ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 721, 795, and 799

[EPA–HQ–OPPT–2010–1039; FRL–8889–3]

RIN 2070–AJ08

Certain Polybrominated Diphenylethers; Significant New Use Rule and Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Agency is proposing to amend the Toxic Substances Control Act (TSCA) section 5(a) Significant New Use Rule (SNUR), for certain polybrominated diphenylethers (PBDEs) by: Designating processing of six PBDEs, or any combination of these chemical substances resulting from a chemical reaction, as a significant new use; designating manufacturing, importing, and processing of a seventh PBDE, decabromodiphenyl ether (decaBDE) for any use which is not ongoing after December 31, 2013, as a significant new use; and making inapplicable the article exemption for SNURs for this action. A person who intends to import or process any of the seven PBDEs included in the proposed SNUR, as part of an article for a significant new use would be required to notify EPA at least 90 days in advance to ensure that the Agency has an opportunity to review and, if necessary, restrict or prohibit a new use before it begins. EPA is also proposing a test rule under TSCA that would require any person who manufactures or processes commercial pentabromodiphenyl ether (c-pentaBDE), commercial octabromodiphenyl ether (c-octaBDE), or commercial decaBDE (c-decaBDE), including in articles, for any use after December 31, 2013, to conduct testing on their effects on health and the environment. EPA is proposing to designate all discontinued uses of PBDEs as significant new uses. The test rule would be promulgated if EPA determines that there are persons who intend to manufacture, import, or process c-pentaBDE, c-octaBDE, or c-decaBDE, for any use, including in articles, after December 31, 2013.

DATES: Comments must be received on or before June 1, 2012.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2010–1039, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Mail:* Document Control Office (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 (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave. NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2010–1039. 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 DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2010–1039. EPA's policy is that all comments received will be included in the docket without change and may be made available online at *http://www.regulations.gov,* 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 regulations.gov or email. The regulations.gov Web site is an ''anonymous access'' system, 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 email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the 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.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information on the SNUR, contact:* John Bowser, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8082; email addresses: *bowser.john@epa.gov*.

For technical information on the test rule, contact: Catherine Roman, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8708; email addresses: *roman.catherine@epa.gov*.

For general information contact: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA–Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be affected by this action if you manufacture or process tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE), hexabromodiphenyl ether (hexaBDE), heptabromodiphenyl ether (heptaBDE), octabromodiphenyl ether (octaBDE), nonabromodiphenyl ether (nonaBDE), or decaBDE, or intend to, including as part of a mixture or article. TSCA defines manufacture to include import. Unless otherwise noted in this preamble, use of the term ''manufacture'' includes import. Manufacturers and processors in certain industries to whom this action may apply include, but are not limited to:

- Manufacturers and processors of subject chemical substances and

mixtures (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

- Textile manufacturers and processors (NAICS codes 313, 314, and 315).
- Furniture manufacturers (NAICS code 337).
- Manufacturers and processors of polyurethane foam (NAICS code 326150).
- Manufacturers of high impact polystyrene (HIPS) and acrylonitrile-butadiene-styrene (ABS) plastics (NAICS codes 325, 326140, and 3261).
- Manufacturers of electronics equipment (NAICS codes 334 and 335).

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. If you have any questions regarding the applicability of this action to a particular entity, consult the appropriate technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. See Units VII. and VIII. for a discussion of how this action may affect import certification and export notification requirements.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. 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:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. 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.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

C. Can I request an opportunity to present oral comments to the Agency?

You may submit a request for an opportunity to present oral comments on this proposed test rule. This request must be made in writing. If such a request is received on or before July 2, 2012, EPA will hold a public meeting on this proposed test rule in Washington, DC. This written request must be submitted to the mailing or hand delivery addresses provided under **ADDRESSES**. If such a request is received, EPA will announce the scheduling of the public meeting in a subsequent document in the **Federal Register**. If a public meeting is announced, and if you are interested in attending or presenting oral and/or written comments at the public meeting, you should follow the instructions provided in the subsequent **Federal Register** document announcing the public meeting.

II. Background

A. What action is the Agency taking?

The Agency is proposing to amend the SNUR at 40 CFR 721.10000 (Ref. 1) that requires any person who intends to manufacture or import tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE), hexabromodiphenyl ether (hexaBDE), heptabromodiphenyl ether (heptaBDE), octabromodiphenyl ether (octaBDE), or nonabromodiphenyl ether (nonaBDE), or any combination of these chemical substances that results from a chemical reaction, for any use on or after January 1, 2005, to notify EPA at least 90 days in advance. EPA is proposing to amend the SNUR by:

1. Designating processing of any of the six PBDEs after December 31, 2013, for any use which is not ongoing as a significant new use.

2. Designating manufacturing, importing, and processing of a seventh PBDE, decabromodiphenyl ether (decaBDE) (Chemical Abstracts Service Registry Number (CASRN) 1163–19–5) for any use which is not ongoing after December 31, 2013, as a significant new use.

3. Making inapplicable for this SNUR, the article exemption for SNURs at 40 CFR 721.45(f).

A person that imports or processes any of the chemical substances identified in the proposed SNUR for a significant new use as part of an article would be subject to the significant new use notification requirements. No person would be able to begin manufacturing, importing, or processing, including as contained in an article, any of the chemical substances identified in the proposed SNUR for a significant new use without first submitting a significant new use notification (SNUN) to EPA. Ongoing uses would be excluded from the SNUR.

EPA will not designate ongoing uses as significant new uses. Persons who manufacture, import, or process any of the chemicals included in the proposed SNUR, including as contained in an article, for an ongoing use, would be free to continue without submitting a SNUN. Note, however, that uses not already ongoing as of April 2, 2012 would not be considered ongoing uses if they later arise, even if they are in existence upon the issuance of a final rule. Furthermore, uses that are ongoing as of April 2, 2012 would not be considered ongoing uses if they have ceased by the date of issuance of a final rule. (See Unit V.C. for further discussion of what constitutes an ongoing use.)

Persons who intend to begin (or resume) commercial manufacture or processing of the chemical substance(s), including in articles, for a significant new use, would have to comply with all applicable SNUN requirements. Under TSCA section 5(b)(1)(A), any person who is required to submit a SNUN for a chemical substance and who is also required to submit test data under a final test rule, must submit the test data at the time that the SNUN is submitted.

In this document, EPA is also proposing to issue a test rule under TSCA section 4(a)(1)(A) that would require any person who manufactures, imports, or processes c-pentaBDE, c-octaBDE, or c-decaBDE including in articles for any use after December 31, 2013 to conduct testing of such

commercial PBDE mixtures to obtain data on health effects, environmental effects, and chemical fate in accordance with the test rule. The effective date of the test rule will be after December 31, 2013; see 40 CFR 799.5350(k) of this proposed rule. The proposed test rule specifies that testing of c-pentaBDE, c-octaBDE, and c-decaBDE be conducted on representative forms of the relevant commercial mixtures. The commercial mixture, c-pentaBDE, typically contains tetraBDE, pentaBDE, and hexaBDE as the predominant components; the commercial mixture, c-octaBDE, typically contains hexaBDE, heptaBDE, octaBDE, and nonaBDE as the predominant components; and the commercial mixture, c-decaBDE, typically contains decaBDE in the highest percent composition.

If EPA finds that manufacture, import, or processing of c-pentaBDE, c-octaBDE, or c-decaBDE for any purpose, including as contained in an article other than as an impurity, will occur after December 31, 2013, EPA will promulgate a final test rule to require persons who manufacture or process those mixtures to conduct testing to obtain data on health effects, environmental effects, and chemical fate of those mixtures. The test rule would apply to all uses, new or ongoing. The existence or absence of a SNUR does not affect a person's obligations under a test rule. The required testing would provide EPA with data necessary to determine the effects on health and the environment if the manufacture and processing of those mixtures and their associated use, distribution in commerce and disposal are not discontinued.

EPA is seeking public comment on both the proposed SNUR and test rule. Comments may address any aspect of the action being proposed. Unit XI. contains a list of specific issues for which the Agency is seeking comment. The actions EPA is proposing are generally described in the ''Polybrominated Diphenyl Ethers (PBDEs) Action Plan Summary'' (PBDE Action Plan) (Ref. 2).

B. Why is the Agency taking this action?

EPA is concerned about the effects PBDEs may have on human health and the environment. As discussed in Unit III. and the PBDE Action Plan (Ref. 2), there is evidence that PBDEs may be toxic to both humans and wildlife. PBDEs have been found in human tissue, wildlife and the environment (Refs. 3–6). However, a panel of experts in the Voluntary Children's Chemical Evaluation Program (VCCEP) reported to EPA that there were insufficient data to fully evaluate the significance of exposure to pentaBDE, octaBDE, and decaBDE (Refs. 7 and 8).

EPA is also concerned that the PBDEs included in these proposed actions are highly persistent in the environment. Some lower brominated PBDEs are both toxic and highly bioaccumulative. Other, more highly brominated forms such as decaBDE may debrominate to the more toxic and bioaccumulative lower brominated forms. However, the overall impact of debromination of decaBDE as a source of the lower brominated PBDE congeners in the environment has not been fully characterized. DecaBDE has been found at high levels in predators such as peregrine falcons. The environmental significance of such accumulations of decaBDE has not been fully characterized. The exact mechanisms or pathways by which the PBDEs, including those contained in articles, move into and through the environment and allow humans and wildlife to become exposed are not fully understood. The data produced by some of the tests included in the proposed test rule would be necessary to determine the effects on the environment if manufacturing and processing of c-pentaBDE, c-octaBDE, and c-decaBDE and their associated use, distribution in commerce, and disposal are not discontinued.

In December 2009, EPA received voluntary commitments from the principal manufacturers and importer of c-decaBDE to phase out manufacture and import for all uses by December 31, 2013 (Refs. 9–11). The phase out of c-decaBDE will be accomplished in two steps. No later than December 31, 2012, the manufacturers and the importer of c-decaBDE would cease manufacture and import for all uses, including in articles, with the exception of military and transportation uses. No later than December 31, 2013, they would cease manufacture and import for all uses including military and transportation uses, including in articles. The principal manufacturers and importer of c-decaBDE stated that the additional time required for phasing out military and transportation uses was due to the stringent engineering requirements and risks associated with these applications as well as the multiple levels of testing and certification required for such product changes. EPA believes manufacture and processing for most uses of decaBDE will have ceased by December 31, 2013, and is proposing to use its authority under TSCA section 5 to designate discontinued uses as significant new uses. Once an activity has been determined, by a rule published in the **Federal Register**, to be a significant new use, persons may not manufacture or process the chemical substance for that activity without first submitting a SNUN to EPA. The Agency would then have an opportunity to review and, if necessary, take action to restrict or prohibit the new use.

C. How would the proposed SNUR and test rule affect PBDEs contained in articles?

The proposed SNUR includes a proposal to eliminate the article exemption for SNURs at 40 CFR 721.45(f), for the covered PBDEs. See 40 CFR 721.10000(c)(1) of this proposed rule. In general, persons who import or process chemical substances contained in articles are exempt from significant new use notification requirements. However, as discussed in Unit III. and the PBDE Action Plan (Ref. 2), there is growing evidence that people and the environment are exposed to PBDEs contained in articles, and that those PBDEs may have adverse effects on human health and the environment. The Agency is concerned that commencement of new uses of PBDEs or resumption of discontinued uses, including in articles, may lead to increased exposure of humans and the environment to these chemicals. Making the article exemption for SNURs inapplicable for this proposed SNUR would ensure that the Agency has an opportunity to review and, if necessary, take action to restrict or prohibit significant new uses of PBDEs in articles before they resume. Thus, anyone who intends to manufacture or process a PBDE for a significant new use, including persons who intend to import or process articles containing a PBDE for a significant new use, would have to submit a SNUN at least 90 days before commencing such activity. Any ongoing uses identified at the point of finalization, including import or processing of articles containing PBDEs, would not be designated as significant new uses. These activities would be allowed to continue without the submission of a SNUN. Eliminating article importers' and article processors' exemption from the requirement to submit a SNUN, as described in this proposed rule, would have no effect on article importers' general exemption from import certification requirements, or on the articles exemption described at 40 CFR 707.60(b), respecting export notifications.

The proposed test rule applies to certain commercial PBDE mixtures, including those contained in articles. See 40 CFR 799.5350(b)(1) of this proposed rule. Importers of articles containing c-pentaBDE, c-octaBDE, or c-

decaBDE are considered manufacturers of these mixtures and would be subject to the proposed test rule, along with persons who domestically manufacture these chemicals in bulk or as part of a mixture. Persons who process c-pentaBDE, c-octaBDE, or c-decaBDE, including persons who process articles containing these mixtures, would also be subject to the proposed test rule. (These testing requirements apply even in circumstances where the manufacture [including import] or processing is for purposes of export from the United States.) Persons who do not know or cannot reasonably ascertain that they manufacture or process a listed test rule mixture (based on all information in their possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), would not be subject to this proposed test rule for the listed mixtures. The proposed test rule would not require testing of articles themselves. The testing would be required of a representative commercial form of the c-PBDE contained in the article. See 40 CFR 799.5350(a)(1) of this proposed rule. Eliminating article importers' and article processors' exemption from the requirement to conduct testing of c-PBDEs, as described in this proposed rule, would have no effect on article importers' general exemption from import certification requirements, or on the articles exemption described at 40 CFR 707.60(b), respecting export notifications.

This proposed rule would not affect the article exemption at 40 CFR 707.60(b) for notices of export under TSCA section 12(b). Thus, persons who export PBDEs contained in articles would remain exempt from the requirement to submit a notice of export respecting such PBDEs. See Unit VII.

Furthermore, this proposed rule would not alter the application of the import certification regulations at 19 CFR 12.118 through 12.127. PBDEs contained in articles would therefore continue to be exempt from import certification requirements under TSCA section 13(b). PBDEs imported in bulk or as part of a mixture would continue to be subject to import certification requirements under TSCA section 13(b), consistent with 19 CFR 12.120(b). See Unit VIII.

D. Why is EPA proposing both a SNUR and a test rule?

EPA has found no evidence of manufacture or processing of c-pentaBDE or c-octaBDE except as impurities. The principal manufacturers and importer of c-decaBDE have informed the Agency that they intend to phase out manufacture and import of the chemical no later than December 31, 2013 (Refs. 9–11). EPA believes that other manufacturers and importers of decaBDE will also cease their activities by that date. EPA is proposing to amend the SNUR to ensure that after these activities have been discontinued, no one resumes them without notifying EPA in advance, thereby providing EPA with an opportunity to review the new uses before they commence. Before promulgating the amended SNUR, EPA will verify through comments on this action, or by other means, that the proposed significant new uses have ceased. EPA seeks comment on whether anyone intends to manufacture, import or process any of the PBDEs included in the proposed SNUR, including in articles, for any of the proposed significant new uses.

EPA is proposing a test rule to obtain information needed to assess the effects on humans and the environment of manufacture, import, or processing of c-pentaBDE, c-octaBDE, or c-decaBDE in the event these activities do not cease by December 31, 2013.

E. Why does the proposed test rule include three commercial PBDE mixtures while the SNUR includes seven PBDE congeners?

The test rule is designed to provide the Agency with data relevant to commercial PBDE products actually in use or intended for use. There are three commercial PBDE products: c-PentaBDE, c-octaBDE, and c-decaBDE. The test rule proposes that testing be conducted on a representative form of each commercial mixture to better understand their potential effects on health and the environment. Some of the data obtained by the test rule would address unmet data needs identified by EPA through the VCCEP. All three of the commercial PBDE products are mixtures, but have different predominant components. Other PBDE congeners may be present in the mixtures in lesser amounts.

The SNUR is designed to provide the Agency with advance notice of manufacture or processing of any one or any combination of the seven PBDEs for a significant new use. Since the composition of any future commercial PBDE products may vary in terms of congener composition, the Agency determined that it would be more effective to include all seven of the individual PBDE congeners in the SNUR. Thus, all congeners in any future commercial PBDE product would be subject to the SNUR reporting requirements.

F. Will EPA promulgate both the test rule and the SNUR?

EPA could promulgate both the test rule and the SNUR. EPA's focus in this proposed rule is on the phase-out of the manufacture and import of PDBEs for all uses, including in articles. EPA's final action would depend on whether the manufacture or processing of c-pentaBDE, c-octaBDE, or c-decaBDE will continue after December 31, 2013, as explained in Units II.F.1. and II.F.2. The existence or absence of a SNUR does not affect a person's obligations under a test rule.

1. *Reporting obligations if continuing existing uses of PBDEs.* If EPA were to learn through comments on this proposed action, or through other means, that a person intended to manufacture or process c-pentaBDE, c-octaBDE, or c-decaBDE after December 31, 2013, EPA would promulgate the test rule. If a person indicated his intention to continue to engage in an activity proposed as a significant new use for any of these c-PBDEs, EPA would promulgate the proposed amendments to the SNUR designating all other uses of that PBDE as significant new uses. EPA would exclude the ongoing uses from the final SNUR. Therefore, a person who is manufacturing, importing or processing the c-PBDEs for an ongoing use after the effective date of the test rule would not need to submit a SNUN for that use and would be allowed to continue those activities while complying with the test rule. (See Unit V.C. for further discussion of what constitutes an ongoing use.) However, if EPA were to learn that the only persons that would be subject to the test rule would be persons that process (rather than manufacture) c-pentaBDE, c-octaBDE, or c-decaBDE as impurities contained in articles, EPA would not require testing because EPA has not determined whether this activity alone may present an unreasonable risk of injury to health or the environment. For example, persons who grind old plastic pallets containing decaBDE for the purpose of reusing the ground material in the fabrication of ''new'' plastic pallets would be considered processors of decaBDE as an impurity, if the decaBDE is unintentionally present in the recycled product (see Unit II.C.). If decaBDE is still being used as a flame retardant in a recycled product, it would have been considered to be processed.

