comments on the proposed PCB use authorization for heat transfer and hydraulic fluid. These comments argued for a use authorization at levels between 25 and 100 ppm PCBs, the levels EPA discussed in the proposed rule. No commenters argued for a significantly higher or lower use authorization. Given the EPA analysis described above, the fact that numerous persons have been able to reach a 50 ppm level in their heat transfer and hydraulic fluids, and the fact that comments advocated a range of 25 to 100 ppm, EPA concludes that 50 ppm is reasonable and is setting its use authorization accordingly. EPA also believes that this reauthorization at 50 ppm PCBs would impose minimal additional costs incurred under the use conditions set in the PCB Ban Rule. The minimal additional costs are imposed by the requirement that workers wear protective gloves.

EPA is aware that the total costs estimated in the RIA for lowering the PCB concentration levels in those heat transfer and hydraulic systems that are above 50 ppm are about an order of magnitude greater than the total costs originally projected in 1979 (44 FR 31534). Despite this large difference in total costs, there are only minor differences between the unit cost estimates underlying the 1979 and the present estimates. The differences in the compliance costs per machine developed for the 1984 analysis do not differ substantially from the 1979 estimates.

Data available to the Agency indicate that most systems can achieve a PCB concentration level of less than 50 ppm. In addition, EPA did not receive comments in this rulemaking that the 1979 economic analysis or the current economic analysis were substantially in error. The differences between costs estimated in the current RIA and the 1979 economic analysis apparently have

resulted from different assumptions in projecting the number of affected heat transfer and hydraulic systems, and the volume capacity of these systems.

#### *D. Availability of Substitutes for PCB Fluid in Hydraulic and Heat Transfer Systems*

There exist numerous substitutes for PCBs in hydraulic and heat transfer fluids that have been successfully used by firms to lower the PCB concentration levels in their contaminated systems to less than 50 ppm. Included among the chemical compounds used in non-PCB substitutes for hydraulic fluid are: (1) Phosphate esters; (2) water/glycol solutions; and (3) water/oil emulsions. Water/glycol-based products constitute the leading non-PCB substitutes. In addition, various non-PCB heat transfer fluids are available, such as: (1) Modified esters; (2) synthetic hydrocarbons; (3) polyaromatic compounds; (4) partially hydrogenated and mixed terphenyls; and (5) blends of diphenyls.

#### *E. No Unreasonable Risk Determination*

The Agency has concluded that the risks associated with these uses of PCBs at concentrations of less than 50 ppm are outweighed by the benefits of the continued use of contaminated hydraulic and heat transfer systems, and the costs that are avoided by not requiring the further removal of the PCBs remaining in these systems at less than 50 ppm after July 1, 1984. Therefore, EPA concludes that authorizing the use of PCBs in these systems at concentrations of less than 50 ppm does not present an unreasonable risk of injury to health or the environment for the following reasons:

1. The reauthorization of the use of PCBs in hydraulic and heat transfer fluid at a concentration level of less than 50 ppm with workers wearing protective gloves under high exposure conditions would adequately safeguard workers from risks to human health. In evaluating the exposure from long-term exposure to PCBs from contaminated systems at a 50 ppm level, EPA assumed daily exposure over a work life of approximately 38.5 years. Thus, while the exposures determined by EPA, particularly the dermal absorption, are relatively high, these exposures are overestimated. Furthermore, the requirement to wear gloves would further reduce these exposures.

2. This proposed reauthorization would impose minimal costs additional to those costs incurred under the use conditions in the PCB Ban Rule. According to the Agency's regulatory impact analysis, without any

reauthorization, the impact would be severe, since all contaminated systems could conceivably be removed from service and disposed of under a strict enforcement of the no use provision of section 6(e) of TSCA. The minimal additional costs are imposed by the requirement that workers wear protective gloves.

3. Compared to the option of authorizing use at a 25 ppm level, this reauthorization is more cost-effective. According to the Agency's regulatory impact analysis, compared with a concentration level of 50 ppm for these uses, a 25 ppm performance standard for affected systems would result in approximately 2,400 incremental pounds of PCBs removed from the environment at an estimated incremental cost of at least \$103 million.

4. Allowing the use of PCBs in contaminated hydraulic and heat transfer systems at a 50 ppm concentration level would avoid severe economic consequences for significant segments of the metal forming, die casting, chemical, plastics and synthetics, and petroleum refining industries.

5. There are adequate non-PCB hydraulic and heat transfer fluids for use in contaminated systems to lower the PCB concentration level at least to 50 ppm.

6. The elimination of PCBs from contaminated hydraulic and heat transfer systems may not be technologically feasible through existing retrofill technologies. For reasons related to the internal geometry, and operating and design characteristics of these systems, PCB residues tend to persist despite draining and retrofilling.

#### **V. Use Authorization for PCBs in the Compressors and the Condensate of Natural Gas Pipelines**

##### *A. Background*

In the 1979 PCB Ban Rule, EPA authorized the use of PCBs in the compressors of natural gas pipelines until May 1, 1980. EPA believed that by May 1, 1980, the PCB concentrations in these compressors could be reduced below 50 ppm. However, the PCB concentrations in some of these compressors could not be reduced to below 50 ppm by that date.

Under a compliance monitoring program instituted by EPA and the pipeline companies, the 28 compressors found to contain PCBs have been drained of the PCB liquid and retrofilled. The compliance monitoring program requires that these compressors be monitored following retrofill to ensure that PCB levels are maintained below 50

ppm. In all of the natural gas pipeline compressors found to contain PCBs, the PCB levels have been reduced below 50 ppm.

Liquids found in natural gas pipelines also have been found to contain elevated PCB levels. PCBs were first identified in liquid found in the gas pipelines in January 1981 when a PCB-containing oily condensate was found in the gas meters of some residential customers of a Long Island, New York, distribution company. Under EPA's direction 33 transmission companies undertook voluntary monitoring of this liquid and the natural gas to determine PCB concentrations. Twelve companies which found elevated PCB concentrations in this liquid continued to supply EPA with monitoring data and developed methods to lower the PCB concentrations in the liquid. In addition, EPA Regional Offices have been collecting data on natural gas distribution systems.

Natural gas pipeline liquid sampled under this monitoring program was found to contain PCBs in concentrations higher than 50 ppm. Thus, liquid in the natural gas pipelines as well as pipeline compressors were found to be contaminated with PCBs. EPA's Compliance Monitoring Staff began implementing remedial plans with four basic objectives: (1) To contain the contamination to limited areas of the transmission system; (2) to eliminate any further entry of PCBs into the system; (3) to remove remaining PCB contamination from these systems; and (4) to ensure proper handling of PCBs that were removed.

PCB contamination in the natural gas pipelines is thought to have occurred through several sources. The major sources of contamination are thought to be: (1) The lubricating oils used in natural gas pipeline compressors; (2) "fogging" of the lines with an oil vapor to minimize the entrainment of dust and other particles in the pipeline system; and (3) migration of PCBs from contaminated lines into other systems. By the 1960s, fogging of pipelines was virtually non-existent due to improved dry filters, and the replacement of cast-iron pipe with welded steel pipes. PCBs have not been used as lubricating oils in compressors since the 1970s.

Since the compliance monitoring program began, two companies have consistently found PCBs below the 50 ppm contamination level in the liquid found in natural gas pipeline systems. Ten transmission companies are still reporting under the compliance monitoring program. These companies are working to remove the remaining

PCB contaminated liquids from their lines.

With the overturning of the 50 ppm regulatory cutoff as a consequence of *EDF v. EPA*, the status of natural gas pipelines with less than 50 ppm PCBs in the compressors and in the pipeline liquid would be in doubt after the stay of the court's mandate is lifted. Several natural gas companies submitted comments on the proposed rule requesting an authorization for the continued use of PCBs in the compressors and in the liquid found in natural gas pipelines. EPA is responding to these comments by authorizing the use of PCBs in compressors and in the liquid found in natural gas pipelines at concentrations of less than 50 ppm.

EPA has determined that the use of PCBs in the compressors and in the liquid found in natural gas pipelines at concentrations of less than 50 ppm does not present an unreasonable risk of injury to human health or the environment. Therefore, EPA is authorizing this use of PCBs.

#### *B. Human Health and Environmental Risks*

The major potential human exposure to PCBs in the compressors and liquid found in natural gas pipelines is occupational. Occupational exposure is limited by several factors. First, natural gas is flammable and toxic; thus, natural gas pipelines are necessarily closed systems. Second, the natural gas pipeline liquid is removed from enclosed fixtures at specific collection points. Third, it appears from data submitted by gas transmission companies that draining of the natural gas pipeline liquid does not occur daily, but approximately monthly. Indeed, companies have often found no natural gas pipeline liquid at collection points during some periods of the year. Fourth, many companies require that employees wear protective clothing when handling this liquid. In order to insure that all workers are aware that this equipment contains PCBs, EPA is requiring that these compressors be marked with PCB labels as described at 40 CFR 761.40.

EPA has also examined monitoring data for indoor air concentrations of PCBs in homes using natural gas. Based on these data, the Agency has found no evidence that PCBs in the compressors or in the liquid of natural gas pipelines are entering customers' homes. Since exposure and toxicity are the two basic elements of risk, if there is no additional exposure to PCBs attributable to the natural gas, there will be no additional risk to the consumers.

The exposure assessment for PCBs in the compressors and liquids of natural

gas pipelines is included as Attachment Z (volume II) of the support document entitled "Final Report: Exposure Assessment for Incidentally Produced Polychlorinated Biphenyls." For further information concerning this exposure assessment, please consult that document.

#### *C. Economic Impact Analysis*

If the Agency does not authorize the use of PCBs in natural gas compressors and the liquids in natural gas pipelines, the result would be a ban on all contaminated compressors and natural gas pipelines after the stay of mandate is lifted by the court. Thus, in the absence of action by EPA, the industry must comply with a zero PCB level.

Only 28 remaining compressors are contaminated with PCBs. The costs of replacing all 28 compressors alone could be \$227 million, based on average capital and installation costs for 1978 through 1981. The cost of pipeline replacement is estimated to be at least \$30 billion, based on average capital and installation costs for 1978 through 1981. These costs do not take into account the unknown amount of distribution system pipeline that would be affected by a ban on PCBs. The combined replacement cost, system down-time, and reductions in natural gas supply during replacement activities would have serious implications for the national economy. Since a use authorization would avoid these costs, these estimates represent the benefits that would result from granting an authorization.

The only cost that would be incurred specifically from this rule would be the cost of labeling the remaining 28 compressors that contain PCBs. EPA is requiring that natural gas pipeline compressors be marked with the M<sub>1</sub> marker described at 40 CFR 761.40. This is the same marker that is currently in use on other PCB-containing equipment. The cost of this labeling is expected to be minimal.

#### *D. Availability of Substitutes for PCBs in Compressors and Natural Gas Pipelines*

As discussed in the background section of this Unit of the preamble, PCBs are no longer used for fogging natural gas pipelines or in compressors as lubricating oils. Several substitutes for PCB lubricating oils are available. These substitutes for PCB fluids have been used in natural gas pipeline compressors for many years.

#### *E. No Unreasonable Risk Determination*

The Agency has concluded that the risks associated with these uses of PCBs at concentrations of less than 50 ppm

are outweighed by the benefits of the continued use of compressors and liquids found in natural gas pipelines containing low levels of PCBs, and the costs that are avoided by not requiring the further removal of PCBs remaining in the compressors and pipeline liquids. Therefore, EPA concludes that authorizing the use of PCBs in these systems at concentrations of less than 50 ppm does not present an unreasonable risk of injury to health or the environment for the following reasons:

1. The authorization of the use of PCBs in compressors and in the liquids of natural gas pipelines at a concentration level of less than 50 ppm would adequately safeguard workers and consumers from risk to human health.

2. According to the Agency's economic impact analysis, the potential impact of no authorization would be severe, since all contaminated systems would conceivably have to be removed from service and disposed of under a strict enforcement of section 6(e) of TSCA.

3. There exist adequate substitutes for PCBs. PCB levels in contaminated systems will continue to decline below 50 ppm without further Agency action as PCB substitutes are used, and as equipment contaminated with PCBs is replaced.

#### **VI. Relationship to Other PCB Regulations**

The major focus of this rule is the control of the manufacture, processing, distribution in commerce, use, and disposal of PCBs that are not now regulated under other EPA rules. This unit reviews other EPA regulations to control PCBs, as well as other relevant Federal rules. Previous units of this preamble have already discussed the relationship of this rule to the Closed and Controlled Waste Manufacturing Processes Rule, and the regulations for disposal of PCBs under TSCA.

#### *A. Amendments to the PCB Electrical Equipment Rule*

Authorizations for the use and servicing of transformers, capacitors, electromagnets, and other electrical equipment with fluid containing 50 ppm or greater PCBs were promulgated in the Electrical Equipment Rule published in the *Federal Register* of August 25, 1982 (47 FR 37342). These authorizations amended the PCB Ban Rule, which included conditions for the servicing of transformers and electromagnets. No section of this rule affects any provision of the Electrical Equipment Rule.

### B. Regulations Under the Federal Pesticide and Food, Drug, and Cosmetic Statutes

Two Federal statutes that affect chemicals which may contain inadvertently generated PCBs are the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 321 *et seq.* If the manufacture, processing, distribution in commerce, or use of a substance is regulated under either FIFRA or FFDCA, the substance is not subject to regulation under TSCA insofar as the substance is manufactured, processed, or distributed in commerce for use solely as a pesticide, food, food additive, drug, cosmetic, or medical device. If a substance has multiple uses, only some of which are regulated under FIFRA or FFDCA, the manufacture, processing, distribution in commerce, and use of the substance for the remaining uses would come within the jurisdiction of TSCA.

The Agency has determined that raw materials, intermediates, and inert ingredients produced or used in the manufacture of pesticides are substances or mixtures that may be regulated under TSCA. Furthermore, while a chemical manufactured for use as a pesticide is regulated under FIFRA, a chemical that is manufactured for undetermined purposes is regulated under TSCA. Thus, PCBs that are unintentional impurities in a chemical that is for undetermined purposes are subject to this regulation from the time they are first manufactured until they are identified as part of a pesticide product.

EPA has determined that since the Food and Drug Administration (FDA) considers intermediates or catalysts to be components of a food, food additive, drug, cosmetic, or medical device regulated under FFDCA, chemicals used as intermediates or catalysts for these purposes are not regulated under TSCA. As soon as the FDA regulates a product, its manufacture, processing, or distribution in commerce solely for an FDA-regulated use is excluded from the jurisdiction of TSCA. Hence, no provisions of this rule will apply to the manufacture, processing, or distribution in commerce of intermediates or catalysts with PCBs generated as unintentional impurities solely for an FDA-regulated use.

### C. PCB Effluent Standards Under Section 307(a) of the Clean Water Act

Under section 307(a) of the Clean Water Act (CWA), 33 U.S.C. 1317, EPA promulgated final effluent standards for

the discharge of PCBs into navigable waters (40 CFR 129.105; 42 FR 6532, February 2, 1977) by manufacturers of intentionally produced PCB fluid (i.e., Aroclor products), manufacturers of electrical capacitors, and manufacturers of electrical transformers; and also prohibits the discharge of Aroclor PCBs as process wastes.

Today's regulation, in contrast, is restricted to inadvertently generated PCBs and certain processes that involve the use of recycled PCB-contaminated materials. Therefore, the TSCA and the CWA section 307 regulations cover different persons and different operations and have no effect on each other. Both regulations apply independently.

### D. PCB Effluent Limitation Guidelines, New Source Performance Standards, and Permits Under the CWA

Industrial wastewater discharges are generally regulated under the CWA, and not under TSCA. Today's rule necessitates that EPA determine what levels of PCBs may be discharged to water in manufacturing and recycling processes under TSCA. Otherwise, all PCB discharges to water would be banned as of the date the court's mandate in *EDF v. EPA* is issued (see Unit II.B of this preamble.). The deadline for promulgating today's TSCA regulation, however, presents a problem in coordinating this regulation with activities under the CWA. The Agency's resolution of this problem and the historical background are explained in this section.

Under the CWA, wastewater discharges are limited by a variety of technology-based effluent limitations and standards with more stringent water quality-based standards applied as needed. Therefore, CWA requirements may differ from those promulgated today. Such requirements may also be imposed by states or local governments instead of or in addition to those mandated by EPA.

The existence of less stringent CWA requirements at a particular facility does not relieve any discharger from the obligation to comply with today's TSCA rule. Similarly, nothing in the TSCA rule affects the authority or prevents EPA or any state or local government from applying or enforcing more stringent requirements to facilities regulated under the CWA or state or local law.

One ongoing CWA rulemaking is particularly relevant to this TSCA rule. On November 18, 1982, EPA proposed CWA effluent limitations guidelines based on "best available technology" (BAT) and "new source performance standards" (NSPS) which would limit

the discharge of Aroclor 1242 from mills in the deink subcategory of the pulp, paper, and paperboard point source category where fine and tissue papers are made (47 FR 52066). The proposed BAT effluent limitations (maximum for any one day) for Aroclor 1242 were: (1) 0.00014 kilograms per thousand kilograms (kg/kkg) where fine paper is produced; and (2) 0.00018 kg/kkg where tissue paper is produced. The proposed NSPS (maximum for any one day) for Aroclor 1242 were: (1) 0.00011 kg/kkg where fine paper is produced; and (2) 0.00014 kg/kkg where tissue paper is produced.

