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Part IV

Environmental Protection Agency

Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 761

[OPTS-62032; TSH-FRL 2456-6]

Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed 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 notice proposes to amend 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 announces EPA's deferral of action on 50 exemption petitions to manufacture, process, and distribute PCBs in commerce and proposes a regulation to authorize the use of PCBs in heat transfer and hydraulic systems at concentrations of less than 50 parts per million (ppm).

DATES: Two days of informal hearings on this proposed rule, if requested will be held on February 21 and 22, 1984, at EPA headquarters in Washington, D.C. On February 21, 1984, the hearing will address the amendment to the Closed and Controlled Waste Manufacturing Processes Rule. On February 22, 1984, the hearing will address exemptions and the use authorization for PCBs in heat transfer and hydraulic systems. The exact times and locations of the hearings will be available by calling EPA's TSCA Assistance Office. Comments on this proposed rule and requests to participate in the informal hearings must be submitted by February 6, 1984. Reply comments made in response to issues raised at the hearings must be submitted no later than one week after the close of the hearings.

ADDRESS: Since some comments are expected to contain confidential business information, all comments should be sent in triplicate to: Document Control Officer (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M Street, SW., Washington, D.C. 20460.

Comments should include the docket number OPTS-62032. Comments received on this proposed rule will be available for reviewing and copying from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays, in Rm. E-107 at the address given above.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, toll free: (800-424-9065), in Washington, D.C.: (554-1404), outside the U.S.A.: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. COMMENTS AND RULEMAKING PROCEDURES

EPA encourages commenters to submit nonconfidential information. However, commenters who believe that they can state their position only by using confidential information may submit it to the Agency marked "CONFIDENTIAL." Please send confidential information via certified mail to the Document Control Officer (see address listed under "**ADDRESS**"). Information marked "CONFIDENTIAL" 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. Whenever confidential information is submitted, it must be accompanied by a nonconfidential summary of the information claimed to be confidential for inclusion in the public record.

EPA will conduct all hearings in accordance with EPA's "Procedures for Conducting Rulemaking under Section 6 of the Toxic Substances Control Act" (40 CFR Part 750). Commenters who want to participate in the informal 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 informal hearings are meant to provide an opportunity for commenters to present additional information or to discuss new issues, not to repeat information already presented in written comments.

II. OVERVIEW OF THIS NOTICE OF PROPOSED RULEMAKING

Section 6(e) of TSCA generally prohibits the manufacture, processing, distribution in commerce, and use of PCBs. In the **Federal Register** of May 31, 1979 (44 FR 31514), EPA issued a regulation that implemented section 6(e). (This rule is hereafter referred to as the PCB Ban Rule.) Among other things, the PCB Ban Rule generally excluded from regulation materials containing PCBs in concentrations of less than 50 ppm. The Environmental Defense Fund (EDF) successfully challenged this 50 ppm cutoff in *EDF* v. *EPA*, 636 F.2d 1267 (D.C. Cir. 1980). As a result of this remanded concentration limit, EPA is proposing three actions on PCBs. These actions are: (1) An amendment of the October 21, 1982 Closed and Controlled Waste Manufacturing Processes Rule; (2) deferral of action on 50 exemption petitions to manufacture, process, and distribute in commerce inadvertently generated PCBs; and (3) a use authorization for PCBs in hydraulic and heat transfer fluid. Units III, IV, and V, respectively, discuss these actions in detail.

III. PROPOSED AMENDMENT TO THE CLOSED AND CONTROLLED WASTE MANUFACTURING PROCESSES RULE

A. 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.

EPA issued the PCB Ban Rule to implement the prohibitions of section 6(e) of TSCA. 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.

EDF obtained judicial review of the PCB Ban Rule in the U.S. Court of Appeals for the District of Coluimbia Circuit in *EDF* v. *EPA*. 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." The court upheld the 11 use authorizations. The court remanded the rule to EPA 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 generate 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 the court's mandate setting aside the classification 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 beginning with an Advanced Notice of Proposed Rulemaking (ANPR). 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 rule will hereafter be referred to as the Electrical Equipment Rule.) Among other things, that rule authorizes for the remainder of their useful lives: (1) PCB-Transformers not posing an exposure risk to food or feed; (2) large PCB capacitors that are located in restricted-access electrical substations; (3) large PCB capacitors that are located in contained and restricted-access indoor installations; and (4) all PCB-containing, mineral oil-filled electrical equipment. The use of PCB-Transformers that pose an exposure risk to food or feed is prohibited after October 1, 1985. The use of large PCB capacitors that are not located in restricted-access areas is prohibited after October 1, 1988. The rule requires weekly, quarterly, or annual inspection of authorized electrical equipment (other than mineral oil equipment) for leaks of dielectric fluid, depending on the location of the equipment and other factors.

The genesis of today's proposed 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 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 that rulemaking. A brief history of the events subsequent to the February 20, 1981 motion will explain how EPA arrived at today's proposed rule.

Throughout the discussions leading to this 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 that generate 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 in 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)(3)(A) 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. 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 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. The court order required EPA to: (1) Issue ANPRs covering PCBs in concentrations of less than 50 ppm; (2) promulgate a final rule within 18 months of the date of the order (i.e., by October 13, 1982) to exclude generation of PCBs in closed and controlled waste manufacturing processes from the prohibitions of section 6(e)(3)(A) of TSCA; and (3) advise the court within 11 months of the date of the order (i.e., 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 PCB 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 these ANPRs, EPA stated that it needed to develop a substantial factual record to support these PCB rulemakings.

Approximately 50 public comments were submitted in response to these ANPRS. Most of the comments were submitted by companies that were inadvertently generating PCBs in the manufacture of other chemicals. The most extensive comment was a survey filed by the CMA, a trade association whose membership includes many of the nation's principal chemical manufacturers.

In accordance with the April 13, 1981 court order, on March 11, 1982, EPA 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 in the Closed and Controlled Waste Manufacturing Processes Rule were resolved. 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. Closed manufacturing processes are processes that generate PCBs but release PCBs in concentrations below the practical limits of quantitation for PCBs in specific media. These limits are 10 micrograms per cubic meter (roughly 0.01 ppm) per resolvable gas chromatographic peak in air emissions, 100 micrograms per liter (roughly 0.1 ppm) per resolvable gas chromatographic peak in water effluent, and 2 micrograms per gram (2 ppm) per resolvabe gas chromatographic peak in products and water streams. Controlled waste manufacturing processes are processes that are defined using the above limits, but the waste stream may contain greater than 2 ppm PCBs as long as these wastes are disposed of properly. According to the rule, wastes with a concentration of 50 ppm or greater PCBs must be disposed of in accordance with the PCB disposal regulations in 40 CFR 761.60. Wastes with a PCB concentration of less than 50 ppm may either be disposed of according to 40 CFR Part 761 or at facilities approved under the provisions of section 3005(c) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C 6925(c).

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, and September 1983.

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. The five basic conditions of the consensus proposal that must be met in order to qualify for the proposed exclusion from the TSCA section 6(e)(3)(A) prohibitions are:

(1) Concentration 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) Quantitation of PCBs is to be calculated after discounting the concentration of monochlorinated and dichlorinated biphenyls by factors of 50 and 5, respectively; and

(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 provides for an "upset provision." This provision would establish procedures for dealing with higher levels of release of PCBs than would be allowed by the rule, provided that such releases are due to factors beyond the control of the operator.

CMA, EDF, and NRDC also concluded that none of the subsections of section 6(e) of TSCA provides the specific framework for any regulation of uncontrolled PCBs less than total prohibition (other than the filing of annual exemptions). However, read together the various subsections demonstrate congressional intent, as found by the Court of Appeals, that practical regulatory alternatives to a total ban are proper if no unreasonable risks of injury are presented.

In addition to the consensus proposal and other comments received on inadvertently generated PCBs, EPA received information on recycled PCBs. Recycled PCBs, are PCBs that were intentionally generated in the past and enter newly manufactured products as PCB-contaminated raw materials. The American Paper Institute (API) and the Asphalt Roofing Manufacturers Association (ARMA) have submitted information to EPA on recycled PCBs in their industries. Inquires to EPA about recycled PCBs have also been made by firms that salvage automobiles and waste oils that are contaminated with PCBs in concentrations of less than 50 ppm. The number of firms engaged in these activities could possibly number in the thousands. EPA has decided to included recycled PCBs in this rulemaking.

Based on the data analyses EPA had completed when it received the consensus proposal, the Agency determained that it was appropriate to use the consensus proposal as a framework for this proposed rule. 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 and additions to that framework. Specifically, EPA stated that the proposed rule: (1) Would include PCBs generated in the past that continue to be incorporated into new products (recycled PCBs); (2) would consider concentration limits lower than 25 ppm for higher risk products; and (3) would not include an upset provision. EPA rejected the upset provision because the Agency concluded that plant upsets could result in high level releases of PCBs in air, water, or products that could cause injury to health or the environment. Such releases should not be excluded from regulation.

B. Overview of the Proposed Amendment

This proposed amendment will offer regulatory relief for those instances of manufacture, processing, distribution in commerce and use of inadvertently generated and recycled PCBs that do not present an unreasonable risk of injury to health or the environment. To achieve this end, EPA is proposing an amendment to the Closed and Controlled Waste Manufacturing Processes Rule that will exclude inadvertently generated and recycled PCBs in certain situations, described below, from the prohibitions of section 6(e) of TSCA.

EPA has considered several approaches to provide regulatory relief from the prohibitions of section 6(e) for PCBs at very low levels that do not present unreasonable riskes to public health. The exemption process of section 6(e)(3)(B) provides one alternative. However, under 6(e)(3)(B), exemption petitions would be required each year for the manufacture, processing, and distribution in commerce of all inadvertently generated and recycled PCBs. This approach would require annual rulemaking on each petition and would be extremely

resource-intensive for the industries that must file annually for exemptions, as well as for EPA. The burden of the exemption process would not be outweighed by the public health benefits obtained from regulating small amounts of PCBs.

Another regulatory strategy EPA considered was to develop regulatory limits on concentration levels for each chemical process in which uncontrolled PCBs are generated. This chemical-by-chemical approach would have relied on individual exposure assessments for the various uses of each chemical that contained or that might contain inadvertently generated PCBs. This chemical-by-chemical approach would have been extremely resource-intensive. In addition, chemical-specific standards would need revision as new processes are discovered that inadvertently generate PCBs.

Prior to receipt of the consensus proposal, EPA considered and proceeded with a regulatory strategy based on a small number of hypothetical worst-case exposure scenarios that were developed to represent a whole group or class of similar exposure situations. These scenarios that assess the exposure to a group of exposure situations, rather than individual situations are referred to as generic exposure assessments. The risks of cancer and reproductive/developmental effects can be estimated from these generic exposure assessments. These estimates of risk would then be used in developing generic exclusions, if warranted, based on a determination that particular classes of processes generating PCBs at low levels would not present unreasonable risks. The generic exposure assessment approach is less resource-intensive than the chemical-specific approach; however, it is protective of human health and the environment. A description of the generic exposure assessment appears in Unit III.D of this preamble.

