

p.m. Open meetings will be held on Thursday, September 5, 1985, at 9:30 a.m. and on Wednesday, September 11, 1985, at 9:30 a.m., in Room 1C30.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meeting may be considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10).

Commissioner Peters, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Wednesday, September 4, 1985, at 2:30 p.m., will be:

Withdrawal of authorization for administrative proceeding of an enforcement nature.

Institution of administrative proceedings of an enforcement nature.

Settlement of administrative proceedings of an enforcement nature.

Institution of injunctive action.

The subject matter of the open meetings scheduled for Thursday, September 5, 1985, and Wednesday, September 11, 1985 from 9:30 a.m. to 5:00 p.m., will be:

The Commission will meet with representatives of the legal, financial, and business communities to discuss major issues of mutual interest and concern, including, but not limited to, tender offer regulation, internationalization of the securities markets, currency and interest rate swaps, and new financial products and services. For further information please contact Alan L. Dye at (202) 272-2014.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Alan L. Dye at (202) 272-2014.

John Wheeler,

Secretary.

August 27, 1985.

[FR Doc. 85-20826 Filed 8-27-85; 4:01 pm]

BILLING CODE 8010-01-M

federal register

Thursday
August 29, 1985

Part II

Department of Transportation

Federal Aviation Administration

**14 CFR Part 61
Certification of Student Recreational,
Recreational, Student Private, and Private
Pilots; Proposed Rule**

**DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration**

14 CFR Part 61

[Docket No. 24695; Notice No. 85-13A]

**Certification of Student Recreational,
Recreational, Student Private, and
Private Pilots**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking
(NPRM); extension of comment period.

SUMMARY: This notice announces the extension of the comment period for Notice of Proposed Rulemaking No. 85-13, which invites comments relative to amending the regulations to establish recreational pilot certificates, introduce new concepts in pilot certification, add a 2-hour annual training requirement for recreational and private pilots, and establish annual review and recent flight experience requirements for recreational and private pilots with less than 400 hours of flight time. The intent of this proposal is to introduce training techniques that involve a more basic approach to flight fundamentals as well as training and testing to a standard in lieu of traditional aeronautical experience requirements. This extension is necessary to afford all interested parties an opportunity to present their views on the proposed rulemaking.

DATE: Comments must be received on or before October 24, 1985.

ADDRESS: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention, Rules Docket (AGC-204), Docket No. 24695, 800 Independence Avenue SW., Washington, DC 20591; or delivered in duplicate to: Room 916, 800 Independence Avenue SW., Washington, DC 20591. All comments must be marked: Docket No. 24695. Comments may be inspected in Room 916 weekdays, except Federal holidays between 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: James F. Byers, Certification Branch, AFO-840, General Aviation and Commercial Division, Office of Flight Operations, 800 Independence Avenue SW., Washington, DC 20591, Telephone (202) 426-8196.

**SUPPLEMENTARY INFORMATION:
Comments Invited**

Interested persons are invited to participate in this proposed rulemaking action by submitting written data, views, or arguments as they may desire. Communications should identify the docket number and be submitted in duplicate to the address indicated above. All communications received on or before the closing date for comments will be considered by the Administrator before taking final action on this

proposed rulemaking. The proposals contained in Notice 85-13 may be changed in light of comments received. All comments submitted will be available in the rules docket for examination by interested parties both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 24695." The postcard will be date/time stamped and returned to the commenter.

Availability of NPRM

Any person may obtain a copy of Notice 85-13 by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-430, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 426-8058. Communications must identify Notice 85-13.

Persons interested in being placed on the mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedures.

Background

On June 25, 1985, the FAA published Notice 85-13 (50 FR 26286), which provided for a 90-day comment period, closing on September 24, 1985. In that notice, the FAA proposed many changes that would have considerable effect on recreational and private pilots. It proposed to amend the regulations to establish a new kind of pilot certificate, a recreational pilot certificate. The notice proposed changes in the process by which private pilots must qualify for pilot certificates. The notice also proposed increased periodic training requirements and review requirements for private pilots. The intent of this proposal is to introduce training techniques that involve a more basic approach to flight fundamentals as well as training to a standard in lieu of traditional experience requirements.

The FAA invited interested persons to submit comments and suggestions as to future action regarding this rulemaking. Since Notice 85-13 was published, several requests have been received for extension of the comment period from persons wishing more time in which to study the proposal and to prepare comments.

This is one of the largest single proposals affecting general aviation pilots issued by the FAA in years. The FAA considers it vital to obtain the comments of all interested persons

concerning the potential safety and economic impact of the proposal and to obtain suggestions for improving it.

The proposal has received intense interest from the general aviation community. One large organization requested 500 additional copies to distribute among its membership.

Conclusion

This document extends the comment period on an NPRM to afford the public and industry with additional time in which to review and respond to this notice. For reasons discussed in Notice 85-13, the FAA has determined the notice involves a proposed regulation which is considered to be significant as defined in Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) and that the notice is not major as defined in Executive Order 12291. In addition, for the above reasons, the FAA certifies that the regulations, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Extension of Comment Period

A major general aviation organization with more than 100,000 members and representing a category of pilots who would be most affected by the proposed rule change to Part 61 has requested that the FAA extend the comment period to allow its members and affected pilots to become familiar with the proposal.

The FAA has become aware that many individuals in industry have not received this notice and may not have had an opportunity to comment on its contents within the original comment period. The FAA recognizes that disseminating material such as Notice 85-13 to all interested persons takes time. In addition, it takes time to fully analyze the proposals so that all potential problem areas are identified and brought to the agency's attention. For this reason, the FAA does not wish to unduly rush this important process.

In consideration of the above, the FAA concludes that the comment period should be extended. Accordingly, the comment period for Notice 85-13 is extended to October 24, 1985.

List of Subjects in 14 CFR Part 61

Aviation safety, Student private pilots, Private pilots, Eligibility requirements, Aeronautical knowledge, Operational experience, Cross country flight privileges, Limitations.

Authority: 49 U.S.C. 1354(a), 1355, 1421, 1422, and 1427; 49 U.S.C. 106(g) (revised, Pub. L. 97-449, January 12, 1983).

Issued in Washington, DC, on August 26, 1985.

William T. Brennan,
Acting Director of Flight Operations.
[FR Doc. 85-20632 Filed 8-26-85; 12:26 pm]

BILLING CODE 4910-13-M

federal register

Thursday
August 29, 1985

Part III

Environmental Protection Agency

40 CFR Part 761

Response to Exemption Petitions;
Proposed Rule and Response to Ward
Transformer Company Petition for
Exemption; Denial of Exemption Petition

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 761

[OPTS-66008C; TSH FRL 2889-3]

Response to Exemption Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This rule proposes action on 22 petitions for exemption from the prohibition against the manufacture, processing, and distribution in commerce of PCBs. In this rule, EPA proposes to: grant eight individual exemption petitions; grant a class exemption including six individual exemption petitions; deny six individual exemption petitions; and dismiss two individual exemption petitions.

DATES: An informal hearing, if requested, will be held in Washington, D.C. approximately October 28, 1985. The exact time and location of the hearing will be available by calling EPA's TSCA Assistance Office listed under "FOR FURTHER INFORMATION CONTACT." Comments on the proposed rule and requests to participate in the informal hearing must be submitted by October 15, 1985. Reply comments made in response to issues raised at the hearing must be submitted no later than 1 week after the date of that hearing.

See Unit I of **SUPPLEMENTARY INFORMATION** for EPA's procedures for conducting rulemaking on these exemption petitions.

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,
Room E-209, 401 M St., SW.,
Washington, DC 20460.

Comments should include the docket number OPTS-66008C. Comments received on this proposed rule will be available for reviewing and copying from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays, in Rm. E-107 at the address given above.

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

Copies of this proposed rule and its support documents can be obtained

from the TSCA Assistance Office listed above.

