

## DEPARTMENT OF THE TREASURY

## Internal Revenue Service

## 26 CFR Part 26

[REG-145988-03]

RIN 1545-BC60

## Predeceased Parent Rule

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Cancellation of notice of public hearing on proposed rulemaking.

**SUMMARY:** This document provides notice of cancellation of a public hearing on proposed rulemaking relating to the predeceased parent rule.

**DATES:** The public hearing originally scheduled for Tuesday, December 14, 2004, at 10 a.m. is cancelled.

**FOR FURTHER INFORMATION CONTACT:** Guy R. Traynor, Procedures and Administration, Publications & Regulations Branch, at (202) 622-3693 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:** A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on Friday, September 3, 2004 (69 FR 53862), announced that a public hearing was scheduled for December 14, 2004 at 10 a.m., in the auditorium of the Internal Revenue Service building, 1111 Constitution Avenue NW., Washington, DC. The subject of the public hearing is proposed regulations under section 2651 of the Internal Revenue Code.

The notice of proposed rulemaking and notice of public hearing, instructed those interested in testifying at the public hearing to submit a request to speak and an outline of topics to be addressed by November 23, 2004. As of November 29, 2004, no one has requested to speak. Therefore, the public hearing scheduled for December 14, 2004 is cancelled.

**Guy R. Traynor,**

*Federal Register Liaison, Publications & Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedures & Administration).*

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 721

[OPPT-2004-0085; FRL-7688-1]

RIN 2070-AJ02

## Certain Polybrominated Diphenylethers; Proposed Significant New Use Rule

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for tetrabromodiphenyl ether (CAS No. 40088-47-9; Benzene, 1,1'-oxybis-, tetrabromo deriv.), pentabromodiphenyl ether (CAS No. 32534-81-9; Benzene, 1,1'-oxybis-, pentabromo deriv.), hexabromodiphenyl ether (CAS No. 36483-60-0; Benzene, 1,1'-oxybis-, hexabromo deriv.), heptabromodiphenyl ether (CAS No. 68928-80-3; Benzene, 1,1'-oxybis-, heptabromo deriv.), octabromodiphenyl ether (CAS No. 32536-52-0; Benzene, 1,1'-oxybis-, octabromo deriv.), or nonabromodiphenyl ether (CAS No. 63936-56-1; Benzene, pentabromo(tetrabromophenoxy)-), and any combination of these substances resulting from a chemical reaction. This proposed rule would require manufacturers and importers to notify EPA at least 90 days before commencing the manufacture or import of any one or more of these chemical substances on or after January 1, 2005 for any use. EPA believes that this action is necessary because these chemical substances may be hazardous to human health and the environment. The required notice would provide EPA with the opportunity to evaluate an intended new use and associated activities and, if necessary, to prohibit or limit that activity before it occurs.

**DATES:** Comments, identified by docket identification (ID) number OPPT-2004-0085, must be received on or before February 4, 2005.

**ADDRESSES:** Submit your comments, identified by docket (ID) number OPPT-2004-0085, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov/>. Follow the on-line instructions for submitting comments.

- **Agency Website:** <http://www.epa.gov/edocket/>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow

the on-line instructions for submitting comments.

- **E-mail:** [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov).
- **Mail:** Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Hand Delivery:** OPPT Document Control Office, EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number OPPT-2004-0085. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to docket ID number OPPT-2004-0085. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at <http://www.epa.gov/edocket/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, [regulations.gov](http://www.regulations.gov), or e-mail. The EPA EDOCKET and the [regulations.gov](http://www.regulations.gov) websites are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL-7181-7).

*Docket:* All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the OPPT Docket, EPA Docket Center, EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744, and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566-0280.

**FOR FURTHER INFORMATION CONTACT:** For general information contact: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (303) 312-6700; e-mail address: [moss.kenneth@epa.gov](mailto:moss.kenneth@epa.gov).

#### SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) one or more of the following polybrominated diphenyl ethers (PBDEs): tetrabromodiphenyl ether ("tetraBDE") (CAS No. 40088-47-9; Benzene, 1,1'-oxybis-, tetrabromo deriv.), pentabromodiphenyl ether ("pentaBDE") (CAS No. 32534-81-9; Benzene, 1,1'-oxybis-, pentabromo deriv.), hexabromodiphenyl ether ("hexaBDE") (CAS No. 36483-60-0; Benzene, 1,1'-oxybis-, hexabromo deriv.), heptabromodiphenyl ether ("heptaBDE") (CAS No. 68928-80-3; Benzene, 1,1'-oxybis-, heptabromo deriv.), octabromodiphenyl ether ("octaBDE") (CAS No. 32536-52-0; Benzene, 1,1'-oxybis-, octabromo

deriv.), or nonabromodiphenyl ether ("nonaBDE") (CAS No. 63936-56-1; Benzene, pentabromo(tetrabromophenoxy)-), and any combination of these substances resulting from a chemical reaction. Persons who intend to import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements, and to the regulations codified at 19 CFR 12.118 through 12.127 and 127.28. Those persons must certify that they are in compliance with the SNUR requirements (see TSCA section 13 (15 U.S.C. 2612) and 19 CFR 12.118 through 12.127 and 127.28). The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after January 5, 2005 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D. Potentially affected entities may include, but are not limited to:

- Manufacturers (defined by statute to include importers) of PBDEs (NAICS 325 and 324110), e.g. chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions at 40 CFR 721.5 for SNUR-related obligations. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

#### B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 721 is available on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

#### C. How Do I Submit Confidential Business Information?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, regulations.gov, or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

### II. Background

#### A. What Action is the Agency Taking?

This proposed rule, when finalized, would require persons to notify EPA at least 90 days before commencing the manufacture (including importation) of tetrabromodiphenyl ether ("tetraBDE") (CAS No. 40088-47-9; Benzene, 1,1'-oxybis-, tetrabromo deriv.), pentabromodiphenyl ether ("pentaBDE") (CAS No. 32534-81-9; Benzene, 1,1'-oxybis-, pentabromo deriv.), hexabromodiphenyl ether ("hexaBDE") (CAS No. 36483-60-0;

Benzene, 1,1'-oxybis-, hexabromo deriv.), heptabromodiphenyl ether ("heptaBDE") (CAS No. 68928-80-3; Benzene, 1,1'-oxybis-, heptabromo deriv.), octabromodiphenyl ether ("octaBDE") (CAS No. 32536-52-0; Benzene, 1,1'-oxybis-, octabromo deriv.), or nonabromodiphenyl ether ("nonaBDE") (CAS No. 63936-56-1; Benzene, pentabromo(tetrabromophenoxy)-), and any combination of these substances resulting from a chemical reaction, for any use on or after January 1, 2005.

#### *B. What is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use (15 U.S.C. 2604 (a)(1)(B)). The mechanism for reporting under this requirement is established under 40 CFR 721.5.

#### *C. Applicability of General Provisions*

General provisions for SNURs appear under subpart A of 40 CFR part 721. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. Persons subject to this SNUR, when finalized, would be required to comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1); the exemptions authorized by TSCA section 5 (h)(1), (h)(2), (h)(3), and (h)(5); and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take regulatory action under TSCA sections 5(e), 5(f), 6, or 7, if appropriate, to control the activities on which it has received the SNUR notice. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a chemical substance identified in a

proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who intend to import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, which appear at 19 CFR 12.118 through 12.127 and 127.28. Such persons must certify that they are in compliance with SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

#### **III. Summary of the Proposed Rule**

PBDEs are members of a broader class of brominated chemicals used as flame retardants; these are called brominated flame retardants, or BFRs. There are commercial PBDE products with different average amounts of bromination: penta-, octa-, and decaBDE. These chemicals are major components of commercial products often used as fire retardants in furniture foam (pentaBDE), plastics for personal computers and small appliances (octaBDE), and plastics for TV cabinets, consumer electronics, wire insulation, and backcoatings for draperies and upholstery (decabromodiphenylether, or decaBDE). The value of these chemicals is their ability to slow ignition and rate of fire growth, and as a result increase available escape time in the event of a fire involving the above products.

Although use of these chemicals is intended to save lives and property, there have been unintended consequences, such as, releases to and accumulation in the environment. Environmental monitoring programs in Europe, Asia, North America, and the Arctic have detected several PBDEs in human breast milk, fish, aquatic birds, and elsewhere in the environment. The human health toxicological endpoints of concern for these chemical substances are liver toxicity, thyroid toxicity, and neurodevelopmental toxicity. More needs to be understood about the environmental fate and the exposure pathways that lead to PBDE presence in wildlife and people. The lower brominated PBDEs (tetraBDE, pentaBDE, and hexaBDE) found in the commercial pentaBDE and octaBDE products are the congeners most often detected in the environment and for which human health and environmental concerns are greater (see Unit IV.B. and C.). These factors, taken together, raise concerns for potential adverse effects in people and wildlife over time if these substances should continue to be produced, released, and built up in the environment.