The regulatory strategy initially pursued by EPA, based on generic exclusions, is more detailed and specific than the consensus approach which sets a simple regulatory limit. EPA has adopted the generic exclusion approach in developing this rulemaking; however, EPA's approach supports the regulatory framework submitted by CMA, EDF, and NRDC in the consensus proposal.

The document entitled "Recommendation of CMA, EDF, and NRDC for a Final EPA Rule on Inadvertent Generation of PCBs" uses the Closed and Controlled Waste Manufacturing Processes Rule as a framework. Thus, in using the consensus proposal to develop this proposed rule, EPA has also used the Closed and Controlled Waste Manufacturing Processes Rule as a framework. Furthermore, the PCB analytical chemistry methodology developed to determine PCB concentration under that rule serves this proposed rule. Basic concepts developed in that rule, have been retained in this proposed rule, such as the provision allowing manufacturers to conduct theoretical assessments in lieu of actual monitoring to determine PCB levels in releases.

In both the Closed and Controlled Waste Manufacturing Processes Rule and this proposed rule, PCB concentration limits are established for products, air emissions, water effluents, and wastes. The Closed and Controlled Waste Manufacturing Processes Rule sets the limits for PCBs in products, air emissions and water effluents 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 limit levels were appropriate. In today's proposed rule the limits are established based on EPA's determination that the activities excluded will not present an unreasonable risk of injury to human health or the environment.

CMA, EDF, and NRDC stated in the consensus proposal that regulating inadvertently generated PCBs presents difficult problems for both the regulated industries and EPA, because Congress did not deal specifically with inadvertently generated PCBs in section 6(e) of TSCA. The only apparent alternatives to the outright ban of these uncontrolled PCBs are: (1) The annual exemption process included in section 6(e)(3)(B) of TSCA, which addresses manufacture, processing, and distribution in commerce; and (2) section 6(e)(2)(B) of TSCA which authorizes the use of PCBs in other than a totally enclosed manner. Both of these provisions use the concept of an unreasonable risk of injury to health or the environment to determine if relief from the section 6(e) prohibition is appropriate.

CMA, EDF, and NRDC also pointed out that inadvertent generation activities involve the manufacture, processing, and use of PCBs. Indeed, previously generated PCBs (recycled PCBs) could be considered to be "used" within the context of section 6(e)(2) of TSCA.

Although CMA, EDF, and NRDC have different views on the toxicology of PCBs, they believe that their recommendation would assure an absence of unreasonable risk of injury to health or the environment. According to the consensus proposal, CMA, EDF and NRDC determined that it was not necessary to discuss the toxicology of PCBs in order to determine that there would not be an unreasonable risk.

EPA has considered the consensus proposal in terms of the required findings of sections 6(a) and 6(e) of TSCA and has decided to adopt an unreasonable risk test to support this proposed rule. By adopting this approach, EPA believes, as do CMA, EDF, and NRDC, that the Agency is consistent with congressional intent and is reasonably regulating inadvertently generated and recycled PCBs.

After the Closed and Controlled Waste Manufacturing Processes rule was published, EPA completed quantitative risk assessments for PCBs. Based on the risk assessment for carcinogenicity as well as information on reproductive/developmental effects, environmental effects, and costs, EPA has determined that the manufacture, processing, distribution in commerce, and use of PCBs below the limits proposed in the consensus proposal would not present an unreasonable risk of injury to human health or the environment. EPA is therefore proposing to exclude these activities from the prohibitions of section 6(e) of TSCA. For further information, see the following documents that have been included in the Official Rulemaking Record: "Quantitative Risk Assessment of Reproductive Risks Associated with PCB Exposure;" "Summary and Update of Carcinogenic Risk Assessments of Polychlorinated Biphenyls;" "Environmental Hazards and Risk Assessments for Various Isomers of Polycholorinated Biphenyls (Monochlorobiphenyl through Hexachlorobiphenyl and Decachlorobiphenyl);" and "Regulatory Impact Analysis of the Proposed Rule Regulating Inadvertent PCB Generation from Uncontrolled Sources."

Based on the risk assessments conducted by EPA and the consensus proposal, the Agency is proposing to exclude from the prohibitions of section 6(e) of TSCA those activities (including manufacture, processing, distribution in commerce, and use) that meet the criteria outlined below:

(1) PCB concentrations in the components of certain consumer products with a high potential for exposure are limited to less than 5 ppm. These consumer products are deodorant bars and soaps, and plastic building materials and products.

(2) PCB concentrations present in all products not named in item (1) above are limited to an annual average of 25 ppm with a 50 ppm maximum.

(3) 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) PCB concentrations discharged from manufacturing or processing sites to water are limited to less than 0.1 ppm for any resolvable gas chromatographic peak.

(5) All process wastes containing 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 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.

(7) The certification, reporting, and record maintenance requirements are met.

EPA's proposal to exclude the above activities from the prohibitions of section 6(e) of TSCA requires an amendment to the definitions in the Closed and Controlled Waste Manufacturing Processes Rule. EPA is proposing to delete the definitions of "closed manufacturing processes" and "controlled waste manufacturing processes" in that rule. In place of these definitions, EPA is proposing a new definition—"excluded manufacturing process," which expands exclusions established by the previous definitions. These exclusions are based on a finding that the products and wastes excluded will not present an unreasonable risk of injury to health or the environment.

In addition, EPA is proposing to establish limits for "recycled PCBs." Recycled PCBs are PCBs that were generated in the past and may enter a manufacturing process as PCB-contaminated raw materials. In general, these are intentionally generated PCBs (i.e. Aroclor) that are found at low concentration. EPA has evaluated the risk of exposure to recycled PCBs and concludes that these risks are substantially similar to those risks for the inadvertently generated PCBs. Therefore, EPA has included recycled PCBs in the exclusions provided by today's proposed rule. However, in quantifying recycled PCBs, the discounting factors for monochlorinated and dichlorinated biphenyls may not be used. This is consistent with the methods used in quantifying other intentionally generated PCBs.

For the purposes of this rulemaking, EPA has set the water effluent regulatory limit at 0.1 ppm per resolvable gas chromatographic peak, which represents the level of quantitation. This is the LOQ set in the Closed and Controlled Waste Manufacturing Processes Rule. In that rule, EPA concluded that for all practical purposes, it would be impossible to determine whether regulation of PCB concentrations below the practical LOQ had any effect on actually reducing releases of PCBs. EPA reaffirms this conclusion.

EPA is proposing the air emission limit of 10 ppm recommended in the consensus proposal. This recommendation is based on the expectation that the concentration at the fenceline of the facility will be at the LOQ.

EPA proposes that companies may conduct actual monitoring or a theoretical assessment of potential PCB concentration levels in products, air emissions, and water effluents. EPA intends to enforce this rule with actual monitoring of PCB levels, using the analytical and sampling methodology outlined in Unit III.I of this preamble.

C. Summary of Available Data

In developing this proposed rule, EPA has considered many sources of information. EPA considered the comments received in response to the ANPR for uncontrolled PCBs, which was published in the **Federal Register** of May 20, 1981 (46 FR 27619). EPA also considered the data submitted by CMA in a document entitled "A Report of a Survey on the Incidental Manufacturing, Processing, Distribution, and Use of Polychlorinated Biphenyls at Concentrations below 50 ppm." EPA also considered the information submitted in relevant PCB exemption petitions. This information has been incorporated into the exposure analysis for this proposed rule.

After reviewing the information submitted, EPA attempted to identify the chemical processes that could inadvertently generate PCBs. EPA initially developed a list of approximately 200 chemical processes with a potential for generating PCBs. (See support document entitled "Summary of Organic Chemical Product Classes Potentially Containing Inadvertently Generated PCBs.") These chemicals were then ranked as high, moderate, or low with respect to their potential to generate PCBs. (See support document entitled "Organic Chemical Processes Leading to Generation of Incidental Polychlorinated Biphenyls.") Seventy chemical processes were determined to have a high potential for PCB generation. EPA focused on this group of 70 chemical processes in developing its generic exposure assessments to support this proposed rule. These 70 chemical processes are listed below:

- Allyl Alcohol
- Allyl Amines
- Aluminum Chloride
- Aminoethylethanolamine
- Benzene Phosphorus Dichloride
- Benzophenone
- Benzotrichloride
- Benzoyl Peroxide
- Carbon Tetrabromide
- Carbon Tetrafluoride
- Chlorendic Acid/Anhydride Esters
- Chlorinated Acetophenones
- Chlorinated Benzenes:
  - Dichlorobenzenes
  - Hexachlorobenzene
  - Monochlorobenzene
  - Pentachlorobenzene
  - 1,2,4,5-Tetrachlorobenzene
  - Trichlorobenzenes
- Chlorinated Benzotrichlorides
- Chlorinated Benzotrifluorides
- Chlorinated, Brominated Methanes
- Chlorinated Ethanes:
  - 1,1-Dichloroethane
  - 1,2-Dichloroethane
  - Hexachloroethane
  - Monochloroethane
  - 1,1,2,2-Tetrachloroethane
  - 1,1,1-Trichloroethane
  - 1,1,2-Trichloroethane
- Chlorinated Ethylenes:
  - 1,1-Dichloroethylene
  - 1,2-Dichloroethylene
  - Monochloroethylene
  - Tetrachloroethylene
  - Trichloroethylene
- Chlorinated, Fluorinated Ethanes
- Chlorinated, Fluorinated Ethylenes
- Chlorinated, Fluorinated Methanes
- Chlorinated Methanes:
  - Carbon Tetrachloride
  - Chloroform
  - Methyl Chloride
  - Methylene Chloride
- Chlorinated Naphthalenes
- Chlorinated Pesticides
- Chlorinated Pigments/Dyes
- Chlorinated Propanediols
- Chlorinated Propanols:
  - Dichlorohydrin
  - Propylene Chlorohydrin
- Chlorinated Propylenes
- Chlorinated, Unsaturated Paraffins
- Chlorobenzaldehyde
- Chlorobenzoic Acid/Esters
- Chlorobenzoyl Peroxide
- bis(2-Chloroisopropyl) Ether
- Dimethoxy Benzophenone
- Dimethyl Benzophenone
- Diphenyl Oxide
- Epichlorohydrin
- Ethylene Diamine

Glycerol
Hexachlorobutadiene
Hexachlorocyclohexane
Hexachlorocyclopentadiene
Linear Alkyl Benzenes
Methallyl Chlorides
Pentachloronitrobenzene
Phenylchlorosilanes
o-Phenylphenol
Phosgene
Propylene Oxide
Tetramethylethylene Diamine
Trichlorophenoxy Acetic Acid

On December 20, 1982, EPA held a public meeting to describe the additional information that would be necessary to develop realistic exposure assessments for this proposed rule. Both environmental groups and industry representatives attended and participated in this meeting. In a further attempt to obtain additional data about manufacture, processing, distribution in commerce, and use of PCBs in concentrations of less than 50 ppm, EPA again described its data needs for this rulemaking at a CMA seminar held on February 17, 1983. EPA stated that it was seeking data about manufacturing processes, intermediate products, industrial end uses, consumer products, production volumes, environmental fate, and potential for occupational and consumer exposure to PCBs. EPA received 25 responses to its informal requests for information. These data were used in developing the exposure scenarios.