There are a number of coordination issues between this action under TSCA and regulation of wastewater discharges under the CWA. For example, the levels proposed under the CWA for pulp and paper mills were based on more extensive data relating just to deink mills, while the levels determined under today's rule are based on data applicable to all water wastestreams. Because the TSCA and CWA regulations would cover the same facilities in the case of deink mills, EPA needs time to coordinate data collected in the rulemaking proceeding for today's rule and the proceeding under the CWA. Additionally, since the November 1982 proposal, the EPA Industrial Environmental Research Laboratory in Cincinnati, Ohio has developed additional data for detecting and quantifying Aroclor in industrial effluents.

EPA would like to consider all these data in support of today's rule to determine whether more stringent limits under TSCA should be set for deink mill discharges. The Agency, however, must respond to the July 1, 1984 deadline. In today's rule, therefore, EPA is setting final limits for recycled PCBs based on the data in the TSCA record and on TSCA authority. These limits may be superseded by more stringent limits established under the CWA.

### VII. Judicial Review

Judicial review of this final rule may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA has decided to promulgate this rule for purposes of judicial review two weeks after publication in the *Federal Register*, as reflected in "DATES" in this notice.

## VIII. Official Rulemaking Record

In accordance with the requirements of section 19(a)(3) of TSCA, EPA is publishing the following list of documents, which constitutes the record of this rulemaking. However, public comments are not listed, because these documents are exempt from Federal Register listing under section 19(a)(3). A full list of these materials will be available on request from EPA's TSCA Assistance Office listed under "FOR FURTHER INFORMATION CONTACT."

## A. Previous Rulemaking Records

- (1) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Disposal and Marking Rule," Docket No. OPTS-68005, 43 FR 7150, February 17, 1978.
- (2) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions Rule," 44 FR 31514, May 31, 1979.
- (3) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs); Proposed Rulemaking for PCB Manufacturing Exemptions," Docket No. OPTS-66001, 44 FR 31564, May 31, 1979.
- (4) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Electrical Equipment," Docket No. OPTS-62015, 47 FR 37342, August 25, 1982.
- (5) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes," Docket No. OPTS-62017, 47 FR 46980, October 21, 1982.
- (6) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Amendment to Use Authorization for PCB Railroad Transformers," Docket No. OPTS-62020, 48 FR 124, January 3, 1983.
- (7) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, and Distribution in Commerce Exemptions," Docket No. OPTS-66008, 48 FR 50486, November 1, 1983.
- (8) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; PCBs in Concentrations Below Fifty Parts Per Million," Docket No. OPTS-62018, 46 FR 27619, May 20, 1981.

## B. Federal Register Notices

- (9) 43 FR 50905, November 1, 1978, USEPA, "Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act; Interim Procedural Rules for Polychlorinated Biphenyls (PCBs) Ban Exemption."
- (10) 44 FR 108, January 2, 1979, USEPA, "Polychlorinated Biphenyls (PCBs); Policy for Implementation and Enforcement."
- (11) 44 FR 31558, May 31, 1979, USEPA, "Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act; Interim Procedural Rules for Exemptions from the Polychlorinated Biphenyl (PCB) Processing and Distribution in Commerce Prohibitions."
- (12) 44 FR 31564, May 31, 1979, USEPA, "Polychlorinated Biphenyls (PCBs); Proposed Rulemaking for PCB Manufacturing Exemptions."
- (13) 44 FR 42727, July 20, 1979, USEPA, "Proposed Rulemaking for Polychlorinated Biphenyls (PCBs); Manufacturing Exemptions; Notice of Receipt of Additional Manufacturing Petitions and Extension of Reply Comment Period."
- (14) 45 FR 14247, March 5, 1980, USEPA, "Polychlorinated Biphenyls (PCBs); Statement of Policy on All Future Exemption Petitions."
- (15) 45 FR 29115, May 1, 1980, USEPA, "Polychlorinated Biphenyls (PCBs); Expiration of the Open Border Policy for PCB Disposal."

## C. Support Documents

- (16) CMA, EDF, NRDC, "Recommendation of the Parties for a Final EPA Rule on Inadvertent Generation of PCBs," April 13, 1983.
- (17) USEPA, OPTS, EED, "Draft Report: Estimation of Environmental Concentrations of Incidentally Generated Polychlorinated Biphenyls" (July 16, 1982).
- (18) USEPA, OPTS, EED, "Draft Report: Modeling of PCBs in Ground Water" (July 14, 1983).
- (19) USEPA, OPTS, EED, "Polychlorinated Biphenyls in Human Adipose Tissue and Mother's Milk" (November 12, 1982).
- (20) USEPA, OPTS, EED, "Exposure Assessment for Polychlorinated Biphenyls (PCBs): Incidental Production, Recycling, and Selected Authorized Uses, Volumes I-IV" (Final Report, May 2, 1984).
- (21) USEPA, OPTS, HERD, "Environmental Risk and Hazard Assessments for Various Isomers of Polychlorinated Biphenyls (Monochlorobiphenyl through Hexachlorobiphenyl and Decachlorobiphenyl)" (April 1984).

(22) USEPA, OPTS, ETD, "Regulatory Impact Analysis of the Final Rule Regulating Inadvertent PCB Generation from Uncontrolled Sources, Volumes I-II" (April 1984).

(23) USEPA, OPTS, ETD, "Regulatory Impact Analysis of PCB Use Authorizations for Hydraulic and Heat Transfer Systems" (June 1984).

(24) USEPA, OPTS, ETD, "Regulatory Impact Analysis of the PCB Use Authorization for Natural Gas Systems" (April 1984).

(25) USEPA, OPTS, EED, "Guidance Document on Sampling and Sample Selection for Uncontrolled PCBs" (1983).

(26) USEPA, OPTS, EED, "Estimation of Releases from Spills of Inadvertently Produced PCBs" (April 1982).

(27) USEPA, OPTS, EED, "Summary of Organic Chemical Product Classes Potentially Containing Inadvertently Generated PCBs" (December 1982).

(28) USEPA, OPTS, EED, "Organic Chemical Processes Leading a Generation of Incidental Polychlorinated Biphenyls" (February 10, 1983).

(29) USEPA, ORD, Environmental Monitoring and Support Laboratory, "TEST METHOD: Organochlorine Pesticides and PCBs—Method 608" (July 1982).

(30) USEPA, OPTS, EED, "Response to Comments on the Proposed Uncontrolled PCBs Rule," (June 1984).

(31) USEPA, OPTS, EED, Memorandum from John Smith (EED, DDB) to Sherry Sterling (EED, CRB), "Practical Limit of Quantitation of EPA Method 608 for Use in Aroclor Analysis of All Wastewaters" (June 5, 1984).

## IX. Executive Order 12291

Under Executive Order 12291, issued February 17, 1981, EPA must determine whether a rule is a "major rule" and, therefore, subject to the requirement that a regulatory impact analysis be prepared. EPA has concluded that this rule is not a major rule as the term is defined in section 1(b) of the Executive Order.

EPA made this determination on the findings that the annual effect of the rule on the economy would be less than \$100 million; it would not cause a major increase in costs or prices for any sector of the economy or for any geographic region; and it would not result in any significant adverse effects on competition, employment, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets. This rule will allow certain manufacturing and recycling of PCBs that would otherwise

be prohibited by section 6(e) of TSCA. In addition, this rule will allow the use of PCBs in certain hydraulic and heat transfer system, and in the compressors and in the condensate of natural gas pipelines. Therefore, this rule will reduce the overall costs and economic impact of section 6(e) of TSCA.

This rule excludes certain manufacturing processes from statutory requirements to file annual petitions for exemption under section 6(e)(3)(B) of TSCA. EPA has estimated in the regulatory impact analysis for this rule that resulting cost savings would range from \$155 million to \$1.6 billion. In addition, EPA is authorizing: (1) The use of PCBs in hydraulic and heat transfer fluid at concentrations of less than 50 ppm for the remaining useful lives of these systems, and (2) the use of PCBs in compressors and in the condensate of natural gas pipelines at concentrations of less than 50 ppm.

Although this rule is not a major rule, EPA has prepared to the extent possible, a Regulatory Impact Analysis using the guidance in the Executive Order. This rule was submitted to the Office of Management and Budget (OMB) prior to publication, as required by the Executive Order.

#### X. Regulatory Flexibility Act

Under section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator may certify that a rule will not, if promulgated have a significant impact on a substantial number of small entities and, therefore, does not require a regulatory flexibility analysis.

This rule excludes certain manufacturing processes from statutory requirements to file annual petitions for exemption under section 6(e)(3)(B) of TSCA. In addition, the rule will allow the indefinite use of PCBs in hydraulic and heat transfer fluid with concentration levels of less than 50 ppm, and in the compressors and condensate of natural gas pipelines at concentrations of less than 50 ppm.

For those persons who would qualify under the conditions of this rule, the effect will be the avoidance of costs associated with section 6(e) of TSCA, and EPA regulations at 40 CFR Part 761. Since EPA expects this rule to have no negative economic effect to any business entity, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

#### XI. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (PRA), 44 U.S.C. 3501 *et seq.*, authorizes the Director of the Office of

Management and Budget (OMB) to review certain information collection requests by Federal agencies. EPA has determined that the recordkeeping, reporting, and certification requirements of this proposed rule constitute a "collection of information," as defined in 44 U.S.C. 3502(4). The information collection requirements in this rule (summarized in Unit II of this preamble) have been submitted to the Office of Management and Budget (OMB) under section 3504(b) of the PRA. OMB has assigned the control number 2070-0008 to this final rule.

#### List of Subjects in 40 CFR Part 761

Hazardous materials, Labeling, Polychlorinated biphenyls, Recordkeeping and reporting requirements, Environmental protection. (Sec. 6, Pub. L. 94-469, 90 Stat. 2020 (15 U.S.C. 2605))

Dated: June 27, 1984.

Alvin L. Alm,  
Acting Administrator.

#### PART 761—[AMENDED]

Therefore, 40 CFR Part 761 is amended as follows:

1. In § 761.1, paragraphs (b) and (f) are revised to read as follows:

##### § 761.1 Applicability.

(b) This part applies to all persons who manufacture, process, distribute in commerce, use, or dispose of PCBs or PCB Items. Substances that are regulated by this rule include, but are not limited to, dielectric fluids, contaminated solvents, oils, waste oils, heat transfer fluids, hydraulic fluids, paints, sludges, slurries, dredge spoils, soils, materials contaminated as a result of spills, and other chemical substances or combination of substances, including impurities and byproducts and any byproduct, intermediate or impurity manufactured at any point in a process. Most of the provisions of this part apply to PCBs only if PCBs are present in concentrations above a specified level. For example, Subpart D applies generally to materials at concentrations of 50 parts per million (ppm) and above. Also certain provisions of Subpart B apply to PCBs inadvertently generated in manufacturing processes at concentrations specified in the definition of "PCB" under § 761.3. No provision specifying a PCB concentration may be avoided as a result of any dilution, unless otherwise specifically provided.

(f) Unless and until superseded by any new more stringent regulations issued under EPA authorities, or any permits or any pretreatment requirements issued by EPA, a state or local government that affect release of PCBs to any particular medium:

(1) Persons who inadvertently manufacture or import PCBs generated as unintentional impurities in excluded manufacturing processes, as defined in § 761.3, are exempt from the requirements of Subpart B of this part, provided that such persons comply with Subpart J of this Part, as applicable.

(2) Persons who process, distribute in commerce, or use products containing PCBs generated in excluded manufacturing processes defined in § 761.3 are exempt from the requirements of Subpart B provided that such persons comply with Subpart J of this part, as applicable.

(3) Persons who process, distribute in commerce, or use products containing recycled PCBs defined in § 761.3, are exempt from the requirements of Subpart B of this part, provided that such persons comply with Subpart J of this part, as applicable.

2. In § 761.3, the definitions of "closed manufacturing process" and "controlled waste manufacturing process" are removed the definitions of "excluded manufacturing process" and "recycled PCBs" are added, and the definitions of "PCB" and "PCB Item" are revised to read as follows:

##### § 761.3 Definitions.

"Closed manufacturing process" [Removed].

"Controlled waste manufacturing process" [Removed].

"Excluded manufacturing process" means a manufacturing process in which quantities of PCBs, as determined in accordance with the definition of inadvertently generated PCBs, calculated as defined, and from which releases to products, air, and water meet the requirements of (1) through (5) of this definition, or the importation of products containing PCBs as unintentional impurities, which products meet the requirements of (1) and (2) of this definition.

(1) The concentration of inadvertently generated PCBs in products leaving any manufacturing site or imported into the United States must have an annual average of less than 25 ppm, with a 50 ppm maximum.

(2) The concentration of inadvertently generated PCBs in the components of detergent bars leaving the manufacturing site or imported into the United States must be less than 5 ppm.

(3) The release of inadvertently generated PCBs at the point at which emissions are vented to ambient air must be less than 10 ppm.

(4) The amount of inadvertently generated PCBs added to water discharged from a manufacturing site must be less than 100 micrograms per resolvable gas chromatographic peak per liter of water discharged.

(5) Disposal of any other process wastes above concentrations of 50 ppm PCB must be in accordance with Subpart D of this part.

"PCB" and "PCBs" means 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 substance. Refer to § 761.1(b) for applicable concentrations of PCBs. PCB and PCBs as contained in PCB items are defined in § 761.3. For any purposes under this Part, inadvertently generated non-Aroclor PCBs are defined as the total PCBs calculated following division of the quantity of monochlorinated biphenyls by 50 and dichlorinated biphenyls by 5.

"PCB Item" is defined as any PCB Article, PCB Article Container, PCB Container, or PCB Equipment, that deliberately or unintentionally contains or has a part of it any PCB or PCBs.

"Recycled PCBs" are defined as those intentionally manufactured PCBs which appear in the processing of paper products or asphalt roofing materials as PCB-contaminated raw materials and which meet the requirements of (1) through (5) of this definition.

(1) The concentration of Aroclor PCBs in paper products leaving any manufacturing site or imported into the United States must have an annual average of less than 25 ppm with a 50 ppm maximum.

(2) There are no detectable concentrations of Aroclor PCBs in asphalt roofing materials.

(3) The release of Aroclor PCBs at the point at which emissions are vented to ambient air must be less than 10 ppm.

(4) The amount of Aroclor PCBs added to water discharged from a processing site must at all times be less than 3 micrograms per liter ( $\mu\text{g}/\text{l}$ ) for total Aroclors (roughly 3 parts per billion (3 ppb)).

(5) Disposal of any other process wastes above concentrations of 50 ppm PCB must be in accordance with Subpart D of this part.

3. In § 761.20 the fourth sentence of the introductory text, paragraphs (a), (b)(1) and (b)(2), the introductory text of paragraph (c), and paragraphs (c)(1) and (c)(2) are revised; and paragraph (c)(4) is added to read as follows:

#### § 761.20 Prohibitions.

\*\*\* In addition, the Administrator hereby finds, under the authority of section 12(a)(2) of TSCA, that the manufacture, processing, and distribution in commerce for export from the United States of PCBs at concentrations of 50 ppm or greater and of PCB Items with PCB concentrations of 50 ppm or greater presents an unreasonable risk of injury to health within the United States.

(a) No person may use any PCB, or any PCB Item regardless of concentration, in any manner other than in a totally enclosed manner within the United States unless authorized under § 761.30, except that an authorization is not required to use those PCBs or PCB Items resulting from an excluded manufacturing process or recycled PCBs defined in § 761.3, provided all applicable conditions of § 761.1(f) are met.

(1) No person may manufacture PCBs for use within the United States or manufacture PCBs for export from the United States without an exemption, except that an exemption is not required for PCBs manufactured in an excluded manufacturing process as defined in § 761.3, provided that all applicable conditions of § 761.1(f) are met.

(2) PCBs at concentrations less than 50 ppm may be imported or exported for purposes of disposal.

(c) No person may process or distribute in commerce any PCB, or any PCB Item regardless of concentration, for use within the United States or for export from the United States without an exemption, except that an exemption is not required to process or distribute in commerce PCBs or PCB Items resulting from an excluded manufacturing process as defined in § 761.3, or to process or distribute in commerce recycled PCBs as defined in § 761.3 provided that all applicable conditions of § 761.1(f) are met.

(1) PCBs at concentrations of 50 ppm or greater, or PCB Items with PCB concentrations of 50 ppm or greater, sold before July 1, 1979 for purposes other

than resale may be distributed in commerce only in a totally enclosed manner after that date.

(2) PCBs at concentrations of 50 ppm or greater, or PCB Items with PCB concentrations of 50 ppm or greater may be processed and distributed in commerce in compliance with the requirements of this Part for purposes of disposal in accordance with the requirements of § 761.60.

(4) PCBs, at concentrations of less than 50 ppm, or PCB Items, with concentrations of less than 50 ppm, may be processed and distributed in commerce for purposes of disposal.

4. In § 761.30, paragraphs (d), (e), and (i) are revised to read as follows:

#### § 761.30 Authorizations.

(d) *Use in heat transfer systems.* After July 1, 1984, intentionally manufactured PCBs may be used in heat transfer systems in a manner other than a totally enclosed manner at a concentration level of less than 50 ppm provided that the requirements of paragraphs (d) (1) through (7) of this section are met.