EPA believes that the commercial products pentaBDE and octaBDE are manufactured in the United States (U.S.) only by Great Lakes Chemical Corporation. Great Lakes has committed to phase-out these chemicals voluntarily by discontinuing their manufacture by the end of 2004 (Ref. 1). EPA is aware of no ongoing production of tetra-, hexa-, hepta- or nonaBDE except as components of the commercial pentaBDE and octaBDE commercial products. EPA believes that any manufacture or import of these chemicals occurring after Great Lakes' phase-out dates would increase the magnitude and duration of exposure to these chemicals. Therefore, EPA is proposing to designate as a significant new use any manufacture or import of the chemical substances listed in Unit II.A. for any use on or after January 1, 2005. Because decaBDE is not included in the voluntary phase-out and therefore remains in commerce after January 1, 2005, it would not be subject to this proposed rule.

Given that, based on information available to EPA, no companies other than Great Lakes Chemical Corporation are currently manufacturing or importing the commercial pentaBDE or octaBDE products, or the PBDE congeners that comprise these products, and given the negative commercial and regulatory environment associated with these chemicals, EPA believes it is unlikely that companies would incur the costs associated with establishing new manufacturing capacity for these chemicals in order to enter this market. This proposed rule, when finalized, would require persons who intend to manufacture or import the chemical substances listed in Unit II.A. to submit a SNUN at least 90 days before commencing the manufacture or importation of any of these chemicals for any use on or after January 1, 2005. The required notice would provide EPA with the opportunity to evaluate the intended use, and, if necessary, to prohibit or limit that use before it occurs. In the event that the phase-out of these chemicals does not progress as described in this proposed rule, EPA may pursue additional regulatory action as appropriate under TSCA sections 4, 6, and 8.

#### **IV. Overview of PBDEs**

See Unit XI. for selected primary references for the information summarized in this unit. For a more complete treatment of PBDEs and comprehensive lists of relevant articles, see the risk assessments developed under EPA's Voluntary Children's Chemical Evaluation Program (VCCEP)

and the reports from the VCCEP Peer Consultation meetings held for these chemicals (Refs. 2–7), in addition to the overview articles (Refs. 8 and 9).

#### *A. Defining the PBDEs Subject to this Proposed SNUR*

The chemical substances that are subject to this proposed rule are listed on the TSCA Inventory. Each individual chemical substance is actually a reaction product of diphenyl ether with a brominating agent. The different products, each having different numbers of bromines depending on reaction stoichiometry, are a normal distribution of possible polybrominated diphenyl ethers. For example, the commercially available “pentaBDE” product, sold under the single CAS No. (32534–81–9), is predominantly an almost equal mixture of tetraBDE and pentaBDE congeners, along with smaller amounts of the higher brominated congeners. It is a reaction product combination of aromatic brominated compounds in which 4–6 hydrogen atoms in the diphenyl oxide structure are replaced by bromine atoms (Refs. 2 and 10). The “octaBDE” product (CAS No. 32536–52–0) consists predominantly of heptaBDE and octaBDE congeners with small amounts of hexa- and nonaBDE. It is a reaction product combination of aromatic brominated compounds in which 6–9 hydrogen atoms in the diphenyl oxide structure are replaced by bromine atoms (Refs. 3 and 10). In order to insure that the PBDEs listed in Unit II.A. would be subject to review before manufacture or import for commercial purposes, this proposed rule would require the reporting for any manufacture or importation of these chemical substances.

#### *B. Health and Environmental Effects*

Existing health hazard information on the subject chemical substances is incomplete (Ref. 8). The currently available toxicity test data indicate the potential for adverse effects in humans, especially for lower brominated congeners (Refs. 8 and 9). The major findings from subchronic and chronic pentaBDE toxicity studies in rodents are induction of hepatic enzymes and effects on thyroid homeostasis. The effects on thyroid homeostasis have raised concerns for the potential for developmental neurotoxicity (Ref. 5). The toxicity database for octaBDE is similar to that of pentaBDE, but less complete (Ref. 6).