SUPPLEMENTARY INFORMATION:

I. Comments and Rulemaking Procedures

A. Confidential Business Information

EPA encourages the submission of nonconfidential information. However, commenters who believe that they can state their position only by using information claimed confidential may submit it in accordance with the requirements of 40 CFR 750.16 (for manufacturing exemptions) and 40 CFR 750.36 (for processing and distribution in commerce exemptions). Commenters who submit confidential information must, at the same time, submit a nonconfidential summary of the information claimed to be confidential for inclusion in the public record. Please mark information claimed confidential "CONFIDENTIAL" and send it via certified mail to the Document Control Officer (see address listed under "ADDRESS"). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. Information not marked "CONFIDENTIAL" will be placed in the public record and may be disclosed publicly by EPA without prior notice.

B. Hearing

EPA will conduct the hearing in accordance with EPA's "Procedures for Conducting Rulemaking Under section 6 of the Toxic Substances Control Act" under 40 CFR Part 750. Persons who want to participate in the informal hearing must write to EPA's TSCA Assistance Office (see address under "FOR FURTHER INFORMATION CONTACT"). All requests to participate must include an outline of topics to be addressed, the amount of time requested for the opening statement, and the names of participants. The informal hearing is meant to provide an opportunity for petitioners and other interested parties to present additional information or to discuss new issues, not to repeat information already presented in written comments.

II. Background

A. Statutory Authority

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

Section 6(e)(3)(B) of TSCA provides that any person may petition the Administrator for an exemption from the prohibition against the manufacture,

processing, and distribution in commerce of PCBs. The Administrator may by rule grant an exemption if the Administrator finds that "(i) an unreasonable risk injury to health or environment would not result, and (ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl." The Administrator may set terms and conditions for an exemption and may grant an exemption for not more than 1 year.

EPA's Interim Procedural Rules for PCB Manufacturing Exemptions describe the required content of manufacturing exemption petitions and the procedures EPA follows in rulemaking on exemption petitions. Those rules were published in the *Federal Register* of November 1, 1978 (43 FR 50905) and are codified at 40 CFR 750.10 through 750.21.

EPA's Interim Procedural Rules for Processing and Distribution in Commerce Exemptions describe the required content of processing and distribution in commerce exemption petitions and the procedures EPA follows in rulemaking on exemption petitions. Those rules were published in the *Federal Register* of May 31, 1979 (44 FR 31560) and are codified at 40 CFR 750.30 through 750.41.

B. History of This Rulemaking

In the *Federal Register* of July 10, 1984 (49 FR 28172), EPA promulgated the final PCBs Exclusions, Exemptions, and Use Authorizations Rule (hereinafter referred to as the Uncontrolled PCB Rule) addressing the manufacture, processing, distribution in commerce, and use of certain inadvertently generated and recycled PCBs in low level concentrations. That rule amends the PCB rule published in the *Federal Register* of October 21, 1982 (47 FR 46980) (the Closed and Controlled Waste Manufacturing Processes Rule) by excluding additional processes from regulation.

In the same issue of the *Federal Register*, the Final PCB Exemptions Rule (49 FR 28154) acted on 109 of the pending exemption petitions and deferred action on the Ward-Transformer petition and on 49 petitions for exemption to manufacture, process, and distribute in commerce inadvertently generated PCBs. EPA believed that many petitions may have been made unnecessary by the Uncontrolled PCBs Rule. A notice of final action addressing the Ward

Transformer petition is published elsewhere in this issue of the Federal Register.

In the July 10, 1984 proposed rule-related notice (49 FR 28203), EPA requested that the 49 petitioners affected by the Uncontrolled PCB Rule evaluate that rule and determine whether they still need an exemption. Any petitioner still needing an exemption was to submit written comments renewing its petition by October 1, 1984. EPA stated that the Agency would issue a notice of proposed rulemaking on renewed petitions. Eight of the 49 petitions were renewed. The other 41 petitioners either withdrew their petitions or failed to renew their petitions by the end of the comment period.

After promulgation of the Final PCB Exemptions Rule, EPA received and accepted for consideration 14 new exemption petitions. Thus, this rule proposes action on 22 petitions for exemption from the prohibitions on the manufacture, processing, and distribution in commerce of PCBs. The November 1, 1983 Proposed PCB Exemptions rule describes in detail the history of PCB regulations. Specific PCB regulations and their history are discussed in later units of this rule where applicable to the disposition of exemption petitions.

C. Effect of This Rule on Previous Policy Statements

In the Federal Register of January 2, 1979 (44 FR 108), EPA announced that petitioners who had previously filed manufacturing exemption petitions could continue the activities for which they sought exemption until EPA acted on their petitions. In the Federal Register of March 5, 1980 (45 FR 14247), EPA extended this policy to allow all petitioners to continue the activities for which they sought exemption until EPA acted on their petitions, as long as activities were underway before January 1, 1979 (for manufacturing) or July 1, 1979 (for processing and distribution in commerce).

The following exemption petitions are for activities which were not underway prior to the appropriate dates: the Mobay petition to distribute in commerce or export PCBs; the Dainichiseika petition to export PCBs; the Supelco petition to export PCBs; the Radian petition to export PCBs; and the ALCOA petitions to distribute in commerce, import and export PCBs. Petitioners have not been allowed to pursue PCB activities under those petitions until EPA takes final action.

Once EPA has acted to grant or deny an exemption petition, EPA's policy of

permitting activities to continue will become unnecessary. In the final PCB Exemptions Rule published in the Federal Register of July 10, 1984 (49 FR 28154), EPA revoked the policy for those pre-1979 petitions on which final action was taken. EPA will revoke the policy for all exemption petitions included in this rulemaking as of the effective date of the final rule.

A petitioner whose exemption is granted will be allowed to manufacture, process or distribute in commerce PCBs only for the period of time granted in the final rule. When the exemption expires, a petitioner will not be permitted to engage in such activities, even if it renews its exemption request, until EPA has acted on that request. This limitation does not apply to manufacturers, processors, and distributors of PCBs in "small quantities for research and development" for whom EPA is proposing to grant exemption in Unit V.D of this proposed rule.

EPA will continue its policy of requiring petitioners who file late exemption petitions to show "good cause" why EPA should accept the petition as described in the notice published in the Federal Register of March 5, 1980 (45 FR 14247). New exemption petitions submitted by petitioners denied exemptions in this rulemaking will be considered as late petitions.

III. Unreasonable Risk Finding

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

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

1. The effect of PCBs on human health and the environment, including the magnitude of PCB exposure to humans and the environment.

2. The benefits to society of granting an exemption and the reasonably ascertainable economic consequences of denying an exemption petition.

These are essentially the same factors that EPA considers under TSCA section 6(c) in deciding whether a chemical substance or mixture presents an unreasonable risk of injury to health or the environment under TSCA section 6(a), and in evaluating uses of PCBs under TSCA section 6(e).

A. Effects on Human Health and the Environment

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

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

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

In addition, EPA finds that PCBs may cause reproductive effects, developmental toxicity, and oncogenicity in humans exposed to PCBs. Available data show that some PCBs have the ability to alter reproductive processes in mammalian species, sometimes even at doses that do not cause other signs of toxicity. Animal data and limited available

human data indicate that prenatal exposure to PCBs can result in various degrees of developmental toxic effects. Postnatal effects have been demonstrated in immature animals, following exposure to PCBs prenatally and via breast milk.

In some cases chloracne may occur in humans exposed to PCBs. Severe cases of chloracne are painful and disfiguring, and symptoms may persist for an extended time. Although the effects of chloracne are reversible, EPA considers these effects to be significant.

2. Environmental effects. Certain PCB congeners are among the most stable chemicals known and decompose very slowly once they are in the environment. They remain in the environment and are taken up and stored in the fatty tissue of organisms. EPA has concluded that PCBs can be concentrated in fresh water 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 food sources containing PCBs. Available data show that PCBs affect the productivity of phytoplankton and the composition of phytoplankton communities; cause deleterious effects on environmentally important freshwater invertebrates; and impair reproductive success in birds and mammals.