EPA has also received information from a number of sources on recycled PCBs. The most complete information was submitted by the API and the ARMA. API, representing nearly 200 companies, submitted comments concerning the processing of other than newly generated PCBs (recycled PCBs). API states 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 raw materials. 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 product.

D. Effects on Human Health

In today's proposed rule, EPA proposes to exclude conditionally from regulation under section 6(e) of TSCA the manufacture, processing, distribution in commerce, and use of certain inadvertently generated PCBs; and the processing, distribution in commerce, and use of recycled PCBs. This proposed exclusion is based on a finding that such PCBs present no unreasonable risk of injury to human health and the environment. EPA, in deciding whether a chemical presents an unreasonable risk, considers the factors outlined in section 6(c) of TSCA.

To determine whether a risk is unreasonable, EPA balances the probability that harm will occur from the chemical under consideration against the cost to society of placing restrictions on that chemical. Specifically, EPA has considered the following factors:

(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 inadvertently generated PCBs; and

(4) The economic impact resulting from the proposed rule's effect upon the national economy, small business, technological innovation, the environment, and public health.

1. HUMAN HEALTH RISKS

In deciding whether to grant an exclusion, EPA considered the effect of PCBs on human health and the environment. The effects of PCBs have been previously described in various document that are part of the rulemaking record for the May 31, 1979, PCB Ban Rule. EPA evaluated this information, 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," which is included in the rulemaking record and summarized below. Copies of this document are available through EPA's TSCA Assistance Office (see address listed under "**FOR FURTHER INFORMATION CONTACT**").

a. 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.

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

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 developmentally toxic effects. Postnatal effects have been demonstrated in immature animals, following exposure to PCBs prenatally and via breast milk.

In addition, 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. EPA finds no evidence to suggest that the animal data would not be predictive of the potential for oncogenic effects in humans.

Available data indicate little or no mutagenic activity from PCBs. EPA believes, however, that more information is needed to draw a conclusion on the possibility of mutagenic effects from PCBs.

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.

b. Risks

Toxicity and exposure are the two basic components of risk. EPA has taken exposure into consideration when evaluating the exclusions proposed in this rule. EPA first estimated the maximum probable human exposures to inadvertently generated PCBs in a quantitive exposure assessment. Using the quantitive exposure assessment, EPA developed quantitative risk assessments. Descriptions of both the quantitative exposure assessment and the quantitative risk assessments appear below.

i. Quantitative exposure assessment. As a part of the risk assessment process, a series of exposure assessments were conducted by EPA. The purpose of the exposure assessments was to estimate the maximum probable human exposures to inadvertently generated PCBs under various scenarios. Included among the various scenarios are occupational, consumer, and general population exposures to PCBs through ingestion, inhalation, and dermal absorption. EPA has also developed

generic exposure assessments for activities that recycle PCBs.

Few data were available to EPA regarding actual exposure to inadvertently generated and recycled PCBs. Thus, in estimating exposure levels, EPA developed a hypothetical worst-case approach. EPA believes that all of the estimated exposures are equal to or greater than actual exposures.

After developing a list of processes most likely to generate PCBs, as described in Unit III.C of this preamble, EPA developed a list of possible exposure scenarios. From this list of exposure scenarios, EPA developed a number of generic exposure scenarios to assess the exposure to PCBs in the workplace and exposures to PCBs in the environment resulting from releases of PCBs to air, water, and solid wastes. These scenarios are representative of known exposures to inadvertently generated and recycled PCBs. Five of these generic exposure scenarios estimated the maximum probable human exposures to inadvertently generated PCBs under five different ambient exposures. The remaining generic exposure scenarios estimated the exposure in 20 different occupational settings. Among the occupational exposure settings considered in this assessment are spray painting operations, pesticide spraying operations, removal of still bottoms from process equipment, and maintenance of process equipment.

In addition, nine scenarios assess consumer exposures to PCBs during the use of products potentially containing PCBs. These consumer exposure scenarios empahsize products whose potential for exposure is large because of high frequency or duration of use.

Detailed descriptions of the exposure scenarios and their findings are included in the support document entitled "Exposure Assessment for Incidentally Produced Polychlorinated Biphenyls."

ii. Quantitative human health risk assessments. EPA published a document in August 1982 entitled "Response to Comments on Health Effects of PCBs Submitted by CMA and the Edison Electric Institute." This document is a comprehensive review of available data concerning the health effects of PCBs. The findings of this document are described in Unit iII.D.1.a above. Toxicity information on PCBs provided in the "Response to Comments on Health Effects of PCBs Submitted by CMA and the Edison Electric Institute" and the quantitative exposure assessment discussed above, have been used in preparing a reproductive/developmental risk assessment and a carcinogenicity risk assessment for PCBs. EPA is not able to prepare a quantitative risk assessment for chloracne since no epidemiology or test animal data were available to make such a risk assessment possible.

CMA, EDF, and NRDC in the consensus proposal estimated that the 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 that the consensus proposal estimates to have entered the environment annually before PCB controls were instituted.

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. Based on these facts, EPA agrees with the consensus proposal that releases of inadvertently generated PCBs would have no measurable effect on the public health.

(1) Reproductive/Developmental Risk Assessment.

The document entitled "Quantitative Risk Assessment of Reproductive Risk Associated with PCB Exposure" is one of the first documents in which EPA attempts to quantify the predicated reproductive/developmental risks. Since EPA will be involved in the development of other, future reproductive/developmental risk assessments, the Agency is particularly interested in receiving comments on basic issues pertaining to reproductive/developmental risk assessments in general. Examples of these issues are: (1) Criteria for selecting the most appropriate model for assessing risk, and (2) whether or not to assume the existence of a threshold for reproductive effects. The results of the PCB reproductive/developmental risk assessment by the methods used indicate that these risks are less than those risks predicted in the PCB carcinogenic risk assessment.

Two studies were used in the reproductive/developmental risk assessment. In the first study, Rhesus monkeys were exposed to PCBs in their diet for 18 months at concentrations of 2.5 and 5.0 ppm. Symptoms observed included reproductive problems such as stillbirths, spontaneous abortions, resorptions, or death of infants prior to weaning. Neonatal toxicity, including lowered birth weight, was also observed. Many problems were encountered in evaluating these data for use in the risk assessment because of difficulties in quantifying actual dosages ingested by the Rhesus monkeys.

The second study used in this assessment was a two-generation study conducted on rats receiving 1, 5, 20, and 100 ppm PCBs in their diet. Death prior to weaning was the observed effect. In general, the number of deaths prior to weaning increased with an increase in dosage level. Data were also included from a post-implantation study conducted at 10, 50, and 100 milligrams per kilogram per day (mg/kg/day) of PCBs. There was no evidence that reproduction and pup survival were affected at 10 and 50 mg/kg/day, but there was a dramatic increase in the percentage of pups dead at weaning at the 100 mg/kg/day dose level.

Several methods were used to calculate reproductive risks for humans from the Rhesus monkey study and the rat study. The usual method of setting a "safe" level of exposure is based on a no observed effect level (NOEL). The lowest and highest "safe" levels derived using this method were 0.05 ug/kg/day and 50.0 ug/kg/day. Ten different models were considered in order to extrapolate to "safe" levels. These models are described in detail in the support document entitled "Quantitative Risk Assessment of Reproductive Risks Associated with PCB Exposure."

The linear interpolation technique using the rat data was selected to extrapolate risks to humans from available exposure scenarios. Because of the better quality or the rat study as compared to the Rhesus monkey study, data from the rat study were selected for use in developing the risk assessment. The model chosen is the most conservative and, therefore, the most protective of human health.

Based on this risk assessment, EPA estimated the risk during organogenesis for approximately 38 exposure scenarios. These 38 scenarios are representative of situations in which women in their child-bearing years would be exposed to PCBs. Most of the exposure scenarios resulted in estimated risks at extremely low levels (only 1 in 100,000 or more people exposed to PCBs would be expected to demonstrate reproductive/developmental effects from that exposure if this estimate of risk is accurate) in spite of the fact that the risks had been estimated using worst-case exposure scenarios and a conservative risk model. However, some of the exposure scenarios estimated the risk to be at higher levels. These 5 scenarios are discussed below.

(a) Continuous exposure via inhalation at the level of quantitation for

PCBs in air 10 micrograms per cubic meter ($\mu g/m^3$): This scenario was included as a point of reference. It assumes that an individual is constantly exposed to 10 $\mu g/m^3$ of PCBs in air for a lifetime. EPA estimates that maximum exposures and risks associated with inhalation of PCBs will be at least 1 order of magnitude lower and typically 2 to 3 orders of magnitude lower for workers, and 3 to 6 orders of magnitude lower for consumers and the general population. Estimated maximum exposure levels are less than levels associated with continuous exposure to the level of quantitation because either: (i) The maximum possible PCB concentration is less than 10 $\mu g/m^3$ under the conditions of the scenario, or (ii) the duration and frequency of exposure are much lower.

(b) Ingestion of fish and water obtained from streams which receive industrial wastewater effluent containing 100 micrograms of PCBs per liter of wastewater ($\mu g/l$). In EPA's exposure scenario, 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 effluents from the chemical and plastics industries, risks of reproductive effects could be high. Consequently, EPA is proposing that the concentrations of PCBs in wastewater effluent must be below the level of quantitation which is 100 $\mu g/l$. Given current, practical analytical chemistry methods, EPA set the baseline level for measuring PCBs at the LOQ because concentration levels lower than the LOQ cannot be reliably measured. Thus, setting the concentration limit for PCBs in plant effluents below the LOQ would in effect be equivalent to a total ban on PCBs in water effluents. In the unlikely case that local conditions may present a higher level of risk, this rule would be superseded by the Water Quality Standards, resulting in an applicable requirement in that plant's water discharge permit.

(c) Inhabiting a new home containing plastic building materials containing PCBs at 25 ppm. The exposure scenario assumes that all plastic building materials emit PCBs continuously and that new homes contain a total of 230 kg (507 pounds) of plastic building materials. It also assumes that all of the PCBs in the plastic materials are released into the indoor air over a two-year period and that an individual inhabits three such new homes for a total lifetime exposure duration of six years. Because of the potential for widespread exposure to consumers who are often unaware of their exposure to toxic chemicals, EPA is proposing a 5 ppm PCB concentration limit for plastic building materials. EPA believes that the risk is significantly less than the worst-case estimate because: (i) Evidence suggests that PCBs are present in plastic only as a contaminant in pigments at a maximum weight percent of plastic of less than 2 ppm, and (ii) PCBs in pigments are unlikely to migrate to air at a rate of 100 percent in 2 years.

(d) Use of soap, assuming PCBs are present in the surfactant constituent of the soap at 25 ppm. This exposure scenario assumes that all of the PCBs present in the soap are dermally absorbed. In actual use, most of the PCBs will be rinsed off before absorption. Thus, the actual exposure is significantly lower and, therefore, the risk is lower than the worst-case estimate presented in the quantitative risk assessment.