With regards to environmental hazards of the subject chemical substances, the European Union (EU) risk assessment for pentaBDE concludes for aquatic and terrestrial ecosystems

that there is a need for specific measures to limit risks. This conclusion is reached because of “concerns for effects on the local aquatic (sediment) and terrestrial environment as a consequence of exposure arising from polyurethane foam production [and] concerns for secondary poisoning to the environmental spheres mentioned in Unit IV.B. both locally and regionally as a consequence of exposure arising from production and/or use of polyurethane foams.” (Ref. 11). For octaBDE, the EU concluded that there is a risk of “secondary poisoning via the earthworm route for the hexabromodiphenyl ether component in the commercial octabromodiphenyl ether product from the use in polymer applications.” There was a need identified for further monitoring to determine whether findings in top predators (including birds’ eggs) is a widespread or localized phenomenon, and for avian reproduction tests (Ref. 12).

#### *C. Exposure and Environmental Fate Data*

Current information suggests strongly that PBDEs as a class are persistent and may bioaccumulate. Environmental monitoring programs in Europe, Asia, North America, and the Arctic have detected many PBDE congeners in human blood and breast milk, fish, aquatic birds, and elsewhere in the environment (Refs. 9, 13, 14, 15, 16, 17, and 18). This widespread presence, combined with persistence, bioaccumulative potential, and toxicity from low level exposures, raises concerns for potential adverse effects to people and wildlife over time should the chemical substances that are subject to this proposed rule continue to be produced, released, and accumulated in the environment.

Of the congeners found in the commercial products, tetraBDE, pentaBDE, and hexaBDE are the PBDEs most frequently detected in wildlife and humans (Refs. 8 and 9). The octanol-water partition coefficient, which is an important property in determining the environmental fate of hydrophobic organic chemicals, particularly in biota, has been measured for a number of PBDEs, and shown to be in the range of optimum bioaccumulation potential (Ref. 19). With the present data, the Agency can only speculate on environmental transport and partitioning of PBDEs in general and specifically regarding the chemical substances that are subject to this proposed rule. While the exact mechanisms or pathways by which the various PBDE congeners end up in the

environment and humans are not known yet, they could include direct releases from manufacturing or processing of the chemicals into products like plastics or textiles, aging and wear of these consumer products (Ref. 20), photolytic breakdown of higher brominated congeners (Ref. 21), and direct exposure during use or via indoor air or house dust (Refs. 22 and 23), as well as bioaccumulation up the food chain (Ref. 24). The small amount of environmental information on octaBDE shows it does not readily degrade, although an exception is in fish, where there is evidence that octaBDE could have the potential to be metabolized to pentaBDE (Ref. 25).

#### *D. Use Information*

The chemical substances subject to this proposed rule, listed in Unit II.A., are the commercial products pentaBDE and octaBDE, and other PBDE congeners that comprise these products and are separately listed on the TSCA Inventory. PentaBDE (often formulated with nonhalogenated organophosphates) has been widely used in formulations for flexible polyurethane foams used in upholstered products ranging from home furniture to seats in airplanes and automobiles. OctaBDE has been primarily used as an additive to a type of plastic known as acrylonitrile-butadiene-styrene (ABS), used in housings for office and medical electronics, the interior and exterior trim of automobiles, telephone handsets, and other products. It is also incorporated into resins (polyamide and polybutylene terephthalate) in the manufacture of electrical connectors and components and automotive interior parts.

World-wide demand for pentaBDE and octaBDE in 2001 was estimated to be 7,500,000 and 3,790,000 kilograms (kg), respectively; demand for these chemicals in the Americas was 7,100,000 kg for pentaBDE and 1,500,000 kg for octaBDE (Ref. 26). On November 3, 2003, Great Lakes Chemical Corporation, the only U.S. manufacturer of pentaBDE and octaBDE, announced a voluntary phase-out of both those commercial products by the end of 2004. According to the information currently available to EPA, Great Lakes is the sole U.S. manufacturer of commercial pentaBDE and octaBDE and EPA also understands that currently there is no import of these commercial products into the U.S. Furthermore, based on available information, none of the other PBDE congeners subject to this proposed rule are currently manufactured or imported into the U.S.