PCBs also are toxic to mammals at very low exposure levels. The survival rate and 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 have also been demonstrated.

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

Minimizing exposure to PCBs should minimize any potential risk. EPA takes exposure into consideration in evaluating exemption petitions.

B. Benefits and Costs

The benefits to society of granting an exemption and the reasonably ascertainable costs of denying a petition vary depending on the petitioner and the activity for which exemption is requested. EPA has taken the benefits and costs into consideration when evaluating each exemption petition. The specific benefits and costs of denying

each petition are discussed in later units of this proposed rule.

IV. Good Faith Efforts Finding

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

V. Disposition of Exemption Petitions

A. Inadvertently Generated PCBs

The Uncontrolled PCB Rule excluded from the prohibition on the manufacture, processing, distribution in commerce, and use of PCBs those PCBs inadvertently generated in an "excluded manufacturing process." An "excluded manufacturing process" as defined at 40 CFR 761.3 is a manufacturing process or importation in which the concentration of inadvertently generated PCBs in the product is limited to an annual average of less than 25 ppm, with a 50 ppm maximum, except that the concentration of inadvertently generated PCBs in the components of detergent bars must be less than 5 ppm. Limits are also placed on the concentration of PCBs discharged to air and water from an excluded manufacturing site.

The following eight petitions for exemption to manufacture, process, and distribute in commerce inadvertently generated PCBs above allowable concentration levels for "excluded manufacturing processes" were renewed. EPA is proposing to dismiss two of these exemption petitions, grant three exemptions, and deny three exemption petitions.

1. Reed Plastics, and U.S. Printing Ink Corporation. EPA received two petitions from processors of pigments containing inadvertently generated PCBs. Reed Plastics (Reed), Holden, MA 01520, and U.S. Printing Ink Corporation (USPI), East Rutherford, NJ 07073, each petitioned for individual exemption to

process pigments containing PCBs at concentrations greater than regulatory limits. These companies currently have to inventories of pigment containing PCBs above regulatory limits. However, they requested exemption to process pigments containing PCBs above regulatory limits in the event that their suppliers exceed regulatory limits. EPA proposes to dismiss both the Reed and USPI petitions. Processors, distributors, and users of inadvertently generated PCBs do not need exemptions, for the reasons discussed below.

The Uncontrolled PCB Rule published in the Federal Register of July 10, 1984 (49 FR 28172), placed limits on the concentration of PCBs leaving the site of processes which generate PCBs as inadvertent byproducts. EPA also placed limits on the concentration of inadvertently generated PCBs in products imported into the United States. The processing, distribution in commerce, and use of products of "excluded manufacturing processes" are excluded from the prohibitions on the processing, distribution in commerce, and use of PCBs. Thus, the intent of the Uncontrolled PCB Rule is to limit the addition of PCBs into the environment by regulating the concentration of inadvertently generated PCBs in products at the point where the PCBs are introduced into commerce.

Processors and distributors of products containing inadvertently generated PCBs have the responsibility of determining that their suppliers' processes qualify as "excluded manufacturing processes," or that their suppliers have exemptions to manufacture or import, and distribute PCBs over regulatory limits. However, manufacturer or importer cannot assign its duty to comply with limits on the concentration of PCBs in products. Thus, EPA will not accept for consideration exemption petitions from processors and distributors of inadvertently generated PCBs except where the petition is for an exemption to process or distribute inadvertently generated PCBs in inventories accumulated prior to the effective date of the Uncontrolled PCB Rule (October 1, 1984).

In considering petitions for exemption to manufacture, import, or distribute in commerce inventories of inadvertently generated PCBs above allowable levels, EPA will evaluate the exposures and risks associated with the further processing, distribution and use of the PCBs. EPA considered such exposure issues when it established average and maximum concentration levels for inadvertently generated PCBs at the point of their introduction into

commerce, and excluded the further processing, distribution and use of those PCBs in the Uncontrolled PCB Rule.

2. *Aluminum Company of America (ALCOA)*. The Aluminum Company of America, Pittsburgh, PA 15219, renewed its petitions for exemption (a) to manufacture anhydrous aluminum chloride (AlCl₃) contaminated with inadvertently generated decachlorobiphenyl above allowable levels; and (b) to distribute in commerce AlCl₃ containing inadvertently generated PCBs above allowable levels.

ALCOA's Anderson County Works produces AlCl₃ and converts 90 percent of the AlCl₃ to aluminum metal. According to information provided by ALCOA, there are no PCBs in the aluminum metal and all PCBs are concentrated in process wastes which are disposed of in accordance with EPA regulations. Thus, the 90 percent of the AlCl₃ which is converted to metallic aluminum is part of an "excluded manufacturing process" since EPA considers a manufacturing process to be all of a series of unit operations at one site resulting in the production of a product. Thus, ALCOA does not need an exemption to manufacture AlCl₃ for use in the production of aluminum metal.

Of the AlCl₃ produced by ALCOA, 10 percent is not converted to aluminum metal. ALCOA petitioned for exemptions to manufacture and distribute in commerce that 10 percent of AlCl₃ as a product as well as the substantial amount of AlCl₃ in inventory which will be distributed in commerce if an exemption is granted. Although the Anderson County Works is currently not in operation, the petitioner requested that it be allowed to manufacture and distribute in commerce 10 percent of its AlCl₃ production capacity as a product in the event that the plant is to be reopened within the exemption period. The existing inventory AlCl₃ will be distributed in commerce, should the exemptions be granted, whether or not the plant is reopened.

EPA proposes to deny both of the ALCOA exemption petitions because granting the exemptions would result in an unreasonable risk of injury to health or the environment and because the petitioner has failed to demonstrate good faith efforts. ALCOA provided no information on the downstream uses of the AlCl₃ although ALCOA did state that customers have been notified of the PCB content in the AlCl₃. EPA has received information indicating that AlCl₃ is commonly used in the manufacture of products such as deodorants, blood coagulants and dermatological antacids. EPA has concluded that the use of AlCl₃

containing PCBs over regulatory limits in such products would result in some additional risk of consumer exposure to PCBs.

Furthermore, the amount of existing inventory which would be distributed in commerce for these uses under an exemption is large. Several times the amount of ALCOA's existing inventory would be distributed in commerce under an exemption if the plant were to become operational for a substantial portion of the 1-year exemption period.

ALCOA estimated that the economic consequences of denying the petitions would involve the costs of shutdown of the plant, the resulting loss of employment in the area, and the cost of conversion to a conventional metallic aluminum production process. EPA does not consider it reasonable to include in the estimated costs of denial the cost of shutting down a plant which is (i) currently not in operation, and (ii) primarily involved in an "excluded manufacturing process" which will not be affected by denial of the petitions.

EPA has estimated the economic impact of denial of the petitions, assuming that the plant will be operational for the entire exemption period. EPA estimated the worst-case incremental cost of denying the petitions, assuming that ALCOA must shut down 10 percent of its AlCl₃ production capacity, to be in the range of \$28,926 to \$31,519 per lb of PCBs prevented from distribution in commerce. Should ALCOA be able to convert all of the AlCl₃ to aluminum metal, EPA estimated the costs of denying the petitions to be \$2,985 to \$2,995 per lb of PCBs prevented from distribution, plus the costs of any necessary modifications to the process. EPA believes the actual cost per lb of PCBs will be closer to the lower-cost estimate.

EPA has determined that the potential risks posed by the large amount of PCBs which would be distributed in commerce under an exemption, the high concentrations of PCBs in the AlCl₃, and the use of the AlCl₃ in dermatological products outweigh the relatively low incremental costs of denying the ALCOA exemption petitions.