2. *Reporting obligations if initiating new uses of PBDEs, including resumption of discontinued uses.* Uses

not ongoing at the time of the proposal would be designated significant new uses in the final SNUR. Uses ongoing at the time of this proposed rule, but discontinued at the time the SNUR is finalized, would also be designated significant new uses. As required under TSCA section 5(b)(1)(A), if EPA has promulgated a final test rule for a chemical substance, any person who is required to submit a SNUN before beginning the manufacture or processing of that chemical substance is also required to submit test data under the final test rule for that chemical substance at the time that the SNUN is submitted. Persons who intend to begin (or resume) commercial manufacture, import, or processing of the chemical substance(s), including in articles, for such uses would have to comply with all applicable SNUN requirements, including submission of data if a test rule is in effect, and wait until EPA's statutorily-defined time period for its review of the SNUN expires before commencing those activities.

EPA expects that the manufacture and processing of the PBDEs identified in this proposed rule, except as impurities, including these PBDEs when contained in articles, will have been discontinued for most uses by the date indicated in the proposed amendments to the SNUR. EPA intends to promulgate amendments to the SNUR designating manufacturing and processing for any use which is not ongoing (including uses first arising after April 2, 2012 and uses discontinued since April 2, 2012) as a significant new use. The proposed SNUR would not apply to any ongoing uses identified at the point of finalization (i.e., uses arising before April 2, 2012 and which have not been discontinued as of the date of finalization). All other uses, including discontinued uses, would be designated as significant new uses. EPA recognizes that certain portions of the proposed significant new use may be still ongoing as of April 2, 2012, and will verify whether they have been discontinued (i.e., whether they are indeed ongoing) before issuing a final SNUR that incorporates them.

G. What is the Agency's authority for taking this action?

1. *SNURs.* 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 SNUN to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). For purposes of TSCA section 5, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

2. *Test rule.* Section 2(b)(1) of TSCA (15 U.S.C. 2601(b)(1)) states that it is the policy of the United States that ''adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [which is defined by statute to include import] and those who process such chemical substances and mixtures[.]'' To implement this policy, TSCA section 4(a)(1)(A) (15 U.S.C. 2603(a)(1)(A)) provides that EPA shall require by a rule published in the **Federal Register** manufacturers or processors or both of chemical substances and mixtures conduct testing, if the EPA Administrator makes the findings under either or both TSCA section 4(a)(1)(A) (an ''A'' finding) and/or TSCA section 4(a)(1)(B) (a ''B'' finding) in a final rule. Under TSCA section 4(a)(1)(A), the EPA Administrator must find that:

> (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
>
> (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such activities on health or the environment can reasonably be determined or predicted, and
>
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data[.]

Under TSCA section 4(a)(1)(B), the EPA Administrator must find that:

> (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture, (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

Under TSCA section 4(a)(2), if the EPA Administrator finds that, in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture; the EPA Administrator shall by rule require that testing be conducted on such mixture.

The purpose of the testing would be to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience, and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

The extent to which such activities may affect health or the environment is dependent in part upon the human and environmental exposures to the chemical substance or mixture occasioned by those activities. As an example, TSCA section 4(b)(2)(A) specifically addresses testing for persistence of a substance. Testing to identify where and in what concentrations a chemical substance or mixture may become present in the environment contributes to an understanding of human and environmental exposures resulting from those activities.

Once the EPA Administrator has made the relevant findings under TSCA section 4(a), EPA may require any health or environmental effects testing for which data are insufficient and which are necessary to develop the data. EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or 4(a)(1)(B)(i) finding as long as EPA also finds that there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and that testing is necessary to develop such data. This approach is explained in more detail in EPA's TSCA section 4(a)(1)(B) Final Statement of Policy (B Policy) published in the **Federal Register** issue of May 14, 1993 (Ref. 12).

In this proposed test rule, based on a preliminary ''A'' finding, EPA would use its authority under TSCA section 4(a) to require the development of data ''which are relevant to a determination that the manufacture, processing,

distribution in commerce, use, or disposal * * * or any combination of such activities'' of any or all of the three c-PBDE mixtures, i.e., c-pentaBDE, c-octaBDE, and c-decaBDE, does or does not present an unreasonable risk of injury to health or the environment.

Pursuant to TSCA section 12(a)(2), EPA is also proposing to use its authority under TSCA section 4(a) to require testing of mixtures named in this proposed test rule which would otherwise be exempted from TSCA under section 12(a)(1). Section 12(a)(1) of TSCA exempts from TSCA the manufacture, processing, or distribution in commerce of a mixture for export from the United States in certain situations. Such testing would be for the purpose of determining whether or not the mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

H. How are the general provisions applicable?

1. *SNUR.* General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, and exemptions to reporting requirements.

However, the article exemption for SNURs at 40 CFR 721.45(f) would not apply to this proposed SNUR. A person who imports or processes a chemical substance that would be covered by this action as part of an article would be subject to SNUN reporting requirements. A person who manufactures or processes a PBDE only as an impurity would be exempt from the SNUR under 40 CFR 721.45(d).

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must 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 submissions 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 SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUN. 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.

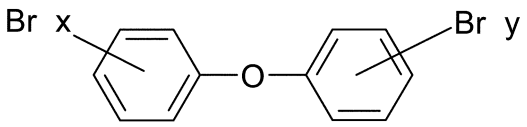
2. *Test rule.* General provisions for test rules appear under 40 CFR part 790 (subparts A, B, C, and E), part 791, part 792, and part 799 (subpart A). These provisions describe persons subject to the rule, procedures for developing test rules, implementation, enforcement, and modification of test rules, exemption from testing, data reimbursement, and good laboratory practice standards. 40 CFR 791.48(b) would not apply to this proposed test rule for the purpose of defining production volume to determine fair reimbursement shares. Production volume would be defined as including amounts of the test chemical substance imported in bulk form, in mixtures, in articles, and the total domestic production of the chemical substance including that produced as a byproduct or as an impurity. See 40 CFR 799.5350(f) of this proposed rule. Also, persons described in 40 CFR 790.2 as subject to a test rule include, among others, importers and processors of a chemical substance or mixture as part of an article. Submission of a SNUN would not affect a person's obligations under a test rule.

III. Overview of PBDEs

A. Chemistry of PBDEs

The PBDEs are a family of chemical substances with a common structure of a brominated diphenyl ether molecule which may have anywhere from 4 to 10 bromine atoms attached (Figure 1).

Figure 1.--Brominated Diphenyl Molecule



$$x + y = 4 - 10$$

Each individual PBDE variant, distinguished from others by both the number of bromine atoms and the placement of those atoms, is referred to as a congener. For example, there are 42 tetrabromodiphenyl ether congeners, each with 4 bromine atoms in different configurations. Specific congeners, also known as isomers, in which both the number and location of bromine atoms is specified are given numbers, e.g., BDE–47. In theory, there could be as many as 209 PBDE congeners, but a much smaller number of congeners are commonly found in the commercial PBDE products and in measurements of PBDEs in humans and the environment (Table 1 of this unit). Scientific studies, particularly those measuring presence of PBDEs in tissues and the environment, often report their findings by BDE number.

PBDE congeners can be grouped as homologs, i.e., according to the number of bromine atoms present in the molecule. The TSCA Chemical Substances Inventory (TSCA Inventory) listings and regulations for PBDEs are based on these homolog groups. (Table 1 of this unit). The PBDE homologs used in flame retardants have between 4 and 10 bromine atoms. EPA regulations of PBDEs generally apply to congeners grouped according to homolog groups rather than specific congener/isomers designated by BDE number.

There are three types of commercial PBDE (c-PBDE) products, c-pentaBDE, c-octaBDE, and c-decaBDE; each commercial product is a mixture of PBDE congeners (see Table 2 of this unit).

TABLE 1—PBDE HOMOLOG GROUPS

Common name	Chemical abstracts (CA) index name	Chemical abstracts service registry number (CASRN)	Number of bromine (Br) atoms
TetraBDE	Benzene, 1,1′-oxybis-, tetrabromo deriv.	40088–47–9	4
PentaBDE	Benzene, 1,1′-oxybis-, pentabromo deriv	32534–81–9	5
HexaBDE	Benzene, 1,1′-oxybis-, hexabromo deriv	36483–60–0	6
HeptaBDE	Benzene, 1,1′-oxybis-, heptabromo deriv	68928–80–3	7
OctaBDE	Benzene, 1,1′-oxybis-, octabromo deriv	32536–52–0	8
NonaBDE	Benzene, 1,1′-oxybis-, 1,2,3,4,5- pentabromo-6- (tetrabromophenoxy)-	63936–56–1	9
DecaBDE	Benzene, 1,1′-oxybis [2,3,4,5,6- pentabromo-	1163–19–5	10

TABLE 2—CONGENERS IN COMMERCIAL PBDE MIXTURES

Commercial mixture	Major components	Minor components
c-PentaBDE	TetraBDE	HexaBDE.
	PentaBDE.	
c-OctaBDE	HeptaBDE	HexaBDE.
	OctaBDE	NonaBDE.
		DecaBDE.
c-DecaBDE	DecaBDE	NonaBDE.

B. Actions Taken to Understand and Limit Risk from Use of PBDEs

EPA has been concerned about the reported health and environmental effects of PBDEs and potential exposure to PBDEs for some time, and has taken several actions to fully understand their effects and to reduce exposure to them. Of particular note are the VCCEP, which was announced in 2000 (Ref. 13), and the 2006 PBDE SNUR (Ref. 1). More recently, EPA articulated its concerns regarding these effects in the PBDE Action Plan (Ref. 2).

c-PentaBDE, c-octaBDE, and c-decaBDE were among the chemical substances evaluated in VCCEP. VCCEP was designed to collect health effects information on chemicals to which children had a high likelihood of being exposed and to characterize the risk to children from that exposure. Sponsors in VCCEP provided health effects and exposure information on a voluntary basis. Through VCCEP the Agency identified data needs for all three c-PBDEs that were beyond what was provided by the sponsors in the initial chemical assessments. The sponsors of c-pentaBDE and c-octaBDE, however, declined to conduct testing to address the identified data needs because of plans to discontinue manufacture of these chemicals in 2004. Later the sponsors of c-decaBDE also declined to conduct testing to provide the data needs identified through VCCEP and subsequently decided to phase out their activities with c-decaBDE. As a result, the sponsoring companies did not meet the additional data needs identified through VCCEP for any of the three c-PBDEs. Tests addressing those data needs are among the tests proposed for c-pentaBDE, c-octaBDE, and c-decaBDE in this proposed rule. c-PentaBDE and c-octaBDE had been widely used as additive flame retardants in a number of applications until their sole U.S. manufacturer, the Great Lakes Chemical Corporation (now Chemtura Corporation) voluntary phased out their production in 2004. c-PentaBDE was used primarily in flexible polyurethane foams. c-OctaBDE was used in acrylonitrile-butadiene-styrene (ABS) plastic which was used in applications such as casing for certain electric and electronic devices used in both offices and homes. When manufacture of c-pentaBDE and c-octaBDE was discontinued, EPA promulgated a SNUR (Ref. 1) which requires that any person who intends to manufacture or import a chemical substance containing any of the congeners present in c-pentaBDE or c-octaBDE (namely tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, and nonaBDE), or any combination of these chemical substances resulting from a chemical reaction, to notify EPA at least 90 days in advance of manufacture or import for any use on or after January 1, 2005. The SNUR does not address processing of PBDEs, nor does it apply to import of articles which contain any of the congeners present in c-pentaBDE or c-octaBDE.

c-DecaBDE is still manufactured and widely used in the United States as an additive flame retardant. The three major product categories in which c-decaBDE is used are: Textiles, electronic equipment, and building and construction materials. Its primary use is in high impact polystyrene (HIPS) based products. However as a result of the voluntary phase-out announced on December 17, 2009 (Refs. 9–11), EPA expects manufacture and processing for most uses of c-decaBDE to be discontinued by the end of 2013.

Other actions EPA has taken with PBDEs include:

1. Supporting the inclusion in voluntary consensus standards of criteria restricting PBDE use as a product component (e.g., in carpets, electronics, and furniture) or use in manufacturing processes.

2. Working with and through programs (i.e., Furniture Flame Retardancy Partnership and the Green Suppliers Network) to identify environmentally safer approaches to meeting fire standards and to improve awareness of concerns related to PBDEs.

C. Human Health Effects

In 2008, EPA published peer-reviewed toxicological reviews of tetraBDE (BDE–47), pentaBDE (BDE–99), hexaBDE (BDE–153), and decaBDE (BDE–209) (Refs. 14–17), to support summary information on EPA's Integrated Risk Information System (IRIS) database (*http://www.epa.gov/iris*). Developmental neurotoxicity was identified as the critical effect for each of the four chemicals. EPA also concluded that the database for decaBDE (BDE–209) provides ''suggestive evidence of carcinogenic potential'' (Ref. 17).

Through EPA's VCCEP, industry-sponsored screening level risk assessments for c-pentaBDE, c-octaBDE, and c-decaBDE were developed to

evaluate the potential risks to children and prospective parents from PBDE exposures (Ref. 13). EPA's evaluation of these assessments considered adverse neurobehavioral effects to be the most sensitive health endpoint following postnatal exposure to PBDEs (Refs. 7 and 8). Effects on spontaneous motor behavior (locomotion, rearing, and total activity) were observed in adult rats after postnatal exposure. Additional effects due to higher exposures to c-pentaBDE were observed in the following studies:

- Repeated-dose toxicity studies for c-pentaBDE showed changes in liver enzyme activity, increased liver weight, and histologic changes in the liver.
- Changes in thyroid hormone T_4 levels and thyroid hyperplasia were noted in oral adult rat studies.
- In limited prenatal developmental studies, decreases in T_4 levels were reported for dams and offspring (Ref. 7).

Additional effects due to higher exposures to c-octaBDE were observed in the following studies:

- Repeated-dose toxicity studies showed changes in liver enzyme activity and increased liver weights.
- In prenatal developmental studies, decreased maternal and pup bodyweight and decreases in thyroid hormone T_4 levels were reported for rat dams and their offspring (Ref. 7).

EPA concluded there was evidence of developmental and reproductive effects from exposure to c-pentaBDE and c-octaBDE, but that additional studies are needed to better characterize potential risks to children (Ref. 7). Through VCCEP, EPA identified 2-generation reproductive toxicity studies with a satellite group for body burden determinations as a data need for both c-pentaBDE and c-octaBDE (Ref. 7). Also through VCCEP, EPA identified anaerobic debromination in aquatic sediments, anaerobic debromination in sludge digesters, and photolysis in the indoor environment as data needs for c-decaBDE to better understand the chemical fate and thereby the potential exposure to decaBDE and lower brominated congeners (Ref. 8).

D. Environmental Hazard

Laboratory studies have shown that c-pentaBDE is capable of producing adverse effects in a variety of organisms including birds, mammals, fish, and invertebrates (Refs. 3 and 18–28). In some cases, these effects were observed at exposure levels similar to levels found in the environment.

E. Environmental Releases and Fate

The exact mechanisms or pathways by which the PBDEs move into and through the environment and allow humans to become exposed are not fully understood, but are likely to include releases from manufacturing of the chemicals, processing c-PBDEs into products like plastics or textiles, aging and wear of products like sofas and electronics, and releases at the end of product life (disposal or recycling). In general, levels of PBDE congeners in humans and the environment are higher in North America than in other regions of the world, which may be attributed to the greater use of c-PBDEs in North America (Refs. 29 and 30). The concentration and distribution of congeners detected in the environment appear to depend on the proximity to a source of the congener and the media tested (Ref. 31).

PBDE congeners with four to ten bromine atoms are highly persistent, based on a large body of environmental monitoring data in both the United States and abroad (Refs. 4, 32, and 33). Available data also indicate that the tetra-, penta-, hexa- and heptaBDE congeners are highly bioaccumulative (Ref. 34). After reviewing the available information, EPA has concluded that decaBDE is a likely contributor to the formation of bioaccumulative and/or potentially bioaccumulative transformation products, such as lower brominated PBDEs, in organisms and in the environment see, e.g., (Refs. 35–38), but the overall impact of this process as a source of the more toxic, lower brominated PBDE congeners has not been fully characterized. DecaBDE undergoes photolytic and possibly microbial debromination under certain conditions (Refs. 33 and 38). Photolysis is expected to be a significant transformation process for decaBDE whenever the substance is significantly exposed to light. For example, it has been found that decaBDE undergoes photolytic debromination in house dust (Ref. 39). DecaBDE would also be exposed to light when waste sludge containing PBDEs is used as a soil amendment, albeit only on the soil surface (Ref. 40). Studies have shown that photodegradation of decaBDE may result in PBDEs from tri- to nona-, although most photolysis studies were done under conditions that do not allow direct extrapolation to environmental conditions. Metabolism of decaBDE in organisms results predominantly in nona-, octa- and heptaBDE formation (as reviewed in Ref. 33). Stapleton (Ref. 38) summarized the effects of decaBDE debromination, noting that the formation potential for the pentaBDE and lower congeners was low, but that the formation of the hepta, octa and nonaBDE congeners was environmentally relevant.

The atmosphere and marine currents can transport PBDEs over relatively long distances (> 1,000 kilometer (km)). Evidence for this comes from the presence of PBDEs in the tissues of deep ocean-dwelling whales and other marine mammals far from anthropogenic sources (Ref. 4), as well as from modeling (Ref. 40). The body burdens of PBDE congeners in a wide variety of biota, indigenous to geographical areas ranging from the equator to the poles also substantiate the PBDE propensity for long-range transport (LRT), and constitute evidence of environmental persistence (Ref. 34).