In an alternate exposure scenario, EPA estimated a typical exposure to PCBs in soap by assuming that a soap film was deposited on the skin and only the PCBs in the film were absorbed. This estimate produced and estimated risk 3 orders of magnitude less than the original exposure scenario for soap. Unlike all of the other scenarios that estimate dermal absorption of PCBs, this scenario assumes that the absorption of PCBs is spread out over time and not instantaneous. This alternate scenario is EPA's best estimate of maximum exposure to PCBs in soap. Because it is impossible to determine whether the exposures and risks estimated using assumptions in the alternate scenario equal or exceed actual exposures, EPA is proposing a 5 ppm concentration limit for PCBs in soap based on the assumption that all PCBs in the soap are absorbed. The actual exposure level will be significantly lower than the estimated exposure; therefore, the actual risk will be lower than the worst-case estimate presented in the quantitative risk assessment.

In fact, PCBs are only hypothesized to occur in soaps and may not be present. If PCBs do not occur in soaps, there would be no risk from PCB exposure in soaps.

(e) Use of skin lotions and creams, assuming PCBs are present in the surfactant constituent of these products at 25 ppm. This exposure scenario assumes daily usage, 100 percent immediate absorption, and generous applications of the 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. EPA has provided this information to the Food and Drug Administration (FDA), the Federal agency that regulates these products, for appropriate action.

The reproductive/developmental effects risk assessment is described in greater detail in the support document entitled "Quantitative Risk Assessment of Reproductive Risk Associated with PCB Exposure."

(2) Carcinogenic risk assessment

The carcinogenic risk assessment reviews three previous PCB risk assessments conducted by FDA, U.S. Congressional Office of Technology Assessment (OTA), and the EPA Cancer Assessment Group (CAG). Finally, the carcinogenic risk assessment includes a risk assessment of PCBs completed by the EPA Office of Toxic Substances (OTS) in September 1983.

The OTS carcinogenic risk assessment was developed using studies conducted by the National Cancer Institute (NCI) and Dr. Renate Kimbrough with three and one positive dose levels, respectively. From these studies, EPA extrapolated carcinogenic risk at certain low exposures. The dose-response data for total malignancies are linear, corresponding well with the "linearized" upper 95 percent confidence limits from the CAG risk assessment.

Based on this risk assessment, EPA estimated the excess carcinogenic risk for over 100 exposure scenarios. These scenarios are representative of known exposures to inadvertently generated or recycled PCBs. In the majority of the exposure scenarios, the estimated risk was at an extremely low level (this effect would be observed in only 1 in 100,000 or more people if this estimated risk is accurate) in spite of the fact that the risks had been estimated using worst-case exposure scenarios and a conservative risk model. For the scenarios listed below, the estimated risk appeared to be at a level that warranted further review of the assumptions used. Thus, EPA reviewed further the following exposure scenarios:

Ambient Inhalation

Exposure at the PCB level of quantitation for air (10 ug/m^3).

Ambient Ingestion

Average adult intake of PCBs via food as reported by FDA in 1978.

Ingestion of fish containing 2 ppm of PCBs.

Ingestion of fish or water obtained from water bodies downstream of chemical plants discharging wastewater containing 100 μ/l of PCBs.

Occupational Inhalation

Exposure at the Occupational Safety and Health Administration (OSHA) standard for PCBs in air (1000 $\mu g/m^3$).

Exposure at the level of quantitation of PCBs in air (10 $\mu g/m^3$).

Exposure at the NIOSH recommended standard for PCBs in air (1 $\mu g/m^3$).

Loading/unloading a powder assuming compliance with the OSHA nuisance dust standard and assuming PCBs are present in the powder at 25 ppm.

Exposure to background levels of fugitive emissions in enclosed chemical manufacturing plants assuming PCBs are present in the process stream at 25 ppm.

Exposure to paint mists during spray painting assuming PCBs are present in the solvent at 25 ppm.

Exposure to evaporative emissions during plastic manufacturing operations assuming PCBs are present in the plastic at 25 ppm.

Exposure during manufacture of asphalt roofing products (various concentrations).

Exposure to evaporative emissions during paper manufacturing assuming PCBs are present in waste at 12 ppm.

Exposure during sampling assuming the process stream contains PCBs at 25 ppm.

Exposure during removal of still bottoms assuming PCBs are present in the still bottoms at 200, 2500, and 5000 ppm.

Exposure to fugitive emissions for a worker stationed 6 meters downwind of leaking equipment assuming PCBs are present in the emitted chemical at 25 ppm.

Exposure to paint mists during spray painting assuming PCBs are present in the solvent at 25 ppm.

Occupational Dermal

Transfer and handling operations assuming PCBs are present at 25 ppm. Specifically: loading/unloading liquid; and, loading/unloading powder.

Processing operations assuming PCBs are present at 25 ppm. Specifically: Closed process operations; open surface tank operations; spray painting operations; grain fumigation operations; non-spray coating operations; product formulation operations; product fabrication operations; metalworking operations; newspaper production; plastic manufacture; and dry cleaning of garments.

Sampling and maintenance operations assuming PCBs are present at 25 ppm in the process stream. Specifically: Sampling process stream; cleaning equipment; off-line repair of equipment; removing filters; removing still bottoms assuming PCBs are present in still bottoms at 200, 2500 and 5000 ppm; and spill cleanup.

Consumer Inhalation

Exposures resulting from inhabiting a new home containing plastic building materials which are assumed to contain PCBs at 25 ppm.

Consumer Dermal

Exposures resulting from use of deodorant soaps assuming PCBs are present in the surfactant at 25 ppm.

Exposures resulting from use of skin lotions assuming PCBs are present in the surfactant at 25 ppm.

(a) Occupational exposures. All except seven of the scenarios listed above represent estimated occupational exposure. EPA has reviewed those scenarios that estimated the occupational exposure to PCBs. In instances where the occupational dermal exposure is estimated, immediate total absorption is assumed. The inhalation and dermal exposure scenarios assume that workers were exposed to PCBs for 38.5 years. Further, protective equipment must be worn by workers handling many of the chemicals in which inadvertently generated PCBs can be found based on industrial hygiene programs prescribed by individual companies and OSHA regulations. Therefore, EPA concludes that the actual risks from such exposures are significantly lower than the worst-case estimates presented in the quantitative risk assessment.

(b) Continuous exposure via inhalation at the level of quantitation for PCBs in air (10 $\mu g/m^3$). This scenario was included as a point of reference. It assumes that an individual is constantly exposed to 10 $\mu g/m^3$ of PCBs in air for a lifetime. EPA estimates that maximum exposures and risks associated with inhalation of PCBs will be at least 1 order of magnitude lower and typically 2 to 3 orders of magnitude lower for workers, and 3 to 6 orders of magnitude lower for consumers and the general population. Estimated maximum exposure levels are less than levels associated with continuous exposure to the level of quantitation because either: (i) The maximum possible PCB concentration is less than 10 $\mu g/m^3$ under the conditions of the scenario, or (ii) the duration and frequency of exposure are much lower.

(c) Food intake at levels reported by FDA in 1978. This scenario assumes that individuals ingest PCBs at the levels found in a food survey conducted by FDA in 1978. If these levels are actually found in food, however, they would most likely come from the estimated hundreds of millions of pounds of intentionally generated PCBs that are found in the environment. Compared to these PCBs, releases of PCBs from activities excluded from the PCB ban by this rule are not expected to result in a significant incremental risk to public health.

(d) Ingestion of fish containing 2 ppm of PCBs. This scenario assumes that all fish eaten contain 2 ppm of PCBs, the FDA proposed tolerance level for PCBs in fish. In addition, this scenario assumes that 6.5 grams of PCBs are eaten by an individual each day for 70 years. If these levels are actually found in fish, however, they would most likely come from the hundreds of millions of pounds of PCBs estimated to be in the environment. When compared to these PCBs, activities excluded under this rule release negligible amounts of PCBs. This rule is not expected to result in significant incremental risk from ingestion of fish. If local conditions indicate a higher level of risk, this rule would be superseded by the Water Quality Standard, resulting in an applicable requirement in that plant's discharge permit.

(e) Ingestion of fish and water obtained from streams which receive industrial wastewater effluent containing 100 micrograms of PCBs per liter of wastewater ($\mu g/l$). In EPA's exposure scenario, 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 effluents from the chemical and plastics industries, risks of reproductive effects could be high. Consequently, EPA has decided that the concentration of PCBs in wastewater effluent must be below the level of quantitation of 100 $\mu g/l$. Given current, practical analytical chemistry methods, EPA set the baseline level for measuring PCBs at the LOQ because concentration levels lower than the LOQ cannot be reliably measured. Thus, setting the concentration limit for PCBs in plant effluents below the LOQ would in effect be equivalent to a total ban on PCBs in water effluents. In the unlikely case that local conditions may present a higher level of risk, this rule would be superseded by the Water Quality Standards, resulting in an applicable requirement in that plant's water discharge permit.

(f) Inhabiting a new home containing plastic building materials containing PCBs at 25 ppm. The exposure scenario assumes that all plastic building materials emit PCBs continuously and that new homes contain a total of 230 kg (507 pounds) of plastic building materials. It also assumes that all of the PCBs in the plastic materials are released into the indoor air over a two-year period and that an individual inhabits three such new homes for a

total lifetime exposure duration of six years. Because of the potential for widespread exposure to consumers who are often unaware of their exposure to toxic chemicals, EPA is proposing a 5 ppm PCB concentration limit for plastic building materials. EPA believes that the risk is significantly less than the worst-case estimate because: (1) Evidence suggests that PCBs are present in plastic only as a contaminant in pigments at maximum weight percent of plastic of less than 2 ppm, and (ii) PCBs in pigments are unlikely to migrate to air at a rate of 100 percent in two years.

(g) Use of soaps assuming that PCBs are present in the surfactant component of the soaps at 25 ppm. This exposure scenario assumes that all of the PCBs present in the soap are dermally absorbed. In actual use, most of the PCBs will be rinsed off before absorption. Thus, the estimated exposure is significantly lower; therefore, the risk is lower than the worst-case estimate presented in the quantitative risk assessment.

In an alternate exposure scenario, EPA estimated a typical exposure to PCBs in soap by assuming that a soap film was absorbed. This estimate produced an estimated risk 3 orders of magnitude less than the original exposure scenario for soap. Unlike all of the other scenarios that estimate dermal absorption of PCBs, this scenario assumes that the absorption of PCBs is spread out over time and not instantaneous. The alternate scenario is EPA's best estimate of maximum exposure to PCBs in soap. Because it is impossible to determine whether the exposures and risks estimated using assumptions in the alternate scenario equal or exceed actual exposures, EPA is proposing a 5 ppm concentration limit for PCBs in soap based on the assumption that all PCBs in the soap are absorbed. The actual exposure level will be significantly lower than the estimated exposure, and the actual risk will be lower than the worst-case estimate presented in the quantitative risk assessment.

In fact, PCBs are only hypothesized to occur in soaps and may not be present. If PCBs do not occur in soaps, there would be no risk from PCB exposure in soaps.