Although the proposed denial of ALCOA's petitions is based on EPA's conclusion that granting the exemptions would result in an unreasonable risk, EPA has also concluded that the Agency can not make a determination of good faith efforts on the part of the petitioner. Although ALCOA has indicated that it has conducted research and development to reduce the PCB concentration in the AlCl₃, ALCOA has provided no information on the amount

of time or money expended in these efforts. The information submitted by ALCOA over the past 5 years shows no significant reduction in the level of PCBs in the AlCl₃. Additionally, there are alternative supplies of AlCl₃ which do not contain PCBs above regulatory limits.

3. *American Hoechst Corporation (Hoechst)*. The American Hoechst Corporation, Somerville, NJ 08876, renewed its petitions for exemption (a) to import diarylide pigment containing inadvertently generated PCBs over allowable levels, and (b) to distribute in commerce pigment containing PCBs above regulatory limits. EPA proposes to grant for a period of 1 year both of the Hoechst petitions because granting an exemption would not result in an unreasonable risk of injury to health or the environment, and the petitioner has demonstrated good faith efforts. EPA proposes, as a condition of the exemption, a requirement that Hoechst notify its customers that the concentration of PCBs in the pigment may exceed the regulatory maximum of 50 ppm.

a. *Unreasonable risk finding*. The concentrations of PCBs in the pigment, submitted as proprietary information, are only slightly above the regulatory limits. The total amount of PCBs imported and distributed in commerce would be less than 2.5 lbs during the exemption period. The pigment would be distributed in commerce for use as a colorant in automotive paints, plastics, and wallpaper. EPA has previously determined that pigments generally compose no more than 20 percent of final products.

American Hoechst estimated the reasonably ascertainable costs of denial to be equal to the lost value of potential sales of the imported pigment. Based on information submitted by Hoechst, EPA has determined that the costs of denial of the petitions will be substantial given the small quantity of PCBs involved. The incremental costs of denying the petitions are estimated to be in the range of \$160,000 to \$580,000 per lb of PCBs in the pigments, less the acquisition cost of the pigment. EPA believes the actual incremental costs to fall in the high end of the range, less acquisition costs, because of the low concentration of PCBs involved. In addition, denial of the petition may result in societal costs due to the use of inferior pigments.

b. *Good faith efforts finding*. American Hoechst has demonstrated good faith efforts (i) to develop a substitute for the pigment, and (ii) to reduce the concentration of PCBs in the

pigment. Since the submission of its original 1978 petition, Hoechst has expended substantial sums in the search for a substitute and in research to reduce the PCB concentration in the pigment. Hoechst maintains that it has thus far found no adequate substitutes. Information submitted by Hoechst since 1978 indicates that the concentration of PCBs in the product has decreased over that time. In proposing to grant the Hoechst exemption petitions, EPA presumes the petitioner's continued good faith efforts. If Hoechst is granted an exemption in the final rule, Hoechst will have a substantial burden of proof should it apply for renewal at the end of the exemption period.

4. *Dainichiseika Color & Chemicals America, Incorporated.* Dainichiseika Color and Chemicals America (Dainichiseika), Clifton, NJ 07012, imported phthalocyanine blue crude from Taiwan in 1982 under a petition for exemption to import crude colorants containing PCBs at concentrations of 50 ppm or greater. EPA policy allowed the petitioner to continue activities until EPA acted on that petition. (See Unit II.C of his preamble.) Before EPA acted, Dainichiseika's U.S. customer withdrew its petition for exemption to process and distribute pigments containing greater than 50 ppm PCBs, leaving Dainichiseika without a domestic buyer.

Dainichiseika withdrew its pending petition for exemption to import PCBs and renewed its exemption petition to distribute its remaining inventory of 62,400 lbs of blue crude containing inadvertently generated PCBs at 80 ppm. The petitioner also requested that should EPA deny its petition for exemption to distribute the crude within the U.S., EPA consider a new Dainichiseika petition for exemption to (a) export the PCBs to a foreign buyer, or (b) reexport the PCBs to the original manufacturer in Taiwan.

EPA proposes to grant Dainichiseika a 1-year exemption to distribute in commerce its existing inventory of 62,400 lbs of phthalocyanine crude contaminated with PCBs at 80 ppm, provided that Dainichiseika notifies its customers of the PCB concentration in the crude. In proposing to grant the exemption, EPA has determined that no unreasonable risk of injury to health or the environment will result, and that the petitioner has demonstrated good faith efforts to comply with the letter and spirit of the PCB regulations.

In proposing to grant the Dainichiseika petition to distribute in commerce its existing inventory of blue crude containing 80 ppm PCBs, EPA also proposes to exempt from the prohibitions on the processing,

distribution in commerce and use of PCBs, the further processing and distribution in commerce of these PCBs. Accordingly processors and distributors of Dainichiseika's inventory of phthalocyanine blue crude would not have to apply for exemptions.

a. *Unreasonable risk finding.* In making the unreasonable risk finding for this petition, EPA has considered the exposures and associated risks involved in the further processing, distribution in commerce and use of the pigment. EPA previously considered these exposure issues when it excluded certain post manufacture activities involving inadvertently generated PCBs from the section 6(e) prohibitions (see Unit V.A.1).

The exposures, and associated risks involved in the distribution in commerce of this crude, as well as the further processing, distribution in commerce and use of the crude are estimated to be on the same order of magnitude as the concentration levels allowed for "excluded manufacturing processes" in the Uncontrolled PCB Rule. The crude will be processed into pigment for use in the manufacture of plastics, paints and printing inks. The rulemaking record in that rule shows that downstream processing of pigments results in the reduction of PCB concentration in consumer products. Pigments generally compose no more than 20 percent of the final paint and printing ink products, and no more than 2 percent of final plastic products. The total amount of PCBs that will be distributed in commerce under this exemption is less than 5 lbs.

Granting this exemption is consistent with the purpose of the Uncontrolled PCB Rule which is to limit the addition of PCBs into the environment by regulating the concentration of inadvertently generated PCBs in products at the point where the PCBs are introduced into commerce. No additional PCBs will be generated and introduced into commerce if this petition is granted. Less than 5 lbs of already existing PCBs will be distributed in commerce under this exemption.

EPA has determined that no unreasonable risk will result from the distribution in commerce of Dainichiseika's inventory of 62,400 lbs of phthalocyanine blue crude containing 80 ppm PCBs, or from the further processing, distribution in commerce and use of this pigment. These determinations are consistent with the unreasonable risk determination made in issuing the Uncontrolled PCB Rule. The economic consequences of denying the Dainichiseika petition, including the lost sale value of the pigment and the

costs of disposal in accordance with EPA regulations at 40 CFR 761.60, would be in the range of \$141,024 to \$162,864.

b. *Good faith efforts finding.* The petitioner imported the pigment under an exemption petition with the reasonable expectation that its U.S. customer could and would legally process and distribute the pigment. Dainichiseika no longer intends to import pigments containing inadvertently generated PCBs above the levels established in the Uncontrolled PCB Rule. The exemption provision at section 6(e)(3)(B) was intended to allow additional time for businesses to comply with PCB regulations under TSCA section 6(e). EPA concludes that Dainichiseika has made and is making good faith efforts to comply with the PCB regulations.

The good faith efforts finding relies heavily on the fact that EPA policy allowed the petitioner to import the existing inventory under a pending petition, as well as the petitioner's intent to comply with EPA regulations issued since the import of the PCBs. Due to these circumstances, EPA is proposing to grant a 1-time exemption, after finding that the concentrations and quantity of PCBs in the blue crude will not pose an unreasonable risk. EPA does not anticipate that any similar exemption petitions will be filed. Any person or company filing a new exemption petition to distribute in commerce inadvertently generated PCBs over regulatory limits will have a substantial burden of proof in demonstrating good faith efforts within the historical context of the PCB regulations.