F. Human Exposure

The use of c-PBDEs as flame retardants in consumer products is believed to be a source of exposure. Dermal exposure may occur through direct contact with c-PBDE-containing products such as computer housings and textiles (Ref. 5). The lower brominated tetra- and penta-congeners have also been detected in the vapor phase of air samples while the higher brominated congeners are found in associated particulate matter, including house dust (Refs. 41 and 42). Lorber (Ref. 42) and EPA (Ref. 5) reported that a significant source of human exposures to PBDEs appears to be their use in commercial products that are part of the indoor environment (computer circuitry, foam cushions, fabrics in curtains, etc). They found that food/water ingestion and inhalation explained less than 20% of the body burden, based upon the estimate of total exposure derived using a pharmacokinetic model. They stated that the remainder of the estimated exposure likely came from house dust through the pathways of ingestion and dermal contact, or some other, unknown source. Other literature indicates that inhalation may be a significant potential route of exposure for the general population (Ref. 5). In addition, PBDE exposure can occur by ingestion of foods that are contaminated (Ref. 43). PBDEs have been detected in human tissue, blood (usually serum), and breast milk (Ref. 44). Exposure to PBDEs in some occupational settings, such as in computer recycling, can be higher than those of the general population (Ref. 45). PBDE use as flame retardants in many household products, and subsequent exposure to indoor house dust containing PBDEs, coupled with the elevated ingestion potential due to increased intakes of food, water, and air per pound of body weight, as well as childhood-specific exposure pathways

such as breast milk consumption and increased contact with the floor, make children especially vulnerable.

Recent human biomonitoring data on PBDEs are available in the Centers for Disease Control and Prevention's (CDC) ''Fourth National Report on Human Exposure to Environmental Chemicals'' (Ref. 46). The PBDE data have also been published in the peer-reviewed literature (Ref. 45). The data were obtained from samples from participants in the 2003–2004 National Health and Nutrition Examination Survey (Ref. 46). Ten PBDE congeners (containing from three to seven bromines) were included in the analysis: BDE–17, BDE–28, BDE–47, BDE–66, BDE–85, BDE–99, BDE–100, BDE–153, BDE–154, and BDE–183; decaBDE was not included.

Participants were aged 12 years and older. BDE–47 was detected in serum from almost all of the participants and it was highest in 12–19 years old, and those over 59 years old.

Furthermore, serum levels were highest in 12–19 year olds for other lower-brominated congeners. In addition, these congeners were significantly correlated with each other—concentration of individual congeners and total PBDE content in blood serum steadily increased annually over a 5-year period, suggesting a similar pathway of exposure via diet, or via direct inhalation or dermal contact.

G. Environmental Exposure

The food chain is likely a large contributor to environmental exposures. In general, PBDE concentrations are highest in sediment samples collected downstream from industrial/urban areas, outfalls from sewage treatment plants, and urban locations without heavy industries. The lowest PBDE concentrations are generally found in sediments collected in remote and agricultural areas. DecaBDE (BDE–209) appears to dominate congener profiles of aquatic sediments. Researchers have determined concentrations of PBDEs in waterways, sediments, and biota from various locations such as the Great Lakes, the San Francisco Bay, and near an unnamed polyurethane foam manufacturing facility for which PBDE contamination was known or suspected (Ref. 5).

Some studies show evidence that concentrations of PBDEs in biota have doubled every 3 to 6 years, the doubling time depending on species, life stage, and location. PBDE levels in trout from the Great Lakes rose from non-detectable in 1975, to approximately 50 nanograms/gram (ng/g) in 1990, and to approximately 200 ng/gm in 2000 (Ref. 47). PBDE concentrations in marine biota in North America are the highest in the world, and are increasing (Ref. 4). After reviewing the available information, EPA has concluded that the extent of accumulation of congeners in biota is directly related to dietary levels of PBDEs. Observed differences in PBDE congener profiles in marine mammals from California, Alaska, and the Gulf of Mexico indicate that diet is a significant source of PBDE exposure in marine wildlife (Ref. 4).

DecaBDE has been found at high levels in predators such as peregrine falcons (Ref. 6). Biomonitoring studies of wild mink from the Great Lakes region revealed that margins of safety for mink are small, and that PBDE concentrations in mink from Hamilton Harbor exceeded the no-observed-adverse-effect concentrations (Ref. 3).

Biomagnification is the process in which the concentration of a chemical in an organism achieves a level that exceeds that in the organism's diet, due to dietary absorption (Ref. 48). Biomagnification occurs as predators up the food chain ingest the accumulated PBDEs in the bodies of their prey (Refs. 4 and 49–51). Environment Canada concluded that the greatest potential risks from PBDEs in the Canadian environment are the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of PBDEs, and effects on benthic organisms that may result from elevated concentrations of certain PBDEs in sediments (Ref. 32). Biomagnification of PBDEs has been observed in fish; PBDE levels in sediment were directly related to increases and decreases in the PBDE levels measured in fish (Ref. 52). Environment Canada concluded that decaBDE is available for uptake in organisms, and may accumulate to high and potentially problematic levels in certain species such as birds of prey or mammalian predators (Ref. 33).

Although not conclusive, some data suggests that PBDEs may debrominate in the bodies of wild birds. Park, *et al.,* (Ref. 47) found that younger peregrine falcons had higher levels of BDE–209 and other highly brominated congeners, whereas older birds had higher levels of the less brominated (hexa) BDE–153, which could not be explained by the BDE–153 levels in diet. Further, in eggs that were collected yearly from the same bird, PBDE congener concentrations changed yearly, with levels of BDE–209 decreasing, and levels of BDE 153 increasing in the last 2 years relative to the former 4 years (but no such obvious changes in polychlorinated biphenyl (PCB) levels). The chemical measurements and comparison in this study are valuable because a similar laboratory study would take many years in similar long-lived avian species (peregrines live 7–15 years or longer), and environmental variables that affect PBDE uptake and biomagnifications, including exposure to other chemicals, might be difficult to simulate. Similar evidence of debromination of decaBDE has been observed in carp (Refs. 38 and 53) and British starlings (Ref. 53).

IV. Proposed Findings

A. SNUR

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of 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.

To determine what would constitute a significant new use of PBDEs, EPA also considered other relevant factors including information about the toxicity of PBDEs as well as exposures and environmental presence resulting from past use.

As discussed in Unit III., there is evidence that PBDEs may be toxic to humans and wildlife. However, there is insufficient data to fully evaluate the significance of observed exposures. EPA is also concerned that the PBDEs included in these proposed amendments to the SNUR are highly persistent in the environment. Some lower brominated PBDEs are highly bioaccumulative, and others may debrominate to the lower brominated forms. In general, levels of PBDEs in humans and the environment are higher in North America than in other regions of the world, which may be attributed to the greater use of PBDEs in North America. Some monitoring data show a steady increase from non-detectable levels when PBDEs first came into use to current levels. The exact mechanisms or pathways by which the PBDEs move into and through the environment and allow humans and wildlife to become exposed are not fully understood, but are likely to include releases from manufacturing of the chemicals,

processing PBDEs into products like plastics or textiles, aging and wear of products like sofas and electronics, and releases at the end of product life (disposal or recycling).

Once the manufacture and processing of PBDEs have been discontinued, EPA expects their presence in humans and the environment to decline over time as has been observed in the past when production and use of other persistent chemicals has ceased.

EPA is concerned that if manufacture and processing of PBDEs were to resume, the anticipated decline in levels in humans and the environment will be disrupted as PBDEs are introduced into the environment at levels greater than would otherwise occur. The result would be that the magnitude and duration of exposure of humans and the environment in the future would likely increase.

B. Test Rule

Based on the data cited in Units III.C. through III.G., EPA has made the following preliminary determinations. First, c-pentaBDE, c-octaBDE, and c-decaBDE may present a hazard to human health. c-PentaBDE, c-octaBDE, and c-decaBDE were all reviewed under EPA's VCCEP. Members of the peer consultation panel for c-pentaBDE and c-octaBDE noted that there are indications of thyroid toxicity in some rodent studies, and thyroid toxicity can have adverse effects on reproductive success and fetal development (Ref. 7). For c-decaBDE, VCCEP identified anaerobic debromination in aquatic sediments, anaerobic debromination in sludge digesters, and photolysis in the indoor environment as a potential source of human and environmental exposure to lower brominated congeners (Ref. 8). Debromination of decaBDE to form lower brominated, more toxic congeners is potentially relevant to effects on both human health and the environment. EPA's IRIS database indicates that neurobehavioral effects are critical endpoints of concern for components of c-pentaBDE and c-decaBDE. EPA has also concluded that there is suggestive evidence of carcinogenic potential for decaBDE (BDE–209), which is the main component of c-decaBDE.

Second, c-pentaBDE and c-decaBDE may present a hazard to the environment. Laboratory studies have shown that c-pentaBDE is capable of producing adverse effects in a variety of organisms including birds, mammals, fish, and invertebrates. In some cases these effects were observed at exposure levels similar to levels found in the environment. c-DecaBDE may contribute to these levels by debrominating to lower, more toxic brominated congeners in the environment.

Third, pentaBDE, octaBDE, and decaBDE congeners, which are among the predominant components of c-pentaBDE, c-octaBDE, and c-decaBDE respectively, are ubiquitous in soil, sediments and living organisms (Ref. 54). PentaBDE, octaBDE, and decaBDE congeners have been found in human tissue, blood and breast milk (Ref. 55). These chemicals persist in the environment and accumulate in organisms that ingest or inhale them. For example, high levels of decaBDE have been found in high trophic level animals, e.g., predatory animals such as the peregrine falcon. However, the predominant congeners present in living organisms tend to be the lower brominated, more toxic forms, which include pentaBDE (Refs. 56 and 57). Infants and children, as well as people who are occupationally exposed, may be exposed at higher levels than the general public.

Based on the evidence of human and environmental exposure to pentaBDE, octaBDE, and decaBDE congeners, which derive from c-pentaBDE, c-octaBDE, and c-decaBDE, coupled with the evidence of human and/or environmental hazard of c-pentaBDE, c-octaBDE, and c-decaBDE, EPA preliminarily finds under TSCA section 4(a)(1)(A)(i) that the manufacture, processing, distribution in commerce, use, and disposal of c-pentaBDE, c-octaBDE, and c-decaBDE, or any combination of such activities, may present an unreasonable risk of injury to human health and the environment.

Through the testing of c-pentaBDE and c-octaBDE in VCCEP, EPA identified 2-generation reproductive toxicity studies with a satellite group for body burden determinations as a data need for c-pentaBDE and c-octaBDE (Ref. 7). For c-decaBDE, VCCEP identified anaerobic debromination in aquatic sediments, anaerobic debromination in sludge digesters, and photolysis in the indoor environment as data needs (Ref. 8). Therefore, EPA also preliminarily finds under TSCA section 4(a)(1)(A)(ii) that there are insufficient data upon which the effects of such manufacture, processing, distribution in commerce, use, and disposal of c-pentaBDE, c-octaBDE, and c-decaBDE, or any combination of such activities, on health or the environment can reasonably be determined or predicted. Under TSCA section 4(a)(1)(A)(iii), EPA preliminarily finds that testing of c-pentaBDE, c-octaBDE, and c-decaBDE with respect to these and other toxic effects is necessary to develop such data.

EPA has determined in accordance with TSCA section 4(a)(2) that the effects of the mixtures, c-pentaBDE, c-octaBDE, and c-decaBDE, may be reasonably and more efficiently determined by testing the commercial products themselves rather than the individual chemical substances which comprise these mixtures. EPA believes that testing of the individual chemical substances that are present in the commercial mixtures at different percentages would be less efficient and less predictive of the effects of the commercial mixtures than testing of representative forms of commercial products as they are manufactured. EPA believes that testing the mixture will best reflect the effects of exposure due to the possible additive, synergistic, and/or antagonistic effects resulting from the possible interaction of congeners in a mixture. EPA believes that testing the commercial products will be more efficient than testing the individual components because fewer tests would be needed to address the Agency's concerns. Nonetheless, EPA is still requesting comment in Units XI.B.4. through XI.B.7. on what the test substance should be and how it should be defined.

V. Proposed Amendments to the SNUR

A. Summary of Proposed Amendments to the SNUR

This proposed rule would amend the SNUR at 40 CFR 721.10000. Under the existing SNUR, any person who intends to manufacture certain PBDEs must notify EPA at least 90 days before commencing the manufacture of any one or more of those chemical substances after January 1, 2005, for any use. The following chemicals substances are subject to reporting under the existing SNUR: TetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, and nonaBDE, or any combination of these chemical substances resulting from a chemical reaction.

Among other activities, the use of a PBDE in the manufacture of an article is considered processing of the PBDE. In the existing SNUR, the Agency did not designate processing of the subject PBDEs as a significant new use because it believed that such activities were ongoing. The Agency now believes that processing of tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, and nonaBDE has been discontinued and therefore is proposing to amend the SNUR to include processing as a significant new use. EPA believes that resumption of the practice of processing

PBDEs would increase exposure to PBDEs and releases of PBDEs to the environment. However, as explained in Unit II.F., if a person indicated that he is engaged in an activity proposed as a significant new use for these PBDEs, EPA would promulgate the proposed amendments to the SNUR designating all other uses of that PBDE as significant new uses. EPA would exclude the ongoing use(s) from the final SNUR. The Agency requests comments on whether there is existing, ongoing processing of these chemical substances.

On December 19, 2009, the principal U.S. manufacturers and importer of decaBDE committed to end production, and importation of decaBDE in the United States for all uses except military uses and transportation uses by December 31, 2012, and for all uses including military and transportation uses by the end of 2013 (Refs. 9–11). The Agency also expects other manufacturers to discontinue manufacture of decaBDE by the end of 2013. Therefore, the Agency is proposing to amend the SNUR by adding, after December 31, 2013, decaBDE to the list of chemical substances subject to reporting and by designating (again, after December 31, 2013) manufacture and processing of decaBDE for any discontinued use as a significant new use. The Agency understands that some downstream users of decaBDE would like the manufacture and processing of decaBDE for some uses to continue after December 31, 2013. The Agency understands that these downstream users believe that there will continue to be critical military and aeronautical uses of decaBDE (some examples are use in insulation, ducting, electronic components) after December 31, 2013. The Agency seeks comments on the extent to which these uses will continue despite the phase-out in the manufacture and import of decaBDE and whether there are any other uses which will not be discontinued by December 31, 2013. Persons who comment are asked to specify both the functional application of the article containing decaBDE, e.g., ductwork for aircraft, and the material to which the decaBDE is added, e.g., high impact polystyrene. Persons who comment should also include definitions of terms, where appropriate.

EPA's objective in proposing these amendments to the PBDE SNUR is to enable the Agency to review and, if necessary, limit or prohibit resumption of any activities which could result in increasing the amount of PBDEs in commerce in the United States.

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 40 CFR part 721 is not generally subject to the notification requirements of 40 CFR 721.25 for that chemical substance, if the person imports or processes the chemical substance as part of an article. However, EPA is concerned that if PBDEs contained in articles are exempt, they could be imported without a SNUN and thereby increase the amount of PBDEs in commerce in the United States without a review by EPA. Therefore, the Agency is proposing that the article exemption for SNURs at 40 CFR 721.45(f) not apply to the rule.

B. Alternatives to the SNUR

Before proposing these amendments to the PBDE SNUR, EPA considered the following alternative regulatory actions:

1. *Promulgate a TSCA section 8(a) reporting rule.* Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they intend to manufacture or process a listed chemical substance for a specific use or any use. However, for PBDEs the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to review human and environmental hazards and exposures associated with the proposed significant new uses and, if necessary, take immediate follow-up regulatory action under TSCA section 5(e) or 5(f) to prohibit or limit the activity before it begins. In view of the level of health and environmental concerns about the chemical substances subject to this proposed rule, if they were used for the proposed significant new uses, EPA believes that a TSCA section 8(a) rule for this chemical substance would not meet EPA's regulatory objectives.

2. *Regulate under TSCA section 6.* EPA may regulate under TSCA section 6 if ''the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture [...] presents or will present an unreasonable risk of injury to health or the environment.'' (TSCA section 6(a)). Given that the chemical substances named in this proposed rule are no longer being manufactured or processed for the proposed significant new uses, or the activities are scheduled to be discontinued, EPA concluded that risk management action under TSCA section 6 is not necessary at this time. These proposed amendments to the SNUR would allow the Agency to address the potential risks associated with the proposed significant new use. EPA is proposing to require that persons who manufacture, import, or process c-pentaBDE, c-octaBDE, or c-decaBDE after December 31, 2013, conduct testing in accordance with the proposed test rule which accompanies these proposed amendments to the SNUR. The data obtained through such testing will assist the Agency in determining whether additional regulatory action is appropriate.

C. Applicability of the SNURs to Uses Begun After the Publication of This Proposed Rule and Uses Begun Prior to the Publication of This Proposed Rule

With respect to uses that are not ongoing as of the date of publication of the proposed rule, as discussed in the **Federal Register** of April 24, 1990 (55 FR 17376) (1990 Decision), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR requirements, because a 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. Thus, persons who begin commercial manufacture or processing of the chemical substance(s), or articles containing those chemical substances that would be regulated through the proposed rule, if finalized, would have to cease any such activity before the effective date of the final rule if and when finalized, where such manufacture or processing was not ongoing at the time of proposal. This applies to all entities that do not currently engage in these activities; it does not apply to entities that are currently engaged in these activities. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. EPA has promulgated provisions (40 CFR 721.45(h)) to allow persons to submit a SNUN before the effective date of the SNUR. If a person were to meet the conditions of 40 CFR 721.45(h), that person would be considered to have met the requirements of the final SNUR for

those activities, when that final SNUR became effective.