## V. Objectives and Rationale of the Rule

As summarized in Unit IV., EPA has concerns regarding the environmental fate and the exposure pathways that lead to PBDE presence in wildlife and people, and the persistence, bioaccumulation, and toxicity (PBT) potential of pentaBDE and octaBDE. Great Lakes Chemical Corporation, the sole manufacturer of these chemicals in the U.S., has chosen voluntarily to discontinue their manufacture for all uses by December 31, 2004. With Great Lakes Chemical Corporation's exit from the market, EPA believes that all U.S. manufacture and import of these chemicals likely will cease. However, EPA is concerned that manufacture or import could be reinitiated in the future, and wants the opportunity to evaluate and control, if appropriate, exposures associated with those activities. Based on the current situation, including substantial production volume, number of uses, potential for widespread release and exposure, as well as the PBT nature of the chemical substances, any new manufacture or import after January 1, 2005 is expected to significantly increase exposures after manufacture and import are discontinued, over that which could otherwise exist. The notice that would be required by this proposed SNUR would provide EPA with the opportunity to evaluate activities associated with a significant new use as proposed herein and an opportunity to protect against unreasonable risks, if any, from exposure to the substances.

Based on these considerations, EPA wants to achieve the following objectives with regard to the significant new uses that are designated in this proposed rule. EPA wants to ensure that:

1. EPA would receive notice of any person's intent to manufacture or import the chemical substances subject to this proposed rule for a designated significant new use before that activity begins.

2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or importing these chemical substances for a significant new use.

3. EPA would be able to regulate prospective manufacturers and importers of these chemical substances before a significant new use occurs, provided such regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7.

## VI. Significant New Use Determination

In making a determination that a use of a chemical substance is a significant

new use, the Agency must consider all relevant factors, including those listed in section 5(a)(2) of TSCA. Those factors are:

- The projected volume of manufacturing and processing of the chemical substance.
- The extent to which the use changes the type or form of exposure to human beings or the environment to a chemical substance.
- The extent to which the use changes the magnitude and duration of exposure to human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Given that no companies other than Great Lakes Chemical Corporation are currently manufacturing or importing commercial pentaBDE or octaBDE in the U.S., the negative commercial and regulatory environment associated with these chemicals (including the EU ban on marketing and use of pentaBDE and octaBDE (Ref. 27) and similar restrictions enacted by certain States in the U.S. (Ref. 28)), and the expectation that viable substitutes will be available including those being considered in the Design for Environment Furniture Flame Retardancy Partnership (Ref. 29), EPA believes it is unlikely that companies would incur the costs associated with establishing new manufacturing capacity for these chemicals in order to enter this market. With Great Lakes Chemical Corporation's exit from the market, EPA believes that all U.S. manufacture and import of these chemicals likely will cease and that any new manufacture or import, for any use, subsequent to Great Lakes Chemical Corporation's December 31, 2004 phase-out date would result in a significant increase in the magnitude and duration of exposures to humans and the environment over that which would otherwise exist. Based on these considerations, EPA has determined that any manufacture or import of the chemical substances listed in Unit II.A. for any use on or after January 1, 2005 is a significant new use.

## VII. Alternatives/Other Options Considered

Before proposing this SNUR, EPA considered the following alternative regulatory actions for the chemical substances that are the subject of this proposed rule.

1. *Promulgate a TSCA section 8(a) reporting rule.* Under a TSCA section 8(a) rule, EPA could generally require any person to report information to the Agency when they intend to

manufacture, import or process the chemical substances listed in Unit II.A. However, the use of TSCA section 8(a) rather than the SNUR authority, would not provide the opportunity for EPA to review human and environmental hazards and exposures associated with the new uses of these substances and, if necessary, to take immediate regulatory action under TSCA section 5(e) or section 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because those firms generally are exempt from TSCA section 8(a) reporting requirements. In view of EPA's concerns about the chemical substances and its interest in having the opportunity to review these substances and regulate them as appropriate, pending the development of exposure and/or hazard information should a significant new use be initiated, the Agency believes that a TSCA section 8(a) rule for certain PBDEs would not meet all of EPA's regulatory objectives.

2. *Regulate the chemical substances subject to this proposed rule under TSCA section 6.* EPA must regulate under TSCA section 6 if there is a reasonable basis to conclude that the manufacture, import, processing, distribution in commerce, use, or disposal of a chemical substance or mixture "presents or will present" an unreasonable risk of injury to human health or the environment. Based on EPA's findings that after December 31, 2004 there would be no manufacture or import of the chemical substances subject to this proposed rule, EPA concluded that risk management action under TSCA section 6 is not necessary at this time. This proposed SNUR would allow the Agency to address the potential risks associated with any intended significant new use of these chemical substances.