5. *Mobay Chemicals Corporation.* Mobay (previously Harmon Colors Corporation), Union, NJ 07083, petitioned for exemption to distribute in commerce its inventory of phthalocyanine pigment containing inadvertently generated PCBs at 150 to 210 ppm. The import of pigments containing greater than 50 ppm PCBs was prohibited at that time. Mobay contends that it had previously obtained assurances from the supplier that the pigment would not be contaminated above the 50 ppm cutoff level. Mobay then submitted a new petition for exemption to distribute in commerce its inventory of this pigment. Mobay requested that, should EPA deny its petition for exemption to distribute in commerce its inventory within the United States, it be granted a 1-time exemption to return the pigments to the original manufacturer in Germany.

EPA proposes to deny the Mobay petition for exemption to distribute in

commerce pigment containing inadvertently generated PCBs above allowable levels, as well as the alternate petition for exemption to reexport the pigment to the original manufacturer in Germany. The Agency can not make the necessary findings of "no unreasonable risk" and "good faith efforts" for either the distribution in commerce petition or the reexport request.

In evaluating this petition, EPA has carefully considered the statutory requirements for evaluation of exemption petitions, Agency policy on exemption petitions for export of PCBs, and what impact the economic consequences of private business transactions should have on Agency decisions concerning exemption petitions. EPA has determined that the Agency will only consider terms of business agreements insofar as they clarify the circumstances involved. It is not the Agency's role to take action merely to redress the economic consequences of business decisions made by petitioners. Any proposed or final action on PCB exemption petitions must be based on the requirements for exercising the Agency's statutory authority to grant exemption petitions as discussed in Units II, III, and IV of this preamble. Furthermore, Agency action on PCB exemption petitions must be consistent with prior policies on exemption petitions, until and unless those policies are changed or amended.

a. Distribution in commerce. EPA proposes to deny the Mobay petition for exemption to distribute in commerce its inventory of pigment containing PCBs over allowable levels because the Agency cannot find that the petitioner has made "good faith efforts" to comply with the limits on inadvertently generated PCBs. The pigments contained PCBs well over the 50 ppm level in effect at the time and the petitioner did not have an exemption to import PCBs above allowable concentration levels. Importers of PCB products are responsible for complying with the PCB regulations.

While the proposed denial is based primarily on the petitioners failure to demonstrate "good faith efforts," the Agency also can not make a finding of "no unreasonable risk." While only a small amount of PCBs would be distributed in commerce under the exemption, the concentrations of PCBs in the pigment are an order of magnitude higher than levels established in the Uncontrolled PCB Rule. EPA estimates that the exposures associated with the distribution in commerce, as well as further processing and use, of the pigment may pose an unreasonable risk

of injury to health or the environment. While the possibility of additional risk is high the economic consequences of denying the petition are relatively low. Denial of the petition will result in costs to Mobay of disposing of the pigment in accordance with the regulations at 40 CFR 761.60. Based on proprietary information submitted by the petitioner, EPA estimated the economic consequences of denying the petition to be in the range of \$74,524 to \$306,000 per lb of PCBs. However, EPA concludes that the cost of denying the petitions will be on the low end of the range because of the relatively high concentration of PCBs in the pigment. Further, the bulk of the cost estimate reflects the lost sale value of the pigment, which is a cost resulting from the business transaction between Mobay and its supplier rather than the consequence of the proposed denial or of a change in the regulatory status of the PCBs.

b. Export. In considering Mobay's request for an alternate exemption to distribute in commerce PCBs for purposes of reexport to the foreign manufacturer, EPA considered whether the return of PCBs to a manufacturer constitutes export, and should be treated in accordance with EPA policy on exemption petitions for export of PCBs. In a policy published in the *Federal Register* of May 1, 1980 (45 FR 29115), EPA specified what petitioners who want to export PCBs must demonstrate to meet the statutory requirements of section 6(e)(3)(B) of TSCA:

- i. EPA will not grant an exemption unless the nation to which export is destined has proper facilities for ultimate disposal.
- ii. EPA will not grant an exemption for an export for a use which is not authorized within the United States.
- iii. In the context of export, good faith efforts to find a substitute means that the burden is on the petitioner to show that there are no substitutes for the PCBs, produced either by the petitioner or a competitor, and that the petitioner proves it has expended time and money searching for a substitute.

Based on consideration of EPA's intent in issuing the above policy, the Agency has determined that petitions for exemption to reexport to a foreign supplier should be evaluated by the same criteria as petitions for exemption to export PCBs for distribution in commerce and use. The Agency treats petitions for export of PCBs more stringently than petitions for exemption to distribute the PCBs within the United States because EPA will have no control

over the distribution, use, and disposal of PCBs once the PCBs have been exported. Whether exported to a foreign customer, or reexported to a foreign supplier, the concern over the ultimate distribution, use and disposal of PCBs remains.

Pigments containing greater than the maximum concentration of 50 ppm are not authorized for use within the United States. The Agency does not know of, and the petitioner has not demonstrated, the existence of proper PCB disposal facilities within Germany. The petitioner did not legally import the PCBs into the United States. In accordance with the discussion of good faith efforts above, EPA must place the responsibility for compliance with import regulations on the importer. The petitioners have, thus, failed to demonstrate "no unreasonable risk" and "good faith efforts" in accordance with the policy for EPA evaluation of exemption petitions to export PCBs.

B. Processing, Distribution in Commerce, Import, and Export of Equipment Containing PCBs, and Equipment Contaminated With PCBs

EPA received from the Aluminum Company of America (ALCOA) three petitions for exemption to (1) process and distribute in commerce within the U.S. hydraulic and heat transfer systems containing PCBs and other equipment contaminated with PCBs; (2) export hydraulic and heat transfer systems containing PCBs and other equipment contaminated with PCBs; and (3) import hydraulic and heat transfer systems containing PCBs, and other equipment contaminated with PCBs. EPA proposes to deny all three ALCOA petitions. The factors EPA considered in evaluating the ALCOA exemption petitions, and EPA's statutory findings on these petitions are discussed below by category of equipment.

1. ALCOA heat transfer and hydraulic systems. On May 31, 1979, the Agency authorized the non-totally enclosed use of PCBs at concentrations above 50 ppm in heat transfer and hydraulic systems. A condition of the use authorization was that all systems that ever contained PCBs at concentrations above 50 ppm were to be tested, flushed, and refilled with fluid containing less than 50 ppm PCBs at least annually until the PCB concentration in the system fell below 50 ppm. All heat transfer and hydraulic systems were to have less than 50 ppm PCBs by July 1, 1984. In the *Federal Register* of July 10, 1984 (49 FR 28172), EPA continued the use authorization for heat transfer and hydraulic systems containing less than 50 ppm PCBs. EPA

did not authorize the continued use of hydraulic systems containing 50 ppm PCBs or greater.

ALCOA has undetermined quantities of heat transfer and hydraulic systems placed in storage for salvage prior to July 1, 1979. Many of these systems contain greater than 50 ppm PCBs, some greater than 1,000 ppm PCBs. ALCOA also owns an undetermined quantity of heat transfer and hydraulic systems currently in operation containing less than 50 ppm PCBs. ALCOA requested exemptions to distribute in commerce, export, and import these systems as salvage.

ALCOA intends to drain all systems containing between 50 and 1,000 ppm PCBs prior to sale. Equipment with greater than 1,000 ppm PCBs will also be flushed with a non-PCB solvent. Outside surfaces of all equipment will be scraped, and steam or solvent cleaned. These activities are authorized under 40 CFR 761.60 for heat transfer and hydraulic systems prior to disposal, or for servicing and maintenance by the owner, but not for purposes of processing these systems for distribution in commerce, export, or import.

EPA has concluded that the petitioner has failed to demonstrate good faith efforts in its handling of heat transfer and hydraulic equipment containing PCBs. EPA is particularly concerned about the equipment placed in storage prior to July 1, 1979. Most of this equipment contains PCBs at 50 ppm or greater, with some containing more than 1,000 ppm PCBs. If this equipment was placed in storage for disposal, 40 CFR 761.65(a) required disposal of the equipment before July 1, 1984. If the equipment was placed in storage for reuse, the systems should all contain less than 50 ppm PCBs if ALCOA was in compliance with the conditions of the use authorization.