In this action, EPA proposes to designate as significant new uses certain uses that are ongoing as of the date of publication of the proposed rule, but for which there is a reasonable expectation that the use will be discontinued in the near future. Such uses would not be designated as significant new uses if they remain ongoing at the time the SNUR is finalized. EPA's 1990 Decision regarding uses commenced after proposal and ongoing at the time the SNUR is finalized (i.e., that they may be designated as significant new uses, notwithstanding the fact that they are ongoing at the time of finalization) is inapplicable to uses that are ongoing as of the date of publication of the proposed rule.

D. Test Data and Other Information

EPA recognizes that TSCA section 5 generally does not require the development of any particular test data before submission of a SNUN, however EPA is also proposing a test rule for c-pentaBDE, c-octaBDE, and c-decaBDE under TSCA section 4(a)(1)(A). Under TSCA section 5(b)(1), if a chemical is subject to a test rule, persons submitting a SNUN are required to submit test data in accordance with the test rule at the time the SNUN is submitted. In the absence of a test rule or a TSCA section 5(b)(4) rule (see TSCA section 5(b)(2)) covering the chemical substance, persons are required to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). As a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, or use. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

1. Human exposure and environmental releases that may result from the significant new uses of the chemical substance.

2. Potential benefits of the chemical substance.

3. Information on risks posed by the chemical substances resulting from the significant new use compared to risks posed by potential substitutes.

E. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the chemical substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50.

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the EPA in accordance with the procedures set forth in 40 CFR 721.25 and 720.40. E–PMN software is available electronically at *http://www.epa.gov/opptintr/newchems.*

VI. Proposed Test Rule

A. What testing is being proposed?

EPA is proposing specific testing and reporting requirements for c-pentaBDE, c-octaBDE, and c-decaBDE. These requirements are presented in Table 3 of this unit.

TABLE 3—PROPOSED TESTING AND REPORTING REQUIREMENTS FOR C-PENTABDE, C-OCTABDE, AND C-DECABDE

Proposed test	Test guideline	Test proposed for:			Deadline for submitting final report (number of months after the effective date in proposed 40 CFR 799.5350(k))
		c-penta BDE	c-octa BDE	c-deca BDE	
Toxicity to freshwater invertebrates of sediment-associated contaminants.	ASTM International (ASTM) E 1706–05e1 and ASTM E 1391–03 [1].	X	X	X	12
Laboratory soil toxicity and bioaccumulation tests with the lumbricid earthworm *Eisenia fetida* and the enchytraeid potworm *Enchytraeus albidu*.	ASTM E 1676–04 and ASTM E 1391–03 [2].	X	X	X	12
Toxicity to polychaetous annilids of sediment-associated contaminants.	ASTM E 1611–00 and ASTM E 1391–03 [1].	X	X	X	12
Laboratory soil toxicity to nematode *Caenorhabditis elegans*.	ASTM E 2172–01 and ASTM E 1391–03 [2].	X	X	X	12
Toxicity to estuarine and marine invertebrates of sediment-associated contaminants.	ASTM E 1367–03, ASTM E 1676–04 [3] and ASTM E 1391–03 [1].	X	X	X	12
Prenatal developmental toxicity in rabbits.	40 CFR 799.9370	X	X	X	12
2-Generation reproductive toxicity with satellite group for body burden determinations.	40 CFR 799.9380	X	X	X	29
Immunotoxicity	40 CFR 799.9780	X	X	X	12
Neurotoxicity screening battery, acute and subchronic.	40 CFR 799.9620	X	X	X	21

TABLE 3—PROPOSED TESTING AND REPORTING REQUIREMENTS FOR c-PENTABDE, c-OCTABDE, AND c-DECABDE—Continued

Proposed test	Test guideline	Test proposed for:			Deadline for submitting final report (number of months after the effective date in proposed 40 CFR 799.5350(k))
		c-penta BDE	c-octa BDE	c-deca BDE	
Developmental neurotoxicity	40 CFR 799.9630	X	X	[4] X	21
Chronic toxicity/carcinogenicity	40 CFR 799.9430	X	X		60
Anaerobic aquatic metabolism	40 CFR 795.25 (modified OCSPP 835.4400 [5]).			X	60
Biodegradation in Anaerobic Digester Sludge.	40 CFR 795.30 (modified OCSPP 835.3280 [5]).			X	24
Photolytic degradation in the indoor environment.	40 CFR 795.65			X	24

[1] ASTM E 1391–03 provides guidance on the collection, storage, characterization, and manipulation of sediments when toxicity to various organisms of sediment-associated contaminants is tested.
[2] ASTM E 1391–03 provides general guidance.
[3] ASTM E 1676–04 provides guidance for collecting laboratory soil.
[4] A developmental neurotoxicity study of decaBDE (Ref. 58) conducted according to the Organization for Economic Cooperation and Development (OECD) Guideline 426 and sponsored by the Bromine Science and Environmental Forum (BSEF) was submitted to EPA. If EPA considers the study to be adequately conducted and the study requirements of OECD Guideline 426 comparable to the study requirements of 40 CFR 799.9630, EPA will most likely accept the study and not finalize the proposed requirement to conduct developmental neurotoxicity testing of c-decaBDE.
[5] Office of Chemical Safety and Pollution Prevention (OCSPP) test guidelines, formerly Office of Toxic Substances and Pollution Prevention (OPPTS) test guidelines, are available online at *http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm.*

The proposed testing requirements are listed in 40 CFR 799.5350(h) and (i) of the proposed regulatory text and include the specification of test guidelines covering health effects testing, ecotoxicity testing, and chemical fate testing. EPA's TSCA 799 test guidelines (40 CFR part 799, subpart H) and the Office of Chemical Safety and Pollution Prevention (OCSPP) 835 series test guidelines (on which 40 CFR 795.25 and 40 CFR 795.30 are based) have been harmonized with the OECD test guidelines. However, EPA is specifying that the 40 CFR parts 799 and 795 test guidelines, as well as ASTM International standards, be used rather than OECD test guidelines because the language in 40 CFR parts 799 and 795 test guidelines and the ASTM International standards makes clear which steps are mandatory and which steps are only recommended. Accordingly, in order to comply with the testing required by a final rule, EPA is proposing that testing must be conducted in accordance with the specified 40 CFR parts 799 and 795 test guidelines and ASTM International standards. In addition, EPA is proposing a guideline developed by the Agency, 40 CFR 795.65, to test for photolytic degradation. Most of the proposed testing requirements for a particular endpoint are specified in one test standard. In the case of certain endpoints, however, additional guidance is provided in a second guideline and possibly a third guideline (e.g., ASTM E 1391–03 provides guidance in the collection, storage, characterization, and manipulation of sediments when toxicity to various organisms of sediment-associated contaminants is tested). The following testing endpoints and test standards are proposed to be required for one or more of the test substances in this proposed rule.

1. *Ecotoxicity.* a. Toxicity to freshwater invertebrates of sediment-associated contaminants conducted in accordance with ASTM E 1706–05e1 (Ref. 59) and following the guidance of ASTM E 1391–03 (Ref. 60). EPA proposes this guideline as appropriate to evaluate the toxicity to freshwater invertebrates of the test substance when associated with whole sediments.

b. Laboratory soil toxicity and bioaccumulation tests with the lumbricid earthworm *Eisenia fetida* and the enchytraeid potworm *Enchytraeus albidu* conducted in accordance with ASTM E 1676–04 (Ref. 61) and following the general guidance of ASTM E 1391–03 (Ref. 60). EPA proposes this guideline as appropriate to evaluate the adverse effects and bioaccumulation in earthworms and potworms of the test substance when associated with soils.

c. Toxicity to polychaetous annilids of sediment-associated contaminants conducted in accordance with ASTM E 1611–00 (Ref. 62) and following the guidance of ASTM E 1391–03 (Ref. 60). EPA proposes this guideline as appropriate to evaluate the toxicity to polychaetous annelids of the test substance when associated with sediment.

d. Laboratory soil toxicity to nematode *Caenorhabditis elegans* conducted in accordance with ASTM E 2172–01 (Ref. 63) and following the general guidance of ASTM E 1391–03 (Ref. 60). EPA proposes this guideline as appropriate to evaluate the adverse effects on nematodes of the test substance when associated with soils.

e. Toxicity to estuarine and marine invertebrates of sediment-associated contaminants conducted in accordance with ASTM E 1367–03 (Ref. 64) and following the guidance of ASTM E 1391–03 (Ref. 60). EPA proposes this guideline as appropriate to evaluate the toxicity to estuarine or marine organisms of the test substance when associated with whole sediments.

2. *Mammalian toxicity.* a. Prenatal developmental toxicity in rabbits conducted in accordance with 40 CFR 799.9370. EPA proposes this guideline as appropriate to provide general information concerning the effects of exposure to the test substance on the pregnant test animal and on the developing organism.

b. 2-Generation reproductive toxicity with a satellite group for body burden determinations conducted in accordance with 40 CFR 799.9380. EPA proposes this guideline as appropriate to provide general information concerning the effects of exposure to the

test substance on the integrity and performance of the male and female reproductive systems, and on the growth and development of the offspring.

c. Immunotoxicity conducted in accordance with 40 CFR 799.9780. EPA proposes this guideline as appropriate to provide information on suppression of the immune system which might occur as a result of repeated exposure to a test substance.

d. Neurotoxicity screening battery, acute and subchronic, conducted in accordance with 40 CFR 799.9620. EPA proposes this guideline as appropriate to provide information on gross functional deficits, level of activity, and histopathological changes in the central and peripheral nervous systems of the test animals as a result of acute and subchronic exposure to a test chemical.

e. Developmental neurotoxicity conducted in accordance with 40 CFR 799.9630. EPA proposes this guideline as appropriate to develop data on the potential functional and morphological hazards to the nervous system which may arise in the offspring from exposure of the mother during pregnancy and lactation.

f. Chronic toxicity/carcinogenicity conducted in accordance with 40 CFR 799.9430. EPA proposes this guideline as appropriate to identify the majority of chronic and carcinogenic effects and determine dose-response relationships in a mammalian species following prolonged and repeated exposure to a test substance.

3. *Chemical fate.* a. Anaerobic aquatic metabolism conducted in accordance with OCSPP 835.4400 as modified for c-decaBDE in 40 CFR 795.25. EPA proposes this guideline as appropriate to assess transformation of decaBDE in anaerobic aquatic sediment systems.

b. Biodegradation in anaerobic digester sludge conducted in accordance with OCSPP 835.3280 as modified for c-decaBDE in 40 CFR 795.30. EPA proposes this guideline as appropriate to assess biotransformation in anaerobic digester sludge.

c. Photolytic degradation of c-decaBDE conducted in accordance with an EPA-developed guideline in 40 CFR 795.65. EPA proposes this guideline as appropriate to assess whether PBDEs can migrate out of plastics/fabrics by volatilization; and if photolytic degradation can take place on the surfaces of plastics and fabrics.

B. When would any testing proposed by this rule begin?

The testing requirements contained in this proposed rule are not effective until and unless the Agency issues a final rule. If any manufacturer or processor of c-pentaBDE, c-octaBDE, or c-decaBDE is subject to the test rule after December 31, 2013, the test sponsor may plan the initiation of any required testing as appropriate to submit the required final report by the deadline indicated as the number of months, shown in 40 CFR 799.5350(j) of the proposed regulatory text, after December 31, 2013.

C. How would the studies proposed under this test rule be conducted?

Persons required to comply with the final rule would have to conduct the necessary testing in accordance with the testing and reporting requirements established in the regulatory text of the final rule, with 40 CFR part 790—Procedures Governing Testing Consent Agreements and Test Rules (except for paragraphs (a), (d), (e), and (f) of 40 CFR 790.45; 40 CFR 790.48; paragraph (a)(2) and paragraph (b) of 40 CFR 790.80; paragraph (e)(1) of 40 CFR 790.82; and 40 CFR 790.85), and with 40 CFR Part 792—Good Laboratory Practice Standards.

D. What forms of test mixtures would be tested under this rule?

The test rule proposes that the test mixtures be the representative forms of pentaBDE-containing commercial mixtures, octaBDE-containing commercial mixtures, and decaBDE-containing commercial mixtures. To fully describe the three test mixtures, the percentage of each of the seven congeners present in each of the three test mixtures must be identified by the test sponsor(s).

Each of the three proposed test mixtures is described by its predominant components. c-PentaBDE is a mixture predominantly comprised of pentaBDE, tetraBDE, and hexaBDE. c-OctaBDE is a mixture predominantly comprised of octaBDE, hexaBDE, heptaBDE, and nonaBDE. c-DecaBDE is a mixture with decaBDE being present in the highest percentage. EPA believes that the proposed testing of c-pentaBDE, c-octaBDE, and c-decaBDE will provide EPA with data necessary to determine the effects of commercial PBDE products on human health and the environment. EPA is seeking comment on whether testing of c-pentaBDE, c-octaBDE, and c-decaBDE should be conducted with the pure congener or each congener in each mixture instead of the commercial products. EPA is also seeking comment on whether its descriptions of the commercial mixtures to be tested accurately predict what commercial forms of pentaBDE, octaBDE, and decaBDE might be produced. Finally, EPA solicits comment on whether more than one commercial form each of c-pentaBDE, c-octaBDE, and c-decaBDE should be tested.

E. Would I be required to test under this rule?

Under TSCA section 4(a)(1)(A)(ii), EPA has made preliminary findings that there are insufficient data and experience to reasonably determine or predict health and environmental effects resulting from the manufacture, processing, use, and distribution in commerce of the mixtures listed in this proposed rule. As a result, under TSCA section 4(b)(3)(B), manufacturers and processors of mixtures listed in this proposed rule, and those who intend to manufacture or process them, would be subject to the rule with regard to those listed mixtures which they manufacture or process.

1. *Would I be subject to this rule?* You would be subject to this rule and may be required to test if you manufacture (which is defined by statute to include import) or process, or intend to manufacture or process, one or more mixtures listed in this proposed test rule during the time period discussed in Unit VI.E.2. You would also be subject to this rule if you manufacture or process the subject mixtures for export from the United States. For this rule, importers of articles which include c-pentaBDE, c-octaBDE, or c-decaBDE would be considered manufacturers and subject to this rule. If you do not know or cannot reasonably ascertain that you manufacture or process a listed test rule mixture (based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), you would not be subject to the rule for that listed mixture.

2. *When would my manufacture or processing (or my intent to do so) cause me to be subject to this rule?* You would be subject to this rule if you manufacture or process, or intend to manufacture or process, a mixture listed in the rule at any time from the effective date in 40 CFR 799.5350(k) of the final test rule to the end of the test data reimbursement period. The term ''reimbursement period'' is defined at 40 CFR 791.3(h) and may vary in length for each mixture to be tested under a final TSCA section 4(a) test rule, depending on what testing is required and when testing is completed. See Unit VI.E.4.

3. *Would I be required to test if I were subject to the rule?* It depends on the nature of your activities. All persons who would be subject to this TSCA

section 4(a) test rule, which, unless otherwise noted in the regulatory text, incorporates EPA's generic procedures applicable to TSCA section 4(a) test rules (contained within 40 CFR part 790), would fall into one of two groups, designated here as Tier 1 and Tier 2. Persons in Tier 1 (those who would have to initially comply with the final rule) would either:

- Submit to EPA letters of intent to conduct testing, conduct this testing, and submit the test data to EPA, or
- Apply to and obtain from EPA exemptions from testing.

Persons in Tier 2 (those who would not have to initially comply with the final rule) would not need to take any action unless they are notified by EPA that they are required to do so (because, for example, no person in Tier 1 had submitted a letter of intent to conduct testing), as described in Unit VI.E.3.d. Note that both persons in Tier 1 who obtain exemptions and persons in Tier 2 would nonetheless be subject to providing reimbursement to persons who actually conduct the testing, as described in Unit VI.E.4.

a. *Who would be in Tier 1 and Tier 2?* All persons who would be subject to the final rule are considered to be in Tier 1 unless they fall within Tier 2. Table 4 of this unit describes who is in Tier 1 and Tier 2.

TABLE 4—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2

Tier 1 (persons initially required to comply)	Tier 2 (persons not initially required to comply)
Persons who manufacture (as defined at TSCA section 3(7)), or intend to manufacture, a test rule mixture and who are not listed under Tier 2. Importers of articles containing polybrominated diphenyl ethers (PBDEs) are manufacturers.	A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a test rule mixture solely as one or more of the following: —As a byproduct (as defined at 40 CFR 791.3(c)); —As an impurity (as defined at 40 CFR 790.3); —As a naturally occurring chemical substance (as defined at 40 CFR 710.4(b)); —As a non-isolated intermediate (as defined at 40 CFR 704.3); —As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i)); —In amounts of less than 500 kilograms (kg) (1,100 pounds (lb)) annually (as described at 40 CFR 790.42(a)(4)); or —In small quantities solely for research and development (R&D) (as described at 40 CFR 790.42(a)(5)). B. Persons who process (as defined at TSCA section 3(10)) or intend to process a test rule mixture including in articles (see 40 CFR 790.42(a)(2)).

Under 40 CFR 790.2, EPA may establish procedures applying to specific test rules that differ from the generic procedures governing TSCA section 4(a) test rules in 40 CFR part 790. For purposes of this proposed rule, EPA is proposing to establish certain requirements that differ from those under 40 CFR part 790.