3. *Require persons that import certain PBDEs as part of articles to comply with the requirements of this proposed SNUR.* Under the general SNUR exemption provisions at 40 CFR 721.45, a person that imports or processes a substance covered by a SNUR identified in subpart E of part 721 is not generally subject to the notification requirements of § 721.25 for that substance, if the person imports or processes the substance as part of an article. See 40 CFR 721.45(f). EPA considered requiring persons that import (processors are not covered by this proposed SNUR) the PBDEs subject to this proposed rule as part of articles to comply with the requirements of this proposed SNUR, due to concerns that exempting articles would render the SNUR less effective

because of the possibility that upholstered products or plastics-containing articles treated with these PBDEs could be imported. The current import status of articles treated with PBDEs, i.e., whether or not import of these articles is presently ongoing, is not known at this time. However, given the negative commercial and regulatory environment associated with these chemicals (including the EU ban on marketing and use of pentaBDE and octaBDE, the EU ban on placing on the market articles containing these substances (Ref. 27)), similar restrictions enacted by certain states in the U.S. (Ref. 28), and the expectation that viable substitutes will be available, EPA believes it would be unlikely that these chemical substances will be imported as part of articles. Based on this belief, and the resultant low likelihood of exposure to pentaBDE and octaBDE imported as part of an article, EPA is not proposing to amend the general SNUR exemption provisions for the purpose of this proposed SNUR. EPA is specifically seeking comments on the issue of whether persons that import the chemical substances listed in Unit II.A. as part of articles should be subject to the reporting requirements of this proposed SNUR.

#### **VIII. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule**

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA believes that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the proposal date of the SNUR, rather than as of the effective date of the final rule. If uses begun after publication of the proposed SNUR were considered to be ongoing, rather than new, it would be difficult for EPA to establish notification requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the proposed rule became final, and then argue that the use was ongoing as of the effective date of the final rule.

Any person who, after publication of this proposed SNUR, begins commercial manufacture or import of the chemical substances listed in Unit II.A. must stop such activity before the effective date of the final rule. Persons who cease those activities will have to meet all SNUR notice requirements and wait until the end of the notice review period, including all extensions, before engaging in any activities designated as significant new uses. If, however, persons who begin commercial manufacture or import of the chemical

substances listed in Unit II.A. between the proposal and the effective date of the final SNUR meet the conditions of advance compliance as codified at 40 CFR 721.45(h), those persons would be considered to have met the requirements of the final SNUR for those activities.

#### **IX. Test Data and Other Information**

EPA recognizes that section 5 of TSCA does not require the development of any particular test data before submission of a SNUN. Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25).

However, in view of the potential health or environmental risks posed by any manufacture or importation of the chemical substances listed in Unit II.A., EPA would recommend in the final rule that potential SNUN submitters include data that would permit a reasoned evaluation of risks posed by these chemical substances during their manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN for these substances, and, for commercial pentaBDE and octaBDE, to take advantage of the data needs assessments as reviewed under the Agency's VCCEP (see VCCEP Peer Consultation meeting reports - Refs. 5 and 6 - and any forthcoming Agency decision under the VCCEP process). As part of this optional pre-notice consultation, EPA would discuss specific data it believes are necessary to evaluate a significant new use. EPA also encourages SNUN submitters to provide all available information that is relevant to assessing the potential for environmental or consumer exposure, as well as information on risks posed by these substances compared to risks posed by possible substitutes. A SNUN submitted without sufficient data to reasonably evaluate risks posed by a significant new use of the chemical substances listed in Unit II.A. may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with these chemicals.

#### **X. Economic Considerations**

EPA has evaluated the potential costs of establishing a SNUR for the chemical substances listed in Unit II.A. These potential costs are related to the submission of SNUNs, the export notification requirements of TSCA section 12(b) and the development of test data. If the firm undertakes testing

to support the submission of a SNUN, costs could range from roughly \$339,000 to over \$1.4 million per chemical, but could be substantially lower if not all recommended tests are performed. EPA notes that, with the possible exception of export notification requirements, the costs of submission of SNUNs will not be incurred by any company unless that company decides to pursue a significant new use as defined in this SNUR. The Agency's economic analysis is available in the public docket for this proposed rule (Ref. 30).

##### *A. SNUNs*

The Agency has analyzed the potential costs of compliance with the proposed SNUR (Ref. 30). EPA's complete economic analysis is available in the public docket. The Agency has estimated the average cost of compliance with the SNUR per chemical (e.g., cost of submitting a SNUN) to be \$6,956 based on 105 burden hours or a total cost of \$13,912 or 210 hours for both chemicals. These estimates do not include the costs of testing or submission of other information to permit a reasoned evaluation of potential risks (see Unit IX.).