(h) 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.

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. EPA has provided this information to the FDA, the Federal agency that regulates these products for appropriate action.

Further details concerning this quantitative risk assessment are presented in the support document entitled "Summary and Update of Carcinogenic Risk Assessments of Polychlorinated Biphenyls."

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 inportant 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 also 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 also 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. For example, in juvenile and adult fish the NOEC for the monochlorinated biphenyl isomers were estimated to be 50–80 micrograms per liter (μg/l); the NOEC for the hexachlorinated biphenyl isomers was estimated to be 0.01 μg/l. Likewise, in the early life-stages of fish (i.e., embryo and sac fry), the NOEC was estimated at 2 to 3 μg/l for the monochlorinated biphenyl isomers and 0.001 μg/l for the hexachlorinated biphenyl isomers. 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 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 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 the level of 10,000 pounds of PCBs released annually, would have no measurable effect on the declining environmental load.

EPA in setting the PCB concentration limit for water effluent below the LOQ, the level below which PCBs can not practically and reliably be measured. Setting the the concentration limit for PCBs below the LOQ would in effect be equivalent to a total ban on PCBs in water effluents.

In addition, reporting requirements are proposed in this rule that would require manufacturers to notify EPA if they are releasing more than 10 pounds of PCBs to air or water annually. Thus, EPA will be able to monitor those streams which are receiving high levels of PCBs from plant effluents. If PCBs released into the water from plants excluded under this rule result in a high potential risk of injury to the environment, this rule would be superseded by the Water Quality Standards resulting in an appropriate requirement in the plant's water discharge permit.

3. DISCOUNTING FACTORS FOR MONOCHLORINATED AND DICHLORINATED BIPHENYLS

The consensus proposal submitted to EPA by CMA, EDF, and NRDC allows for the discounting of monochlorinated biphenyls by a factor of 50 and dichlorinated biphenyls by a factor of 5.

In their recommendation, CMA, EDF, and NRDC stated that 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.

Both General Electric and Dow Chemical Company have petitioned the Agency under section 21 of TSCA to amend the PCB regulations to include discounting factors for the lower chlorinated PCBs. EPA denied these petitions, but stated in the denials that this issue would be considered in this rulemaking.

In support of these discounting factors, CMA, EDF, and NRDC considered data by Moolinaar (1982) as well as information provided by Dow Chemical Company in its 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 are less persistent than trichlorinated biphenyls.

To illustrate how these discounting factors would work, assume a product (not a deodorant bar, soap, or plastic building material) 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 ÷ 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).

After consideration of the available information, EPA is proposing the concept for discounting the monochlorinated and dichlorinated biphenyls. This action is based on evidence that these species are less persistent and bioaccumulate less than the more highly chlorinated biphenyls, and upon evidence that monochlorinated and dichlorinated biphenyls are not found in adipose tissue.

E. 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 inadvertently to 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 III.C of this preamble, EPA developed a list of approximately 200 chemical processes with a potential for inadvertently generating 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 soaps. These products are widespread in our society. Products, such as soap and paint, are considered essential, nonluxury 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, substitutes are not available for products contaminated with low level PCBs at the same or equivalent cost as PCB-contaminated products. In general, industry has not been successful in modifying processes to prevent the incidental formation of any PCBs. CMA has furthermore commented that research programs to study ways to reduce incidental PCB formation are very costly and have met with limited success.

EPA estimated the cost of controlling the level of inadvertently generated PCBs in a number of products through process modifications. Estimates range from approximately $77 million to $451 million if plants continue operations for 10 years. This situation contrasts markedly with the costs of controlling intentionally generated PCBs (i.e., Aroclors) since the costs of controlling or avoiding these PCBs are relatively small. Also, several Aroclor substitutes exist. As an example, Unit V.D. of this preamble states that there are at least three non-PCB substitutes for the Aroclor fluids once used in hydraulic systems.

2. ECONOMIC CONSEQUENCES

EPA has several options for dealing with the uncontrolled PCBs. EPA could allow the total ban of section 6(e) to take effect. Also, EPA could set the permissible levels of PCBs either higher or lower than those proposed in this rule.

Had EPA allowed the ban to become effective, companies could: (1) Modify the processes that incidentally 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. As stated above, industry has commented that substituting products or substituting processes to eliminate incidentally generated PCBs is not generally feasible. Thus, the selection of this regulatory option could result in a major disruption in commerce.

In the Regulatory Impact Analysis (RIA) prepared for this proposed rule, it is estimated that the total costs of the exemption petition process 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. (See support document entitled "Regulatory Impact Analysis of the Proposed Rule

Regulating Inadvertent PCB Generation from Uncontrolled Sources.")

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 proposed rule with respect to uncontrolled PCBs result from the certification, recordkeeping, and reporting requirements. These costs were estimated in the RIA to range from $9.63 million to $59 million over a 10 year period. Thus, this proposed rule presents very low costs in comparison with more restrictive approaches.

EPA estimates that this proposed 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 allow companies to develop new processes that inadvertently generate low level concentrations of PCBs. EPA estimates that the discounting factors for monochlorinated and dichlorinated biphenyls are likely to save industry $800 thousand to $4.7 million each year.

The RIA concludes that small businesses generating inadvertent PCBs will benefit form the provisions of this proposed rule. EPA bases this conclusion on its determination that all of the small businesses identified as being affected by section 6(e) of TSCA will be excluded from control. Thus, these small businesses will avoid the expense associated with filing annual exemption petitions.

With respect to technological innovation, it is reasonable to assume that at lest some portion of the sums that industry will save by not being subjected to a total PCB ban will go to research and development activities.

F. 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 proposed rule are outweighed by the costs that would be incurred if these PCBs were to be banned. The extremely high costs of eliminating the very low risks that can 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 proposed in this rule do not present an unreasonable risk of injury to health or the environment. The following facts support this conclusion.

1. EPA has estimated the carcinogenic, reproductive/developmental, and environmental risks associated with exposure to inadvertently generated and recycled PCBs at the levels excluded by this proposed rule. It is estimated that the risks associated with the vast majority of these worst-case exposure scenarios are of minimal significance.

For those products that EPA believes have a higher exposure potential, EPA has set a lower, more protective concentration limit of 5 ppm. This limit is more protective of consumers who are often unaware of potential hazards from exposure to chemicals in consumer use products.

2. Monochlorinated and dichlorinated biphenyls are not found in adipose tissue, and these PCBs are not as persistent in the environment as the more chlorinated PCBs. Therefore, discount factors established in this rule will not present serious health risks.

3. Although the number of processes that inadvertently generate PCBs may be large, the total quantity of such PCBs is several orders of magnitude less than the quantities previously intentionally manufactured (i.e., Aroclor PCBs). It is estimated that 10 million pounds entered the environment annually before PCB controls were instituted, and that a total of 180 million pounds entered the environment prior to institution of PCB controls.

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

5. 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.

6. 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, if this rule is issued as proposed, 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.

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

G. Disposal Requirements

Section 761.190 of this proposed rule requires that any processs waste containing 50 ppm or greater PCBs, which are present as a result of inadvertent generation or recycling, must comply with certain disposal provisions of the PCB Ban Rule. These provisions are: (1) Incinerate PCB process waste in accordance with § 761.60; (2) landfill such PCB waste in a landfill approved under the provisions of §§ 761.60 and 761.75; and (3) store such PCB waste for incineration or landfilling in accordance with the requirements of § 761.65(b)(1).

In the PCB Ban Rule, EPA concluded that the 50 ppm disposal standard provided adequate protection to human health and the environment. EPA reaffirms this conclusion and will retain the 50 ppm PCB standard for disposal. In determining the concentration of inadvertently generated PCBs for disposal purposes, the discounting factors for monochlorinated and dichlorinated biphenyls (50 and 5 respectively) may be used.

H. Recordkeeping, Reporting, and Certification

1. RECORDKEEPING AND REPORTING

The consensus proposal contains certain recordkeeping and reporting requirements. According to the consensus proposal, manufacturers who intend to take advantage of this exclusion must notify EPA of products leaving the manufacturing site or imported products that contain greater than 2 micrograms of PCBs per gram of product ($\mu g/g$) for any resolvable gas chromatographic peak (2 ppm). The consensus proposal states that the notification must include the number, type, and location of excluded manufacturing processes. In addition, these notices must include a certification, signed by an appropriate corporate official, that: (1) The manufacturer is in compliance with all requirements of the regulation; (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.

Manufacturers who wish to take advantage of the exclusion must also notify the Agency if they are releasing

more than 10 pounds of PCBs to air or water annually. Furthermore, the consensus proposal provides that the total quantity of PCBs in products leaving the site of an excluded manufacturing process in any calendar year must be reported to EPA 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. These notices must be submitted to EPA within 90 days of publication of this regulation in the **Federal Register** or 90 days of starting up processes or commencing importation for which such reports are required.

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, and the date and time of the analysis.

EPA agrees with the recordkeeping and reporting requirements arrived at jointly by industry and environmental groups and has incorporated them in §§ 761.185, 761.187, and 761.193 of the proposed rule. EPA intends to use the information required under this proposed rule used in the development of an enforcement strategy and compliance monitoring program.

EPA proposes that two additional minor requirements be added to the actual monitoring requirements proposed. EPA proposes that the monitoring information include: (1) The identification of the sample matrix; and (2) the lot numbers for the sample. Without this information, EPA cannot adequately determine what has been analyzed. EPA believes that the identification of the sample matrix and the lot numbers for the sample will not significantly increase the reporting time or cost to the regulated industry. EPA proposes that these requirements also apply to recycled PCBs. Further, EPA is proposing that if the certification is based on a theoretical analysis, that the estimates of PCB levels generated and released must be submitted with the certification.

A report will not be required for those PCBs in air, waste, and products below the 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 released in water below the LOQ may present high risks (as described in Unit III.D.1 of this preamble). In light of this fact, theoretical assessments that predict a plant will release more than 10 pounds of PCBs annually in the water effluent must be submitted to EPA, even if PCBs are not quantitated in the effluent during monitoring. Since CMA, EDF, and NRDC recommended the basic recordkeeping and reporting requirements proposed in this rule and described above, EPA believes that the reporting requirements proposed in this rule do not present an unreasonable burden on the regulated industry.

2. CERTIFICATION

The consensus proposal provides that a report must be filed with EPA whenever a product leaving the site of an excluded manufacturing process or being imported contains greater than 2 micrograms of PCBs per gram of product for any resolvable gas chromatographic peak. In addition to this report, excluded manufacturers and importers must certify that they are in compliance with this proposed regulation, including requirements for products, air, and water releases, and process waste disposal. The certification must include the basis for the determination that they are in compliance with this regulation (i.e., either actual monitoring or theoretical assessments). Finally, the excluded manufacturers and importers must certify that the records specified in this proposed regulation are maintained.

EPA agrees with the certification program recommended in the consensus proposal and has adopted it as § 761.185 of the proposed rule. As proposed, this certification must be submitted within 90 days of starting up a process or commencing importation of PCBs. This certification process must be repeated whenever chemical process conditions are significantly modified to make the previous certification invalid. Only minor changes to the consensus proposal, such as where to submit such certification, have been made in this proposed rule.