In this proposed test rule, EPA has configured the tiers in 40 CFR 790.42 as in certain previous test rules. In addition to processors, manufacturers of less than 500 kilograms (kg) (1,100 pounds (lb)) per year (''small-volume manufacturers''), and manufacturers of small quantities for research and development (''R&D manufacturers''), EPA has added the following persons to Tier 2: Manufacturers of byproducts, manufacturers of impurities, manufacturers of naturally occurring chemical substances, manufacturers of non-isolated intermediates, and manufacturers of components of Class 2 chemical substances. The Agency took administrative burden and complexity into account in determining who was to be in Tier 1 in this proposed rule. EPA believes that those persons in Tier 1 who would conduct testing under this proposed rule, when finalized, would generally be large chemical manufacturers who, in the experience of the Agency, have traditionally conducted testing or participated in testing consortia under previous TSCA section 4(a) test rules.

The Agency also believes that manufacturers of byproducts, impurities, naturally occurring chemical substances, manufacturers of non-isolated intermediates, and manufacturers of components of Class 2 chemical substances historically have not themselves participated in testing or contributed to reimbursement of those persons who have conducted testing. EPA understands that these manufacturers may include persons for whom the marginal transaction costs involved in negotiating and administering testing arrangements are deemed likely to raise the expense and burden of testing to a level that is disproportional to the additional benefits of including these persons in Tier 1. Therefore, EPA is not proposing to burden these persons with Tier 1 requirements (e.g., submitting requests for exemptions). Nevertheless, these persons, along with all other persons in Tier 2, would be subject to reimbursement obligations to persons who actually conduct the testing, as described in Unit VI.E.4.

Section 4(b)(3)(B) of TSCA requires all manufacturers and/or processors of a mixture to test that mixture if EPA has made findings under TSCA sections 4(a)(1)(A)(ii) or 4(a)(1)(B)(ii) for that mixture, and issued a TSCA section 4(a) test rule requiring testing. However, practicality must be a factor in determining who is subject to a particular test rule. Thus, persons who do not know or cannot reasonably ascertain that they are manufacturing or processing a mixture subject to this proposed rule, e.g., manufacturers or processors of a mixture as a trace contaminant who are not aware of or cannot reasonably ascertain these activities would not be subject to the rule. See Unit VI.E.1. and 40 CFR 799.5350(b)(2) of this proposed rule.

EPA believes it is possible that there will be no persons in Tiers 1 and 2A that will be subject to the test rule. If EPA learns that the only persons that would be subject to the rule would be persons that process c-pentaBDE, c-octaBDE, or c-decaBDE as impurities contained in articles, EPA will not require testing because EPA has not determined whether this activity alone may present an unreasonable risk of injury to health or the environment. EPA is seeking comment on whether the Agency should address persons who manufacture or process PBDEs as impurities whether or not they are contained in articles, and whether such persons should be required to conduct testing.

b. *Subdivision of Tier 2 entities.* The Agency is proposing to prioritize which persons in Tier 2 would be required to

perform testing, if needed. Specifically, the Agency is proposing that Tier 2 entities be subdivided into:

i. Tier 2A—manufacturers, i.e., those who manufacture, or intend to manufacture, a test rule chemical substance including in articles solely as one or more of the following: A byproduct, an impurity, a naturally occurring chemical substance, a non-isolated intermediate, a component of a Class 2 chemical substance, in amounts less than 1,100 lb annually, or in small quantities solely for research and development.

ii. Tier 2B–processors, i.e., those who process, or intend to process, a test rule mixture in any form including in articles. The terms ''process'' and ''processor'' are defined by TSCA sections 3(10) and 3(11), respectively.

If the Agency needs testing from persons in Tier 2, EPA would seek testing from persons in Tier 2A before proceeding to Tier 2B. It is appropriate to require manufacturers in Tier 2A to submit letters of intent to test or exemption applications before processors are called upon because the Agency believes that testing costs are traditionally passed along by manufacturers to processors, enabling them to share in the costs of testing (Ref. 65). In addition, ''[t]here are [typically] so many processors [of a given test rule chemical] that it would be difficult to include them all in the technical decisions about the tests and in the financial decisions about how to allocate the costs'' (Ref. 66).

c. *When would it be appropriate for a person who would be required to comply with the rule to apply for an exemption rather than to submit a letter of intent to conduct testing?* You may apply for an exemption if you believe that the required testing will be performed by another person (or a consortium of persons formed under TSCA section 4(b)(3)(A)). You can find procedures relating to exemptions in 40 CFR 790.80 through 790.99, and 799.5350(c)(2), (c)(5), (c)(7), and (c)(11) of this proposed rule. In this proposed rule, EPA would not require the submission of equivalence data (i.e., data demonstrating that your chemical substance or mixture is equivalent to the chemical substance or mixture actually being tested) as a condition for approval of your exemption. Therefore, 40 CFR 790.82(e)(1) and 790.85 would not apply to this proposed rule.

d. *What would happen if I submitted an exemption application?* EPA believes that requiring the collection of duplicative data is unnecessarily burdensome. As a result, if EPA has received a letter of intent to test from another source or has received (or expects to receive) the test data that would be required under this rule, the Agency would conditionally approve your exemption application under 40 CFR 790.87.

The Agency would terminate conditional exemptions if a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA. EPA may then require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and 799.5350(c)(8) of the proposed regulatory text. In addition, the Agency would terminate a conditional exemption if no letter of intent to test has been received by persons required to comply with the rule. See, e.g., 40 CFR 799.5350(c)(6) of this proposed rule. Note that the provisions at 40 CFR 790.48(b) have been incorporated into the regulatory text of this proposed rule; thus, persons subject to this rule are not required to comply with 40 CFR 790.48 itself (see 40 CFR 799.5350(c)(4) through (c)(7) and 40 CFR 799.5350(d)(3) of this proposed rule). Persons who obtain exemptions or receive automatic conditional exemptions would nonetheless be subject to providing reimbursement to persons who do actually conduct the testing, as described in Unit VI.E.4.

e. *What would my obligations be if I were in Tier 2?* If you are in Tier 2, you would be subject to the rule and you would be responsible for providing reimbursement to persons in Tier 1, as described in Unit VI.E.4. There is no difference whether you are in Tier 2A or Tier 2B as regards reimbursement. EPA is not aware of any circumstances in which test rule Tier 1 entities have sought reimbursement from Tier 2 entities either through private agreements or by soliciting the involvement of the Agency under the reimbursement regulations at 40 CFR part 791.

Concerning testing, if you are in Tier 2, you are considered to have an automatic conditional exemption. You would not need to submit a letter of intent to test or an exemption application unless you are notified by EPA that you are required to do so. As previously noted, Tier 2A manufacturers would be notified to test before Tier 2B processors (Unit VI.E.3.ii.).

If a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA, the Agency may require you to submit a notice of intent to test or submit an exemption application. See 40 CFR 790.93 and 799.5350(c)(10) of the proposed regulatory text.

In addition, you would need to submit a notice of intent to test or an exemption application if:

- No manufacturer in Tier 1 has notified EPA of its intent to conduct testing.
- EPA has published a **Federal Register** document directing persons in Tier 2 to submit to EPA letters of intent to conduct testing or exemption applications.

See 40 CFR 799.5350(c)(4), (c)(5), (c)(6), and (c)(7) of the proposed regulatory text. The Agency would conditionally approve an exemption application under 40 CFR 790.87, if EPA has received a letter of intent to test or has received (or expects to receive) the test data required under this rule.

f. *What would happen if no one submitted a letter of intent to conduct testing?* EPA anticipates that, if there were manufacturers or processors of those chemical substances subject to the final rule, it would receive letters of intent to conduct testing for all of the tests specified for each mixture from one of those persons. However, in the event it does not receive a letter of intent for one or more of the tests required by the final rule for any of the mixtures in the final rule within 30 days after the publication of a **Federal Register** document notifying Tier 2 processors of the obligation to submit a letter of intent to conduct testing or to apply for an exemption from testing, EPA would notify all manufacturers and processors of the mixture of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter of intent has been submitted. This letter or **Federal Register** document would additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and would give them an opportunity to take corrective action. If no one has notified EPA of its intent to conduct the required testing of the mixture within 30 days after receipt of the certified letter or publication of the **Federal Register** document, all manufacturers and processors subject to the final rule with respect to that mixture who are not already in violation of the final rule would be in violation of the final rule.

4. *How do the reimbursement procedures work?* In the past, persons subject to test rules have independently worked out among themselves their respective financial contributions to those persons who have actually

conducted the testing. However, if persons are unable to agree privately on reimbursement, they may take advantage of EPA's reimbursement procedures at 40 CFR part 791, promulgated under the authority of TSCA section 4(c). These procedures include: The opportunity for a hearing with the American Arbitration Association; publication by EPA of a document in the **Federal Register** concerning the request for a hearing; and the appointment of a hearing officer to propose an order for fair and equitable reimbursement. The hearing officer may base his or her proposed order on the production volume formula set out at 40 CFR 791.48, but is not obligated to do so. The hearing officer's proposed order may become the Agency's final order, which is reviewable in Federal court (40 CFR 791.60). Under this proposed rule, for the purpose of determining fair reimbursement shares if the hearing officer chooses to use a formula based on production volume, the total production volume will include amounts of a mixture produced as an impurity and amounts imported in articles.

F. What reporting requirements are proposed under this test rule?

If you were required to test, you would be required to submit a final report for a specific test by the deadline indicated in Table 3 in Unit VI.A. as the number of months after the effective date of the final rule; this deadline is also shown in 40 CFR 799.5350(j) of the proposed regulatory text.

EPA is also proposing that a robust summary of the final report for each specific test be required to be submitted electronically in addition to and at the same time as the final report. The term ''robust summary'' is used to describe the technical information necessary to adequately describe an experiment or study and includes the objectives, methods, results, and conclusions of the full study report which can be either an experiment or in some cases an estimation or prediction method. Guidance for the compilation of robust summaries is described in a document entitled ''Draft Guidance on Developing Robust Summaries'' (Ref. 67).

G. What would I need to do if I cannot complete the testing required by the final rule?

A person who submits a letter of intent to test under the final rule and who subsequently anticipates difficulties in completing the testing by the deadline set forth in the final rule may submit a modification request to the Agency, pursuant to 40 CFR 790.55. EPA will determine whether modification of the test schedule is appropriate, and may first seek public comment on the modification.

H. Would there be sufficient test facilities and personnel to undertake the testing proposed under this test rule?

EPA's most recent analysis of laboratory capacity (Ref. 68) indicates that available test facilities and personnel would adequately accommodate the testing proposed in this rule.

I. Might EPA seek further testing of the chemical substances in this proposed test rule?

If EPA determines that it needs additional data regarding any of the chemical substances included in this proposed rule, the Agency would seek further health and/or environmental effects testing for these mixtures. Should the Agency decide to seek such additional testing via a test rule, EPA would initiate a separate action for that purpose.

VII. Export Notification

A. SNUR

Any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR 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. Any person who exports, or intends to export, tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, and nonaBDE became subject to those requirements with the proposal of the SNUR in 2004 (Ref. 69). This proposed rule would not affect the article exemption at 40 CFR 707.60(b) for notices of export under TSCA section 12(b). Persons who export PBDEs contained in articles would not be required to submit a notice of export respecting such PBDEs.

B. Test Rule

Any person who exports, or intends to export, one of the mixtures contained in this proposed test rule would be subject to the export notification requirements in TSCA section 12(b)(1) (15 U.S.C. 2611(b)) and at 40 CFR part 707, subpart D, but only after the final rule is promulgated and only if the mixture is contained in the final rule. This proposed rulemaking would not affect the article exemption at 40 CFR 707.60(b) for notices of export under TSCA section 12(b). Persons who export PBDE mixtures contained in articles would not be required to submit a notice of export respecting such mixtures.

C. Should articles containing PBDEs be exempt from export notification requirements?

The Agency believes that production and processing of all PBDEs, including in articles, will have ceased in the United States by the end of 2013 but if there are any ongoing uses they would not be subject to a final SNUR. The purpose of the proposed SNUR is to designate new and discontinued uses as significant new uses and to ensure that the Agency has an opportunity to review and, if necessary, take action to restrict or prohibit significant new uses of PBDEs, including in articles, before they resume. The purpose of the proposed test rule is to provide EPA with data necessary to determine the effects on health and the environment if the manufacture and processing of commercial PBDEs and the associated use, distribution in commerce and disposal are not discontinued. The Agency believes that the above objectives will be adequately met with respect to articles by making article exemptions for SNURs and test rules inapplicable for this action. The Agency considered including provisions in the proposed SNUR and test rule requiring that the PBDEs contained in articles be subject to TSCA section 12(b) export notification requirements. However, the Agency does not believe that making exporters of PBDEs contained in articles subject to TSCA section 12(b) export notification requirements would significantly increase the effectiveness of this proposed rule. The Agency is concerned that the potential burdens associated with administration and compliance with export notification requirements for PBDEs contained in articles could be significant. In view of the expected costs the Agency decided that PBDEs contained in articles should continue to be exempt from export notification requirements. The Agency is seeking comment on the need for (and the cost of) making PBDEs contained in articles subject to export notification requirements.

VIII. Import Certification

A. SNUR

Persons who import a chemical substance in bulk or as part of a mixture are subject to the TSCA section 13 (15 U.S.C. 2612) import requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies with

all applicable rules and orders under TSCA, including any SNUR requirements. This rule would not affect the exemption from import certification under TSCA section 13(b) for chemicals contained in articles. Persons who import PBDEs contained in articles would not be subject to import certification requirements. PBDEs imported in bulk or as part of a mixture would continue to be subject to import certification requirements under TSCA section 13(b), consistent with 19 CFR 12.120(b). The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. For additional guidance, please refer to EPA's TSCA Import Compliance Checklist at *http://www.epa.gov/oppt/import-export/pubs/checklist.pdf*.

B. Test Rule

Section 13 of TSCA import certification requirements do not pertain to TSCA section 4 test rules. Although importers must satisfy all applicable requirements of TSCA section 4, compliance with those provisions is not related to individual chemical shipments and therefore does not affect import certification.

C. Should articles containing PBDEs be exempt from import certification requirements?

The Agency believes that manufacture, including import, and processing of all PBDEs, including in articles, will have ceased in the United States by the end of 2013. The purpose of the proposed SNUR is to designate new and discontinued uses as significant new uses and to ensure that the Agency has an opportunity to review and, if necessary, take action to restrict or prohibit significant new uses of PBDEs, including in articles, before they resume. The Agency believes that the above objective will be adequately met with respect to articles by making the article exemption for SNURs inapplicable for this action. The Agency does not believe that making importers of PBDEs contained in articles subject to TSCA section 13 import certification requirements would significantly increase the effectiveness of this proposed rule.

The Agency considered including provisions in the proposed SNUR requiring that the PBDEs contained in articles be subject to TSCA section 13 import certification requirements. However, the Agency is concerned that the potential burdens associated with administration and compliance with import certification requirements could be significant. The Agency decided that PBDEs contained in articles should continue to be exempt from import certification requirements. The Agency is seeking comment on the need for (and the cost of) making PBDEs contained in articles subject to import certification requirements.

IX. The Dates That the SNUR, Proposed Amended SNUR, and Proposed Test Rule Requirements Apply to the Seven PBDEs and the Three Commercial Mixtures

The SNUR that became effective on August 14, 2006, requires that persons that intend to manufacture, including import, any of six PBDEs (tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, and nonaBDE) for any use after January 1, 2005, submit a SNUN to EPA at least 90 days in advance. Processing of the PBDEs was not designated as a significant new use because EPA believed that it was an ongoing activity at the time of proposal. Articles were exempt from that SNUR. EPA now believes that processing of these six PBDEs for any use and import of articles containing them have been discontinued. These proposed amendments to the SNUR would designate processing for any use after December 31, 2013, a significant new use. The proposed amended SNUR would also make inapplicable the article exemption at 40 CFR 721.45(f). Therefore, a person who intends to import or process any of the six PBDEs as part of an article after December 31, 2013, would not be exempt from submitting a SNUN. EPA will promulgate the amended SNUR after it has verified that the proposed significant new uses have been discontinued. For a discussion of applicability of the SNUR to uses begun after the publication of this proposed rule see Unit V.C.

Any person who manufactures or processes or intends to manufacture or process c-pentaBDE, c-octaBDE, or c-decaBDE after December 31, 2013, would be subject to the test rule.

On December 2009, the principal manufacturers and importer of decaBDE announced their intent to phase out their activities with decaBDE and committed to do so by December 31, 2012 for all uses, except military and transportation, and by December 31, 2013, for all uses including military and transportation, with possibly an additional 6 months to sell remaining inventory of decaBDE (Refs. 9–11). The Agency does not believe that manufacturers would need additional time to sell remaining inventory or that processors would require any additional time to use existing stocks, and has not proposed any additional time in this action. EPA is seeking comment on this in Unit XI.A.2.

With this action, EPA is also proposing to amend the 2006 PBDE SNUR at 40 CFR 721.10000 after December 31, 2013, by designating manufacture and processing of decaBDE for any use which is not ongoing, including in articles, as a significant new use. Persons that intend to manufacture or process decaBDE for a significant new use would be required to submit a SNUN to EPA at least 90 days before commencing such activity.

If EPA determined that any person intends to manufacture or process c-pentaBDE c-octa BDE, or c-decaBDE for any use after December 31, 2013, EPA would promulgate the test rule and they would be subject to the test rule requirements.

X. Economic Considerations

A. SNUR

The proposed amendment to the SNUR would require persons intending to engage in significant new use to submit a SNUN, incurring an estimated submission cost of $8,143 per chemical substance, plus other costs (Ref. 70). In addition to the firms that make a SNUN submission, the proposed amendments to the SNUR may also impact firms that do not make a submission. By avoiding a significant new use, a firm can avoid submission and testing costs but may incur other compliance costs. The firm may also incur ''hidden'' costs; for example, it could forego profitable opportunities to use the chemical substance in an application that would be a significant new use or limit production volume to avoid a significant new use. Costs are estimated at the firm level and reflect the burden of a SNUR on the firms that make a submission. The hidden costs to the firms that do not make a submission are not quantified. EPA receives only a handful of SNUNs per year due to SNURs. However, the number of firms affected by not making submissions to EPA is not known; therefore, costs are not aggregated across the affected entities.