##### *B. Export Notification*

As noted in Unit II.C. of this document, persons who intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)). These provisions require that, for chemicals subject to a proposed or final SNUR, a company notify EPA of the first shipment to a particular country in a calendar year of an affected chemical substance. EPA estimated that the one-time cost of preparing and submitting an export notification to be \$89.29. The total costs of export notification will vary per chemical, depending on the number of required notifications (i.e., number of countries to which the chemical is exported).

EPA is unable to estimate the total number of TSCA section 12(b) notifications that will be received as a result of this proposed SNUR, or the total number of companies that will file these notices. However, EPA expects that the total cost of complying with the export notification provisions of TSCA section 12(b) will be limited based on historical experience with TSCA section 12(b) notifications and the fact that no companies have currently been identified that currently market any of the chemical substances that are the subject of this proposed rule commercially. If companies were to

manufacture for export only any of the chemical substances covered by this proposed SNUR, such companies would incur the minimal costs associated with export notification despite the fact they would not be subject to the SNUR notification requirements. See TSCA section 12(a) and 40 CFR 721.45(g). EPA is not aware of any companies in this situation.

## XI. References

- These references have been placed in the public docket that was established under docket ID number OPPTS-2004-0085 for this rulemaking.
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  - Voluntary Children's Chemical Evaluation Program (VCCEP) Tier 1 Assessment of the Potential Health Risks to Children Associated with Exposure to Commercial for Pentabromodiphenyl ether (CAS No. 32534-81-9), April 21, 2003; Great Lakes Chemical Corporation.
  - Voluntary Children's Chemical Evaluation Program (VCCEP) Tier 1 Assessment of the Potential Health Risks to Children Associated with Exposure to Commercial for Octabromodiphenyl ether (CAS No. 32536-52-0), April 21, 2003; Great Lakes Chemical Corporation.
  - Voluntary Children's Chemical Evaluation Program (VCCEP) Data Summary, Decabromodiphenyl ether (CAS No. 1163-19-5), December 17, 2002; American Chemistry Council's Brominated Flame Retardant Industry Panel.
  - Report of the Peer Consultation Meeting (June 3 and 4, 2003) on Pentabromodiphenyl ether; Great Lakes Chemical Corporation for the Voluntary Children's Chemical Evaluation Program (VCCEP); January 22, 2004.
  - Report of the Peer Consultation Meeting (June 3 and 4, 2003) on Octabromodiphenyl ether; Great Lakes Chemical Corporation for the Voluntary Children's Chemical Evaluation Program (VCCEP); January 22, 2004.
  - Report of the Peer Consultation Meeting (April 2 and 3, 2003) on Decabromodiphenyl ether; American Chemistry Council's Brominated Flame Retardant Industry Panel for the Voluntary Children's Chemical Evaluation Program (VCCEP); September 30, 2003.
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  - California Bill AB 302, bill text. "An act to add Chapter 10 (commencing with Section 108920) to Part 3 of Division 104 of the Health and Safety Code, relating to toxic substances." Signed by the California Governor on August 9, 2003.

29. Design for the Environment Program, USEPA. September 2004. Environmentally Preferable Approaches for Achieving Fire Furniture Safety Standards.

30. Lehman, T., USEPA. June 18, 2004. Economic Analysis for Certain Polybrominated Diphenylethers; Proposed Significant New Use Rule.

## XII. Statutory and Executive Order Reviews

### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that proposed or final SNURs are not a "significant regulatory action" subject to review by OMB, because they do not meet the criteria in section 3(f) of the Executive Order.

### B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control number 2070-0038 (EPA ICR No. 1188.07). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to

include the OMB control number in any correspondence, but do not submit any completed forms to this address.

### C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this proposed SNUR will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows. A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." By definition of the word "new," and based on all information currently available to EPA, it appears that no small or large entities will be engaged in such activity on or after January 1, 2005. Since a SNUR only requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN, no economic impact will even occur until someone decides to engage in those activities. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 1,000 SNURs, the Agency receives on average only 10 notices per year. Of those SNUNs submitted, none appear to be from small entities in response to any SNUR. In addition, the estimated reporting cost for submission of a SNUN (see Unit X.), are minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impact of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published on June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

### D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rulemaking. As such, EPA has determined that this regulatory action does not impose any enforceable duty,

contain any unfunded mandate, or otherwise have any affect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

### E. Executive Order 13132: Federalism

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

### F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This does not significantly or uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), do not apply to this proposed rule.