Furthermore, EPA has concluded that granting exemptions to ALCOA to process, distribute in commerce, import, and export the heat transfer and hydraulic systems would pose an unreasonable risk of injury to health or the environment due to the high concentrations of PCBs involved and the normal leaks and spills associated with the handling of this equipment. Without specific information on the concentrations of PCBs, the number of systems, or on the amount of PCB waste that would be generated during the exemption period, EPA cannot estimate the costs of denying the ALCOA petitions. Thus, EPA cannot make the statutory finding that granting these exemptions would not result in an unreasonable risk.

2. *ALCOA equipment contaminated with PCBs.* Under current EPA regulations and policies, no non-PCB equipment or material contaminated with PCBs may be processed, distributed in commerce, or used. However, EPA recognizes the tremendous economic and societal costs or requiring the disposal of all equipment and materials contaminated with PCBs. Therefore, EPA maintained the policy of allowing the owners of such items to work with the EPA Regional Offices in decontaminating the equipment or materials. When the Regional Office determines the decontamination to be adequate, the items are allowed to be used and distributed in commerce. EPA is currently drafting a national clean-up policy to provide a framework for consistent Regional clean-up efforts.

ALCOA has undetermined quantities and types of non-PCB equipment which are contaminated with PCBs, and anticipates that additional equipment may be found to be contaminated with PCBs during the exemption period. ALCOA requests exemptions to process, distribute in commerce, export, and import this equipment after decontamination to 50 $\mu\text{g}/100\text{ cm}^2$. ALCOA has provided little or no information on the types and quantities of equipment contaminated with PCBs and the levels at which the equipment is contaminated. After additional communications with the petitioner, EPA concluded that the petitioner itself has no real knowledge of the magnitude of the contamination problem. Without more specific information, EPA cannot determine reasonably ascertainable costs of denying an exemption to sell this equipment. Therefore, EPA cannot find that granting exemptions to distribute, export, and import this equipment will pose an unreasonable risk of injury to health and the environment.

EPA also finds that the petitioner has not demonstrated good cause for requesting an exemption to distribute equipment contaminated with PCBs when there exists an alternative mechanism for the petitioner to decontaminate the equipment and receive approval for the sale of that equipment. The petitioner did comment that without an exemption, it would be forced to deal with authorities in several different Regions. As indicated above, EPA is developing a national clean-up policy to standardize the policies of the Regions as much as possible. Even in the absence of a national policy, EPA cannot fully evaluate blanket exemption petitions for activities involving

contaminated equipment under the section 6(e)(3)(B) exemptions process.

3. *Benefits and costs.* ALCOA estimated the reasonably ascertainable costs of denying the petitions based on past sales of salvage equipment. ALCOA's petitions stated that the value of equipment sold for reuse in 1982-83 totalled \$2.5 million. ALCOA estimated that the value of salvage equipment sold for reuse in the first 10 months of 1984 totalled \$3.5 million. EPA cannot, reasonably estimate the economic consequences to ALCOA of denying the petitions without information on the types of equipment involved, the quantity of equipment involved, and the proportion of ALCOA's business which would be derived from the sales of PCB and PCB-contaminated equipment during the exemption period. Given adequate information, EPA would calculate the economic costs of denial as the sales value of the equipment less the costs to ALCOA of processing the equipment and disposing of the PCB and PCB-contaminated fluids and other wastes. A reasonable estimate of the cost of denial would be further mitigated should the petitioner be able to decontaminate the equipment to the satisfaction of the appropriate EPA Regional Offices and obtain permission to sell the equipment.

Thus, EPA has concluded that the costs of denial are not likely to be of such a magnitude to outweigh the potential risk of injury to health and the environment which would result from granting the petitions.

C. Research and Development

In the Federal Register of July 10, 1984, (49 FR 28193), EPA authorized indefinitely the use of PCBs in "small quantities for research and development." "Small quantities for research and development" is defined at 40 CFR 761.3 as "any quantity of PCBs (1) that is originally packaged in one or more hermetically sealed containers of a volume of no more than five (5.0) milliliters, and (2) that is used only for purposes of scientific experimentation or analysis, or chemical research on, or analysis of, PCBs, but not for research or analysis for the development of a PCB product." EPA concluded that authorizing this use of PCBs does not present an unreasonable risk of injury to health or the environment, considering the effects on human health and the environment; the potential for exposure to PCBs; the benefits of using PCBs and the availability of substitutes; and the economic impact of various regulatory options.

In the Final PCB Exemptions Rule (49 FR 26154) EPA determined that there are no substitutes for PCBs for the continuation of important health, environmental, and analytical research, and that substitutes for PCBs in such applications will not be developed in the future. In this regard, there is a unique need for exemptions to manufacture, process, distribute in commerce, and export PCBs in small quantities for research and development. EPA determined that the manufacture, processing, distribution in commerce, export, and use of PCBs in small quantities for research and development will not pose an unreasonable risk of injury to health or the environment because of the small quantities involved and the procedures used to minimize human and environmental exposure to PCBs.

Based upon these prior EPA conclusions and specific information submitted by petitioners, EPA proposes to grant three individual exemptions to manufacture PCBs in small quantities for research and development, two individual exemptions to export PCBs in small quantities for research and development, and a class exemption for processors and distributors of PCBs in small quantities for research and development.

In general, the goal of section 6(e) is to phase out the manufacture, processing, distribution in commerce, and use of PCBs. EPA believes that this goal does not apply to critical health, environmental, and scientific research on PCBs. In fact, PCBs will always be needed to ensure that the goal of TSCA section 6(e) is being met. In the Final PCB Exemptions Rule, EPA stated that the exemptions granted in that Rule for the manufacture, processing, distribution in commerce, and export of PCBs in small quantities for research and development would be automatically renewed at the end of each year unless the petitioner changes the quantity of PCBs or manner of manufacturing, processing, distributing in commerce, or exporting PCBs.

EPA intends to continue this policy. EPA would also automatically renew the manufacturing and export petitions which it proposes below to grant unless the petitioner notifies EPA of a change in the quantity of PCBs manufactured or exported, or in the manner of manufacturing or exporting the PCBs. Each year, EPA would automatically renew the class exemption for processing and distributing PCBs in commerce in small quantities for research and development until such time as EPA receives information

affecting EPA's conclusion that granting the exemption will not result in an unreasonable risk of injury to health or the environment. EPA would also reserve the authority to exclude any processor or distributor from the class exemption upon determining that maintaining its exemption will pose an unreasonable risk of injury to health or the environment. Any changes in the disposition of individual exemptions, the class exemption, or exemptions for individuals within the class exemption would be published in a notice of proposed rulemaking. The petitioner would be allowed to continue its activities until a final rule is promulgated.

1. *Manufacture and export.* EPA received three petitions for exemption to manufacture small quantities of PCBs for research and development and two petitions for exemption to export small quantities of PCBs for research and development.

The Midwest Research Institute, Kansas City, MO 64110, the Radian Corporation, Austin TX 78766, and Wellington Science USA, College Station, TX 77840, petitioned for exemptions to manufacture PCBs in small quantities for research and development. Two of these petitioners want to manufacture less than 100 grams of PCBs per year. Radian Corporation will manufacture less than 500 grams in 1 year. EPA proposes to grant all three petitions for exemption to manufacture PCBs in small quantities for research and development based on the determinations discussed below in Units V.C.1.a and V.C.1.b.

The Radian Corporation and Supelco, Inc., Bellefonte, PA 16823, petitioned for exemptions to export PCBs in small quantities for research and development. Radian will export less than 500 grams of PCBs in 1 year. Supelco will export less than 5 grams of PCBs in 1 year. EPA proposes to grant both petitions for exemption to export PCBs in small quantities for research and development for reasons discussed below.