B. Test Rule

EPA has prepared an economic assessment entitled ''Economic Impact Analysis for the Proposed Section 4 Test Rule for c-Pentabromodiphenyl Ether, c-Octabromodiphenyl Ether, and c-Decabromodiphenyl Ether'' (Ref. 71), a copy of which has been placed in the docket for this rule. The economic analysis evaluates the costs associated with the testing that would be required by a final test rule. The analysis looks

at costs due to testing all three mixtures and to each mixture separately. The total costs to industry of compliance, including testing and administrative costs, for all three mixtures are estimated under the low- and high-cost scenarios to be $9.68 million and $15.1 million, respectively. The testing cost (not including administrative costs) to comply with the test rule requirements for c-pentaBDE or c-octaBDE under the low- and high-cost scenarios would be $2.8 million and $4.7 million, respectively. The testing cost (not including administrative costs) to comply with the test rule requirements for c-decaBDE under the low- and high-cost scenarios would be $1.8 million and $2.5 million, respectively. (Ref. 71) These costs would only be incurred if there were entities that manufacture or process c-pentaBDE, c-octaBDE, or c-decaBDE, including in articles, after the effective date of the test rule.

Currently, there are no known entities that manufacture or process c-pentaBDE or c-octaBDE in the United States except as impurities, so an economic impact analysis could not be done for these two chemical substances.

EPA has identified six ultimate parent companies that manufacture or import c-decaBDE in the United States. The total annualized compliance costs for decaBDE are estimated to be, under low- and high-cost scenarios, $264,582 and $360,218, respectively. To evaluate the potential for an adverse economic impact of testing on manufacturers and importers of c-decaBDE, EPA employed an initial screening approach that estimated the impact of testing requirements as a percentage of c-decaBDE's sale price. This measure compares annual revenues from the sale of a mixture to the annualized compliance cost for that mixture to assess the percentage of testing costs that can be accommodated by the revenue stream generated by that mixture over a number of years. Compliance costs include costs of testing and administering the testing, as well as reporting costs. In addition, they include the estimated cost of the TSCA section 12(b) export notification requirements, which, under the final rule, would be required for the first export to a particular country of a mixture subject to the rule, estimated to range from $26.86 per notice to $85.70 per notice (Ref. 70). These export notification requirements (included in the total and annualized cost estimates) that would be triggered by the final rule are expected to have a negligible impact on exporters.

Annualized compliance costs divide testing expenditures into an equivalent, constant yearly expenditure over a longer period of time. To calculate the percent price impact, testing costs (including laboratory and administrative expenditures) are annualized over 15 years using a 7% discount rate. These annualized testing costs are then divided by the estimated annual revenue of the mixture to derive a cost-to-sales ratio.

For five companies manufacturing or importing c-decaBDE, the cost-to-sales ratios is 3% or less. One company was identified as a small business by TSCA's employment-based definition and has a cost-to-sales ratio greater than 3%. Mixtures for which the price impact is expected to exceed 1% of the revenue from that chemical substance have a higher potential for adverse economic impact. However, EPA also compared the annualized cost of testing c-decaBDE to company revenue because, in some cases, companies may choose to use revenue sources other than the profits from the individual mixture to pay for testing. EPA estimates that the costs of testing will exceed 1% of company revenue for only one of the affected companies, i.e., the company identified as a small business.

While processors are legally subject to this test rule if they process c-decaBDE after December 31, 2013, processors of c-decaBDE would be required to comply with the requirements of the rule only if they are directed to do so by EPA as described in 40 CFR 799.5350(c)(6) and (c)(8) of the proposed regulatory text. EPA would only require processors to test if no subject person in Tier 1 or Tier 2A has submitted a notice of its intent to conduct testing, or if under 40 CFR 790.93, a problem occurs with the initiation, conduct, or completion of the required testing or the submission of the required data to EPA. Because processors would not need to comply with the rule initially if there are persons in Tiers 1 or 2A subject to the rule, the economic assessment does not address processors.

The benefits resulting from this proposed test rule are discussed qualitatively in the ''Economic Impact Analysis for the Proposed Section 4 Test rule for c-Pentabromodiphenyl Ether, c-Octabromodiphenyl Ether, and c-Decabromodiphenyl Ether'' (Ref. 71). EPA believes the major benefits of the test rule will be the development of hazard information on these chemical substances and the use of this information by the public, industry, and government.

XI. Request for Public Comment

A. Solicitation of Comments on the Proposed Amendments to the SNUR

1. EPA welcomes comments on any aspect of the proposed amendments to the SNUR, but is especially interested in comments regarding the possibility that manufacture and processing for some uses of decaBDE may continue after December 31, 2013. The Agency seeks information on such uses.

2. EPA is projecting c-decaBDE will no longer be available and that processors will discontinue their activities by December 31, 2013. Should EPA assume that processors will continue their activities beyond that date? For example, should EPA assume that processors will continue their activities for 6 months after manufacture of decaBDE ceases? Should EPA designate processing of decaBDE after June 30, 2014, or some other date, a significant new use?

3. EPA welcomes comments on the designation of a significant new use of tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, and nonaBDE as manufacture and processing for any use including in articles after December 31, 2013.

4. EPA is proposing to make inapplicable the article exemption for SNURs at 40 CFR 721.45(f). A person who intends to process a chemical substance identified in that section as part of an article, other than as an impurity, would not be exempt from submitting a SNUN. EPA welcomes comment on this proposed course of action.

5. EPA requests comment on when to finalize the proposed amendments to the SNUR. Should they be finalized before or after the phase-out of decaBDE?

6. EPA requests comment on whether the proposed significant new uses are ongoing and will still be ongoing after December 31, 2013.

B. Solicitation of Comments on the Proposed Test Rule

1. EPA is soliciting comment regarding additional information pertaining to potential exposure of the general population, consumers, and workers to c-pentaBDE, c-octaBDE, and c-decaBDE. Also, the Agency solicits comment regarding additional information pertaining to environmental releases of any of these three PBDE mixtures.

2. EPA is soliciting comments which identify existing studies that may satisfy the data needs identified in the proposed test rule. To the extent that data relevant to the testing specified in

this proposed test rule are known to exist, EPA strongly encourages the submission of this information as comments to the proposed test rule. Such data submitted to EPA must be in the form of full copies of unpublished studies or full citations of published studies, and accompanied by a robust summary (Ref. 67). To the extent that studies proposed in this action are currently available, and the data are judged sufficient by EPA, testing for the endpoint/mixture combination will not be required in a final test rule.

3. EPA is soliciting comment on what test substances should be required for pentaBDE, octaBDE, and decaBDE. EPA is proposing that the test substances be the representative commercial forms with the percent congener composition identified by the test sponsor(s). Instead, should the test substances be the 99% pure pentaBDE, octaBDE, and decaBDE with an isomer composition identified for each?

4. EPA is soliciting comment on whether a purity level of 99% or greater can be attained for pentaBDE, octaBDE, and decaBDE.

5. EPA is soliciting comment on whether the descriptions in the proposed regulatory text in 40 CFR 799.5350(a) of the commercial mixtures to be tested adequately encompass the range of commercial forms of pentaBDE, octaBDE, and decaBDE that might be produced.

6. EPA is soliciting comment on whether, for the purpose of the testing proposed in this proposed rule, a single commercial form each of pentaBDE, octaBDE, and decaBDE can be representative of the possible variations of those commercial mixtures. If not, should more than one commercial form each of pentaBDE, octaBDE, and decaBDE be tested? How should those forms be determined?

7. EPA is soliciting comment on whether testing should be required of tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE, and decaBDE comparable to that proposed for c-pentaBDE, c-octaBDE, and c-decaBDE if they are present in commercial PBDE products.

8. EPA is also soliciting comment on the proposed test guidelines, the proposed requirement for submission of robust summaries, the proposed deadlines to submit final reports, and the economic impact analysis detailing the burdens and costs that would result from complying with a final test rule.

9. The Agency invites comment on the potential use of voluntary consensus standards in the proposed test rule, and, specifically, invites the public to identify potentially applicable voluntary consensus standard(s) and to explain why such voluntary consensus standard(s) should be used here.

10. EPA is interested in receiving comments on whether the Agency should consider establishing an alternate definition for small business to use in the small entity impact analyses for future TSCA section 4(a) test rules, and what size cutoff may be appropriate.

11. EPA is soliciting comment on whether, in a future rulemaking, persons who manufacture or process c-PBDEs contained in articles as impurities should be required to conduct testing. EPA also solicits comment on whether persons who manufacture or process c-PBDEs as impurities not contained in articles should be required to test.

XII. References

As indicated under **ADDRESSES**, a docket has been established for this proposed rule under docket ID number EPA–HQ–OPPT–2010–1039. The following is a listing of the documents that have been placed in the docket. The docket includes information considered by EPA in developing this proposed rule, including the documents listed in this unit, which are physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents are physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not physically located in the docket, please consult the appropriate technical person listed under **FOR FURTHER INFORMATION CONTACT**. The docket is available for review as specified under **ADDRESSES**.

A. Documents Cited in the Preamble and Available in the Docket

1. EPA. Significant New Use Rule for Certain Polybrominated Diphenylethers. 40 CFR 721.10000.

2. EPA, 2009. Polybrominated Diphenyl Ethers (PBDEs) Action Plan. Available online at: *http://www.epa.gov/oppt/existingchemicals/pubs/pbdes_ap_2009_1230_final.pdf.*

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7. EPA, Risk Assessment Division (RAD), OPPT. Voluntary Children's Chemical Evaluation Program: Data Needs Decision Document for Pentabromodiphenyl Ether and Octabromodiphenyl Ether. June 2005.

8. EPA, RAD, OPPT. Voluntary Children's Chemical Evaluation Program: Data Needs Decision Document for Decabromodiphenyl Ether. June 2005.

9. Albermarle Corporation. Letter from David W. Clary, Albemarle Corp., to Lisa P. Jackson, EPA. EPA–Industry DecaBDE Phase-Out Initiative. December 15, 2009.

10. Chemtura Corporation. Letter from Craig A. Rogerson, Chemtura Corp., to Lisa P. Jackson, EPA. DecaBDE Phase-Out Initiative. December 17, 2009.

11. ICL Industrial Products. Letter from Nissim Adar to Lisa P. Jackson, EPA. Voluntary Phase-Out of DecaBDE. December 15, 2009.

12. EPA. TSCA Section 4(a)(1)(B) Final Statement of Policy. Notice. **Federal Register** (58 FR 28736, May 14, 1993), pp. 28738–28739.

13. EPA. VCCEP Web site homepage online at: *http://www.epa.gov/oppt/vccep.*

14. EPA, 2008a. Toxicological Review of 2, 2', 4, 4' -Tetrabromodiphenyl Ether (BDE–47), EPA/635/R–07/005F. June 2008.

15. EPA, 2008b. Toxicological Review of 2, 2', 4 ,4',5–Pentabromodiphenyl Ether (BDE–99), EPA/635/R–07/006F. June 2008.

16. EPA, 2008c. Toxicological Review of 2, 2', 4, 4', 5, 5'-Hexabromodiphenyl Ether (BDE–153), EPA/635/R–07/007F. June 2008.

17. EPA, 2008d. Toxicological Review of Decabromodiphenyl Ether (BDE–209), EPA/635/R–07/008F. June 2008.

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B. Documents Not Cited in the Preamble and Available in the Docket

The following documents are not cited in the preamble but are in the docket because they are considered germane to this proposed rule.

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XIII. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), this action has been designated a ''significant regulatory action'' by the Office of Management and Budget (OMB). Accordingly, EPA submitted this action to OMB for review and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, EPA has prepared two economic analyses of the potential impacts associated with this action. A copy of these economic analyses, entitled ''Economic Impact Analysis for the Proposed Section 4 Test Rule for c-Pentabromodiphenyl Ether, c-Octabromodiphenyl Ether, and c-Decabromodiphenyl Ether'' (Ref. 71) and ''Economic Analysis of the Proposed Significant New Use Rule for Polybrominated Diphenyl Ethers'' (Ref. 70), are available in the docket for this proposed rule and are summarized in Unit X.

B. Paperwork Reduction Act

This proposed rule does not impose any paperwork collection requirements that would require additional review and/or approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The information collection requirements related to the proposed SNUR (i.e., the submission of a SNUN) have been approved by OMB pursuant to PRA under OMB control number 2070–0038 (EPA ICR No. 1188). The information collection requirements related to the proposed test rule have been approved by OMB pursuant to the PRA under OMB control number 2070–0033 (EPA ICR No. 1139). Although the test rule information collection activities are approved, the additional burden associated with this test rule is not yet covered by the approved ICR until the final rule is effective. In the context of developing a new test rule, the Agency must determine whether the total annual burden covered by the approved ICR needs to be amended to accommodate the burden associated with the new test rule. If so, the Agency must submit an Information Correction Worksheet (ICW) to OMB and obtain OMB approval of an increase in the total approved annual burden in the OMB inventory.

The information collection activities related to export notification under TSCA section 12(b)(1) are already approved under OMB control number 2070–0030 (EPA ICR No. 0795). This rulemaking does not propose any new or changes to the export notification requirements, and is not expected to result in any substantive changes in the burden estimates for EPA ICR No. 0795 that would require additional review and/or approval by OMB.

Under PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information that is subject to approval under PRA, unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations codified in chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

To submit a SNUN, EPA estimates that the industry burden hours per chemical to be 92 hours (Ref. 70). The standard chemical testing program involves the submission of letters of intent to test (or exemption applications), study plans, semi-annual progress reports, test results, and administrative costs. For this proposed rule, EPA estimates the total industry burden hours for all three mixtures to be 37,074 hours (56,717 hours) for the low (high) cost scenario. Average industry burden hours per mixture are estimated to be 12,358 hours (18,906 hours) in the low (high) cost scenario (Ref. 70).

The estimated burden of the information collection activities related to export notification is estimated to average 1 burden hour for each mixture/country combination for an initial notification and 0.5 hours for each subsequent notification (Ref. 70). In estimating the total burden hours approved for the information collection activities related to export notification, the Agency has included sufficient burden hours to accommodate any

export notifications that may be required by the Agency's issuance of final test rules. As such, EPA does not expect to need to request an increase in the total burden hours approved by OMB for export notifications.

As defined by PRA and 5 CFR 1320.3(b), ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to: Review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments to EPA as part of your overall comments on this proposed action in the manner specified under **ADDRESSES**. In developing the final rule, the Agency will address any comments received regarding the information collection requirements contained in this proposed rule.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* after considering the potential economic impacts of this proposed rule on small entities, the Agency hereby certifies that this proposed rule does not have a significant adverse economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the economic analyses for this proposed rule (Refs. 70 and 71), which are summarized in Unit X., and copies of which are available in the docket for this proposed rule. The following is a brief summary of the factual basis for this certification.

Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined in accordance with RFA as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201.

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Based on the industry profile that EPA prepared as part of the economic analysis for this rulemaking (Ref. 71), EPA has determined that this proposed rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency's analysis presents only the estimated potential impacts on small business.

Two factors are examined in EPA's small entity impact analysis (Ref. 71) in order to characterize the potential small entity impacts of this proposed rule on small business:

- The size of the adverse economic impact (measured as the ratio of the cost-to-sales or cost-to-revenue).
- The total number of small entities that experience the adverse economic impact.

Section 601(3) of RFA establishes as the default definition of ''small business'' the definition used in section 3 of the Small Business Act, 15 U.S.C. 632, under which the SBA establishes small business size standards (13 CFR 121.201). For this proposed rule, EPA has analyzed the potential small business impacts using the size standards established under this default definition. The SBA size standards, which are primarily intended to determine whether a business entity is eligible for government programs and preferences reserved for small businesses (13 CFR 121.101), ''seek to ensure that a concern that meets a specific size standard is not dominant in its field of operation.'' (13 CFR 121.102(b)). See section 632(a)(1) of the Small Business Act. In analyzing potential impacts, the RFA recognizes that it may be appropriate at times to use an alternate definition of small business. As such, section 601(3) of RFA provides that an agency may establish a different definition of small business after consultation with the SBA Office of Advocacy and after notice and an opportunity for public comment. Even though the Agency has used the default SBA definition of small business to conduct its analysis of potential small business impacts for this proposed rule, EPA does not believe that the SBA size standards are generally the best size standards to use in assessing potential small entity impacts with regard to TSCA section 4(a) test rules.

The SBA size standard is generally based on the number of employees an entity in a particular industrial sector may have. For example, in the chemical manufacturing industrial sector (i.e., NAICS code 325 and NAICS code 324110), approximately 98% of the firms would be classified as small businesses under the default SBA definition. The SBA size standard for 75% of this industry sector is 500 employees, and the size standard for 23% of this industry sector is either 750; 1,000; or 1,500 employees. When assessing the potential impacts of test rules on chemical manufacturers, EPA believes that a standard based on total annual sales may provide a more appropriate means to judge the ability of a chemical manufacturing firm to support chemical testing without significant costs or burdens.