I. Quantitation of PCB Concentration Levels

1. ANALYTICAL CHEMISTRY METHODOLOGY

The consensus proposal recommends the use of the analytical chemistry methods developed for the Closed and Controlled Waste Manufacturing Processes Rule in determining the 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 proposed rule. Thus, the analytical chemistry methodology that will be used as part of this proposed rule will follow 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." This document presents proposed methods for chemically analyzing inadvertently generated PCBs in commercial products, product waste streams, water effluent, and air. The proposed analytical chemistry methods are based on determination of quantities of PCBs using gas chromatography/electron impact mass spectrometry (GC/EIMS). Capillary column gas chromatography (CGC) and packed column gas chromatography (PCG) are presented as alternative approaches. This analytical chemistry methodology for commercial products and product waste streams relies heavily on a strong quality assurance program.

2. SAMPLING SCHEME

EPA is proposing a sampling technique that will be used by the Agency when it monitors for compliance during an enforcement inspection. The sequential sampling protocol that EPA is proposing bases the decision to take a further sample on the results of analyses already performed. 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 PCB levels in product, air, and water samples which are strongly compliant (very low PCB levels) or strongly noncompliant (very high PCB levels). Under the proposed sequential sampling protocol, no more than seven samples would be analyzed. Detailed information about the proposed 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. 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.

The consensus proposal states that for any sample matrix with all resolvable gas chromatographic peaks below the limit of quantitation, the specified practical limit of detection for that medium will be assigned for those chromatographic peaks. CMA, EDF, and NRDC recommend that for each resolvable gas chromatographic peak, which is below the LOQ but above the LOD, the specified practical LOD for that medium would be the quantitated value for that peak. Thus, the consensus proposal recommends a baseline that is an arbitrary value below the LOQ.

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 the 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.

EPA reaffirms these conclusions reached in the Closed and Controlled Waste Manufacturing Processes Rule. Therefore, EPA proposes that the baseline for quantitating PCBs be established at the LOQ.

IV. NOTICE OF DEFERRAL OF ACTION ON PCB EXEMPTION PETITIONS

A. Statutory Authority

Section 6(e)(3)(B) of TSCA permits the Administrator to grant by rule exemptions from the ban on the manufacture, processing, and distribution in commerce of PCBs, 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." EPA may set terms and conditions for an exemption and may grant an exemption for not more than one year.

To determine whether a risk is unreasonable, EPA balances the probability that harm will occur against the benefits to society from granting or denying each exemption. Specifically, EPA considers the effects of PCBs on human health and the environment, including the magnitude of PCB exposure to humans and the environment; and the benefits to society of granting an exemption and the reasonably ascertainable costs to a petitioner of denying an exemption petition.

To determine whether a petitioner has demonstrated good faith efforts, 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 did to substitute non-PCBs for PCBs or to show why it did not seek to substitute non-PCBs for PCBs.

B. Background

EPA's Interim Procedural Rules for PCB Manufacturing Exemptions, 40 CFR 750.10 *et seq.*, were published in the **Federal Register** of November 1, 1978 (43 FR 50905). These rules describe the required content of manufacturing exemption petitions and the procedures EPA will follow in rulemaking on these petitions.

In the **Federal Register** of January 2, 1979 (44 FR 108), EPA announced that petitioners who had previously filed manufacturing exemption petitions could continue manufacturing or importation activity for which they sought exemption until EPA acted on their petitions.

EPA's Interim Procedural Rules for PCB Processing and Distribution in Commerce Exemptions, 40 CFR 750.30 *et seq.*, were published in the **Federal Register** of May 31, 1979 (44 FR 31558). These rules describe the required content of processing and distribution in commerce exemption petitions and the procedures EPA will follow in rulemaking on these petitions.

EPA's proposed rule for PCB manufacturing exemptions, which addressed the 79 manufacturing exemption petitions received at that time, was published in the **Federal Register** of May 31, 1979 (44 FR 31564). Many of these petitions addressed the inadvertent manufacture of PCBs, the major subject of this rulemaking. EPA held a hearing and received comments on that rule. EPA included additional manufacturing exemption petitions and extended the reply comment period on the proposed rule in a notice published in the **Federal Register** of July 20, 1979 (44 FR 42727). EPA has not issued a final rule in that rulemaking proceeding.

In the **Federal Register** of March 5, 1980 (45 FR 14247), EPA applied the policy stated in the January 2, 1979 **Federal Register** notice to those petitioners who had filed manufacturing, processing, and distribution in commerce exemption petitions after December 1, 1978 (for manufacturing) and July 1, 1979 (for processing and distribution in commerce). In that notice, EPA required persons filing late petitions for exemption to show "good cause" why EPA should accept the petition. If a petitioner shows "good cause," EPA permits it to continue the activities for which it seeks exemption until EPA acts on the exemption petition, as long as the activities were underway before January 1, 1979 (for manufacturing) and before July 1, 1979 (for processing and distribution in commerce).

In June 1982, EPA sent a letter to each of approximately 400 petitioners (including the submitters of the 79 manufacturing petitions mentioned above) who had previously requested an exemption to manufacture, process, or distribute in commerce PCBs. Since the information in many of the petitions was old, EPA asked these petitioners to renew their petitions, if necessary, by submitting updated information. EPA received and accepted 172 exemption petitions to manufacture, process and distribute in commerce PCBs (including 164 renewed and eight newly filed petitions), which EPA evaluated according to the requirements of TSCA and the Interim Procedural Rules for PCB Exemptions. The remainder of the petitions were withdrawn by petitioners, dismissed by EPA when they were not renewed, or dismissed by EPA because the activities for which exemption was requested did not require an exemption.

EPA next issued a proposed rule entitled, "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, and Distribution in Commerce Exemption Petitions," which was published in the **Federal Register** of November 1, 1983 (48 FR 50486), which addresses these 172 exemption petitions. In that rule, EPA proposed to grant 49 petitions, deny 73 petitions, and defer action on 50 petitions. The 50 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 III of this preamble would affect the disposition of these 50 petitions.

Each of the petitions considered here, 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). In accordance with EPA's January 2, 1979 **Federal Register** notice (44 FR 108) and its March 5, 1980 **Federal Register** notice (45 FR 14247), each of these petitioners (except Mobay Chemical Corp.) is permitted to continue the activities for which it seeks exemption until EPA acts on the exemption petition, because such activities were underway before the effective dates of the ban on PCBs. Mobay Chemical Corp. is not permitted to engage in the activities for which it seeks exemption until EPA acts on that exemption petition, because such activities were not underway before July 1, 1979.

C. Reasons for Deferral of Actions on Exemption Petitions

As described in other units of this preamble, EPA is setting new regulatory limits for the inadvertent manufacture, processing, distribution in commerce, and use of PCBs. EPA recognizes that these new regulatory limits will affect many of the 50 pending exemption petitions to manufacture, process, and distribute in commerce inadvertently generated PCBs. 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 an exemption. Other petitioners are engaged in activities that involve concentrations of PCBs at levels above the new limits and, therefore, will still require an exemption to continue their activities.

Each of the petitioners has submitted information in an attempt to demonstrate that granting an exemption would not result in an unreasonable risk of injury to health or the environment and to show good faith efforts to develop substitutes for PCBs. The information, however, was submitted before EPA decided to propose today's rule with its new regulatory cutoffs. If this rule is issued in substantially the same form as proposed, many of the exemptions may no longer be required. Consequently, EPA will defer action on the exemption petitions listed below until publication of the final rule.

EPA is hereby notifying each petitioner to review its activities to determine whether the final rule, if substantially the same as the proposed rule, will make an exemption unnecessary. If an exemption is still required, a petitioner must amend its petition with the necessary current information by the effective date of this rule. EPA intends to promulgate a final rule on inadvertently generated PCBs by July 1, 1984. The provisions of that rule will become effective 90 days after the final rule is issued. Each petitioner, therefore, will have until 90 days after the rule is issued to submit updated information to renew its petition.

In accordance with EPA's policy statement published in the **Federal Register** of March 5, 1980 (45 FR 14247), each petitioner that renews its exemption petition will be permitted to continue the activities for which it seeks exemption until EPA acts on the exemption petition, provided that the activities were underway before January 1, 1979 (for manufacturing) and July 1, 1979 (for processing and distribution in commerce).

If a petitioner does not renew its exemption petition by 90 days after the promulgation of the rule, EPA will assume that it 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 new 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.

EPA recognizes that the new regulatory limits in this proposed rule are likely to affect other persons who have not yet submitted exemption petitions. Such persons may submit exemption petitions now or, if they prefer, during the 90 days between promulgation and the effective date of the final rule. The exemption petitions on which EPA is delaying action are listed below:

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, 30, and 30.1).
General Electric Co., Fairfield, CT 06431 (ME 39).
Hilton-Davis Chemical Co., Division of Sterling Drug Inc., Cincinnati, OH 45237 (ME 50).
Honeywell, Inc., Waltham, MA 02154 (ME 51).
Olin Corp., Stamford, CT 06904 (ME 75).
PPG Industries, Inc., Pittsburgh, PA 15222 (ME 81 and 81.1).
SDS Biotech Corp., Painesville, OH 44077 (ME 28 and 28.1).
Stauffer Chemical Co., Westport, CT 06880 (ME 90).

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 43215 (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 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 Sterline 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., Novel 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 283).
United States Printing Ink Co., East Rutherford, NJ 07073 (PDE 164.3).

V. PROPOSED AMENDMENT TO THE 1979 USE AUTHORIZATIONS FOR PCBS IN HYDRAULIC AND HEAT TRANSFER FLUID

A. Background

PCBs were manufactured for hydraulic and heat transfer systems for use in a variety of industries until 1972. The aluminum, copper, iron and steel forming industries used hydraulic systems with commercial 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 these 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 retrofilling with non-PCB fluids would reduce the PCB concentration levels in those systems to below 50 ppm by July 1, 1984.

EPA adopted a regulatory limit of 50 ppm PCBs in the PCB Ban Rule. This limit also applied to the use authorizations for heat transfer and hydraulic fluids. EPA believed that by July 1, 1984, under the conditions of the use authorizations, all heat transfer and hydraulic systems originally containing PCBs would have been retrofilled to reduce PCB levels to less than 50 ppm. 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 would have been placed in doubt after July 1, 1984. Systems with more than 50 ppm PCBs are unlawful after that date, because the use authorization expires then. Therefore, EPA is clarifying the status of these systems by authorizing the use of PCBs in these systems at concentrations of less than 50 ppm for their remaining useful lives. Thus, under this proposed rule, hydraulic and heat transfer systems cannot be filled (i.e., "topped off") with fluids containing 50 ppm or greater of PCBs.

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 proposed regulatory action. In determining whether these uses of PCBs at concentrations of less than 50 ppm present unreasonable risks, EPA considers 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.

Based on the carcinogenicity risk assessment and the regulatory impact analysis conducted by the Agency, EPA has determined that the use of PCBs in hydraulic and heat transfer fluid at concentrations of less than 50 ppm does not present an unreasonable risk of injury to human health or the environment. Therefore, EPA proposes to amend 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.