(1) Each person who owns a heat transfer system that ever contained PCBs at concentrations above 50 ppm must test for the concentration of PCBs in the heat transfer fluid of such a system no later than November 1, 1979, and at least annually thereafter. All test sampling must be performed at least three months after the most recent fluid refilling. When a test shows that the PCB concentration is less than 50 ppm, testing under this paragraph is no longer required.

(2) Within six months of a test performed under paragraph (d)(1) of this section that indicates that a system's fluid contains 50 ppm or greater PCB (0.005% on a dry weight basis), the system must be drained of the PCBs and refilled with fluid containing less than 50 ppm PCB. Topping-off with heat transfer fluids containing PCB concentrations of less than 50 ppm is permitted.

(3) After November 1, 1979, no heat transfer system that is used in the manufacture or processing of any food, drug, cosmetic or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, may contain transfer fluid with 50 ppm or greater PCB (0.005% on a dry weight basis).

(4) Addition of fluids containing PCB concentrations greater than 50 ppm is prohibited.

(5) Data obtained as a result of paragraph (d)(1) of this section must be

retained for five years after the heat transfer system reaches 50 ppm PCB.

(6) Each person who owns a heat transfer system that contains PCBs must provide workers with gloves made of viton elastomer to protect workers from dermal exposure to PCBs.

(7) All persons who maintain a heat transfer system must wear viton elastomer gloves while doing maintenance work on that system.

(e) *Use in hydraulic systems.* After July 1, 1984, intentionally manufactured PCBs may be used in hydraulic systems in a manner other than a totally enclosed manner at a concentration level of less than 50 ppm provided that the requirements in paragraphs (e) (1) through (7) of this section are met.

(1) Each person who owns a hydraulic system that ever contained PCBs at concentrations above 50 ppm must test for the concentration of PCBs in the hydraulic fluid of each system no later than November 1, 1979, and at least annually thereafter. All test sampling must be performed at least three months after the most recent fluid refilling. When a test shows that the PCB concentration is less than 50 ppm, testing under this paragraph is no longer required.

(2) Within six months of a test under paragraph (e)(1) of this section that indicates that a system's fluid contains 50 ppm or greater PCB (0.005% on a dry weight basis), the system must be drained of the PCBs and refilled with fluid containing less than 50 ppm PCB. Topping-off with hydraulic fluids containing PCB concentrations less than 50 ppm to reduce PCB concentrations is permitted.

(3) Addition of PCBs at concentrations of greater than 50 ppm is prohibited.

(4) Hydraulic fluid may be drained from a hydraulic system and filtered, distilled, or otherwise serviced in order to reduce the PCB concentration below 50 ppm.

(5) Data obtained as a result of paragraph (e)(1) of this section must be retained for five years after the hydraulic system reaches 50 ppm.

(6) Each person who owns a hydraulic system that contains PCBs must provide gloves made of viton elastomer to protect workers from dermal exposure to PCBs.

(7) All persons who maintain a hydraulic system that contains PCBs must wear viton elastomer gloves while doing maintenance work on that system.

(i) *Use in compressors and in the liquid of natural gas pipelines.* PCBs may be used indefinitely in the compressors and in the liquids of

natural gas pipelines at a concentration level of less than 50 ppm provided that they are marked in accordance with § 761.45(a).

5. In § 761.60, paragraphs (a)(1), the introductory text of (a)(4) and (a)(5), (a)(6), (b)(3), the introductory text of (b)(5), (b)(6), the introductory text of (c)(1), (c)(3), and (d)(1) are revised to read as follows:

**§ 761.60 Disposal requirements.**

(a) *PCBs.* (1) Except as provided in paragraphs (a) (2), (3), (4), and (5) of this section, PCBs at concentrations of 50 ppm or greater must be disposed of in an incinerator which complies with § 761.70.

(4) Any non-liquid PCBs at concentrations of 50 ppm or greater in the form of contaminated soil, rags, or other debris shall be disposed of:

(5) All dredged materials and municipal sewage treatment sludges that contain PCBs at concentrations of 50 ppm or greater shall be disposed of:

(6) When storage is desired prior to disposal, PCBs at concentrations of 50 ppm or greater shall be stored in a facility which complies with § 761.65.

(b) *PCB hydraulic machines.* PCB hydraulic machines containing PCBs at concentrations of 50 ppm or greater such as die casting machines may be disposed of as municipal solid waste or salvage provided that the machines are drained of all free-flowing liquid and the liquid is disposed of in accordance with the provisions of paragraph (a) of this section. If the PCB liquid contains 1000 ppm PCB or greater, then the hydraulic machine must be flushed prior to disposal with a solvent containing less than 50 ppm PCB under transformer solvents at paragraph (b)(1)(i)(B) of this section and the solvent disposed of in accordance with paragraph (a) of this section.

(5) *Other PCB Articles.* PCB articles with concentrations at 50 ppm or greater must be disposed of:

(6) *Storage of PCB Articles.* Except for a PCB Article described in paragraph (b)(2)(ii) of this section and hydraulic machines that comply with the municipal solid waste disposal provisions described in paragraph (b)(3) of this section, any PCB Article, with PCB concentrations at 50 ppm or greater,

shall be stored in accordance with § 761.65 prior to disposal.

(c) *PCB Containers.* (1) Unless decontaminated in compliance with § 761.79 or as provided in paragraph (c)(2) of this section, a PCB container with PCB concentrations at 50 ppm or greater shall be disposed of:

(3) Prior to disposal, a PCB container with PCB concentrations at 50 ppm or greater shall be stored in a facility which complies with § 761.65.

(d) *Spills.* (1) Spills and other uncontrolled discharges of PCBs at concentrations of 50 ppm or greater constitute the disposal of PCBs.

6. In § 761.65 the following introductory text is added at the beginning of the section:

**§ 761.65 Storage for disposal.**

This section applies to the storage for disposal of PCBs at concentrations of 50 ppm or greater and PCB Items with PCB concentrations of 50 ppm or greater.

7. In § 761.70, the following introductory text is added to the beginning of the section:

**§ 761.70 Incineration.**

This section applies to facilities used to incinerate PCBs required to be incinerated by this part.

8. In § 761.75, the following introductory text is added to the beginning of the section:

**§ 761.75 Chemical waste landfills.**

This section applies to facilities used to dispose of PCBs in accordance with the part.

9. In § 761.180, the following introductory text is added to the beginning of the section:

**§ 761.180 Records and monitoring.**

This section contains recordkeeping and reporting requirements that apply to PCBs, PCB Items, and PCB storage and disposal facilities that are subject to the requirements of the part.

10. In § 761.185, the section is revised and OMB control number 2070-0008 is added to read as follows:

**§ 761.185 Certification program and retention of records by importers and persons generating PCBs in excluded manufacturing processes.**

(a) In addition to meeting the basic requirements of § 761.1(f) and the

definition of excluded manufacturing processes at § 761.3, manufacturers with processes inadvertently generating PCBs and importers of products containing inadvertently generated PCBs must report to EPA any excluded manufacturing process or imports for which the concentration of PCBs in products leaving the manufacturing site or imported is greater than 2 micrograms per gram (2 µg/g, roughly 2 ppm) for any resolvable gas chromatographic peak. Such reports must be filed by October 1, 1984 or, if no processes or imports require reports at the time, within 90 days of having processes or imports for which such reports are required.

(b) Manufacturers required to report by paragraph (a) of this section must transmit a letter notifying EPA of the number, the type, and the location of excluded manufacturing processes in which PCBs are generated when the PCB level in products leaving any manufacturing site is greater than 2 µg/g for any resolvable gas chromatographic peak. Importers required to report by paragraph (a) of this section must transmit a letter notifying EPA of the concentration of PCBs in imported products when the PCB concentration of products being imported is greater than 2 µg/g for any resolvable gas chromatographic peak. Persons must also certify the following:

(1) Their compliance with all applicable requirements of § 761.1(f), including any applicable requirements for air and water releases and process waste disposal.

(2) Whether determinations of compliance are based on actual monitoring of PCB levels or on theoretical assessments.

(3) That such determinations of compliance are being maintained.

(4) If the determination of compliance is based on a theoretical assessment, the letter must also notify EPA of the estimated PCB concentration levels generated and released.

(c) Any person who reports pursuant to paragraph (a) of this section:

(1) Must have performed either a theoretical analysis or actual monitoring of PCB concentrations.

(2) Must maintain for a period of three years after ceasing process operations or importation, or for seven years, whichever is shorter, records containing the following information:

(i) *Theoretical analysis.*

Manufacturers records must include: the reaction or reactions believed to be generating PCBs; the levels of PCBs generated; and the levels of PCBs released. Importers records must include: the reaction or reactions

believed to be generating PCBs and the levels of PCBs generated; the basis for all estimations of PCB concentrations; and the name and qualifications of the person or persons performing the theoretical analysis; or

(ii) *Actual monitoring.* (A) The method of analysis.

(B) The results of the analysis, including data from the Quality Assurance Plan.

(C) Description of the sample matrix.

(D) The name of the analyst or analysts.

(E) The data and time of the analysis.

(F) Numbers for the lots from which the samples are taken.

(d) The certification required by paragraph (b) of this section must be signed by a responsible corporate officer. This certification must be maintained by each facility or importer for a period of three years after ceasing process operation or importation, or for seven years, whichever is shorter, and must be made available to EPA upon request. For the purpose of this section, a responsible corporate officer means:

(1) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation.

(2) The manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding \$25,000,000 (in second quarter 1980 dollars), if authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

(e) Any person signing a document under paragraph (d) of this section shall also make the following certification:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate information. Based on my inquiry of the person or persons directly responsible for the gathering information, the information is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for falsifying information, including the possibility of fines and imprisonment for knowing violations.

Dated: \_\_\_\_\_

Signature: \_\_\_\_\_

(f) This report must be submitted to the U.S. Environmental Protection Agency, Document Processing Center, P.O. Box 2070, Rockville, MD 20852, Attention: PCB Notification. This report must be submitted by October 1, 1984 or

within 90 days of starting up processes or commencing importation of PCBs.

(g) This certification process must be repeated whenever process conditions are significantly modified to make the previous certification no longer valid.

(Approved by the Office of Management and Budget under control number 2070-0008)

11. Section 761.187 and OMB control number 2070-0008 are added to read as follows:

**§ 761.187 Reporting importers and by persons generating PCBs in excluded manufacturing processes.**

In addition to meeting the basic requirements of § 761.1(f) and the definition of excluded manufacturing process at § 761.3, PCB-generating manufacturing processes or importers of PCB-containing products shall be considered "excluded manufacturing processes" only when the following conditions are met:

(a) Data are reported to the EPA by the owner/operator or importer concerning the total quantity of PCBs in product from excluded manufacturing processes leaving any manufacturing site in any calendar year when such quantity exceeds 0.0025 percent of that site's rated capacity for such manufacturing processes as of October 1, 1984; or the total quantity of PCBs imported in any calendar year when such quantity exceeds 0.0025 percent of the average total quantity of such product containing PCBs imported by such importer during the years 1978, 1979, 1980, 1981 and 1982.

(b) Data are reported to the EPA by the owner/operator concerning the total quantity of inadvertently generated PCBs released to the air from excluded manufacturing processes at any manufacturing site in any calendar year when such quantity exceeds 10 pounds.

(c) Data are reported to the EPA by the owner/operator concerning the total quantity of inadvertently generated PCBs released to water from excluded manufacturing processes from any manufacturing site in any calendar year when such quantity exceeds 10 pounds.

(d) These reports must be submitted to the U.S. Environmental Protection Agency, Document Processing Center, P.O. Box 2070, Rockville, Maryland 20852, Attention: PCB Notification.

(Approved by the Office of Management and Budget under control number 2070-0008)

12. Section 761.193 and OMB control number 2070-0008 are added to read as follows:

**§ 761.193 Maintenance of monitoring records by persons who import, manufacture, process, distribute in commerce, or use chemicals containing inadvertently generated PCBs.**

(a) Persons who import, manufacture, process, distribute in commerce, or use chemicals containing PCBs present as a result of inadvertent generation or recycling who perform any actual monitoring of PCB concentrations must maintain records of any such monitoring for a period of three years after a process ceases operation or importing ceases, or for seven years, whichever is shorter.

(b) Monitoring records maintained pursuant to paragraph (a) of this section must contain:

- (1) The method of analysis.
- (2) The results of the analysis, including data from the Quality Assurance Plan.
- (3) Description of the sample matrix.
- (4) The name of the analyst or analysts.
- (5) The date and time of the analysis.
- (6) Numbers for the lots from which the samples are taken.

(Approved by the Office of Management and Budget under control number 2070-0008)

[FR Doc. 84-17903 Filed 7-9-84; 8:45 am]

BILLING CODE 6560-50-M

**40 CFR Part 761**

[OPTS-62031A; TSH FRL-2590-2]

**Toxic Substances Control Act; Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions Use in Microscopy and Research and Development**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This final rule amends portions of an existing EPA rule concerning certain chemical substances known as polychlorinated biphenyls (PCBs). EPA is amending the PCB Ban rule, published in the *Federal Register* of May 3, 1979 (44 FR 31514) by: (1) Authorizing indefinitely the use of PCBs as mounting media in microscopy, (2) authorizing indefinitely the use of PCBs as immersion oils in low fluorescence microscopy, (3) authorizing indefinitely the use of PCBs as optical liquids, and (4) authorizing indefinitely the use of small quantities of PCBs for use in research and development. EPA has determined that these uses of PCBs do not pose unreasonable risks to public health or the environment. EPA is not

authorizing the use of PCBs as calibration standards.

**DATES:** These amendments shall be considered promulgated for purpose of judicial review under section 19 of the Toxic Substances Control Act (TSCA) at 1:00 p.m. Eastern Daylight Time on July 24, 1984. These amendments shall be effective on July 1, 1984.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 6(e) of the Toxic Substances Control Act (TSCA) generally prohibits the use of PCBs after January 1, 1978. The statute does, however, set forth two exceptions under which EPA may, by rule, allow a particular use of PCBs to continue. Under section 6(e)(2) of TSCA, EPA may allow PCBs to be used in a "totally enclosed manner." A "totally enclosed manner" is defined by TSCA to be "any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant, as determined by the Administrator by rule." TSCA also allows EPA to authorize the use of PCBs in a manner other than a totally enclosed manner if the Agency finds that the use "will not present an unreasonable risk of injury to health or the environment."

EPA promulgated a rule at 40 CFR Part 761, which was published in the *Federal Register* of May 31, 1979 (44 FR 31514), to implement section 6(e) (2) and (3) of TSCA. EPA authorized, among other provisions of this rule, the non-totally enclosed use of PCBs for 11 activities. These authorizations were for the following activities: (1) Servicing of electrical transformers, (2) use in and servicing of railroad transformers, (3) use in and servicing of mining equipment, (4) use in carbonless copy paper, (5) use in pigments, (6) servicing of electromagnets, (7) use in natural gas pipeline compressors, (8) use in hydraulic systems, (9) use in heat transfer systems, (10) use in small quantities for research and development, and (11) use in microscopy mounting medium.

In the May 31, 1979 PCB Ban Rule, EPA also excluded from regulation materials containing PCBs in concentrations under 50 parts per million (ppm), and determined that the

use of electrical transformers, capacitors, and electromagnets was "totally enclosed."

The Environmental Defense Fund (EDF) petitioned the U.S. Court of Appeals for the District of Columbia Circuit to review: (1) EPA's determination that the use of electrical transformers, capacitors, and electromagnets was totally enclosed, (2) EPA's decision to set a regulatory cutoff at 5 ppm, and (3) EPA's decision to authorize the continued use of the 11 non-totally enclosed uses of PCBs. On October 30, 1980, the Court invalidated the regulatory exclusion for PCB concentrations below 50 ppm and the determination that the use of transformers, capacitors and electromagnets was totally enclosed. However, the Court decided that there was substantial evidence in the record to support EPA's decisions on the 11 use authorizations. Thus, the Court upheld the 11 use authorizations (*Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 636 F.2d 1267).

Subsequent to the promulgation of the rule on May 31, 1979 and the 1980 Court decision, three of these use authorizations were amended. These amendments were promulgated for the use and servicing of PCBs in electrical equipment transformers, electromagnets, and railroad transformers. Of the remaining use authorizations, four expire on July 1, 1984: Heat transfer systems, hydraulic systems, microscopy as a mounting medium, and small quantities for research and development. The four use authorizations that expire on July 1, 1984, contain various conditions.

Section 761.30(d) authorizes the use of PCBs in heat transfer systems until July 1, 1984, subject to conditions regarding testing and requirements for reducing PCB concentrations. The authorization for the use of PCBs in hydraulic systems until July 1, 1984, in § 761.30(e) contains similar requirements for testing and reducing PCB concentrations until the PCB concentration in the equipment reaches 50 ppm. (Since the May 31, 1979 PCB Ban Rule established a regulatory cutoff at 50 ppm for the manufacture, processing, distribution in commerce, and use of PCBs, EPA essentially left unregulated heat transfer and hydraulic systems containing less than 50 ppm.)