EPA is currently determining what level of annual sales would provide the most appropriate size cutoff with regard to various segments of the chemical industry usually impacted by TSCA section 4(a) test rules, but has not yet reached a determination. As stated above, therefore, the factual basis for the RFA determination for this proposed rule is based on an analysis using the default SBA size standards. Although EPA is not currently proposing to establish an alternate definition for use in the analysis conducted for this proposed rule, the analysis for this proposed rule also presents the results of calculations using a standard based on total annual sales (40 CFR 704.3). EPA is interested in receiving comments on whether the Agency should consider establishing an alternate definition for small business to use in the small entity impact analyses for future TSCA section 4(a) test rules, and what size cutoff may be appropriate.

The SBA has developed 6 digit NAICS code-specific size standards based on employment thresholds. These size standards range from 500 to 1,500 employees for the various 6 digit NAICS codes that are potentially impacted (Ref. 71). For a conservative estimate of the number of small businesses affected by this rule, the Agency chose an employment threshold of less than 1,500 employees for all businesses regardless of the NAIC-specific threshold to determine small business status.

For manufacturers and importers of decaBDE covered by this proposed rule, six parent companies (ultimate corporate entity, or UCE) were

identified and sales and employment data were obtained for companies where data were publicly available. Parent company sales data were used to identify companies that qualified as a ''small business'' for purposes of the RFA analysis. Based on the TSCA employment standard (1,500 employees or less), one company was identified as small. This company had cost-to-sales ratios of greater than 3% under both the low- and high-cost scenarios. Given these results, the Agency has determined that there is not a significant economic impact on a substantial number of small entities as a result of this proposed rule, if finalized.

The estimated cost of the TSCA section 12(b)(1) export notification, which, as a result of the final rule, would be required for the first export to a particular country of a mixture subject to the rule, is estimated to be $85.70 for the first time that an exporter must comply with TSCA section 12(b)(1) export notification requirements, and $26.86 for each subsequent export notification submitted by that exporter (Ref. 70). EPA has concluded that the costs of TSCA section 12(b)(1) export notification would have a negligible impact on exporters of the mixtures in the final rule, regardless of the size of the exporter.

Any comments regarding the impacts that this action may impose on small entities, or regarding whether the Agency should consider establishing an alternate definition of small business to be used for analytical purposes for future test rules and what size cutoff may be appropriate, should be submitted to the Agency in the manner specified under **ADDRESSES**.

D. Unfunded Mandates Reform Act

This action does not contain any Federal mandates for State, local, or Tribal Governments or the private sector under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538. EPA has determined that this regulatory action will not result in annual expenditures of $100 million or more for State, local, and Tribal Governments, in the aggregate, or for the private sector. For the private sector, it is estimated that the total aggregate costs of this proposed rule would be $15.1 million. The total annualized costs of this proposed rule to the private sector are estimated to be $5.34 and 5.75 million using a 3% and 7% discount rate over 3 years (high cost scenario). In addition, since EPA does not have any information to indicate that any State, local, or Tribal Government manufactures or processes the mixtures covered by this action such that this rule would apply directly to State, local, or Tribal governments, EPA has determined that this proposed rule would not significantly or uniquely affect small governments. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

E. Executive Order 13132

Under Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), EPA has determined that this proposed rule does not have ''federalism implications'' because it will not have substantial direct effects on the 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 the Executive Order. The proposed test rule would establish testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain mixtures. The proposed amendments to the SNUR would establish notification and submission requirements that apply to manufacturers (including importers) before certain chemicals may be manufactured or imported. Because EPA has no information to indicate that any State or local government manufactures or processes the chemical substances and mixtures covered by this action, the proposed SNUR-Test Rule does not apply directly to States and localities and will not affect State and local governments. Thus, Executive Order 13132 does not apply to this proposed rule.

F. Executive Order 13175

Under Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), EPA has determined that this proposed rule does not have tribal implications because it will not have any effect on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in the Executive Order. As indicated previously, EPA has no information to indicate that any tribal government manufactures or processes the chemical substances or mixtures covered by this action. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Executive Order 13045

EPA interprets Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. Nevertheless, the information obtained by this proposed rule could inform the Agency's decisionmaking process regarding mixtures to which children may be disproportionately exposed. The proposed test rule would establish testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain mixtures, and would result in the development of data about those mixture substances that can subsequently be used to assist the Agency and others in determining whether the mixtures in the proposed test rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks. Similarly, the proposed amendments to the SNUR would allow EPA to review available information to identify and take action to address potential risk because it would require manufacturers to submit notification and hazard information in the form of a SNUN to EPA before a chemical may be manufactured or imported.

H. Executive Order 13211

This action is not a ''significant energy action'' as defined in Executive Order 13211, entitled ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy as described in the Executive Order.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), 15 U.S.C. 272 note, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB,

explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The proposed test rule involves technical standards because it proposes to require the use of particular test methods. If the Agency makes findings under TSCA section 4(a), EPA is required by TSCA section 4(b) to include specific standards or test methods that are to be used for the development of the data required in the test rules issued under TSCA section 4. For some of the testing that would be required by the final rule, EPA is proposing the use of voluntary consensus standards issued by ASTM International which evaluate the same type of toxicity as the TSCA 799 test guidelines and OECD test guidelines, where applicable. Copies of the ASTM International standards referenced in the proposed regulatory text at 40 CFR 799.5350 (h)(2)(i) through (h)(2)(v) have been placed in the docket for this proposed rule where they are available for reading, but not copying. You may obtain copies of the ASTM International standards from the ASTM International, 100 Bar Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959, or by calling (877) 909–ASTM, or at: *http://www.astm.org.* In the final rule, EPA intends to seek approval from the Director of the Federal Register for the incorporation by reference of the ASTM International standards used in the final rule in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

EPA is not aware of any potentially applicable voluntary consensus standards which evaluate prenatal developmental toxicity, 2-generation reproductive toxicity, developmental neurotoxicity, immunotoxicity, or chronic toxicity/carcinogenicity, or screen for neurotoxicity which could be considered in lieu of the TSCA 799 test guidelines, 40 CFR 799.9370, 799.9380, 799.9630, 799.9780, 799.9430, and 799.9620, respectively, upon which the test standards in the proposed rule are based.

EPA is also not aware of any potentially applicable voluntary consensus standards which evaluate anaerobic aquatic metabolism, biodegradation in anaerobic digester sludge, or photolytic degradation in the indoor environment. As a result, EPA is proposing the use of three guidelines which are published in full at 40 CFR 795.25, 795.30, and 795.65.

The Agency invites comment on the potential use of voluntary consensus standards in the proposed test rule, and, specifically, invites the public to identify potentially applicable consensus standard(s) and to explain why such standard(s) should be used here.

J. Executive Order 12898

This proposed rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities that require special consideration by the Agency under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994). The Agency believes that the information collected under this proposed rule, if finalized, will assist EPA and others in determining the potential hazards and risks associated with the mixtures covered by this proposed rule. Although not directly impacting environmental justice-related concerns, this information will enable the Agency to better protect human health and the environment, including in low-income and minority communities.

K. Executive Order 12630

EPA has complied with Executive Order 12630, entitled ''Government Actions and Interference with Constitutionally Protected Property Rights (Takings)'' (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

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

40 CFR Part 721

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

40 CFR Part 795

Environmental protection, Chemicals, Hazardous substances, Health, Laboratories, Reporting and recordkeeping requirements.

40 CFR Part 799

Environmental protection, Chemicals, Hazardous substances, Laboratories, Reporting and recordkeeping requirements.

Dated: March 20, 2012.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721—[AMENDED]

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

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

2. Revise § 721.10000 to read as follows:

§ 721.10000 Certain polybrominated diphenylethers.

(a) *Chemical substances subject to significant new use reporting.* (1) The chemical substances identified as 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.), and nonabromodiphenyl ether (nonaBDE) (CAS No. 63936–56–1; benzene, pentabromo(tetrabromophenoxy)-), or any combination of these chemical substances resulting from a chemical reaction are subject to reporting under this section for the significant new uses described in paragraph (b)(1) of this section.

(2) Decabromodiphenyl ether (decaBDE) (CAS No. 1163–19–5; benzene, 1,1′-oxybis[2,3,4,5,6-pentabromo-) is subject to reporting under this section for the significant new uses described in paragraph (b)(2) of this section.

(b) *Significant new uses.* (1) The significant new uses for chemical substances identified in paragraph (a)(1) of this section are:

(i) Manufacture or import for any use on or after January 1, 2005.

(ii) Processing for any use after December 31, 2013.

(2) The significant new uses for the chemical identified in paragraph (a)(2) of this section are:

(i) Manufacturing, importing, or processing for any use after December 31, 2013.

(ii) [Reserved]

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

(1) *Revocation of certain notification exemptions.* The provisions of § 721.45(f) do not apply to this section. A person who imports or processes a chemical substance identified in this section as part of an article is not exempt from submitting a SNUN.

(2) [Reserved]

PART 795—[AMENDED]

3. The authority citation for part 795 continues to read as follows:

Authority: 15 U.S.C. 2603.

4. Add § 795.25 to subpart B to read as follows:

§ 795.25 Anaerobic aquatic metabolism of decabromodiphenyl ether.

(a) *Source.* OCSPP Series 835—Fate, Transport and Transformation Test Guidelines, OCSPP Test Guideline 835.4400—Anaerobic Aquatic Metabolism.

(b) *Introduction.* Chemicals can enter shallow or deep surface waters by a wide variety of routes including direct application, run-off, groundwater seepage drainage, waste disposal, industrial or agricultural effluent, and atmospheric deposition. This study plan describes a laboratory test method to assess transformation of the test substance in anaerobic aquatic sediment systems. ^{14}C-labeled decabromodiphenyl ether (decaBDE) shall be used to help ensure mass balance over time.

(c) *Objectives.* The objectives of the study are to:

(1) Measure the rate of transformation of the test substance, decaBDE.

(2) Identify and quantify all detectable degradation products.

(3) Identify and quantify the transformation pathways and rate of formation and degradation of intermediate products in the water, vapor, and sediment phases.

(4) Measure the distribution of the test substance and degradation products and intermediates within each phase in the test system.

(d) *Experimental design.* The test shall be conducted using six sediments and their associated waters at two concentrations (one trace; the other significantly higher), using ^{14}C-labeled test substance. Sediments shall be selected to include a variety of sediment types and shall include sediments known to contain polybrominated diphenyl ethers (PBDEs) and polychlorinated biphenyls (PCBs).

(1) Untreated live and killed controls and test substance-dosed biotic and abiotic systems shall be prepared for each sediment type. Based on published studies on the biodegradation of decaBDE in sediments, the half-life of decaBDE may be long. Tokarz (2008) reported sediment half-lives ranging from 6 to 50 years with an average of 14 years. Therefore, it is expected that untreated control, test substance-dosed live, and killed control systems will be incubated at approximately 20 °C for at least 36 months. However, the actual study duration shall be dependent on the analytical results for initial sampling periods. The total duration and interval for later samples may be changed depending on the observed rate of degradation.

(2) Duplicate test vessels for each treatment (i.e., treated and control) option, each test substance concentration and each sediment shall be sacrificed at appropriate time intervals. Test substance-dosed systems shall be used for quantification of parent material and degradation products. Untreated controls shall be used to determine background levels of the parent material and other PBDEs over time. Sampling shall be performed at time zero and seven times thereafter. Additional sample vessels may be prepared for additional analyses, if necessary. These vessels shall be sampled at the request of the sponsor in consultation with EPA. Additional untreated chambers shall be prepared for use as matrix fortification samples, water-sediment characterizations, and viability controls, as necessary.

(e) *Materials and methods*—(1) *OCSPP test guidelines.* The test system and study conditions are selected to comply with the OCSPP Series 835—Fate, Transport and Transformation Test Guidelines, OCSPP Test Guideline 835.4400 (at paragraph (k)(2) of this section) with appropriate modifications, if any, for decaBDE.

(2) *Test substance.* Information on the characterization of test, control or reference substances is required by Good Laboratory Practice (GLP) Standards and Principles. Ring-labeled, ^{14}C-labeled test substance shall be used. The sponsor is responsible for providing the test substance and verification that it has been characterized according to GLP requirements prior to its use in the study. If verification of GLP test substance characterization is not provided, it shall be noted in the compliance statement of the final report. The sponsor is responsible for all information related to the test substance including the following descriptions of the radiolabeled form of the test substance: Name, lot number, specific activity, radiochemical purity, sample form, solubility in water, and storage conditions. For the nonlabeled form of the test substance, the sponsor is responsible for the following descriptions: Name, lot number, purity, sample form, solubility in water, and storage conditions. The sponsor must agree to accept any unused test substance and/or test substance containers remaining at the end of the study.

(3) *Test substance preparation and administration.* A dispersal powder of test substance shall be prepared using an inert carrier (e.g., silica gel, quartz sand). Radiolabeled test substance shall be placed in a round bottom flask and dissolved with an appropriate solvent (i.e., tetrahydrofuran). The inert carrier shall be added to the flask and the solvent shall be evaporated using a rotary evaporator until the carrier is dry. This method of creating a dispersal powder is an appropriate route of administration for poorly water-soluble materials. Prior to the test, characteristics of sorption of the test substance on various carriers shall be evaluated.

(4) *Sediments and associated waters.* Sediments and associated water shall be obtained from at least six different sites known or suspected to be contaminated with PBDEs including, but not limited to decaBDE, and PCBs. Selection and approval of the collection sites shall be the responsibility of the study Sponsor and must be approved by EPA.

(i) Sediments shall be collected and handled using strict anaerobic procedures (for example see Loveley and Phillips (1986) at paragraph (k)(1) of this section). They shall be immediately sealed under nitrogen and transported and stored to maintain anaerobic conditions. All collection containers shall be stored in a nitrogen atmosphere until and during use. In addition, the containers shall be purged with nitrogen in the field after collection. The anaerobic sediment and associated waters shall be taken from the same location. The reduction potential or Redox potential (Eh) of the sediment shall be measured prior to collection and should be less than −150 millivolt (mV). The dissolved oxygen concentration of the overlying water shall be measured and should be less than 0.5 milligram/Liter (mg/L). The sediments and water shall be transported to the lab under anaerobic conditions. The sediments and associated waters may be stored at room temperature in sealed containers for up to 7 days. If longer storage is necessary, the sediments and associated waters

may be stored in sealed containers in a refrigerator for up to 4 weeks. Prior to use, the sediment shall be settled, then separated from the water by decanting. The settled sediment shall be wet-sieved using a 2 millimeter (mm) sieve. All handling of anaerobic sediment after collection and prior to testing shall be performed under a constant flow of nitrogen. At a minimum, the following properties of the sediment shall be determined:

(A) Particle size (i.e., percentage of sand, silt, and clay).

(B) Organic carbon content.

(C) Microbial biomass.

(D) Nitrate, sulfate and iron species.

(E) Percent water.

(F) Microbial biomass (fumigation extraction method).

(G) pH.

(H) Concentration of humic material.

(I) Concentrations of electron acceptors including methane, nitrate, nitrite, sulfate, sulfide, and iron species.

(ii) Similar characterization of the aqueous phase shall be performed prior to the start of the test. Prior to the test, resazurin shall be added to the water at a nominal concentration of 1 mg/L. The water shall be sparged with nitrogen until a light pink color is obtained and the dissolved oxygen concentration is less than 0.1 mg/L. Redox conditions in the test vessels shall be monitored by measuring dissolved hydrogen gas and Eh at each sampling. The test vessels shall be stored under nitrogen or other inert atmosphere throughout the test.

(5) *Test apparatus and conditions.* The test vessels shall be 1–L glass bottles sealed with butyl rubber septa and screw caps. Prior to beginning the study, the integrity of the test vessels and caps and their ability to maintain anaerobic conditions and prevent leakage of hydrogen (H_2) and other gas species for long periods shall be verified. The test vessels shall be identified by project number, test substance identity (ID), test concentration, and a unique identifier. The test vessels shall be incubated under an atmosphere of nitrogen at approximately 20 °C in an anaerobic glove box. Test temperatures shall be recorded each working day using a minimum/maximum thermometer. The need for venting of the test systems shall be evaluated prior to the start of the study. The procedure for venting and frequency shall be added to the study protocol, if necessary, prior to beginning the study.

(6) *Preparation of the test chambers and acclimation.* Test chambers shall be prepared in an anaerobic glove box or under a constant flow of nitrogen. Appropriate amounts of sediment and water shall be added to each test chamber so the resulting water: Sediment volume ratio is between approximately 1:3 and 1:4. The depth of the sediment layer shall depend upon the characteristics of the specific sediment. As a practical example, 200 gram (g) dry weight equivalent of sediment and 250 milliliter (mL) of associated water typically result in a sediment layer of 6.5 centimeter (cm) and a water layer of 2.5 cm. Amounts of sediment and water to be added may be determined prior to the preparation of the test chambers. The sediment/water samples shall be acclimated under the same conditions as in the test for at least 7 days prior to the start of the test.

(7) *Characterization of water-sediment systems.* The pH, total organic carbon concentration, dissolved oxygen concentration, Eh of the water and sediment (including microbial biomass), and other parameters/characteristics of the water-sediment media in the test vessels shall be measured at each sampling period noted in Table 1 of this paragraph. The sediment and water shall be kept anaerobic with an Eh lower than –100 mV.

TABLE 1—MEASUREMENTS AT VARIOUS STAGES OF THE TEST PROCEDURE

Parameter	Stage of test procedure					
	Field sampling	Post-handling	Start of acclimation	Start of test	During test	End of test
Water:						
Origin/source	X					
Temperature	X					
pH	X		X	X	X	X
Total organic carbon (TOC) concentration			X	X		X
Oxygen (O_2) concentration	X		X	X	X	X
Eh (Redox potential)			X	X	X	X
Sediment:						
Origin/Source	X					
Depth of layer	X					
pH		X	X	X	X	X
Particle size		X				
TOC		X	X	X		X
Microbial biomass		X		X		X
Eh	X		X	X	X	X

(8) *Application of the test substance.* Chambers containing the sediment/water systems shall be fortified at the start of the test with the test substance by applying the test material to the water layer. Methods for mixing the test material with sediment shall be evaluated prior to the start of the test. Methods to be evaluated shall include but are not limited to mixing by hand and the use of roller and tumbling mixers.