The Agency is also considering the option of raising the standard to the 100 ppm concentration level. While this option may not be as costly to industry as reducing PCB levels to below 50 ppm, this option appears to present a greater risk of injury to human health.

B. Human Health and Environmental Risks

In determining whether to amend 40 CFR 761.30 (d) and (e), EPA has generated exposure and risk assessments for these uses of PCBs. For a review of the general methodology for exposure and risk assessments and a general analysis of the health and environmental effects of PCBs, see Unit III.D 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." Finally, EPA has developed estimates of carcinogenic risks for persons exposed to PCBs in hydraulic and heat transfer systems at 50 ppm. Further details concerning the carcinogenic risk assessment for various exposure scenarios for these uses are included in the support document "Carcinogenic Risk Assessments of Polychlorinated Biphenyls."

Two categories of factors are particularly important to the exposure and carcinogenic risk assessments 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 assessment 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 preliminary risk calculations for machine operations, and maintenance and repair workers, EPA estimated the carcinogenic risk from long-term dermal and inhalation exposure to PCBs in hydraulic and heat transfer systems. The inhalation exposure scenarios resulted in estimated carcinogenic risks at extremely low levels (this effect

would be observed in only 1 in 100,000 or more people if this estimated risk is accurate). However, the dermal absorption scenarios have a higher estimated risk. In estimating the carcinogenic risk 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 estimated risks are highly conservative and EPA believes that in actuality, the risks are much lower.

C. Regulatory Impact Analysis

EPA has developed a regulatory impact analysis for the reauthorization of these uses of PCBs. Two categories of engineering and economic data were developed for this analysis: (1) Information on the existing PCBs in use in hydraulic and heat transfer systems (presented as a distribution of the estimated number of contaminated systems by PCB concentration level); and (2) technical factors on the mechanics of PCB use in these systems (system fluid capacity, leakage and recycling rates, and the reduction efficiency for PCB elimination through draining and refilling with non-PCB fluids).

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 (40 CFR 761.30 (d) and (e)) at each concentration level.

In its Regulatory Impact analysis (RIA), EPA considered four regulatory options: (1) Not reauthorizing any use of PCBs in hydraulic and heat transfer systems; (2) reauthorizing the use of PCBs in these systems at a 25 ppm concentration level; (3) reauthorizing the use of PCBs in these systems at PCB levels greater than 50 ppm; and (4) 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 on 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 compared to the reauthorization of these uses of PCBs at a 50 ppm concentration level, a 25 ppm performance standard for these systems would result in approximately 2,400 incremental pounds of PCBs removed from the environment. EPA also has determined that if the standard is relaxed to 100 ppm, the total estimated PCB poundage under the 100 ppm option is 4,000 pounds greater than if the 50 ppm option is selected. However, this 100 ppm option is less protective of human health than either the 25 or 50 ppm option given the predicted occupational exposures to PCBs from heat transfer and hydraulic systems.

The results of the RIA indicate that the 100 ppm option yields an incremental cost per PCB pound removed of $300. The incremental cost per pound removed with the 50 ppm standard is about $18,000. Selection of the 25 ppm option yields a cost of $37,000 per pound of PCB removed.

EPA is aware that the costs estimated in the RIA for this proposed rule are several orders of magnitude greater than the costs originally projected in 1979 for reducing PCB concentrations in heat transfer and hydraulic systems (44 FR 31534–31535). This discrepancy results from different assumptions in projecting the number of affected heat transfer and hydraulic systems and the volume capacity of those systems. According to the rulemaking record, a number of companies have been able technologically to reduce the concentrations of PCBs in heat transfer and hydraulic systems to meet the current 50 ppm standard.

EPA believes that industry can provide information to the Agency during the comment period that will improve the RIA. In particular, EPA is interested in learning about any technological difficulties that industry may have encountered in retrofilling their contaminated systems to reach the 50 ppm level. In addition, EPA is interested in any information on the costs of reducing PCB concentrations from 100 ppm to 50 ppm.

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 with the following chemical compositions: (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 pm 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 proposed reauthorization of the use of PCBs in hydraulic and heat transfer fluid at a concentration level of less than 50 ppm would adequately safeguard workers from risks to human health. In assessing the carcinogenic risk 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, estimated risks for these exposure scenarios, particularly dermal absorption, were relatively high. However, these risk numbers are highly conservative and EPA believes that in actuality, the risks are much lower.

2. This proposed reauthorization would impose no 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 this use authorization.

3. Compared with other options, including considerations for a 25 ppm PCB concentration level for these uses, this reauthorization at a 50 ppm level would be the most cost-effective option. According to the Agency's regulatory impact analysis, compared with a PCB 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 for incremental costs of at least $87 million.

4. 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 exist 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.

VI. RELATIONSHIP TO OTHER PCB REGULATIONS

The major focus of this proposed 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.

A. PCB Disposal Rule

The final PCB disposal rule was published as part of the comprehensive PCB Ban Rule in the **Federal Register** of May 31, 1979 (44 FR 31514). In summary, the PCB disposal rule states that PCBs in concentrations of less than 50 ppm are not required to be disposed of in any special manner; liquid PCBs in concentrations between 50 ppm and 500 ppm are required to be disposed of in an incinerator that complies with the standards in 40 CFR 761.70, in a chemical waste landfill, or in a high efficiency boiler; nonliquid PCBs are required to be disposed of in an incinerator that complies with the standards in 40 CFR 761.70 or in a chemical waste landfill; and liquid PCBs in concentrations of 500 ppm or greater are required to be disposed of in an incinerator that complies with the standards in 40 CFR 761.70.

Section 761.190 of this proposed rule does not alter the disposal standards in the PCB Ban Rule. This section provides that any process waste containing PCBs at concentrations of 50 ppm or greater, which are present as a result of inadvertent generation or recycling, must comply with the incineration, landfilling, and storage for disposal provisions of the PCB Ban Rule. The discounting provisions for monochlorinated and dichlorinated biphenyls in § 761.3(jj) of this proposed rule apply to the disposal requirements of the proposed § 761.190. This discounting provision is applicable only to inadvertently generated PCBs.

B. Amendments to the PCB Electrical Equipment Rule

Authorizations for the use and servicing and 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 proposed rule affects any provision of the Electrical Equipment Rule.

C. 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 as a pesticide, food, food additive, drug, cosmetic, or 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 pesticide is regulated under FIFRA, a chemical that is manufactured for undetermined purposes is regulated under TSCA. This has particular applicability to § 761.1(f) of this proposed rule. That section refers to PCBs generated as unintentional impurities in excluded manufacturing processes, as defined in § 761.3(kk), at 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 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 proposed 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.

D. PCB Effluent Standards Under the Clean Water Act

Under section 307(a) of the Clean Water Act, 33 U.S.C. 1317, EPA promulgated final effluent standards for the discharge of PCBs into navigable waters. These PCB effluent standards, promulgated at 40 CFR 129.105, were published in the **Federal Register** of February 2, 1977 (42 FR 6532). These effluent standards apply to manufacturers of intentionally produced PCB fluid (i.e., Aroclor products), manufacturers of electrical capacitors, and manufacturers of electrical transformers. These rules also set an ambient water criterion for PCBs in navigable waters of 0.001 μg/l.

As applied to the manufacturing processes specified in 40 CFR 129.105, these effluent standards prohibit the discharge of Aroclor PCBs as process wastes. The analytical method used in measuring PCB concentrations in effluent discharges and determining compliance with the effluent standard is

an analytical method for measuring Aroclor PCBs.

In § 761.3(kk)(4) of this proposed rule, EPA has set the water effluent standard for incidentally generated PCBs in manufacturing processes. The proposed effluent standard for this category of PCBs is set at the LOQ, which is 0.1 ppm of PCBs (after discounting for monochlorinated or dichorinated biphenyls, if appropriate) for resolvable gas chromatographic peak per liter of water discharged. This standard is restricted to the regulation of inadvertently generated PCBs under section 6(e) of TSCA and does not affect the applicability of the effluent standards for intentionally manufactured PCB fluid measured as Aroclor PCBs in 40 CFR 129.105. In addition, the discounting provisions for monochlorinated and dichlorinated biphenyls proposed in 40 CFR 761.3(jj) do not affect the applicability of the PCB effluent standards for intentionally manufactured PCB fluid in 40 CFR 129.105.

E. Effluent Limitations and New Source Performance Standards Under the Clean Water Act for the Pulp, Paper, and Paperboard Industry

On November 18, 1982, EPA proposed effluent limitations based on "best available technology" (BAT) and "new source performance standards" under the Clean Water Act, 33 U.S.C. 1251 *et seq.*, for the discharge of PCBs into navigable waters of the United States from mills in the pulp, paper, and paperboard industry. This proposed rule was published in the Federal Register of November 18, 1982 (47 FR 52066), and presented technology-based standards for the use of a commercial mixture, Aroclor 1242, in the generation of fine paper and tissue paper at mills in the deink subcategory.

EPA has determined that some wastepapers used in the production of fine paper and tissue paper at mills in the deink subcategory are contaminated with Aroclor 1242. Aroclor 1242 was once used in the manufacture of carbonless copy paper. PCB-contaminated papers were recycled and now PCBs contaminate a portion of the wastepaper used in the manufacture of fine paper and tissue paper from deinked wastepaper. This leads to the discharge of PCB-containing wastewaters from many mills in the deink subcategory.

The proposed standards for effluent limitations of Aroclor 1242 based on BAT for this industrial subcategory are: (1) 0.00014 kilograms per thousand kilograms (kg/kkg) and 1.4 μg/l for production of fine paper; and (2) 0.00018 kg/kkg and 1.8 μg/l for the production of tissue paper. The proposed new source performance standards for Aroclor 1242 for this industrial subcategory are: (1) 0.00011 kg/kkg and 1.6 μg/l for the production of fine papers; and (2) 0.00014 kg/kkg and 1.8 μg/l for the production of tissue paper. These standards are based on maximum discharge limits for one day.

If promulgated as a final rule, these proposed effluent standards and new source performance standards will not modify any provisions of this proposed rule on uncontrolled PCBs. These proposed standards are solely applicable to activities controlled by the Clean Water Act.

F. Regulatory Developments Under Section 405 of the Clean Water Act for the Regulation of PCB-Contaminated Sludge

Section 405 of the Clean Water Act, 33 U.S.C. 1345, requires EPA to issue regulations that will identify uses for sludge, specify factors to be considered in determining measures and practices applicable to such uses, and identify concentrations of pollutants which interfere with such uses. One set of regulations has been issued by EPA under the authority of section 405, the land disposal criteria for solid waste facilities (40 CFR Part 257), which were promulgated in 1979 under the dual authority of the Clean Water Act and the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 *et seq.*

A wide range of concentrations of chemical constituents, including recycled PCBs, may be present in municipal sludges. A variety of factors influence the composition of sludges. These municipal sludges generated from publicly-owned treatment woks have been processed as fertilizer and other soil nutrient products.