The use authorization for the use of PCBs as a mounting medium in microscopy until July 1, 1984, in § 761.30(k), contains no special conditions or requirements. The use authorization for the use of small quantities of PCBs for research and

development until July 1, 1984, in § 761.30(j), requires that PCBs used in this manner be originally contained in hermetically sealed, five-milliliter containers, and that they be used only for purposes of scientific experimentation on or chemical analysis of PCBs.

In the *Federal Register* of November 17, 1983 (48 FR 52402), EPA proposed to amend the May 1979 use authorizations for the use of PCBs as mounting medium and the use of PCBs in small quantities for research and development. EPA proposed to authorize indefinitely the use of PCBs as mounting media in art and historic conservation, and to authorize indefinitely the use of small quantities of PCBs in research and development. EPA received 15 comments on the proposed use authorizations and held a public hearing on January 16, 1984 in Washington, D.C. At the hearing, three parties provided testimony on the proposed use authorizations.

In this final rule, EPA is amending the May 1979 use authorizations for the use of PCBs as a mounting medium in microscopy and the use in small quantities for research and development. EPA is authorizing the use of PCBs as mounting media in microscopy indefinitely, and, authorizing the use of small quantities of PCBs in research and development indefinitely. EPA is also issuing indefinite use authorizations for the use of PCBs in immersion oils for fluorescence microscopy, and the use of PCBs as optical liquids. EPA became aware of these uses of PCBs through public comments on the proposed rule and testimony supplied at the January 16, 1984 public hearing. Information was provided that indicated that there are no adequate substitutes for PCBs in these areas.

Comments submitted in response to the proposed rule also suggested that EPA consider authorizing the use of PCBs as calibration standards for refractometers. EPA has determined that there are adequate substitutes for PCBs for use as calibration standards for refractometers. Therefore, EPA is not authorizing this use of PCBs.

The second phase of rulemaking on the manufacture, processing, distribution in commerce, and use of PCBs in concentrations below 50 ppm was proposed in the *Federal Register* of December 8, 1983 (48 FR 55076). In this related rulemaking, EPA proposed to authorize indefinitely the use of heat transfer and hydraulic systems that contain less than 50 ppm PCBs.

## II. Summary of the Final Rule

EPA is authorizing the use of PCBs: (1) As a mounting medium in microscopy, (2) as an immersion oil in fluorescence microscopy, (3) as optical liquids, and (4) in small quantities for research and development. EPA is not authorizing the use of PCBs as calibration standards. This final rule modifies and clarifies some of the requirements discussed in the proposed rule because of information obtained during the public comment period and at the public hearing on the proposed rule.

Briefly, in the proposed rule EPA: (1) Authorized indefinitely the use of PCBs as a microscopic mounting medium in the field of art and historic conservation and (2) authorized indefinitely the use of small quantities of PCBs in research and development.

In response to comments received on the proposed rule, EPA has broadened the use authorization for the use of PCBs as a mounting medium in art and historic conservation to include the use of PCBs as a microscopic mounting medium in all fields of use. EPA is also authorizing the use of PCBs as an immersion oil in fluorescence microscopy and as optical liquids. Although EPA considered, as part of this rulemaking, authorizing the use of PCBs as calibration standards for refractometers, available information suggested that adequate non-PCB substitute materials are available for this use. Therefore, EPA is not authorizing the use of PCBs as calibration standards for refractometers.

Comments submitted in response to the proposed rule regarding the use of small quantities of PCBs as immersion oils, as optical liquids, and as calibration standards suggested that EPA consider authorizing these other apparently ongoing research-related uses of PCBs. Comments regarding these uses were accompanied by a request for EPA to expand existing use authorizations to include the use of PCBs as immersion oils in fluorescence microscopy, the use of PCBs as an optical liquid, and the use of PCBs as calibration standards for refractometers.

EPA determined that authorizing the use of small quantities of PCBs as immersion oils in fluorescence microscopy, the use of PCBs as optical liquids in scientific experimentation, and the use of PCBs as calibration standards for refractometers (as suggested in comments submitted in response to the proposed rule) would require separate determinations that these uses do not pose unreasonable risks to public health and the environment. EPA completed analyses

of these other uses and has made a determination that PCBs used as immersion oils in fluorescence microscopy and as optical liquids do not pose unreasonable risks to public health or the environment, and, is therefore issuing use authorizations for these specific uses as part of this final rule. EPA has also made a determination that adequate non-PCB substitutes exist for use as calibration standards for refractometers. Therefore, EPA is not issuing a new use authorization for this use.

## III. Use Authorizations

In order to authorize a use of PCBs under section 6(e)(2)(B) of TSCA, EPA must find that such use "will not present an unreasonable risk of injury to health or the environment." To determine whether a risk is unreasonable, EPA must balance the probability that harm will occur from the use, against the adverse effects on society of the proposed regulatory action. In determining whether an unreasonable risk is present, EPA has considered the following factors:

1. The effects of PCBs on human health and the environment.
2. The magnitude of PCB exposure to humans and the environment.
3. The benefits of using PCBs and the availability of substitutes for PCB uses.
4. The economic impact resulting from the rule's effect upon the national economy, small business, and technological innovation.

These factors are listed in section 6(c) of TSCA and are applicable to determinations concerning whether a chemical presents an unreasonable risk under section 6 (a) and (e) of TSCA.

The remaining units of this preamble will discuss these key factors in the unreasonable risk determinations made in this rule. Finally, they will present specific findings for the determinations that the use of PCBs as mounting media, low fluorescence immersion oil, as optical fluids, and in small quantities for research and development do not present unreasonable risks. The remaining units will also address EPA's decision not to authorize the use of PCBs as calibration standards for refractometers.

### A. Effects on Human Health and the Environment

In determining whether use authorizations are warranted, EPA first considered information regarding the effects of PCBs on human health and the environment. The effects of PCBs were described in various documents which were part of the rulemaking record for

the May 31, 1979 rule. EPA has reviewed this information, new information submitted to the Agency since 1979, as well as other recent literature on the effects of PCBs. The results of this analysis are presented in the document "Response to Comments on Health Effects on PCBs." Copies of this document are available through the TSCA Assistance Office (see "FOR FURTHER INFORMATION CONTACT"). Summaries of the Agency's conclusions in the areas of the health and environmental effects of PCBs are presented below.

### 1. Health Effects

Based upon available information, EPA has concluded that persons exposed to PCBs can develop chloracne. Although the effects of chloracne are reversible, EPA does not consider this effect of exposure to PCBs to be insignificant.

In addition to chloracne, EPA has identified reproductive effects, developmental toxicity, and oncogenicity as additional areas of concern. Effects in these areas have been identified in animal studies and are, therefore, considered to be effects which have the potential to be produced in humans. Available data show that some PCBs have the ability to alter reproductive processes in mammalian species, sometimes at doses that do not result in other signs of toxicity. Animal data indicate that prenatal exposure to PCBs can result in various degrees of developmental effects. Postnatal effects have also been demonstrated in immature animals following exposure to PCBs prenatally and via breast milk.

Furthermore, available animal studies suggest an oncogenic potential of PCBs (the degree of which would be dependent on exposure). Available epidemiological data are not adequate to confirm or negate the oncogenic potential in humans at this time. Although additional epidemiological research is needed in order to correlate human and animal data, EPA does not find any evidence to suggest that the animal data would not be predictive of human potential.

From available data, EPA believes that PCBs produce little or no mutagenic activity. However, more information is needed to draw a final conclusion on the potential mutagenicity of PCBs.

### 2. Environmental Effects

PCBs have been shown to affect the productivity of phytoplankton and the composition of phytoplankton communities. Further, deleterious effects on environmentally important freshwater invertebrates from PCBs

have also been demonstrated. PCBs have also been shown to impair reproductive success in both birds and mammals.

It has also been demonstrated that PCBs are toxic to fish at very low levels. The survival rate and the reproductive success of fish can be adversely affected in the presence of PCBs. Various sublethal physiological effects attributed to PCBs. Various sublethal physiological effects attributed to PCBs have been recorded in the literature. Abnormalities in fish bone development and reproductive organs have also been associated with exposure to PCBs.

EPA has concluded that PCBs can concentrate and be transferred in freshwater and marine organisms. Transfer up the food chain from phytoplankton to invertebrates, fish, and mammals can ultimately result in human exposure to PCBs through the consumption of PCB-containing food.

### B. Potential for Exposure to PCBs

Toxicity and exposure are the two basic components of risk. As indicated above, EPA believes that in addition to chloracne, based on animal data there is a potential for reproductive effects and developmental toxicity as well as oncogenicity in humans exposed to PCBs. EPA also believes that PCBs do present a hazard to the environment.

However, minimizing exposure to PCBs should minimize any potential risk. In determining if a particular use of PCBs presents an unreasonable risk, EPA assesses the potential for exposure of humans or the environment to PCBs as a result of the use. Further, as part of its analysis, EPA considers the need for regulatory requirements to reduce exposure or eliminate exposure associated with the use of PCBs.

#### 1. Exposure From the Use of PCBs as a Mounting Medium

PCBs, including Aroclor 1254, 1260, 5442 and 5460, have been used in microscopy since the 1930s. Although microscopists initially used quart samples of PCBs that were provided free of charge, eventually, several firms began developing and marketing PCBs as a microscope mounting medium.

In the field of microscopy, PCBs are used in art and historic conservation to preserve specimens permanently, and in the identification and preservation of small environmental, forensic, and industrial contaminant particles. PCBs were also used prior to 1979 in microscope immersion oils. The identification of these particles is based on the morphological and optical properties of these particles as they appear relative to the optical properties

of PCBs. EPA estimates that there are about 850 laboratories in which PCBs are used in the preparation of permanent slides. Assuming that there are one to three microscopists per laboratory, the size of the worker population potentially exposed to PCBs from this use ranges from 850 to 2,550.

In mounting a specimen, a particle is placed on a slide, a coverslip is placed over the particle, and a drop of PCBs is placed near the interface of the coverslip and the slide. The PCBs move beneath the coverslip through capillary action and the particle is thereby permanently mounted. The slide is prepared on a lightly heated surface (which increases the volatility of the PCBs and the potential for inhalation exposure during use), and excess PCBs are wiped from the preparation with a tissue (resulting in some potential for dermal exposure). A one ounce quantity lasts typically 3 to 5 years. EPA estimates that about 430 ounces of PCBs currently exist in laboratories and are being used as mounting media.

Although users are exposed to only small quantities of PCB mounting medium (less than one ounce per year per user), these products do contain high concentrations of PCBs. Thus, the use of PCBs for microscopic mounting does pose some level of risk to users. However, EPA marking regulations (40 CFR Part 761, Subpart C) require the labeling of containers, and microscopists who use PCBs are for the most part highly trained workers who are accustomed to working with PCBs as well as other potentially toxic materials. Because of the small quantities of PCBs used in this application and the highly trained nature of these workers, EPA expects that exposure to workers from this use is limited.

#### 2. Exposure From the Use of PCBs in Immersion Oils for Low Fluorescence Microscopy

Comments submitted in response to the proposed rule indicate that PCBs are useful as microscope immersion oils in medical research. These comments indicate that small amounts of PCB immersion oils with low auto-fluorescence are useful in cancer studies where fluorescence microscopy is used. The technique used in immersion microscopy involves placing a drop of immersion oil on the coverslip of a slide and lowering the objective lens of the microscope until it just touches the oil.

EPA is also aware of a medical diagnostic procedure that involves the use of microscope immersion oils. According to one source, examination of the nail-fold capillaries can provide

useful information in a variety of rheumatic disorders. The capillaries are best seen when a clear viscous liquid is applied to the skin surface, and microscope immersion oil is commonly used for this purpose. This technique is termed capillary microscopy.

Although PCB-containing immersion oil was used in many applications prior to the issuance of the May 1979 PCB Ban Rule, today, the only critical use of PCBs in immersion microscopy appears to be their use in fluorescence microscopy. EPA believes that the use of PCB immersion oil in capillary microscopy is not a critical use of PCBs. In fact, sources in the medical community (physicians and representatives of the American Medical Association) have indicated that many physicians and diagnosticians are unaware that some immersion oils even contain PCBs. This is because containers of PCB immersion oil produced prior to 1978 were not required to be labeled as containing PCBs. Since very small amounts of immersion oils are used per application, older supplies of this unlabeled material are still being used in medical laboratories. Physicians and representatives of the American Medical Association have indicated to EPA that PCB-free immersion oil is an adequate substitute for this use pattern.

Data submitted as part of the May 1979 rulemaking record indicate that technicians in hospital laboratories would spend about an hour per day using immersion microscopes. The 1970 census reportedly showed 119,308 employed laboratory technologists. The census also reportedly showed 55,000 biological scientists, many of whom may use immersion oils.

Comments submitted in response to the November 17, 1983 proposed rule suggest that following the issuance of the May 1979 PCB Ban Rule, 97 percent of users of immersion oils were able to switch to substitute materials. Of the approximately 5,229 remaining users, the comments further indicate that during the last few years, 97 percent of these users were able to switch to newly developed immersion oils. Based on these comments, and the data from the 1970 census, EPA believes that only 50 to 157 researchers now find PCB immersion oil useful for specialized fluorescence microscopy uses.

Although EPA estimates that less than 0.01 cubic centimeter (cc) of PCB immersion oil is used per application, the low fluorescence immersion oil reportedly contains 34 percent PCBs. Further, skin contact with immersion oil may be frequent, because lenses and slides used in immersion oil microscopy are wiped clean of excess oil with tissue

following the completion of laboratory studies. As was the case with the use of PCBs in microscope mounting medium, there is also some potential for inhalation exposure to PCBs from this use pattern because of the use of illuminators in conjunction with microscopes. The illuminators could serve as a heat source and increase the volatility of the PCBs.

In capillary microscopy the potential for significant exposure to PCBs is much greater because the oil is applied directly and intentionally to the skin of patients. Although small amounts of immersion oils are applied, given the expected high rate of dermal absorption of PCBs, intentional skin application may result in significant exposure to PCBs.

The use of PCB immersion oil in fluorescence microscopy requires only relatively small amounts of PCBs. Comments submitted in response to the proposed rule indicate that scientists and laboratory workers are highly trained and experienced in the handling of toxic chemicals. Further, the May 1979 PCB Ban Rule included marking regulations that require containers to be labeled as containing PCBs. Given the highly trained nature of these workers, the relatively small amounts of PCBs used per application, and the fact that products containing PCBs must be labeled as such, EPA has concluded that this use results in only a limited potential for exposure to PCBs.

Although the use of PCBs in capillary microscopy also requires only relatively small amounts of PCBs, given the expected high rate of dermal absorption of PCBs, intentional application to the skin may result in significant exposure to PCBs. EPA has concluded that the use of PCBs in capillary microscopy may result in significant exposure to PCBs.

### 3. Exposure From the Use of PCBs in Small Quantities for Research and Development

PCBs are used in toxicological and environmental testing. They are also used in analytical chemistry as "reference standards" for the analysis of unknown compounds that may contain PCBs.

These uses require only relatively small amounts of PCBs. Further, EPA marking regulations require containers to be labeled as containing PCBs. In addition, EPA regulations require PCBs used in small quantities for research and development to be hermetically sealed in five-milliliter containers. This volume restriction was instituted to ensure that the use of PCBs in research and development resulted in only limited exposure to PCBs.

Given the highly trained nature of laboratory workers and scientists, the small amounts of PCBs used, and the fact that products containing PCBs must be labeled as such, EPA has concluded that the use of small quantities of PCBs for research and development results in only a limited potential for exposure to PCBs.

### 4. Exposure From the Use of PCBs as Optical Fluids

According to comments received on the proposed rule, as is the case with the use of PCB low fluorescence immersion oil, the number of researchers utilizing PCBs as optical liquids is relatively small: About 50 researchers. These comments indicate that scientists in the fields of space, communications, and defense-related research use 0.02 cc to 4 liters of PCBs in certain specialized optical applications including use in fiber optic connectors. Although the amount of PCBs used per application may be up to 4 liters, comments submitted in response to the proposed rule indicate that the PCBs used in these applications are contained in optical equipment and thus exist in a permanent or semi-permanent state.

This use of PCBs requires only a relatively small amount of PCBs. Further, during use, these PCBs are contained in optical equipment such as in fiber optic connectors, where they exist in a permanent or semi-permanent state. Given the highly trained nature of scientists, the relatively small amounts of PCBs used per application, and the fact that the PCBs are contained within optical equipment, EPA has concluded that this use results in only a limited potential for exposure to PCBs.

### 5. Exposure From the Use of PCBs as Calibration Standards

Comments submitted in response to the proposed rule indicate that PCBs are useful as calibration standards. These comments indicate that small amounts of PCBs are used as calibration standards for refractometer calibration.

The technique used in calibrating a refractometer involves placing 0.01 cc of PCBs in the refractometer and calibrating the refractometer based on the known refractive index of the PCBs. Since refractometers are used to measure the refractive indices of substances, it is important to calibrate accurately the instrument before using it to measure experimentally the refractive indices of other materials.

The calibration of a refractometer occurs in a laboratory setting at a frequency of about once per week. Assuming that there are refractometers

in most laboratories, and that the 1970 census data are correct, EPA estimates that about 174,000 technologists could potentially use PCBs as calibration standards. However, there are many other different materials, with known refractive indices that could also be used for purposes of calibrating refractometers.