In Unit V.B.3 of this proposed rule, EPA described the Agency's criteria for the statutory determination of no unreasonable risk for exemption petitions to export PCBs. EPA treats petitions for exemption to export PCBs more stringently than petitions for exemption to distribute PCBs in commerce within the United States because EPA will have no control over the distribution, use, and disposal of the PCBs once the PCBs have been exported. Those concerns are mitigated in the export of PCBs for research and

development by the viscosity, quantity, and packaging of the PCBs as well as the careful handling of the PCBs by trained personnel.

a. *Unreasonable risk finding.* EPA concluded that granting exemptions to manufacture and export PCBs in small quantities for research and development would not present an unreasonable risk of injury to health or the environment. All of these petitioners want to manufacture or export less than 500 grams of PCBs. The PCBs are manufactured using laboratory practices that are designed to minimize human and environmental exposure to hazardous substances. The risk of exposure to PCBs during the storage and shipment of PCBs is small because the PCBs are packaged in hermetically sealed containers, and are properly marked with warning labels. The risk of exposure to humans and the environment in the ultimate use of these PCBs is minimized by the small quantities of PCBs used in each application, the viscosity of the PCBs, and the careful handling procedures typical of laboratory work. Finally, granting these exemptions will benefit society by allowing important health, environmental, and analytical research to continue.

b. *Good faith efforts finding.* EPA determined in the Final PCB Exemptions Rule that the good faith efforts finding is not relevant to petitions to manufacture or export PCBs in small quantities for research and development because there are no substitutes for PCBs in health and environmental research. Pure PCBs are needed for this research because commercial PCBs contain a mixture of isomers and contaminants which may adversely effect experimental results.

2. *Processing and distribution in commerce.* EPA received six petitions for exemptions to process and distribute in commerce PCBs in small quantities for research and development. In addition, EPA received comments on the need for a class exemption to process and distribute PCBs in small quantities for research and development.

EPA proposes to grant a class exemption for the processing and distribution in commerce of PCBs in small quantities for research and development. The class exemption will include all persons or business entities which process and distribute in commerce PCBs in accordance with the definition of "small quantities for research and development" as specified at 40 CFR 761.3. EPA proposes to place the following terms and conditions on the class exemption: (a) That all

processors and distributors maintain records of their PCB activities for a period of 5 years; and (b) that any person or company which expects to process or distribute in commerce 100 grams (.22 lb) or more PCBs for research and development in 1 year report to EPA and identify the sites of PCB activities and the quantity of PCBs to be processed or distributed in commerce.

The following six companies which submitted individual petitions for exemption to process and distribute in commerce PCBs in small quantities for research and development would be included in the class exemption: Alltech Applied Sciences; Midwest Research Institute; Pathfinder Laboratories; Radian Corporation; Supelco Incorporated; and Wellington Sciences USA. EPA would reserve the right to exclude any individual from the class petition by rulemaking.

EPA has determined that there is a unique need for exemptions to process and distribute in commerce PCBs in small quantities for research and development. EPA believes that this need can best be met by granting a class exemption to all processors and distributors of PCBs in small quantities for research and development. Based on information submitted in, and pertaining to, petitions for processing and distribution in commerce of PCBs in small quantities for research and development, EPA has concluded that all processing and distribution in commerce exemption petitions would be granted provided that the definition of "small quantities for research and development" is met.

Because of the nature of research and development activities, the absence of a class exemption causes special difficulties, and places substantial burdens on EPA as well as on processors and distributors. EPA has determined that petitions to process and distribute in commerce PCBs in small quantities for research and development which provide sufficient data on handling procedures would be granted by EPA. This proposed class petition would eliminate the unnecessary use of resources in filing, evaluating and acting on those petitions.

EPA is proposing the reporting requirement on processors and distributors of 100 grams or more PCBs to ensure that unreasonable risks to health or the environment will not be posed by commercial processors and distributors handling large quantities of PCBs per year. However, EPA is not proposing to place a reporting requirement on processors and distributors handling less than 100 grams per year because the Agency has

concluded that the lack of a reporting requirement does not pose an unreasonable risk in situations such as those discussed below.

Many users of PCBs who wish to return analytical standards to the supplier because of over-shipment or the delivery of incorrect standards, must petition for exemption and wait for a minimum of 1 year due to the lengthy exemption process, or dispose of the PCBs. These standards, if returned, can be used by another company. EPA has also received comments indicating that if used standards could be returned to processors (repackaged in hermetically sealed containers of a volume of no more than 5 ml), many could be reprocessed under controlled conditions and reused. Thus, this class exemption would potentially reduce the need to manufacture and dispose of PCBs used in research and development.

In addition, many users of PCBs in research and development are involved, in the course of their work, in activities technically classified as processing and distribution in commerce. These users are currently processing and distributing in commerce, without an exemption, under the assumption that these activities are functions of use and thus authorized as use.

a. Unreasonable risk finding. EPA has previously determined that the processing and distribution of PCBs in small quantities for research and development do not pose unreasonable risk of injury to health and the environment. Most of the processors and distributors included in this exemption would be handling less than 100 grams of PCBs per year. Commercial distributors of analytical standards for research and development who would process 100 grams or more of PCBs in one year would be required to report to EPA. The PCBs will be processed using laboratory standards designed to minimize human and environmental exposure to hazardous substances. They will be packaged and distributed in hermetically sealed containers in quantities no larger than 5 ml.

Granting the exemption will benefit society by allowing health, environmental and analytical research to continue. Granting the exemption will encourage the recycling and reuse of PCBs in controlled laboratory settings and discourage manufacture and import of PCBs for research and development. Furthermore, substantial numbers of petitions for exemption which would otherwise be filed, processed, and ultimately granted, will be avoided by granting the class exemption. EPA has estimated the incremental costs of filing one exemption petition to be \$17,383.

The incremental cost to EPA of processing an exemption petition is estimated to be \$7,742.

b. Good faith efforts finding. EPA has determined that the good faith efforts finding is not relevant here, because there are no substitutes for PCBs in health and environmental research. Pure PCBs are needed for this research because commercial PCBs contain a mixture of isomers and contaminants which may adversely affect experimental results.

VI. Executive Order 12291

Under Executive Order 12291, issued February 17, 1981, EPA must judge whether a rule is a "major rule" and therefore subject to the requirement that a regulatory impact analysis be prepared. EPA has determined that this proposed rule is not a "major rule" as that term is defined in section 1(b) of the Executive Order because (a) the annual effect on the economy will be an order of magnitude less than \$100 million; (b) it will not cause any noticeable increase in costs or prices for any sector of the economy or for any geographic region; and (c) it will not result in any significant adverse effects on competition, employment, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets.

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

VII. Regulatory Flexibility Act

Section 603 of the Regulatory Flexibility Act (the Act), 5 U.S.C. 603, requires EPA to prepare and make available for comment an initial regulatory flexibility analysis in connection with any rulemaking for which EPA must issue a general notice of proposed rulemaking. The initial regulatory flexibility analysis must describe the effect of a rule on small business entities.

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

EPA proposes to deny no exemption petitions submitted by small businesses. Therefore, in accordance with section

605(b) of the Act and the authority delegated to me to act on petitions submitted under TSCA section 6(e)(3)(B), I certify that this rule will not have a significant impact on a substantial number of small entities.

VIII. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* An Information Collection Request document (ICR #0857) has been prepared by EPA and a copy may be obtained from: Control Officer, Information Management Branch; EPA; 401 M St., S.W. (PM-223); Washington, D.C. 20460 or by calling (202) 382-2742. Submit comments on these requirements to EPA and: Office of Information and Regulatory Affairs; OMB; 726 Jackson Place, N.W., Washington, D.C. 20503 marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB comments or public comments on the information collection request.