Although there are no specific standards under 40 CFR Part 761 for the use of PCB-contaminated sludge in soil nutrient products, 40 CFR 761.60(a)(5) presents disposal requirements for dredged materials and municipal sewage treatment sludges. Sludge with concentrations of 50 ppm or greater PCBs must be disposed of in an incinerator that complies with 40 CFR 761.70, in a chemical waste landfill that complies with 40 CFR 761.75 or disposed of in an alternate method approved by the Regional Administrator (40 CFR 761.60(a)(5)). Solid wastes containing PCBs in concentrations of less than 50 ppm may be subject to 40 CFR 257.3–5(b) when they are applied to land used for producing animal feed. EPA requests comments from interested parties on this issue.

VII. 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 proposed rule is not a major rule as the term is defined in section 1(b) of the Executive Order.

EPA had determined that this proposed rule is not "major" under the criteria of section 1(b), because 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. If promulgated, this proposed rule would allow certain manufacturing and recyling of PCBs that would otherwise be prohibited by section 6(e) of TSCA. In addition, this proposed rule would allow the use of PCBs in certain hydraulic and heat transfer systems. Therefore, this proposed rule would reduce the overall costs and economic impact of section 6(e) of TSCA.

This proposed rule would exclude 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 proposed rule that resulting cost savings from this rule would range from $950 million to $5.6 billion over the next 10 years. In addition, the proposed amendment to the PCB Ban Rule would authorize for the remaining useful lives of the systems the use of PCBs in hydraulic and heat transfer fluid at concentrations of less than 50 ppm.

Although this proposed 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 proposed rule was submitted to the Office of Management and Budget (OMB) prior to publication, as required by the Executive Order.

VIII. 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 proposed rule would exclude certain manufacturing processes from statutory requirements to file annual petitions for exemption under section 6(e)(3)(B) of TSCA. In addition, the proposed rule would allow the indefinite use of PCBs in hydraulic and heat transfer fluid with concentration levels of less than 50 ppm.

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

IX. PAPERWORK REDUCTION ACT

The Paperwork Reduction Act of 1980 (PRA), 44 U.S.C. 3501 *et seq.*, authorizes the Director of 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 proposed rule (summarized in Unit III.H of this preamble) have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB marked ATTENTION: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

X. 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 proposed rulemaking. A supplementary list or lists may be published any time on or before the date the final rule is issued. However, public comments, the transcript of the rulemaking hearing, or submissions made at the rulemaking hearing or in connection with it will not be 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 Manfacturing 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, Draft Final Report: Exposure Assessment for Incidentally Produced Polychlorinated Biphenyls (PCBs), Volumes I–IV" (August 15, 1983).

(21) USEPA, OPTS, EED, "Carcinogenic Risk Assessments of Polychlorinated Biphenyls (PCBs)" (September 1, 1983).

(22) USEPA, OPTS, EED, "Quantitative Risk Assessment of Reproductive Risks Associated with Polychlorinated Biphenyl (PCB) Exposure" (September 1, 1983).

(23) USEPA, OPTS, HERD, "Environmental Risk and Hazard Assessments for Various Isomers of Polychlorinated Biphenyls (Monochlorobiphenyl through Hexachlorobiphenyl and Decachlorobiphenyl)" (September 1, 1983).

(24) USEPA, OPTS, ETD, "Regulatory Impact Analysis of the Proposed Rule Regulating Inadvertent PCB Generation

from Uncontrolled Sources, Volumes I–II" (September 1983).

(25) USEPA, OPTS, EED, "Regulatory Impact Analysis of PCB Use Authorizations for Hydraulic and Heat Transfer Systems" (September 1983).

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

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

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

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

(30) USEPA, OPTS, EED, Letter from John H. Craddock, Monsanto Industrial Chemicals Company to Michael Phillips, EPA (June 10, 1983).

(31) USEPA, OPTS, EED, Telephone Communication between Sherell Sterling, EPA, and Tim Hardy, Kirkland and Ellis, "Discounting Factors for Monochlorinated and Dichlorinated Biphenyls" (August 8, 1983).

(32) USEPA, OPTS, EED, Telephone Communication between Sherell Sterling, EPA, and Ellen Silbergeld, EDF, "Discounting Factors for Monochlorinated and Dichlorinated Biphenyls" (August 3, 1983).

(33) USEPA, OPTS, EED, Letter from Daniel F. Meyer, Dow Corning Corporation to William J. Gunter, EPA (September 29, 1983).

List of Subjects in 40 CFR Part 761

Hazardous materials, Polychlorinated biphenyls, Recordkeeping and reporting requirements, Environmental protection.

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

Dated: December 1, 1983.

William D. Ruckelshaus,

Administrator.

PART 761—[AMENDED]

Therefore, it is proposed that 40 CFR Part 761 be 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. Unless otherwise specifically provided in §§ 761.1(f) and § 761.3 (jj), (kk), and (oo) the terms PCB and PCBs are used to refer to any chemical substances and combinations of substances that contain 50 ppm (on a dry weight basis) or greater of PCBs, as defined in § 761.3(s). Any chemical substance or combinations of substances that contain less than 50 ppm PCBs because of any dilution are included as PCBs unless otherwise specifically provided. Substances that are regulated by this Part 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.

* * * * *

(f) Unless and until superseded by any new medium-specific regulations:

(1) Persons who inadvertently manufacture or import PCBs generated as unintentional impurities in excluded manufacturing processes, as defined in § 761.3(kk), are exempt from the requirements of Subparts B and D, provided that such persons further comply with §§ 761.185, 761.187, 761.190, and 761.193.

(2) Persons who process, distribute in commerce, or use products containing PCBs as a result of inadvertent generation of PCBs are exempt from the requirements of Subparts B and D, provided that such persons comply with §§ 761.190 and 761.193.

(3) Persons exempt from the requirements of Subparts B and D of Part 761 are:

(i) Persons who process, distribute in commerce, or use recycled PCBs, as long as any process waste containing PCBs at concentrations greater than 50 parts per million is stored for incineration or landfilling in accordance with the requirements of § 761.65(b)(1), and incinerated or landfilled in accordance with the requirements of §§ 761.60 and 761.75;

(ii) Persons who import, process, distribute in commerce or use chemicals containing PCBs present as a result of recycling PCBs as long as records of any actual monitoring of PCB concentrations are maintained for a period of three years after a process ceases operation or importing ceases, or for seven years, whichever is shorter. Monitoring records maintained must contain:

(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 date and time of the analysis.

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

(iii) Persons who process, distribute in commerce, or use recycled PCBs and release to products, air, and water recycled PCBs as long as they meet the requirements of paragraphs (f)(3)(iii) (A) through (C) of this section, or persons who import products containing recycled PCBs as long as they meet the requirements of paragraphs (f)(3)(iii) (A) and (B) of this section.

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

(B) The concentration of recycled PCBs in consumer products with a high exposure potential leaving the processing site or imported into the United States must be less than 5 ppm. Consumer products that are controlled by this provision are deodorant bars and soaps, and plastic building materials and products.

(C) The release of recycled PCBs at the point at which emissions are vented to ambient air from the processing site must be less than 10 ppm.

2. In § 761.3, paragraph (nn) is removed, paragraphs (jj) and (kk) are revised, and paragraph (oo) is added to read as follows:

§ 761.3 Definitions.

* * * * *

(jj) For purposes of §§761.1(f) (1) and (2), 761.3(kk), 761.185, 761.190, and 761.193, "PCBs" means the total PCBs calculated following division of the quantity of monochlorinated biphenyls by 50 and dichlorinated biphenyls by 5. In determining the quantity of PBCs, the analytical methods used shall not quantitate the value of resolvable chromatographic peaks below the limits of quantitation for each medium.

(kk) "Excluded manufacturing process" means a manufacturing process in which PBCs, as defined in § 761.3(jj), are inadvertently generated and from which releases to products, air, and water meet the requirements of §§ 761.3(kk) (1), (2), (3) and (4), or the importation of products containing PBCs as unintentional impurities, which products meet the requirements of §§ 761.3(kk) (1) and (2).

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

(2) The concentration of PBCs in consumer products with a high exposure potential leaving the manufacturing site or imported into the United States must be less than 5 ppm. Consumer products

that are controlled by this provision are deodorant bars and soaps, and plastic building materials and products.

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

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

* * * * *

(nn) [Reserved]

(oo) "Recycling PCBs" means processing, distribution in commerce, and use of intentionally manufactured PCBs that may enter a manufacturing process as PCB-contaminated raw materials and are processed, distributed in commerce, and used.

3. In § 761.30, paragraphs (d) and (e) 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.

(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.

4. Section 761.185 is revised 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 § 761.3(kk), manufacturers with processes inadvertently generating PCBs and importers or products containing inadvertently generated PCBs must report to EPA, by filing a document as described in paragraph (b) of this section, 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 for any resolvable gas chromatographic peak. Such reports must be filed within 90 days after promulgation of this regulation or, if no processes or imports require reports at that time, within 90 days of having processes or imports for which such reports are required.

(b) Persons 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, or of imports in which the concentration of PCBs in products leaving any manufacturing site or being imported is greater than 2 micrograms per gram (2 ppm) for any resolvable gas chromatographic peak. Such persons must also certify:

(1) Their compliance with all requirements of § 761.1(f), including 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 a process ceases operations or importing cases, or for seven years, whichever is shorter, records containing the following information:

(i) *Theoretical analysis.* (A) The reaction or reactions believed to be generating PCBs, the levels of PCBs generated, and the levels of PCBs released.

(B) The basis for all estimations of PCB concentrations.

(C) 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 date 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 a process or importing ceases operation, 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 decisionmaking functions for the corporation; or

(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 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 Director, Office of Toxic Substances, U.S. Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460, Attention: Chief, Chemical Regulation Branch within 90 days of issuing this regulation or 90 days of starting up processes or commencing importation of PCBs. For purposes of § 761.185, the term PCBs is defined by § 761.3(jj).

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

5. Section 761.187 is added to read as follows:

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

In addition to meeting the basic requirements of §§ 761.1(f) and 761.3(kk), PCB-generating manufacturing processes or importers of PCB-containing products shall be considered "excluded manufacturing processes" only if the owner/operator or importer reports the following data to EPA:

(a) 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 (the date this regulation is promulgated); 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) 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) 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 Director, Office of Toxic Substances, Attention; Chief, Chemical Regulation Branch at the address given in § 761.185(f).

(e) For purposes of paragraphs (a), (b), and (c) of this section, the term "PCBs" is defined by § 761.3(jj).

6. Section 761.190 is added to read as follows:

§ 761.190 Process waste disposal by generators and processors of chemical substances containing inadvertently generated PCB impurities.

Persons who manufacture, process distribute in commerce, or use chemicals containing PCBs present as a result of inadvertent generation or recycling must, for any process waste containing PCBs at concentrations greater than 50 parts per million, incinerate or landfill such waste in accordance with the requirements of §§ 761.60 and 761.75, and store such waste for incineration of landfilling in accordance with the requirements of § 761.65(b)(1).

7. Section 761.193 is 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 to three years after a process ceases operation or importing cases, 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.

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