Although EPA estimates that about 0.01 cc of PCB calibration standard is used per application, the calibration standards contain high concentrations of PCBs. Further, skin contact with calibration standards may occur during use because calibrating a refractometer involves the transfer of the PCBs to a small cell within the instrument and the subsequent removal and cleansing of the cell following the completion of the calibration exercise.

EPA recognizes that the PCBs as calibration standards requires only relatively small amounts of PCBs. Further, EPA acknowledges that scientists and researchers are highly trained and generally experienced in the handling of toxic chemicals such as PCBs, and PCB products must be labeled as containing PCBs. Given these factors, EPA believes that the use of PCBs as calibration standards for refractometers results in a limited potential for exposure to PCBs.

### *C. The Benefits of Using PCBs and the Availability of Substitutes*

#### 1. Mounting Medium

PCBs have been reported to be an ideal mounting medium for light microscopy primarily because of their stability, refractive index, viscosity, and thermoplastic properties. In the past, the principal users have been mineralogists and chemical microscopists employed in chemical laboratories such as police crime laboratories, museum conservation laboratories, industrial laboratories, where contaminant particles in drugs, food, and plastics are identified, and in laboratories studying environmental contaminants.

Although testimony at the September 1978 public hearing on the original authorization for the use of PCBs as a mounting medium indicated that a substitute mounting medium would be available before July 1, 1984, comments submitted in response to the November 17, 1983 proposed rule suggest that adequate substitute materials still are not available in some areas of use.

In April 1983, EPA sent letters to persons who testified about this use at the September 1978 public hearing. In particular, EPA requested current information on the availability of substitute materials. Two responses

indicated that an adequate substitute for use in art and historic conservation was still not yet available. One firm did indicate that they had tested a number of different materials over the last five years, and that a potential substitute material was currently undergoing testing. A review of petitions submitted to EPA for exemption from the ban on the manufacture, processing, and distribution in commerce of PCBs indicated that at least one firm expects to develop a substitute mounting medium by January of 1985. However, firms currently testing this material on a trial basis are less confident about the efficacy of this material.

In the proposed rule, EPA believed that the only essential use of PCBs as a mounting medium was in the field of art and historic conservation. That is, EPA believed that no adequate substitutes existed for this particular use pattern. Because of the nature of art and historic conservation, rare particles must be permanently mounted in a medium that will not discolor or lose its optical properties in time. Based on information submitted by users of PCB mounting medium, EPA believes that the only medium that displays this property is PCB.

Although the stability of PCBs makes them attractive to other users as well, EPA believed that these other users are not frequently called upon to prepare permanent slides of particles that can be considered to be rare. Comments submitted in response to the proposed rule indicate that EPA's basic assumption was correct: That other users are not frequently called upon to prepare permanent slides of rare particles. However, these comments also indicate that in the relatively rare circumstances where a permanent mount is needed in fields other than art and historic conservation, there is no adequate substitute for PCBs at this time. Although mounting media exist with similar refractive indices and viscosities to PCBs, these media reportedly discolor in time. Examples of other uses where PCBs are necessary include the preservation of crime evidence and the preservation of samples from manufacturing process upsets.

#### 2. Immersion Oils

Comments received in response to the proposed rule indicate that PCB immersion oil has the lowest fluorescence of any currently available formulation, and that this property is particularly important in fluorescence microscopy where the immersion oil must not fluoresce, so as to compete with the fluorescence of the specimen

under analysis. Testimony at the September 1978 public hearing on the original use authorizations indicated that substitute immersion oils for PCBs were available. Thus, in 1979, EPA decided not to authorize the use of PCBs in immersion oil. However, comments submitted in response to the November 17, 1983 proposed rule indicate that the substitute immersion oils, which were thought to be in existence in 1979, proved to be inadequate for certain specialized uses.

According to comments submitted in response to the proposed rule, since 1979 no completely satisfactory substitute for PCBs has been found, and, that after extensive research, there appears to be no other material with the desirable low auto-fluorescence, low dispersion, and high refractive index of PCBs.

According to sources in the medical community, adequate substitutes for PCB immersion oils are, however, available for use in capillary microscopy.

#### 3. Research and Development

Other chemicals cannot be substituted in toxicological, environmental or analytical testing for PCBs.

#### 4. PCBs in Optical Fluids

Comments on the use of PCBs as optical liquids in space, communications, and defense-related research projects indicate that for certain specialized optical uses, including the use of PCBs in fiber optic connectors and tunable light receivers, there are no adequate substitutes for PCBs. According to comments on the proposed rule, there are relatively few compounds with as high a refractive index as PCBs and none that also have the long term stability.

An example of an optical use of PCBs, where their use is essential, is the use of PCBs with tunable light receivers for the analysis of light from the solar telescope to be installed in Skylab II. According to these comments, PCBs are necessary in these light receivers because of their stability and ability to transmit light better in the blue and green regions of the spectrum than other potential substitute fluids. This region of the spectrum is where starlight is transmitted.

#### 5. Calibration Standards

Although comments on the proposed rule indicate a desire to have PCBs available for use as calibration standards for refractometers, EPA believes that adequate substitute materials exist for PCBs for this use

pattern. As discussed in the preceding unit, comments on the proposed rule indicate that there are compounds available with the high refractive index of PCBs. Further, in the rulemaking record to the May 31, 1979 PCB Ban Rule, one of the major producers of microscope immersion oils indicated that they had produced PCB-free immersion oils that could be used as calibration liquids; the refractive indices of these materials are high and known to four significant figures. Since long term stability is not really an essential feature for a calibration standard (as long as the stability is known), EPA believes that these other materials with similar refractive indices to PCBs could be used for purposes of calibrating refractometers. EPA believes that although substitute materials may not have the long term stability of PCBs, their stability is known. Therefore, EPA believes that non-PCB materials can be substituted for use as calibration standards for refractometers.

#### D. Economic Impact of Regulatory Options

##### 1. Mounting Medium

The May 1979 PCB Ban Rule (44 FR 31514) authorized the use of PCBs as a mounting medium for microscope slides until July 1, 1984. In anticipation of this expiration date, EPA considered the following major options: allowing the authorization for use as a mounting medium to expire on July 1, 1984; extending the authorization to allow all or limited uses of PCBs for microscopic mounting for a limited time; and, amending the authorization to allow all or limited uses of PCBs for microscopic mounting for an indefinite period of time.

*a. Allowing the authorization to expire on July 1, 1984.* The direct cost of a ban can be represented as the lost sales to the producers (netted out against any increase in sales of substitutes), and the lost value of a permanent slide mount with desirable optical properties to the users. The cost to the producers of allowing the use authorization to expire on July 1, 1984, is about \$2,500 per year, which includes a consideration of the lost sales plus the costs of collection and disposal in EPA-approved PCB disposal facilities.

In addition, there are other potential costs associated with the loss of use of PCBs for permanent mounting. In areas such as art and historic conservation, crime investigation, and certain industrial uses (where EPA believes that no adequate substitutes exist), the impacts of banning PCB use may be significant. However, it is difficult to

estimate the monetary value of being unable to prepare a permanent slide mount of a sample of a rare art or historic work, a piece of crime evidence, or a sample from a manufacturing process upset. Comments submitted in response to the proposed rule suggest that these potential costs could be significant.

*b. Extending the use authorization to allow all or limited uses of PCBs to continue for several years.* Under this option, the economic impact of an immediate ban could be reduced. First, this option would allow additional time for the development of substitutes in areas where none exist. Second, this option would allow the continued sale and use of PCBs for the length of the extension to the authorization.

In the proposed rule, EPA authorized the use of PCBs as a mounting medium only in the field of art and historic conservation. Comments received in response to the proposed rule indicate that there are essential uses of PCBs as a mounting medium in areas other than art and historic conservation. For this reason, EPA did not consider limiting the use of PCBs as a mounting medium in this final rule.

*c. Amending the use authorization to allow the use of PCBs to continue indefinitely.* Allowing PCBs to be used indefinitely as a mounting medium for microscope slides would have no negative economic impact on users or producers of the medium.

##### 2. Immersion Oil

In response to comments received on the proposed rule, EPA considered three major options for the use of PCBs in immersion oil for fluorescence microscopy: Not authorizing the use of PCBs in immersion oil; authorizing the use of PCBs in immersion oil for several years; and, authorizing the use of PCBs in immersion oil indefinitely.

*a. Not authorizing the use of PCBs in immersion oil.* Since this use is currently not an authorized use, there is no direct cost associated with not authorizing the use of PCBs in this manner. However, although there are no lost sales to consider, there are other potential indirect costs associated with not being able to use PCBs as low fluorescence immersion oils. In certain areas of medical research, such as in cancer studies, comments on the proposed rule indicate that there are no adequate substitutes for PCB low fluorescence immersion oils. It is difficult to estimate the monetary value of not being able to obtain the best view of a sample under analysis as part of a cancer research study. However, comments submitted on the proposed rule indicate that PCB low

fluorescence immersion oil is very valuable in cancer research studies.

Sources in the medical community have indicated, however, that PCBs are not valued in capillary microscopy because PCB-free substitute materials are available for this use pattern. In this case, then, there would be no direct costs (i.e., lost sales) or indirect costs associated with not authorizing the use of PCB immersion oils in capillary microscopy.

*b. Authorizing the use of PCBs in immersion oil for several years.* This option would allow the use of PCBs for an additional period of time, while research continues for the development of substitutes in areas where none exist. EPA is concerned, however, about the cost to industry and EPA of reconsidering this use authorization should it expire prior to the development of an adequate substitute.

*c. Authorizing the use of PCBs in immersion oils indefinitely.* Allowing PCBs to be used in immersion oil would have no negative economic impact on users of the medium.

##### 3. Research and Development

Small quantities of PCBs are used in toxicological testing, in environmental sampling, and in analytical testing by industry, the public, and governmental agencies. Analytically pure samples of PCBs are probably used every day in laboratories throughout the country. Although allowing the statutory ban to become effective is theoretically one available alternative, EPA believes an immediate ban on these uses of PCBs would be unacceptable since it would disrupt a broad range of beneficial activities throughout the United States.

Further, EPA believes that analytically pure PCBs will be needed for the foreseeable future. Thus, EPA is issuing an indefinite use authorization for the use of small quantities of PCBs in research and development. This option has no negative economic impact on producers or users of small quantities of PCBs in research and development.

##### 4. PCBs in Optical Liquids

In response to comments on the proposed rule, EPA considered three major options for the use of small quantities of PCBs as optical liquids: not authorizing the use of PCBs in optical liquids; authorizing the use of PCBs in optical liquids for several years; and, authorizing the use of PCBs in optical fluids indefinitely.

*a. Not authorizing the use of PCBs in optical fluids.* Since this use is not currently an authorized use, there are no direct costs of not authorizing the use of

PCBs as optical fluids. However, there may be indirect costs associated with researchers being unable to use PCBs in certain critical areas of research. As was the case with the use of PCBs in mounting medium and immersion oil, it is difficult to quantify the monetary value of being unable to use PCBs in optical research-related equipment. However, comments on the proposed rule indicate that PCBs are very valuable as optical liquids.

*b. Authorizing the use of PCBs in optical liquids for several years.* As was the case with the use authorizations for the use of PCBs in mounting medium and immersion oil, EPA is concerned about the costs to industry and EPA of reconsidering this use authorization, should it expire prior to the development of adequate substitute materials.

*c. Authorizing the use of PCBs in optical liquids indefinitely.* There is no negative economic impact associated with this option.

#### 5. Calibration Standards for Refractometers

In response to comments received on the proposed rule, EPA considered three major options for the use of PCBs as calibration standards for refractometers: not authorizing this use; authorizing this use for a fixed period of time; and, authorizing this use indefinitely.

*a. Not authorizing the use of PCBs as calibration standards.* Since the use of PCBs as calibration standards is not currently an authorized use, there is no direct cost of not authorizing the use of PCBs in this manner. Further, EPA believes that there is little indirect cost associated with not authorizing the use of PCBs as calibration standards, because EPA believes that adequate non-PCB substitutes exist for this use pattern.

*b. Authorizing the use of PCBs as calibration standards for several years.* This option would allow the use of PCBs as calibration standards for several years, while research continues for the development of a calibration standard with the long-term stability of PCBs. EPA is concerned, however, about the cost to industry and EPA of reconsidering this use authorization should it expire prior to the development of a substitute with the long term stability of PCBs.

*c. Authorizing the use of PCBs as calibration standards indefinitely.* Allowing PCBs to be used as calibration standards indefinitely would have no negative economic impact on users of the medium.

#### E. Risk Benefit Assessment

##### 1. Use as a Mounting Medium in Microscopy

The use of PCBs as a mounting medium presents some level of risk to microscopists because EPA believes that PCBs are toxic and that there is a potential for exposure to these PCBs during use. EPA recognized the risks posed to users of PCB mounting medium in the May 1979 use authorization but nevertheless authorized the use until July 1, 1984. In its May 1979 decision, EPA determined that the continued use of PCBs in this manner until July 1, 1984, did not pose an unreasonable risk to public health or the environment because of the small quantities of PCBs used and the lack of an adequate substitute.

Allowing an immediate ban to take effect as of July 1, 1984, could result in substantial costs to specific groups of users for whom an adequate substitute is not yet available. At the same time, an immediate ban would be the most environmentally attractive alternative because it would result in a reduction in exposure to PCBs and could stimulate the immediate development of substitute materials.

Extending the May 1979 use authorization for several more years reduces the immediate impact of a ban, but increases human and environmental exposure to PCBs compared to a ban. Extending the authorization for several years could create uncertainty in the regulated community about the possibility of future extensions to the authorization. In addition, future extensions to this use authorization would require both Agency and industry resources.

Amending the use authorization to allow the indefinite use of PCBs as a mounting medium eliminates any negative economic impact on producers or users of the material. However, this option is the least attractive alternative environmentally, since it allows the indefinite use of PCBs.

Limiting the use of PCBs to use only in art and historic conservation would reduce the environmental impact of an indefinite use authorization. However, EPA believes that in most fields of microscopy there would be occasions where the use of PCBs for the preparation of a permanent mount would be necessary. Finally, this option eliminates the uncertainty associated with a timed authorization and future costs to industry and EPA of reconsidering this use authorization. Should EPA become aware of the development of an adequate substitute for use in art and historic conservation

(through its yearly review of petitions for exemption to manufacture, process, and distribute in commerce PCBs), EPA will consider amending the indefinite use authorization and allow it to expire.

##### 2. Use of PCBs as Immersion Oils

The use of PCBs as low fluorescence immersion oils presents some level of risk to microscopists because EPA believes that PCBs are toxic and that there is a potential for exposure to these PCBs during use. However, EPA also believes that scientists and researchers are highly trained and generally experienced in the use of toxic materials such as PCBs. These factors limit the potential for exposure to PCBs during their use as low fluorescence immersion oils.

The use of PCB immersion oil in capillary microscopy presents a higher potential risk because this technique involves the direct and intentional application of PCBs to the skin surface. EPA believes that PCBs are toxic and that exposure to PCBs should be avoided. Further, EPA believes that adequate substitutes for PCBs exist in capillary microscopy.

Since the use of PCBs in capillary microscopy is not currently an authorized use, there is no direct cost (lost sales) associated with not authorizing this particular use. There are also no indirect costs to consider, because adequate substitutes for PCBs exist for use in capillary microscopy.

Although not authorizing this use of PCBs as low fluorescence immersion oils would result in little direct economic impact on users of this immersion oil, in certain limited areas of medical research, there are no adequate substitutes for PCBs. At the same time, not authorizing this use would be the most attractive alternative environmentally because it would result in no additional exposure to PCBs.

Allowing the use of PCBs as immersion oils in fluorescence microscopy for several years would reduce the immediate economic impact of a ban, but would also increase exposure to PCBs when compared to the option of not authorizing this use. In addition, should adequate substitute materials not be developed by the expiration date of the authorization, EPA and industry may have to expend additional resources re-examining this use for a possible time extension to the authorization.

Allowing the indefinite use of PCBs as immersion oils in fluorescence microscopy eliminates any economic impact on producers or users of the oil. However, this is the least attractive

option environmentally, since this essentially allows a new use of PCBs (with the associated additional exposure to PCBs) to occur indefinitely. This option eliminates the uncertainty associated with use authorizations with fixed expiration dates, and eliminates future costs to industry and EPA of reconsidering this use pattern should adequate substitute materials not be developed by the expiration date of the authorization.

Should EPA become aware of the development of an adequate substitute for PCB immersion oil in fluorescence microscopy (through its yearly review of petitions for exemption to manufacture, process, and/or distribute in commerce PCBs for use as immersion oil), EPA will consider amending the indefinite use authorization and allow it to expire.

### 3. Use of PCBs in Small Quantities for Research and Development

The use of PCBs in research and development presents some level of risk to users because EPA believes that PCBs are toxic. While there is some potential for exposure to PCBs during their use in research and development, EPA recognized the low potential for exposure when it originally authorized the use of PCBs in small quantities for research and development until July 1, 1984. In its May 1979 decision, EPA determined that the continued use of PCBs in research and development until July 1, 1984, did not pose an unreasonable risk to public health or the environment. This was because of the importance of ongoing research on the effects of PCBs and the need, by both industry and government, to have analytical standards. EPA determined that the limited exposure associated with the use of small quantities of PCBs for research and development did not pose an unreasonable risk in light of the potential benefits of continued research.