IX. Official Rulemaking Record

For the convenience of the public and EPA, all of the information originally submitted in docket number OPTS-66001 (manufacturing exemptions) and OPTS-66002 (processing and distribution in commerce exemptions) was consolidated into docket number OPTS-66008. Information and comments submitted in response to the July 10, 1984 proposed rule related notice (49 FR 28203) were filed in docket number OPTS-66008B.

In accordance with the requirements of section 19(a)(3) of TSCA, EPA is issuing 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). However, these documents will be included in the public record, and a full list of these materials will be available upon request from EPA's TSCA Assistance Office listed under FOR FURTHER INFORMATION CONTACT.

A. Previous Rulemaking Records

(1) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Disposal and Marking Rule," Docket No.

OPTS-66005, 43 FR 7150, February 17, 1978.

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

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

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

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

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

(7) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Response to Individual and Class Petitions for Exemptions," Docket No. OPTS-66008A, 49 FR 28154, July 10, 1984.

(8) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Exclusions, Exemptions, and Use Authorizations," Docket No. OPTS-62032A, 49 FR 28172, July 10, 1984.

(9) Official Rulemaking Record from "Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Use in Microscopy and Research and Development," Docket No. OPTS-62031A, 49 FR 28193, July 10, 1984.

B. Federal Register Notices

(10) 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."

(11) 44 FR 108, January 2, 1979, USEPA, "Polychlorinated Biphenyls (PCBs); Policy for Implementation and Enforcement."

(12) 44 FR 31558, May 31, 1979, USEPA, "Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act; Interim Procedural Rules for Exemptions from the Polychlorinated Biphenyls (PCBs) Processing and Distribution in Commerce Prohibitions."

(13) 44 FR 31564, May 31, 1979, USEPA, "Polychlorinated Biphenyls (PCBs); Proposed Rulemaking for PCB Manufacturing Exemptions."

(14) 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."

(15) 45 FR 14247, March 5, 1980, USEPA, "Polychlorinated Biphenyls (PCBs); Statement of Policy on All Future Exemption Petitions."

(16) 45 FR 29115, May 1, 1980, USEPA, "Polychlorinated Biphenyls (PCBs); Expiration of Open Border Policy for PCB Disposal."

(17) 48 FR 50486, November 1, 1983, USEPA, "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce Exemptions; Proposed Rule," Docket No. OPTS 66008.

(18) 48 FR 52402, November 17, 1983, USEPA, "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Microscopy and Research and Development; Proposed Rule," Docket No. OPTS-62031.

(19) 48 FR 55076, December 8, 1983, USEPA, "Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations; Proposed Rule," Docket No. OPTS-62032.

(20) 49 FR 28203, July 10, 1984, USEPA, "Polychlorinated Biphenyls (PCBs); Request for Additional Comments on Certain Individual and Class Petitions for Exemption," Docket No. OPTS-66008B.

(21) 49 FR 39986, October 11, 1984, USEPA, "Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Use in Electrical Transformers; Proposed Rule," Docket No. 82035A.

C. Support Documents

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

(23) USEPA, OPTS, ETD, "PCB Exemption Petitions Economic Impact Analysis" (April 1984).

(24) USEPA, OPTS, ETD, "PCB Exemption Petitions Economic Impact Analysis" (May 1985).

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

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

D. Other References

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

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

(29) PCB Exemption Petitions, Additional Data and Related Communications in Docket No. OPTS-66008B.

List of Subjects in 40 CFR Part 761

Hazardous substances, Labeling, Polychlorinated biphenyls, Recordkeeping and reporting requirements, Environmental protection.

Dated: August 18, 1985.

Don R. Clay,

Director, Office of Toxic Substances.

Therefore, it is proposed that 40 CFR Part 761 be amended as follows:

1. The authority citation for Part 761 continues to read as follows:

PART 761—[AMENDED]

Authority: 15 U.S.C. 2605, 2607, and 2611.

2. In § 761.80 by adding paragraphs (f) (4), (5), and (6), (m) (5) and (6), and (o), (p), and (q), and revising paragraphs (g) and (n) to read as follows:

§ 761.80 Manufacturing, processing, and distribution in commerce exemptions.

(f) * * *

(4) Midwest Research Institute, Kansas City, MO 64110 (ME-3.1).

(5) Radian Corp., Austin, TX 78766 (ME-81.2).

(6) Wellington Sciences USA, College Station, TX 77840 (ME-104.1).

(g) The Administrator grants a class exemption to all processors and distributors of PCBs in small quantities for research and development provided that the following conditions are met:

(1) All processors and distributors must maintain records of their PCB activities for a period of 5 years.

(2) Any person or company which expects to process or distribute in commerce 100 grams (.22 lb) or more PCBs in 1 year must report to EPA identifying the sites of PCB activities

and the quantity of PCBs to be processed or distributed in commerce.

* * * * *

(m) * * *

(5) Supelco, Inc., Bellefonte, PA 16823-0048 (PDE-41.2).

(6) Radian Corp., Austin, TX 78766 (PDE-182.1).

(n) The 1-year exemption granted to petitioners in paragraphs (f), (l), and (m) of this section shall be renewed automatically unless a petitioner notifies EPA of any increase in the amount of PCBs to be manufactured, imported, or exported or any change in the manner of manufacture, import, or export of PCBs. EPA will consider the submission of such information to be a renewed petition for exemption. EPA will evaluate the information in the renewed exemption petition, issue a proposed rule for public comment, and issue either a final rule granting the exemption or a notice denying the exemption. Until EPA acts on the petition, the petitioner will be allowed to continue the activities for which it requests exemption.

(o) The 1-year class exemption granted to all processors and distributors of PCBs in small quantities for research and development in paragraph (g) of this section shall be renewed automatically unless information is submitted affecting EPA's conclusion that the class exemption, or the activities of any individual or company included in the exemption, will not pose an unreasonable risk of injury to health or the environment. EPA will evaluate the information, issue a proposed rule for public comment, and issue a final rule affecting the class exemption or individuals or companies included in the class exemption. Until EPA issues a final rule, individuals and companies included in the class exemption will be allowed to continue processing and distributing PCBs in small quantities for research and development.

(p) The Administrator grants the following petitioners an exemption for 1 year to import inadvertently generated PCBs at concentrations above those specified for "excluded manufacturing processes" at § 761.3:

(1) American Hoechst Corp., Somerville, NJ 08876 (ME-5).

(i) The exemption is limited to the pigment specified in the American Hoechst petition.

(ii) [Reserved]

(2) [Reserved]

(q) The Administrator grants the following petitioners, and their customers, an exemption for 1 year to process and distribute in commerce inadvertently generated PCBs at

concentration above those specified for "excluded manufacturing processes" at § 761.3 provided that the conditions for each exemption are met:

(1) American Hoechst Corp., Somerville, NJ 08876 (PDE-13).

(i) The petitioner must notify customers that the product may contain PCBs over the 50 ppm maximum concentration level for inadvertently generated PCBs.

(ii) The exemption is limited to the pigment specified in the American Hoechst petition.

(2) Dainichiseika Color & Chemicals America, Inc., Clifton, NJ 07012 (PDE-58).

(i) The petitioners must notify customers that the product contains PCBs over the 50 ppm maximum concentration level for inadvertently generated PCBs.

(ii) The exemption is limited to the 82,400 lbs of phthalocyanine blue crude in Dainichiseika's inventory.

[FR Doc. 85-20662 Filed 8-28-85; 8:45 am]

BILLING CODE 6860-50

40 CFR Part 761

[OPTS-66008D; TSH FRL 2864-4]

Response to Ward Transformer Company Petition for Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Denial of Exemption Petition.

SUMMARY: In this notice of denial, EPA is denying the Ward Transformer Company, Incorporated, petition for an exemption to buy and sell used PCB-contaminated transformers.

DATE: This petition denial shall become effective on August 29, 1985.

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

Copies of this rule and its support documents can be obtained from the TSCA Assistance Office listed above.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority

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