### G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children. Although the chemicals that are addressed in this significant new use rule might present such risks to children, significant new use rules are administrative actions that require chemical manufacturers to submit a significant new use notice to EPA before a chemical may be manufactured or imported. Therefore, this action does not in and of itself affect children's health.

### H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply,*

*Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

*I. National Technology Transfer Advancement Act*

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

*K. Executive Order 12630: Governmental Actions and Interference with Constitutionally Protected Property Rights (Takings)*

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this proposed rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the Executive Order.

*L. Executive Order 12988: Civil Justice Reform*

In issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

**List of Subjects in 40 CFR Part 721**

Environmental protection, Chemicals, Hazardous substances, Premanufacture notification, Reporting and recordkeeping requirements.

Dated: November 30, 2004.

**Charles M. Auer,**

*Director, Office of Pollution Prevention and Toxics.*

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

**PART 721—[AMENDED]**

1. The authority citation for part 721 would continue to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

2. By adding new § 721.10000 to subpart E to read as follows:

**§ 721.10000 Certain polybrominated diphenylethers.**

(a) *Chemical substances and significant new uses subject to reporting.*

(1) The chemical substances identified as tetrabromodiphenyl ether (CAS No. 40088-47-9; Benzene, 1,1'-oxybis-, tetrabromo deriv.), pentabromodiphenyl ether (CAS No. 32534-81-9; Benzene, 1,1'-oxybis-, pentabromo deriv.), hexabromodiphenyl ether (CAS No. 36483-60-0; Benzene, 1,1'-oxybis-, hexabromo deriv.), heptabromodiphenyl ether (CAS No. 68928-80-3; Benzene, 1,1'-oxybis-, heptabromo deriv.), octabromodiphenyl ether (CAS No. 32536-52-0; Benzene, 1,1'-oxybis-, octabromo deriv.), and nonabromodiphenyl ether (CAS No. 63936-56-1; Benzene, pentabromo(tetrabromophenoxy)-), and any combination of these substances resulting from a chemical reaction are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is manufacture or import for any use on or after January 1, 2005.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Persons who must report.* Section 721.5 applies to this section except for section 721.5(a)(2). A person who intends to manufacture or import for commercial purposes the substances identified in paragraph (a)(1) of this section and intends to distribute the substance in commerce must submit a significant new use notice.

(2) [Reserved]

[FR Doc. 04-26731 Filed 12-1-04; 2:54 pm]

**BILLING CODE 6560-50-S**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

**RIN 1018-AT65**

**Endangered and Threatened Wildlife and Plants; Establishment of an Additional Manatee Protection Area in Lee County, FL**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; notice of public hearing and reopening of public comment period.

**SUMMARY:** We, the Fish and Wildlife Service (Service), provide notice that the public comment period for the proposed rule to establish the Pine Island-Estero Bay Manatee Refuge in Lee County, Florida, is reopened to allow all interested parties to submit written comments on the proposed rule. We are reopening the public comment period to accommodate those individuals and communities that are continuing to recover from the effects of both Hurricane Charley and Hurricane Frances. Comments previously submitted during the initial comment period need not be resubmitted as they will be incorporated into the public record and will be fully considered in the final determination on the proposal.

**DATES:** The original comment period closed on October 5, 2004. The comment period is hereby reopened until February 2, 2005. Comments from all interested parties must be received by the closing date. Any comments received after the closing date may not be considered in the final decision on this proposal. Furthermore, the public hearing that was originally scheduled for Wednesday, September 8, 2004, has been rescheduled for Wednesday, January 12, 2005, from 6:30 p.m. to 9:30 p.m. in Fort Myers, Florida. See additional information on the public comment process in the **SUPPLEMENTARY INFORMATION** section.

**ADDRESSES:** A formal public hearing will be held on Wednesday, January 12, 2005, from 6:30 p.m. to 9:30 p.m. at the Harborside Convention Hall, 1375 Monroe Street, Fort Myers, Florida.

If you wish to comment, you may submit your comments by any one of several methods:

1. You may submit written comments and information by mail to the Field Supervisor, South Florida Field Office, U.S. Fish and Wildlife Service, Attn: Proposed Manatee Refuge, 1339 20th Street, Vero Beach, Florida 32960.