Although allowing an immediate ban to take effect as of July 1, 1984, would reduce exposure to PCBs, EPA believes that such a ban could disrupt a broad range of beneficial ongoing activities. These activities include toxicological and environmental testing and analytical testing. Although amending the May 1979 use authorization by extending it for several years would reduce exposure to PCBs compared to an indefinite use authorization it would serve only to delay the economic impact of a ban for several years. Finally, creating an indefinite use authorization would result in no economic impact to either producers or users of these materials, but, would increase exposure to PCBs compared to the two alternatives discussed above.

### 4. Use of PCBs as Optical Fluids

The use of PCBs as optical fluids presents some risk to users because PCBs are toxic, and there is some potential for exposure to PCBs during use. However, PCBs used as optical fluids are in a permanent or semi-permanent state in optical equipment. Further, scientists and researchers are highly trained workers, generally experienced in the use of toxic chemicals such as PCBs.

Although not allowing this use of PCBs would result in little direct economic impact on users of this material, EPA believes that in certain optical research areas, including the use of PCBs in fiber optic connectors and tunable light receivers, there are no adequate substitutes for PCBs. At the same time, not authorizing this use would be the most attractive alternative environmentally, because it would result in no additional exposure to PCBs.

Allowing the use of PCBs as optical fluids for several years would reduce the immediate impact of a ban, but, would increase exposure to PCBs when compared to the option of not authorizing this use. In addition, should adequate substitute materials not be developed prior to the expiration date of the authorization, EPA and industry may have to expend additional resources re-examining this use for a possible time extension.

Authorizing the indefinite use of PCBs as optical fluids eliminates any economic impact on producers or users of this material. However, this is the least attractive alternative environmentally, since this essentially allows a new use of PCBs (with the associated additional exposure to PCBs) to occur. This option eliminates the uncertainty associated with use authorizations that have fixed expiration dates, and also eliminates future costs to EPA and industry of reconsidering this use pattern should adequate substitute materials not be developed by the expiration date of the authorization.

Should EPA become aware of the development of adequate substitutes for PCB optical fluids (through its yearly review of petitions for exemption to manufacture, process, or distribute in commerce PCB optical liquids), EPA will consider amending the indefinite use authorization and allow it to expire.

### 5. Use of PCBs as Calibration Standards

The use of PCBs as calibration standards for refractometers presents some level of risk to users because EPA believes that PCBs are toxic and that there is some potential for exposure to

these PCBs during use. However, factors such as the highly trained nature of researchers, their experience in handling toxic chemicals, and the fact that PCB products must be labeled as containing PCBs mitigate the risks associated with this use of PCBs.

Since the use of PCBs as calibration standards for refractometers is not currently an authorized use, there are not direct costs (lost sales) associated with not authorizing this particular use. Further, there are no indirect costs to consider, since EPA believes that adequate substitutes exist for the use of PCBs in this manner.

Not authorizing the use of PCB as calibration standards is the most attractive alternative environmentally, because selecting this option would mean no additional exposure to PCBs. Further, because EPA believes that adequate substitutes exist for PCBs, there are no direct or indirect costs associated with not authorizing this use.

Authorizing the use of PCBs for a fixed period of time or indefinitely would serve only to increase exposure to PCBs in an area where other adequate substitute materials exist.

### *F. Findings on the Use of PCBs as a Mounting Medium in Microscopy, as an Immersion Oil, as an Optical Fluid, and in Small Quantities for Research and Development*

#### 1. Mounting Medium

In view of the analysis above, EPA proposes to authorize the use of PCBs as a mounting medium indefinitely. EPA believes that authorizing the use of PCBs as a mounting medium indefinitely does not present an unreasonable risk for the following reasons:

a. If EPA did not authorize the use of PCBs as a mounting medium, mounts of specimens, including some rare and valuable specimens, could discolor in time and be lost.

b. There are no substitutes for PCBs as mounting media in the preparation of permanent mounts.

c. Releases of PCBs to the environment and exposure to humans and biological organisms from the use of PCBs in this relatively small field is expected to be limited because of the highly trained nature of scientists, their experience in handling toxic chemicals, the small quantities used, and the fact that PCB products must be labeled as containing PCBs.

EPA will monitor progress in the development of substitute materials for use in microscope mounting by reviewing information submitted annually through the exemption petition

process. Should substitute materials be developed, EPA will consider amending this authorization to allow it to expire.

#### 2. Immersion Oil

In view of the analysis above, EPA is authorizing the use of PCBs as low fluorescence immersion oils indefinitely. EPA is not authorizing the use of PCB immersion oils in capillary microscopy. EPA has concluded that the use of PCBs as immersion oils in fluorescence microscopy does not pose unreasonable risk to public health or the environment for the following reasons:

a. If EPA did not authorize the use of low fluorescence PCB immersion oils, the use of PCB immersion oils in beneficial areas including certain types of medical research would be banned.

b. Releases of PCBs to the environment and exposure to humans and other biological organisms from the use of PCB immersion oils in low fluorescence microscopy are expected to be minimal because of the highly trained nature of scientists, their general experience in handling toxic chemicals, the small quantities used, and the fact that PCB products must be labeled as containing PCBs.

c. There are no adequate substitutes for PCBs in certain specialized low-fluorescence uses.

#### 3. Research and Development

In view of the analysis above, EPA proposes to authorize the use of small quantities of PCBs for research and development indefinitely. EPA has concluded that the use of small quantities of PCBs for research and development indefinitely does not pose an unreasonable risk to public health or the environment for the following reasons:

a. If EPA did not authorize the use of small quantities of PCBs for research and development, beneficial toxicological, environmental, and analytical testing of PCBs would be banned.

b. Releases of PCBs to the environment and exposure to humans and other biological organisms from the use of PCBs in small quantities for research and development are expected to be minimal.

c. There are no substitutes for PCBs in research and development.

d. Analytical grade PCBs are needed for the foreseeable future.

#### 4. Use of PCBs Optical Liquids

In view of the analysis above, EPA is authorizing the use of PCBs as optical liquids. EPA has concluded that the use of PCBs optical liquids does not pose an

unreasonable risk to public health or the environment for the following reasons:

a. If EPA did not authorize the use of PCBs as optical liquids, the use of PCBs in beneficial areas including space, communications, and defense-related research would be banned.

b. Releases of PCBs to the environment and exposure to humans and other biological organisms from the use of PCBs as optical liquids are expected to be minimal because of the highly trained nature of scientists, their general experience in handling toxic chemicals such as PCBs, the small quantities of PCBs used and the sealed nature of their use, and the fact that PCB products must be labeled as containing PCBs.

c. There are no adequate substitutes for PCBs.

#### 5. Calibration Standards

In view of the analysis presented above, EPA is not authorizing the use of PCBs as calibration standards for refractometers.

#### IV. Executive Order 12291

Under Executive Order 12291, issued February 17, 1981, EPA must judge whether a rule is a "major rule" and, therefore, subject to the requirement that a Regulatory Impacts Analysis be prepared. EPA has determined that this amendment to the PCB rule is not a major rule as the term is defined in section 1(b) of the Executive Order.

EPA has determined that the amendment is not "major" under the criteria of section 1(b) because the annual effect of the rule on the economy will be substantially less than \$100 million; it will not cause a major increase in costs or prices for any sector of the economy or for any geographic region; and it will not result in any adverse effects on competition, employment, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets. In fact, this rule allows uses of PCBs in mounting medium and research and development to continue that would otherwise be prohibited by section 6(e) of TSCA after July 1, 1984. This rule also allows two additional uses of PCBs; the use as immersion oil and the use as optical fluids.

This amendment was submitted to the Office of Management and Budget (OMB) as required by the Executive Order 12291.

#### V. Regulatory Flexibility Act

Under section 604(b) of the Regulatory Flexibility Act, 5 U.S.C. 603, the Administrator may certify that a rule

will not have a significant impact on a substantial number of small entities and, therefore, does not require a regulatory flexibility analysis.

The effect of this rule is to avoid the disruption of a broad range of activities and to reduce the costs of complying with TSCA. This rule will reduce the burden on small businesses that would otherwise be encountered if the July 1, 1984 ban on the use of PCBs as a mounting medium and in small quantities for research and development went into effect. This rule also allows two additional previously unauthorized uses of PCBs. Since no negative economic impact is expected upon any business activity from the promulgation of this rule, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

#### VI. Paperwork Reduction Act

This rule does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

#### VII. Official Record of Rulemaking

In accordance with the requirements of section 19(A)(3)(E) of TSCA, EPA is issuing the following list of documents which constitute the record of this rulemaking. Public comments, the transcript of the rulemaking hearing, or submissions made at the rulemaking hearing or in connection with it are not listed because these documents are exempt from *Federal Register* listing under section 19(a)(3). A full list of these materials will be available on request by contacting the TSCA Public Information Officer (see **ADDRESSES**).

##### A. Previous Rulemaking Records

(1) Official rulemaking record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibition Rule" published in the *Federal Register* of May 31, 1979, (44 FR 31514).

(2) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Disposal and Marking Final Regulation" published in the *Federal Register* of February 17, 1978, (43 FR 7150).

(3) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution, and Use in Closed and Controlled Waste Manufacturing Processes" published in the *Federal Register* of October 21, 1982, (47 FR 46980).

(4) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution,

in Commerce and Use Prohibitions; Use in Electrical Equipment" published in the *Federal Register* of August 25, 1982, (47 FR 37342).

(5) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Manufacture, Processing, Distribution in Commerce and Use Prohibitions; Use in Microscopy and Research and Development" published in the *Federal Register* of November 17, 1983, (48 FR 52402).

(6) Official rulemaking record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce Exemptions; Proposed Rules" published in the *Federal Register* of November 1, 1983 (48 FR 50486).

#### B. Federal Register Notices

(7) USEPA, "Polychlorinated Biphenyls (PCBs) Disposal and Marking Final Regulation". 43 FR 7150, February 17, 1978.

(8) USEPA, "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions". 44 FR 31514, May 31, 1979.

(9) USEPA, "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Use in Electrical Equipment". 47 FR 37342, August 25, 1982.

(10) USEPA, "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes". 47 FR 46980, October 21, 1982.

(11) USEPA, "Polychlorinated Biphenyls (PCBs) Manufacture, Processing, Distribution in Commerce and Use Prohibitions; Use in Microscopy and Research and Development". 48 FR 52402, November 17, 1983.

(12) USEPA, "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce Exemptions; Proposed Rules". 48 FR 50486, November 1, 1983.

#### C. Support Documents

(13) USEPA, OPTS, EED, "Letter Soliciting Data on Use Authorization for Use of PCBs in Microscopy." April 13, 1983.

(14) Philadelphia Museum of Art, Marigene H. Butler, "Comments on Use Authorization for Microscopy." April 29, 1983.

(15) USEPA, OPTS, EED, "Record of Telephone Communication Between Martha Goodway of the Smithsonian and Denise Keehner of EPA." May 9(?), 1983.

(16) R.P. Cargille Laboratories, Inc., William J. Sacher, "Petition for PCB Processing and Distribution in Commerce Exemption." July 18, 1983.

(17) McCrone Research Institute, Walter C. McCrone, "Petition from PCB Processing and Distribution in Commerce Prohibitions." July 9, 1983.

(18) McCrone Research Institute, Walter C. McCrone, "Letter Describing Safety Precautions in Handling of PCBs." January 7, 1983.

(19) Journal of the American Medical Association, "Letter: Polychlorinated Biphenyls in Microscope Immersion Oil." April 1, 1983.

#### VIII. Judicial Review

Judicial review of this final rule may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA has decided to promulgate this rule for purposes of judicial review two weeks after publication in the *Federal Register*, as reflected in "DATES" in this notice. The effective date has, in turn been calculated from the promulgation date.

#### List of Subjects in 40 CFR Part 761

Hazardous materials, Labeling, Polychlorinated biphenyls, Recordkeeping and reporting requirements, Environmental protection. (Sec. 8, Pub. L. 94-469; 90 Stat. 2025 (15 U.S.C. 2605))

Dated: June 27, 1984.

Alvin L. Alm,  
Acting Administrator.

#### PART 761—[AMENDED]

Therefore, 40 CFR 761.30 is amended by revising paragraphs (j) and (k) and

adding paragraphs (n) and (o) to read as follows:

#### § 761.30 Authorizations.

\* \* \* \* \*

(j) *Small quantities for research and development.* PCBs may be used in small quantities for research and development, as defined in § 761.3(ee), in a manner other than a totally enclosed manner, indefinitely. Manufacture, processing, and distribution in commerce of PCBs in small quantities for research and development is permitted only for persons who have been granted an exemption under TSCA section 6(e)(3)(B).

(k) *Microscopy mounting medium.* PCBs may be used as a permanent microscopic mounting medium in a manner other than a totally enclosed manner indefinitely. Manufacture, processing, and distribution in commerce of PCBs for purposes of use as a mounting medium are permitted only for persons who are granted an exemption under TSCA section 6(e)(3)(B).

\* \* \* \* \*

(n) *Microscopy immersion oil.* PCBs may be used as an immersion oil in fluorescence microscopy, in a manner other than a totally enclosed manner indefinitely. Manufacture, processing, and distribution in commerce of PCBs for purposes of use as a low fluorescence immersion oil are permitted only for persons who are granted an exemption under TSCA section 6(e)(3)(B).

(o) *Optical liquids.* PCBs may be used as optical liquids in a manner other than a totally enclosed manner indefinitely. Manufacture, processing, and distribution in commerce of PCBs for purposes of use as optical liquids are permitted only for persons who are granted an exemption under TSCA section 6(e)(3)(B).

[FR Doc. 84-17901 Filed 7-9-84; 8:45 am]  
BILLING CODE 6560-50-M

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 761

[OPTS-66008B; TSH-FRL-2584-7]

#### Polychlorinated Biphenyls (PCBs); Request for Additional Comments on Certain Individual and Class Petitions for Exemption

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of request for additional comments on certain individual and class petitions for exemption.

**SUMMARY:** This proposed rule related notice addresses 50 of the remaining individual and class petitions for exemption from the prohibition against the manufacture, processing, and distribution in commerce of PCBs. EPA is issuing this notice to solicit comments on 49 petitions for exemption to manufacturers, process and distribute in commerce substances or mixtures inadvertently contaminated with 50 parts per million (ppm) or greater PCBs. All of these petitions are affected by the final PCB Exclusions, Exemptions, and Use Authorizations Rule (hereinafter referred to as the Uncontrolled PCB Rule) published elsewhere in this issue of the **Federal Register**, which may make an exemption unnecessary. EPA also is issuing this notice to solicit comments on Ward Transfer Co., Inc.'s petition for exemption to buy and sell used PCB-contaminated transformers. In evaluating this exemption petition, EPA raised a new issue about whether granting an exemption would result in an unreasonable risk or injury to health or the environment.

**DATES:** (1) The 49 petitioners whose exemption petitions are affected by the Uncontrolled PCB Rule must evaluate that rule and decide whether they still need an exemption to continue their activities. If a petitioner still needs an exemption, it must submit written comments renewing its exemption petition no later than October 1, 1984.

(2) For Ward Transformer Co., Inc.'s exemption petition, EPA will accept comments from petitioner and other interested parties until August 23, 1984.

(3) An informal public hearing, if requested, will be held in Washington, D.C., on September 6, 1984. The exact time and location of the hearing will be available by calling EPA's TSCA Assistance Office. EPA intends to evaluate the comments submitted and to conduct rulemaking in accordance with the procedures described in Unit II of this preamble. Reply comments made in

response to issues raised at the hearing must be submitted no later than one week after the hearing.

**ADDRESSES:** Since some comments pertaining to the 51 deferred exemption petitions may contain confidential business information, all comments should be sent in triplicate to: TSCA Public Information Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St., SW., Washington, D.C. 20460.

Comments should include the docket number OPTS-66008B. Comments received on this proposed rule related notice will be available for reviewing and copying from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays, in Rm. E-107, Environmental Protection Agency, 401 M St., SW., Washington, D.C.

The exact time and location of the hearing, if requested, will be available by calling EPA's TSCA Assistance Office.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), in Washington, D.C.: (554-1404), outside the USA: (Operator-202-554-1414).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

The proposed PCB Exemptions Rule published in the **Federal Register** of November 1, 1983 (48 FR 50486) addressed 172 pending individual and class exemption petitions. During the comment period on the proposed rule, 17 of the 172 exemption petitions were withdrawn or dismissed, and four new exemption petitions were accepted for consideration. Thus, 159 exemption petitions remain to be resolved. EPA is taking action on 109 exemption petitions in the final PCB Exemptions Rule published elsewhere in this issue of the **Federal Register**. In this proposed rule related notice, EPA is soliciting comments on the other 50 exemption petitions.

##### II. Comments and Rulemaking Procedures

EPA encourages commentors to submit nonconfidential information. However, commentors who believe that they can state their position only by using confidential information may submit it to the Agency in accordance with the requirements of 40 CFR 750.16 (for manufacturing exemptions) or 40 CFR 750.36 (for processing and

distribution in commerce exemptions). Persons who submit confidential information must, at the same time, submit a nonconfidential summary of the information claimed to be confidential for inclusion in the public record. Please mark confidential information "CONFIDENTIAL" and send it via certified mail to the TSCA Public Information Office (see address listed under "ADDRESS"). Information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR Part 2. Information not marked "CONFIDENTIAL" will be placed in the public record and may be publicly disclosed by EPA without prior notice.

EPA will conduct all public hearings in accordance with EPA's "Procedures for Conducting Rulemaking Under section 6 of the Toxic Substances Control Act" (40 CFR Part 750). Commentors who want to participate in the public hearings must write to EPA's TSCA Assistance Office (see address listed under "FOR FURTHER INFORMATION CONTACT") and indicate that they want to participate. The public hearings are meant to provide an opportunity for commentors to present additional information or to discuss new issues, not to repeat information already presented to EPA in written comments.

##### III. Background

###### A. Statutory Authority

Section 6(e) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e), generally prohibits the manufacture of PCBs after January 1, 1979, and the processing and distribution in commerce of PCBs after July 1, 1979.

Section 6(e)(3)(B) of TSCA provides that any person may petition the Administrator for an exemption from the prohibition against the manufacture, processing, and distribution in commerce of PCBs. The Administrator may by rule grant an exemption if the Administrator finds that "(i) an unreasonable risk of injury to health or environment would not result, and (ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl." The Administrator may set terms and conditions for an exemption and may grant an exemption for not more than one year.

EPA's Interim Procedural Rules for PCB Manufacturing Exemptions describe the required content of manufacturing exemption petitions and

the procedures EPA follows in rulemaking on exemption petitions. Those rules were published in the *Federal Register* of November 1, 1978 (43 FR 50905) and are codified at 40 CFR 750.10-750.21.

EPA's Interim Procedural Rules for PCB Processing and Distribution in Commerce Exemptions describe the required content of processing and distribution in commerce exemption petitions and the procedures EPA follows in rulemaking on exemption petitions. Those rules were published in the *Federal Register* of May 31, 1979 (44 FR 31558) and are codified at 40 CFR 750.30-750.41.

#### B. History of PCB Rulemaking

The history of PCB rulemaking is described in detail in the proposed PCB Exemptions Rule published in the *Federal Register* of November 1, 1983 (48 FR 50486). Since that proposed rule was published, EPA has issued two final rules that affect EPA's disposition of these pending exemption petitions.

First, the Uncontrolled PCB Rule published elsewhere in this issue of the *Federal Register* addresses the manufacture, processing, distribution in commerce, and use of certain inadvertently generated and recycled PCBs in low level concentrations. Among other things, that rule does the following: (1) Amends the PCB rule published in the *Federal Register* of October 21, 1982 (47 FR 46980) [the Closed and Controlled Waste Manufacturing Processes Rule] by excluding additional processes from regulation; and (2) defers action on 49 petitions for exemption to manufacture, process, and distribute in commerce inadvertently generated PCB pending the submission of additional information by petitioners.

Second, the PCB Exemptions Rule published elsewhere in this issue of the *Federal Register* takes final action on 109 of the pending exemption petitions and defers action on the 50 exemption petitions addressed in this proposed rule related notice.

#### C. Effect of This Notice on Previous Policy Statements

In the *Federal Register* of January 2, 1979 (44 FR 108), EPA announced that petitioners who had previously filed manufacturing exemption petitions could continue the activities for which they sought exemption until EPA acted on their petitions. In the *Federal Register* of March 5, 1980 (45 FR 14247), EPA extended this policy to allow all petitioners to continue the activities for which they sought exemption until EPA acted on their petitions, as long as the

activities were underway before January 1, 1979 (for manufacturing) and July 1, 1979 (for processing and distribution in commerce).

The 49 petitioners whose exemption petitions are affected by the Uncontrolled PCB Rule must evaluate that rule and decide whether they still need an exemption to continue their activities. If a petitioner still needs an exemption, it must submit written comments renewing its exemption petition no later than October 1, 1984. If an exemption petition is renewed, EPA will allow the petitioner to continue the activities for which it requests exemption until EPA has acted to grant or deny the exemption. If the exemption petition is not renewed, EPA will dismiss the exemption petition.

In evaluating Ward Transformer Co., Inc.'s petition for exemption to buy and sell used PCB-contaminated transformers, EPA is raising a new issue about whether granting an exemption would result in an unreasonable risk to health or the environment. This issue is discussed in detail in Unit VII of this preamble. EPA will accept comments until August 23, 1984. EPA will allow the petitioner to continue buying and selling used PCB-contaminated transformers until EPA has acted to grant or deny the exemption.

EPA intends to continue its policy of requiring petitioners who file late exemption petitions to show "good cause" why EPA should accept the petition for consideration, as described in the notice published in the *Federal Register* of March 5, 1980 (45 FR 14247).

#### IV. Unreasonable Risk Finding

Section 6(e)(3)(B)(i) of TSCA requires a petitioner to show that granting an exemption would not result in an unreasonable risk of injury to health or the environment.

To determine whether a risk is unreasonable, EPA balances the probability that harm will occur against the benefits to society from granting an exemption. Specifically, EPA considers the following factors:

1. The effects of PCBs on human health and the environment, including the magnitude of PCB exposure to humans and the environment.
2. The benefits to society of granting an exemption and the reasonably ascertainable economic consequences of denying an exemption petition.

These are the same factors that EPA must consider in deciding whether a chemical substance or mixture presents an unreasonable risk of injury to health or the environment under sections 6(a) and 6(e) of TSCA.

#### A. Effects on Human Health and the Environment

In deciding whether to grant an exemption, EPA considers the effects of PCBs on human health and the environment, including the magnitude of PCB exposure to humans and the environment. The effects of PCBs are described in various documents that are part of the rulemaking record for the PCB Ban Rule published in the *Federal Register* of May 31, 1979 (44 FR 31514). Before the proposed PCB Exemptions Rule was published, EPA evaluated this information, plus new information submitted to the Agency and other recent literature. The results are presented in EPA's "Response to Comments on Health Effects of PCBs" (August 19, 1982). During the comment period on the proposed PCB Exemptions Rule, two commentators presented additional information about the adverse health effects of PCBs. EPA evaluated this information, as well as other recent literature, and has determined that none of the information submitted changes EPA's conclusions about the health effects of PCBs. The results are presented in EPA's "Response to Comments on the Proposed PCB Exemptions Rule" (June 1984) and "Response to Comments on the Proposed Uncontrolled PCB Rule" (June 1984). All of these documents are included in the rulemaking record and are summarized below. Copies of these documents are available from EPA's TSCA Assistance Office (see address listed under "FOR FURTHER INFORMATION CONTACT").

##### 1. Health Effects

EPA has determined that PCBs are toxic and persistent. PCBs can enter the body through the lungs, gastrointestinal tract, and skin, circulate throughout the body, and be stored in the fatty tissue.

Available animal studies indicate an oncogenic potential, the degree of which would depend on exposure. Available epidemiological data are not adequate to confirm or negate oncogenic potential in humans at this time. Further epidemiological research is needed to correlate human and animal data, but EPA finds no evidence to suggest that the animal data would not predict an oncogenic potential in humans.

In addition, EPA finds that PCBs may cause reproductive effects, developmental toxicity, and oncogenicity in humans exposed to PCBs. Available data show that some PCBs have the ability to alter reproductive processes in mammalian species, sometimes even at doses that

do not cause other signs of toxicity. Animal data and limited available human data indicate that prenatal exposure to PCBs can result in various degrees of developmental toxic effects. Postnatal effects have been demonstrated on immature animals, following exposure to PCBs prenatally and via breast milk.

In some cases chloracne may occur in humans exposed to PCBs. Severe cases of chloracne are painful, disfiguring, and may require a long time before the symptoms disappear. Although the effects of chloracne are reversible, EPA considers these effects to be significant.

## 2. Environmental Effects

Certain PCB congeners are among the most stable chemicals known and decompose very slowly once they are released into the environment. They remain in the environment and are taken up and stored in the fatty tissue of organisms. EPA has concluded that PCBs can be concentrated in freshwater and marine organisms. The transfer of PCBs up the food chain from phytoplankton to invertebrates, fish, and mammals can result ultimately in human exposure through consumption of PCB-containing food sources.

Available data show that PCBs affect the productivity of phytoplankton and the composition of phytoplankton communities; cause deleterious effects on environmentally important freshwater invertebrates; and impair reproductive success in birds and mammals.

PCBs also are toxic to fish at very low exposure levels. The survival rate and the reproductive success of fish can be adversely affected in the presence of PCBs. Various sublethal physiological effects attributed to PCBs have been recorded in the literature. Abnormalities in bone development and reproductive organs also have been demonstrated.

## 3. Risks

Toxicity and exposure are the two basic components of risk. Based on animal data, EPA concluded that in addition to chloracne, there is the potential for reproductive effects, developmental toxicity, and oncogenicity in humans. EPA also concluded that PCBs present a hazard to the environment.

Minimizing exposure to PCBs should minimize any potential risk. EPA takes exposure into consideration when evaluating each exemption petition, as discussed in later units of this preamble.

## B. Benefits and Costs

The benefits to society of granting an exemption vary, depending on the

activity for which exemption is requested. The reasonably ascertainable costs of denying an exemption vary, depending on the individual petitioner. EPA takes the benefits and costs into consideration when evaluating each exemption petition, as discussed in later units of this preamble.

## V. Good Faith Efforts Finding

Section 6(e)(3)(B)(ii) of TSCA requires petitioners to make good faith efforts to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for PCBs. EPA considers several factors in determining whether a petitioner has made good faith efforts. For each exemption petition, EPA considers the kind of exemption the petitioner is requesting, whether substitutes exist and are readily available, and whether the petitioner expended time and money to develop or search for a substitute. In each case, the burden is on the petitioner to show specifically what it does to substitute non-PCBs for PCBs or to show why it does not seek to substitute non-PCBs for PCBs. EPA considers the attempt to make good faith efforts when evaluating each exemption petition, as discussed in later units of this preamble.

## VI. Actions Affected by the Uncontrolled PCB Rule

In earlier proposed PCB Exemptions Rule, EPA deferred action on 49 petitions for exemption to manufacture, process, or distribute in commerce substances or mixtures inadvertently contaminated with 50 ppm or greater PCBs. EPA did so because the activities for which each of these petitioners requested exemption would be affected by the ongoing Uncontrolled PCB Rulemaking. Only 49 of these exemption petitions remain to be resolved because EPA dropped one of the exemption petitions which is not affected by the Uncontrolled PCB Rule and which was incorrectly included in the earlier proposed PCB Exemptions Rule.

In this notice EPA is still deferring action on these 49 exemption petitions because the final Uncontrolled PCB Rule, published elsewhere in this issue of the Federal Register, sets new regulatory cutoffs for the inadvertent manufacture, processing, distribution in commerce, and use of certain PCBs. EPA recognizes that the new regulatory cutoffs may affect many of the 49 petitions for exemption to manufacture, process, or distribute in commerce inadvertently generated PCBs. For example, some petitioners are engaged in activities that, because of the

discounting for monochlorinated and dichlorinated biphenyls, involve concentrations of PCBs at levels below the new regulatory cutoffs and, therefore, will no longer need an exemption. On the other hand, other petitioners are engaged in activities that involve concentrations of PCBs at levels above the new regulatory cutoffs, and, therefore, will still need an exemption to continue their activities.

Each petitioner should review the Uncontrolled PCB Rule to decide whether it still needs an exemption. If an exemption is still needed, a petitioner must renew its exemption petition by submitting updated information to show that granting an exemption would not result in an unreasonable risk of injury to health or the environment and to show that it made good faith efforts to develop non-PCB substitutes for PCBs. Petitioners must submit the information required by 40 CFR 750.10-750.21 (for manufacturing exemption petitions) and 40 CFR 750.30-750.41 (for processing and distribution in commerce exemption petitions) no later than October 1, 1984. EPA will evaluate the new information submitted and will then propose to grant or deny each petition based on the information submitted.

If a petitioner does not renew its exemption petition by October 1, 1984, EPA will assume that the petitioner no longer needs an exemption and will dismiss the exemption petition. The effect of such a dismissal is that the petitioner would not be allowed to continue the activities if it does not notify EPA of compliance with the Uncontrolled PCB Rule. The continuation of such activities would be a violation of section 15 of TSCA and would make the petitioner liable for penalties under section 16 of TSCA.

Each of the 49 exemption petitions, except for one petition submitted by Mobay Chemical Corp., is for activities that were underway before January 1, 1979 (for manufacturing) or July 1, 1979 (for processing and distribution in commerce). Each of these petitioners (except Mobay Chemical Corp.) is still allowed to continue the activities for which it requested exemption until EPA acts on the petition, in accordance with the EPA policy described in Unit III.C of this preamble. Mobay Chemical Corp. is not allowed to engage in the activities for which it requested exemption until EPA acts on the petition, because such activities were not underway before July 1, 1979.

Therefore, each of the following 49 exemption petitioners should evaluate the effects of the Uncontrolled PCB Rule

and, if necessary, renew its exemption petition by October 1, 1984:

#### A. Manufacturing Exemptions

Aluminum Co. of America, Pittsburgh, PA 15219 (ME-3).  
 American Hoechst Corp., Somerville, NJ 08876 (ME-5).  
 Diamond Shamrock Corp., Pasadena, TX 77501 (ME-27).  
 Dow Chemical Co., Midland, MI 48640 (ME-29, ME-30 and ME-30.1).  
 General Electric Co., Fairfield, CT 06431 (ME-39).  
 Hilton-Davis Chemical Co., Division of Sterling Drug Inc., Cincinnati, OH 45237 (ME-50).  
 Olin Corp., Stamford, CT 06904 (ME-75).  
 PPG Industries, Inc., Pittsburgh, PA 15222 (ME-81 and ME-81.1).  
 SDS Biotech Corp., Painesville, OH 44077 (ME-28 and ME-28.1).  
 Stauffer Chemical Co., Westport, CT 06880 (ME-90).

#### B Processing and Distribution in Commerce Exemptions

Acme Printing Ink Co., Chicago, IL 60607 (PDE-164.1).  
 Aluminum Co. of America, Pittsburgh, PA 15219 (PDE-13).  
 American Can Co., Greenwich, CT 06830 (PDE-14).  
 American Cyanamid Co., Savannah, GA 31402 (PDE-16).  
 American Hoechst Corp., Somerville, NJ 08876 (PDE-70.5).  
 American Paper Institute, Inc., Washington, DC 20036 (PDE-89).  
 American Thermoplastics Corp., Subsidiary of Phillips Petroleum Co., Houston, TX 77020 (PDE-245.1).  
 Binney & Smith, Inc., Easton, PA 18042 (PDE-34).  
 Buckeye Printing Ink Co., Inc., Columbus, OH 43209 (PDE-164.2).  
 Chemical Specialties Manufacturers Association, Washington, DC 20036 (PDE-42).  
 Columbia Paint Corp., Huntington, WV 25728 (PDE-47).  
 Crown Metro, Inc., Greenville, SC 29606 (PDE-70.1).  
 Daicolor Division, Dainichiseika Color & Chemicals America, Inc., Pine Brook, NJ 07058 (PDE-58).  
 Dow Chemical Co., Midland, MI 48640 (PDE-64 and PDE-67).  
 Dow Chemical Co., Plaquemine, LA 70764 (PDE-68).  
 Eastman Kodak Co., Eastman Chemicals Division, Kingsport, TN 37662 (PDE-70.6).  
 Forrest Paint Co., Eugene, OR 97402 (PDE-90).  
 Galaxie Chemical Corp., Paterson, NJ 07524 (PDE-95).  
 Goodyear Tire & Rubber Co., Akron, OH 44316 (PDE-102).

Hilton-Davis Chemical Co., Division of Sterling Drug Inc., Cincinnati, OH 45237 (PDE-70.4).  
 Ideal Toy Corp., Hollis, NY 11423 (PDE-70.3).  
 Inmont Corp., Clifton, NJ 07015 (PDE-123).  
 Minnesota Mining & Manufacturing Co., St. Paul, MN 55133 (PDE-157.2).  
 Mobay Chemical Corp., Dyes and Pigments Division, Union, NJ 07083 (PDE-157.10).  
 National Association of Chemical Distributors, Chicago, IL 60602 (PDE-162).  
 National Paint and Coatings Association, Washington, DC 20005 (PDE-167).  
 Prestige Printing Ink Co., Fort Worth, TX 76105 (PDE-70.2).  
 Reed Plastics Corp., Holden, MA 01520 (PDE-224).  
 Soap and Detergent Association, New York, NY 10016 (PDE-244).  
 Society of the Plastics Industry, Inc., New York, NY 10017 (PDE-245).  
 Uniroyal Chemical Co., Rovol Polymers Group, Naugatuck, CT 06770 (PDE-283).  
 Uniroyal, Inc., Middlebury, CT 06749 (PDE-284).  
 U.S. Department of the Treasury, Bureau of Engraving and Printing, Washington, DC 20228 (PDE-288).  
 United States Printing Ink Co., East Rutherford, NJ 07073 (PDE-164.3).

#### VII. Ward Transformer Co., Inc.

Ward Transformer Co., Inc., Raleigh, NC 27622 (PDE-294), submitted a petition for exemption to process and distribute in commerce PCBs in buying and selling used PCB-contaminated transformers. Since the requested exemption is for an activity that was underway before July 1, 1979, the petitioner has been allowed to continue the activities for which it requested exemption until EPA acts on the petition, in accordance with the EPA policy described in Unit III.C of this preamble.

The petitioner is engaged in the following activities for which an exemption is required: (1) Buying and selling PCB transformers or PCB-contaminated transformers without introducing PCBs into these transformers; and (2) buying PCB transformers or PCB-contaminated transformers, introducing non-PCB fluid into these transformers, and then selling them before they have been reclassified as non-PCB transformers in accordance with the provisions of 40 CFR 761.30(a)(2)(v). The petitioner needs an exemption, because it is distributing in commerce PCBs, as defined in section 3(4) of TSCA and 40 CFR 761.3(i).

In the earlier proposed rule, EPA described certain activities that do not require an exemption. Section 6(e)(3)(C) of TSCA and 40 CFR 761.20(c)(1) allow a person to distribute in commerce PCB transformers and PCB-contaminated transformers without the need for an exemption, provided the following conditions are met:

(1) The transformer was originally distributed in commerce before July 1, 1979, for purposes other than resale.  
 (2) The transformer is totally enclosed (i.e., intact and nonleaking) when it is distributed in commerce.  
 (3) No PCBs are introduced into the transformer (including PCB fluid or PCB-contaminated fluid originally removed from and returned to the same transformer.)

(4) The transformer is distributed in commerce only within the United States. Unless each of the four conditions described above is met, a person must petition for and obtain an exemption from EPA before processing or distributing in commerce PCBs in buying and selling used PCB transformers and PCB-contaminated transformers.

EPA originally proposed to deny Ward Transformer's exemption petition, because the petitioner did not show that granting an exemption would not result in an unreasonable risk of injury to health or the environment. EPA determined that granting an exemption would result in some additional risk of exposure to humans or the environment to PCBs, due to the normal leaks and spills in handling liquid PCBs and transformers containing PCBs. In addition, EPA determined that the costs of denying these petitions would be small. Based on the limited information submitted by the petitioner, EPA estimated the incremental costs of denial to be \$90 to \$240 for an average size PCB-contaminated transformer, assuming that all the transformer fluid had to be replaced and disposed of. EPA recognized that the additional costs resulting from denial might render a portion of petitioner's buying and selling activity unprofitable, but concluded that the added risk of exposure to PCBs and the small costs of denial outweighed the relatively small benefits to society of granting an exemption.

Since Ward Transformer did not submit enough information to meet the first statutory requirement for obtaining an exemption, EPA did not base the proposed denial on the second requirement of TSCA section 6(e)(3)(B), which is that petitioner must make good faith efforts to substitute non-PCBs for PCBs.

During the comment period on the proposed rule, EPA received the following comments:

Ward Transformer commented that EPA should grant it an exemption to process and distribute in commerce PCB-contaminated fluid in buying and selling used PCB-contaminated transformers for the following reasons: (1) Granting an exemption would result in no unreasonable risk of injury to health or the environment, because Ward Transformer's bulk oil storage facilities, storage yard containment, runoff control, and waste water treatment comply with all EPA regulations for handling, storing, and disposing of PCBs; (2) Ward Transformer uses only non-PCB fluid (i.e., less than 50 ppm PCBs) to refill the used transformers that it buys and sells; and (3) denying an exemption would cause Ward Transformer to go out of business, because sales of 200 used transformers in 1982 represented 33 percent of its business and sales of 95 used transformers in 1983 represented 30 percent of its business. Ward Transformer commented that since all of these transformers were retrofilled with non-PCBs, it has shown good faith efforts to substitute non-PCBs for PCBs. During the public hearing on the proposed rule, EPA asked Ward Transformer why it does not reclassify PCB-contaminated transformers to non-PCB transformers in accordance with 40 CFR 761.30(a)(2)(v) before selling them. In its reply comment, Ward Transformer explained that it is not technically feasible for it to reclassify PCB-contaminated transformers to non-PCB transformers before selling them, because it does not have the facilities to energize and place "in service" for 90 days transformers having many different sizes and voltages. In addition, Ward Transformer stated that it would be prohibitively expensive to do so (an estimated \$100,000 per transformer in electricity costs alone).

The Electrical Apparatus Service Association (EASA) also submitted comments in support of granting an exemption to Ward Transformer and 264 other companies it represents. EASA's comments are basically the same as those of Ward Transformer: granting an exemption would allow a company to replace a customer's burned-out transformer in days instead of months, thereby helping small utilities and industrial companies provide efficient and reliable electrical service throughout the United States; would not result in human or environmental exposure to PCBs; and would avoid large costs of denial. During the public

hearing on the proposed rule, EPA asked EASA why a company does not reclassify PCB-contaminated transformers to non-PCB transformers in accordance with 40 CFR 761.30(a)(2)(v) before selling them. In its reply comment, EASA explained that it is not technically feasible for companies to reclassify PCB-contaminated transformers to non-PCB transformers in accordance with 40 CFR 761.30(a)(2)(v) before selling them, because repair shops do not have the facilities to energize and place "in service" for 90 days transformers having many different sizes and voltages.

In considering Ward Transformer's petition for an exemption, EPA is aware that Robert Ward, Jr., an officer of Ward Transformer, was convicted under the criminal provisions of section 16(b) of TSCA, 15 U.S.C. 2615, of knowingly or willfully causing the unlawful disposal of PCBs, and under 18 U.S.C. 2 of aiding and abetting the unlawful disposal of PCBs (*United States v. Ward*, 676 F.2d 94 (4th Cir. 1982), *cert. denied*, 103 S. Ct. 79 (1982)). Throughout this rulemaking, neither EPA nor Ward Transformer has raised the issue of Mr. Ward's PCB-related conviction as a factor in deciding whether to grant an exemption to Ward Transformer. In the absence of information to the contrary, EPA believes that Mr. Ward's conduct creates a cause for concern that granting an exemption to Ward Transformer may result in an unreasonable risk of injury to health or the environment. This concern can be allayed if Ward Transformer submits clear and convincing evidence to show that granting an exemption would not result in such a risk.

Therefore, EPA specifically solicits the following information on the issue of unreasonable risk: (1) A description of the methods Ward Transformer uses to protect workers during the buying, servicing, and selling of PCB transformers and PCB-contaminated transformers; (2) records of the amount of PCB fluid and PCB-contaminated fluid Ward Transformer collected and disposed of since July 1, 1982; (3) records of the PCB disposal sites and the owners or operators of those sites where Ward Transformer disposed of PCB fluid and PCB-contaminated fluid since July 1, 1982; (4) records of how many PCB transformers and PCB-contaminated transformers Ward Transformer purchased and from whom since July 1, 1982; (5) records of how many PCB transformers and PCB-contaminated transformers Ward Transformer sold and to whom since July 1, 1982; (6) the amount of Ward Transformer's total

sales (in dollars) since July 1, 1982; and (7) the reasonably ascertainable loss of sales (in dollars) if EPA were to deny an exemption to buy and sell used PCB-contaminated transformers. In addition, Ward Transformer should provide an affirmation that it has acted since July 1, 1982 in a manner that indicates good faith compliance with all applicable federal, state, and local laws and regulations for the protection of human health and the environment. Based on the information submitted on the earlier proposed rule and additional information submitted in response to this notice, EPA will take final action to grant or deny Ward Transformer's exemption petition.

EPA realizes that delaying final action on Ward Transformer's exemption petition will allow it to continue the activities for which it requested an exemption until EPA acts on the petition. In the interest of fairness or other similarly situated petitioners, whose exemption petitions are being granted or denied in the final PCB Exemptions Rule published elsewhere in this issue of the **Federal Register**, EPA intends to issue a final rule as soon as possible. If EPA does grant an exemption to Ward Transformer, EPA intends to make the exemption expire on the same date as the one-year exemption granted to other companies in the final PCB Exemptions Rule published elsewhere in this issue of the **Federal Register**.

#### VIII. Official Rulemaking Record

For the convenience of the public and EPA, all of the information originally submitted in docket number OPTS-66001 (manufacturing exemptions) and OPTS-66002 (processing and distribution in commerce exemptions) was consolidated into docket number OPTS-66008. Information and comments submitted in response to this proposed rule related notice will be filed in docket number OPTS-66008B.

In accordance with the requirements of section 19(a)(3) of TSCA, EPA is publishing the following list of documents which constitutes the record of this rulemaking. A supplementary list or lists may be published any time on or before the date the final rule is issued. Public comment, the transcript of the rulemaking hearing, and submissions made at the rulemaking hearing or in connection with it are not listed, because these documents are exempt from **Federal Register** listing under section 19(a)(3). However, these documents are included in the public record, and a full list of these materials is available on request from EPA's

TSCA Assistance Office listed under  
**FOR FURTHER INFORMATION CONTACT.**

#### A. Previous Rulemaking Records

(1) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Disposal and Marking Rule," Docket No. OPTS-66005, 43 FR 7150, February 17, 1978.

(2) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions Rule," 44 FR 31514, May 31 1979.

(3) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs); Proposed Rulemaking for PCB Manufacturing Exemptions," Docket No. OPTS-66001, 44 FR 31564, May 31, 1979.

(4) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Electrical Equipment," Docket No. OPTS-62015, 47 FR 37342, August 25, 1982.

(5) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes," Docket No. OPTS-62017, 47 FR 46980, October 21, 1982.

(6) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Amendment to Use Authorization for PCB Railroad Transformers," Docket No. OPTS-62020, 48 FR 124, January 3, 1983.

(7) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs); Manufacture, Processing, Distribution in Commerce, and Use Prohibitions; Use in Microscopy and Research and Development," Docket No. OPTS-62031, 48 FR 52402, November 17, 1983.

#### B. Federal Register Notices

(8) 43 FR 50905, November 1, 1978, USEPA, "Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act; Interim Procedural Rules for Polychlorinated Biphenyls (PCBs); Ban Exemption."

(9) 44 FR 108, January 2, 1979, USEPA, "Polychlorinated Biphenyls (PCBs); Policy for Implementation and Enforcement."

(10) 44 FR 31558, May 31, 1979, USEPA, "Procedures for Rulemaking Under section 6 of the Toxic Substances Control Act; Interim Procedural Rules for Exemptions from the Polychlorinated Biphenyls (PCBs) Processing and Distribution in Commerce Prohibitions."

(11) 44 FR 31564, May 31, 1979, USEPA, "Polychlorinated Biphenyls (PCBs); Proposed Rulemaking for PCB Manufacturing Exemptions."

(12) 44 FR 42727, July 20, 1979, USEPA, "Proposed Rulemaking for Polychlorinated Biphenyls (PCBs); Manufacturing Exemptions; Notice of Receipt of Additional Manufacturing Petitions and Extension of Reply Comment Period."

(13) 45 FR 14247, March 5, 1980, USEPA, "Polychlorinated Biphenyls (PCBs); Statement of Policy on All Future Exemption Petitions."

(14) 45 FR 29115, May 1, 1980, USEPA, "Polychlorinated Biphenyls (PCBs); Expiration of the Open Border Policy for PCB Disposal."

(15) 48 FR 50486, November 1, 1983, USEPA, "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce Exemptions; Proposed Rule," Docket No. OPTS-66008.

(16) 48 FR 52402, November 17, 1983, USEPA, "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Microscopy and Research and Development; Proposed Rule," Docket No. OPTS-62031.

(17) 48 FR 55076, December 8, 1983, USEPA, "Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations; Proposed Rule," Docket No. OPTS-62032.

#### C. Support Documents

(18) USEPA, OPTS, EED, Letter from Marigene H. Butler, Philadelphia Museum of Art, to Martin P. Halper, EPA, "Use of PCBs in Microscopy" (April 29, 1983).

(19) USEPA, OPTS, EED, Telephone Communication between Denise Keehner, EPA, and Martha Goodway, Smithsonian Institution, "Use of PCBs in Microscopy" (May 9, 1983).

(20) USEPA, OPTS, EED, "Response to Comments on the Proposed Uncontrolled PCB Rule" (June 1984).

(21) USEPA, OPTS, EED, "Response to Comments on the Proposed PCB Exemptions Rule" (June 1984).

(22) USEPA, OPTS, EED, "PCB Exemption Petitions Economic Impact Analysis" (Apr. 1984).

(23) USEPA, OPTS, HERD, "Response to Comments on Health Effects of PCBs" (August 19, 1982).

(24) USEPA, OPTS, "Support Document/Voluntary Environmental Impact Statement and PCB Manufacturing, Processing, Distribution in Commerce, and Use in Ban Regulation: Economic Impact Analysis" (Apr. 1979).

#### D. Reports

(25) USEPA, ORD, EMSL, "A Method for Sampling and Analysis of Polychlorinated Biphenyls (PCBs) in Ambient Air" (August 1978), EPA-600/4-78-048.

#### E. Other

(26) Manufacturing Exemption Petitions and Related Communications in Docket No. OPTS-66001.

(27) Processing and Distribution in Commerce Exemption Petitions and Related Communications in Docket No. OPTS-66002.

#### IX. Executive Order 12291

Under Executive Order 12291, issued February 17, 1981, EPA must judge whether a rule is a "major rule" and, therefore, subject to the requirement that a Regulatory Impact Analysis be prepared. EPA has determined that this proposed rule related notice is not a "major rule" as that term is defined in section 1(b) of the Executive Order.

EPA has concluded that this proposed rule related notice is not a "major" rule under the criteria of section 1(b) because the annual effect on the economy will be considerably less than \$100 million; it will not cause any noticeable increase in costs or prices for any sector of the economy or for any geographic region; and it will not result in any significant adverse effects on competition, employment, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets. Indeed, this proposed rule related notice allows the continued manufacture, processing, and distribution in commerce of PCBs that would otherwise be prohibited by section 6(e)(3)(A) of TSCA for the petitioners who met the requirements of section 6(e)(3)(B) of TSCA and the Interim Procedural Rules for PCB Exemptions.

Although this proposed rule related notice is not a major rule, EPA has analyzed the economic impact using the guidance in the Executive Order to the extent possible. This proposed rule related notice was submitted to the Office of Management and Budget (OMB) for review prior to publication, as required by the Executive Order.

#### X. Regulatory Flexibility Act

Section 603 of the Regulatory Flexibility Act (the Act), 5 U.S.C. 603, requires EPA to prepare and make available for comment an initial regulatory flexibility analysis in connection with any rulemaking for which EPA must publish a general

notice of proposed rulemaking. The initial regulatory flexibility analysis must describe the effect of a rule on small business entities.

Section 605(b) of the Act, however, provides that section 603 of the Act "shall not apply to any proposed or final rule if the head of the Agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities."

EPA estimated the costs of denying Ward Transformer Co., Inc.'s petition for exemption to buy and sell used PCB-contaminated transformers. EPA estimated the incremental costs of denial to be \$160 for a used 46-gallon PCB-contaminated transformer. Ward Transformer stated that it sold 200 transformers in 1982 and 95 transformers in 1983. Assuming that granting an exemption would allow Ward Transformer to sell 150 PCB-contaminated transformers during a one-year exemption, EPA estimated the total costs of denial to be \$24,000.

EPA did not estimate the costs of denial for the 49 exemption petitions affected by the Uncontrolled PCB Rule. At this point, EPA cannot predict how many exemption petitions will be renewed and, if renewed, how many will be granted or denied. EPA will estimate the economic impact of denial

on small business entities after it receives any renewed petitions.

Therefore, in accordance with section 605(b) of the Act, I certify that a final rule, if promulgated, will not have a significant economic impact on a Substantial number of small entities. EPA solicits comments from petitioners and other interested persons concerning the economic impact of this proposed rule related notice on small business entities. In addition, EPA is sending a copy of this proposed rule related notice to the Chief Counsel for Advocacy of the Small Business Administration.

EPA further notes that section 606 of the Act states that the requirements of Section 603 do not alter in any manner standards otherwise applicable by law to agency action. In general, the manufacture, processing, and distribution in commerce of PCBs are prohibited by section 6(e)(3)(A) of TSCA and the PCB regulations, 40 CFR Part 761. Section 6(e)(3)(B) of TSCA permits EPA to grant exemptions from these prohibitions, if the Administrator finds that a petitioner has shown that granting an exemption would not result in an unreasonable risk of injury to health or the environment and that it has made good faith efforts to develop substitutes for PCBs. Both small and large businesses must meet the same

statutory standard. Thus, even if EPA believed that it was an economically or socially desirable policy to grant an exemption to a small business, it could do so only if the small business met the requirements set forth in TSCA.

#### XI. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, authorizes the Director of OMB to review certain information collection requests by Federal agencies. EPA's original request to collect information for this rulemaking was approved by OMB and was assigned OMB Control Number 2000-0466. EPA's subsequent request to collect information for this rulemaking through December 31, 1984, was approved by OMB and was assigned OMB Control Number 2070-0021.

#### List of Subjects in 40 CFR Part 761

Hazardous materials, labeling, polychlorinated biphenyls, recordkeeping and reporting requirements, environmental protection.

(Sec. 6, Pub. L. 94-469, 90 Stat. 2020 (15 U.S.C. 2605))

Dated: June 27, 1984.

Alvin L. Alm,

Acting Administrator.

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