(9) *Preparation of abiotic systems.* Test substance-dosed abiotic controls shall be heat-sterilized (autoclaved three times at 120 °C for 60 minutes (min) on 3 consecutive days). A preliminary evaluation of the effects of heat sterilization on the test substance shall be conducted prior to the start of the study. If this method is found to be unsatisfactory, irradiation shall be used to sterilize the test systems.

(10) *Sample collection.* Proposed sampling intervals are day 0 and months 3, 6, 12, 18, 24, 30, and 36. If analysis of initial sampling results suggests more rapid degradation, the sampling interval may be modified after consultation with EPA using procedures specified in 40 CFR 790.50. The actual sampling intervals shall be documented in the

study records and in the final report. Duplicate test vessels for each treatment (i.e., treated and control) option, each test substance concentration and each sediment shall be sacrificed at appropriate time intervals.

(11) *Headspace analysis.* The headspace of the treated systems shall be analyzed for radiolabeled mineralization products including $^{14}CO_2$- hydrocarbons and $^{14}CO_2$ and $^{14}CH_4$ using purge and trap methods. At each sampling time prior to extraction of the test system, the septum shall be pierced using a needle connected to an appropriate trap and the vessel headspace shall be purged and trapped using a hydrocarbon trap followed by a mineralization trapping apparatus. The headspace within each of test chamber shall be continuously purged with a flow of nitrogen for a minimum of 1 hour and passed through a gas collection system consisting of a hydrocarbon trap and two sets of carbon dioxide (CO_2) traps and a combustion apparatus. The displaced gases shall initially pass through a sorption tube containing appropriate solid phase to trap any hydrocarbon degradation products present, then one empty bottle followed by two more bottles, each containing approximately 100 mL of 1.5 normal (N) potassium hydroxide (KOH) (CO_2 trapping solution), followed by another empty bottle. The gas shall be combined with a flow of oxygen and channeled through a quartz column that is packed with cupric oxide and maintained at approximately 800 °C in a tube furnace to combust methane to CO_2. Because Br may poison the surface of the cupric oxide, a preliminary experiment shall be run to test this, and the protocol adjusted if necessary. The gas exiting the combustion column shall be passed through an empty bottle followed by two additional CO_2 traps.

(12) *Sample processing and analysis for total radioactivity.* After purging, the overlying water shall be removed with minimal disturbance to the sediment and assayed for total radioactivity by liquid scintillation counting (LSC). Sediment samples shall be analyzed using combustion followed by LSC to determine the total amount of radioactivity associated with the sediment. Water and sediment samples shall be extracted following aggressive methods designed to extract the maximum amount of parent and degradation products from the sediment. These shall be evaluated and verified and approved by EPA prior to the start of the study. These methods shall be able to detect and quantify parent and degradates at least as well as those reported in the literature for PBDE analysis. The extraction method shall be robust, for example sequential extraction by solvent washing, soxhlet extraction, and supercritical fluid extraction, but shall not substantially change the test substance or degradation products, or the structure of the matrix itself. Solvent extracts and extracted solids shall be analyzed to determine total residual radioactivity. Untreated controls shall be extracted in the same manner as the test substance treated systems.

(13) *Characterization of extracted radioactivity.* Water and sediment extracts from the treated and untreated systems shall be analyzed for radiolabeled test substance and degradation products using high performance liquid chromatography (HPLC) and gas chromatography (GC) with mass spectrometry (MS) and radiochemical detection. Methods of analysis shall be verified prior to the start of the study and shall be at least as sensitive and accurate as reported in the literature for analysis of PBDEs and products.

(14) *Quantification of test substance and degradation products.* Water and sediment extracts from the untreated controls and treated systems shall be analyzed for quantification of BDE–209 (decaBDE) and trace level lower brominated diphenyl ethers (BDEs) including but not limited to BDE–202 (octaBDE), BDE–197 (octaBDE), and BDE–201 (octaBDE), as well as, brominated dibenzofurans. This analysis shall be conducted using gas chromatography/electron capture negative chemical ionization mass spectrometry (GC/ECNI–MS). Expected limits of detection (LOD) and quantitation (LOQ) for reasonably anticipated products shall be determined and reported to EPA prior to starting the test. All debromination products shall be measured in each sample, including background and time zero samples, and both biotic systems and abiotic (inhibited) controls.

(15) *Viability controls.* The assessment of the metabolic activity of untreated sediment/water systems shall be conducted within 1 week of each sampling interval. Duplicate incubation vessels for each sediment, which have been incubated in parallel under the same conditions, shall be dosed at approximately 100 milligram/kilogram (mg/kg) sediment dry weight with a combination of radiolabeled and nonlabeled substance suitable (i.e., glucose, benzoic acid) for viability determination. The methods and procedures used shall be documented in the study protocol prior to beginning the study.

(16) *Treatment of results.* Total mass balance of radioactivity shall be calculated at each sampling interval. Results shall be reported as total and percentage of added radioactivity. The behavior of the test substance and major and minor metabolites in the whole system as well as water, gas, and sediment compartments shall be evaluated. Regression analysis of the percentage of test substance and major metabolites as a function of time shall be performed and the time for 50% degradation (D_T50) and the time for 90% degradation (D_T90) of the test substance and major metabolites shall be calculated, when possible. The ratio of BDE–209 (decaBDE) to all detected degradation products shall be determined. All analytical results and all raw data shall be submitted to EPA, including the mass of each analyte at each time.

(f) *Records to be maintained.* Records to be submitted to EPA shall include, but are not limited to, the following:

(1) The original signed protocol and any amendments.

(2) Identification and characterization of the test substance as provided by sponsor.

(3) Experiment initiation and termination dates.

(4) Stock solution concentration calculations and solution preparation.

(5) Inoculum source and pretreatment data.

(6) Results of LSC and HPLC and/or other analysis (e.g., GC or GC/ECNI–MS).

(7) Temperature data recorded during test period.

(8) Copy of final report.

(g) *Final report.* A final report of the results of the study shall be prepared and submitted to EPA. The final report shall include, but is not limited to the following, when applicable:

(1) Name and address of facility performing the study.

(2) Dates on which the study was initiated and completed.

(3) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(4) Identification and characterization of the test substance as provided by Sponsor.

(5) A summary and analysis of the data and a statement of the conclusions drawn from the analysis.

(6) A description of the transformations and calculations performed on the data.

(7) A description of the methods used and reference to any standard method employed.

(8) A description of the test system.

(9) A description of the preparation of the test solutions, the testing

concentrations, and the duration of the test.

(10) A description of sampling and analytical methods, including level of detection, level of quantification, and references.

(11) A description of the test results including measured values for individual PBDE congeners and PBDF homolog group.

(12) A description of all circumstances that may affect the quality or integrity of the data.

(13) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel involved in the study.

(14) The signed and dated reports of each of the individual scientists or other professionals involved in the study, if applicable.

(15) The location where the raw data and final report are to be stored.

(16) A statement prepared by the Quality Assurance Unit listing the types of inspections, the dates that the study inspections were made and the findings reported to the Study Director and Management.

(17) A copy of all raw data including but not limited to chromatograms, lab notebooks and data sheets, etc.

(h) *Changes to the final report.* If it is necessary to make corrections or additions to the final report after it has been accepted, such changes shall be made in the form of an amendment issued by the Study Director. The amendment shall clearly identify the part of the study that is being amended and the reasons for the alteration. Amendments shall be signed and dated by the Study Director and Laboratory Quality Assurance Officer.

(i) *Changes to the protocol.* Planned changes to the protocol shall be in the form of written amendments signed by the Study Director and approved by the sponsor's representative and submitted to EPA using procedures in 40 CFR 790.50. Amendments shall be considered as part of the protocol and shall be attached to the final protocol. Any other changes shall be in the form of written deviations signed by the Study Director and filed with the raw data. All changes to the protocol shall be indicated in the final report. Changes to the test standard require prior approval from EPA using procedures in 40 CFR 790.55.

(j) *Good laboratory practices.* This study shall be conducted in accordance with the Good Laboratory Practice Standards (GLPs) for EPA and shall be consistent with the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice. Each study conducted by the testing facility shall be routinely examined by the facility's Quality Assurance Unit for compliance with GLPs, Standard Operating Procedures (SOPs), and the specified protocol. A statement of compliance with GLPs shall be prepared for all portions of the study conducted by the testing facility. The sponsor is responsible for compliance with GLPs for procedures that may be performed by other laboratories (e.g., residue analyses). Raw data for all work performed at the testing facility and a copy of the final report shall be filed by project number in archives located on the facility's site or at an alternative location to be specified in the final report.

(k) *Literature cited in this section.* (1) Lovley, D.R. and Phillips, E.J.P. Organic matter mineralization with reduction of ferric iron in anaerobic sediments. *Applied and Environmental Microbiology.* 51:683–689. 1986.

(2) EPA. OCSPP Series 835—Fate, Transport and Transformation Test Guidelines. OCSPP Test Guideline 835.4400—Anaerobic Aquatic Metabolism. EPA 712–C–08–019. October 2008.

(3) Tokarz, J.A., III; Ahn, M.Y.; Leng, J.; Filley, T.R.; and Nies, L. Reductive debromination of polybrominated diphenyl ethers in anaerobic-sediment and a biomimetic system. *Environmental Science & Technology.* 42:1157–1164. 2008.

5. Add § 795.30 to subpart B to read as follows:

§ 795.30 Biodegradation in anaerobic digester sludge of decabromodiphenyl ether.

(a) *Source.* OCSPP Series 835—Fate, Transport and Transformation Test Guidelines, OCSPP Test Guideline 835.3280—Simulation Test to Assess the Primary and Ultimate Biodegradability of Chemicals Discharged to Wastewater (see the Mineralization and Transformation in Anaerobic Digester Sludge unit).

(b) *Introduction.* Anaerobic digesters are commonly used in municipal wastewater treatment plants to stabilize various plant sludges. The digestion process reduces the amount of solids present in the sludge, destroys pathogenic bacteria and viruses, and removes the biodegradable portion of the sludge. A test for biodegradation during anaerobic sludge digestion is particularly relevant for sorbing substances, which partition to primary and secondary sludge. This test is useful for determining the concentration of a substance present in the sludge leaving a treatment plant as well as demonstrating the potential for anaerobic biodegradation. The test is characterized by reducing conditions, a high level of anaerobic biomass, and a level of test substance based on expected wastewater concentrations and partitioning behavior. The test is designed to assess the extent to which a substance can be degraded during anaerobic digestion. This protocol describes the methods employed in determining the biodegradability of the test substance in anaerobic digester sludge.

(c) *Objectives.* The objective of the study is to assess the potential for mineralization and transformation of decabromodiphenyl ether (decaBDE) in anaerobic digester sludge, and the quantity and identity of degradants (if present).

(d) *Experimental design.* The test shall be conducted using digester sludge from six different sources. Untreated control and test substance-dosed systems shall be prepared for each sludge source. Additionally, an abiotic control shall be prepared. The test substance treatment systems shall be dosed at two concentrations with ^{14}C-labeled test substance or a combination of radiolabeled and nonlabeled forms of the test substance. A very low concentration is used to establish environmentally relevant transformation kinetics; whereas a higher concentration is required to quantify product formation. The test systems shall be incubated at approximately 35 °C for approximately 10 months; e.g., approximately 300 days. Studies using anaerobic digester sludge normally involve incubating sludge for 60 days, which is about twice the normal residence time of sludge in anaerobic digesters. The extended length of this study is based on a half-life of the test substance in sludge without added primers of 1,400 days as reported by Gerecke *et al.* at paragraphs (k)(1) and (k)(2) of this section, and the general recommendation that test duration be at least 20% of the anticipated half-life.

(1) Based on the length of the study, bench-scale anaerobic reactor systems with semi-continuous feeding shall be used. A system consists of a 5 liter (L) glass reactor containing an anaerobic digester sludge mixture incubated at 35 °C and gas collection bladder. On a weekly basis, supernatant shall be removed from the reactor and replaced with an anoxic mixture of settled activated sludge solids (secondary sludge) and fresh anaerobic digester sludge solids.

(2) Test substance-dosed systems shall be used for quantification of parent

material and degradation products. Untreated controls shall be used to determine background levels of the parent material and other polybrominated diphenyl ethers. Sampling shall be performed at time zero and seven times thereafter.

(e) *Materials and methods.* The test system and study conditions are selected to comply with OCSPP Test Guideline 835.3280 at paragraph (k)(3) of this section.

(1) *Test substance.* Information on the characterization of test, control or reference substances is required by Good Laboratory Practice Standards (GLPs) and principles. The sponsor is responsible for providing verification that the test substance has been characterized according to GLP requirements prior to its use in the study. If verification of GLP test substance characterization is not provided, it shall be noted in the compliance statement of the final report. The sponsor is responsible for all information related to the test substance. Following are descriptions of the radiolabeled form of the test substance: Name, lot number, specific activity, radiochemical purity, radiolabel position, identities and percentages of all brominated diphenylethers, sample form, solubility in water, and storage conditions. Following are descriptions of the nonlabeled form of the test substance: Name, lot number, purity, identities and percentages of all brominated diphenyl ethers, sample form, solubility in water, and storage conditions. The sponsor must agree to accept any unused test substance and/or test substance containers remaining at the end of the study.

(2) *Test substance preparation and administration.* A dispersal powder of test substance shall be prepared using an inert carrier (e.g., silica gel, quartz sand). A combination of radiolabeled and nonlabeled test substance shall be placed in a round bottom flask and dissolved with an appropriate solvent (i.e., tetrahydrofuran). The inert carrier shall be added to the flask and the solvent shall be evaporated using a rotary evaporator until the sediment is dry. This method of creating a dispersal powder is an appropriate route of administration for poorly water-soluble materials. Prior to the test, the adsorption characteristics of the test substance on various carriers shall be evaluated.

(3) *Test inoculum.* Anaerobic digester sludge shall be obtained from at least six different sites. Selection of the collection sites shall be the responsibility of the study Sponsor, with review and final approval by the EPA. All collection containers shall be purged with nitrogen and immediately sealed prior to use. In addition, purging the containers with nitrogen in the field after collection shall be performed if possible. Sludge shall be screened using a 2 millimeter (mm) mesh screen to remove debris and may be held for up to 7 days prior to the start of the test. The total solids level of the digester sludge shall be measured and should be in the range of 4–6% (40,000–60,000 (milligrams (mg)/L). On the day the test is to start, the inoculum shall be diluted with mineral salts solution to an initial solids level of approximately 25,000 mg/L. If the solids concentration is too low, the solids can be allowed to settle, the supernatant decanted, and the sludge resuspended in mineral salts solution. A final solids level and pH shall then be determined. All handling of anaerobic sludge after collection and prior to testing shall be performed under a constant flow of nitrogen or in an anaerobic glove box.

(4) *Mineral salts solution.* A mineral salts solution shall be prepared using high quality water. All chemicals used in the preparation of the solution shall be reagent grade or better, if available. The solution shall be autoclaved for 30 min and allowed to cool overnight in an anaerobic chamber or under an anaerobic atmosphere. The solution shall contain the following constituents per L of high quality water, as set forth in Table 1 of this paragraph:

TABLE 1—CONSTITUENTS OF HIGH QUALITY WATER

Chemical constituent	Gram/liter
Anhydrous potassium dihydrogen phosphate (KH_2PO_4)	0.27
Disodium hydrogen phosphate dodecahydrate ($Na_2HPO_4{\cdot}12H_2O$)	1.12
Ammonium chloride (NH_4Cl)	0.53
Calcium chloride dihydrate ($CaCl_2{\cdot}2H_2O$)	0.075
Magnesium chloride hexahydrate ($MgCl_2{\cdot}6H_2O$)	0.10
Iron (II) chloride tetrahydrate ($FeCl_2{\cdot}4H_2O$)	0.02

(5) *Digester sludge feed.* The source guideline for this study, OCSPP Test Guideline 835.3280, has no provision for feeding. However, due to the length of the study, periodic feeding is needed. The anaerobic digester sludge shall be fed an anoxic mixture of settled activated sludge solids (secondary sludge) and fresh anaerobic digester sludge solids. Activated sludge shall be collected from a sewage treatment plant receiving waste from predominantly domestic sources. The sludge shall be sieved using a 2 mm mesh screen to remove debris, then dewatered using filtration. A feed solution shall be prepared at a sludge solids concentration of approximately 50 gram (g)/L using mineral salts solution. The feed solution shall be stored under nitrogen and refrigerated. In addition, freshly prepared solutions should be stored for at least 1 week prior to use.

(6) *Test apparatus and conditions.* The test reactors shall be 5–L glass bottles and shall be identified by project number, test substance ID, test concentration, and unique identifier. The reactors shall be sealed with black rubber stoppers with stopcock ports and connections used for the addition of feed sludge, sample removal and gas collection bag. The test reactors shall be incubated at 35 ± 3 °C and in the dark. Reactor contents shall be mixed for at least 10 min. every day using a magnetic stirrer and test temperatures shall be measured each working day using a min/max thermometer.

(7) *Preparation of the test reactors.* Working under a constant flow of nitrogen, 1.5 L of anaerobic digester sludge (4–6% solids), mineral salts solution to achieve an initial solids level of approximately 25,000 mg/L, and test substance dispersal powder shall be combined in the reactor. The headspace in the reactor shall be purged with nitrogen, then the reactor sealed and transferred to the incubator.

(8) *Reactor maintenance.* The contents of the reactors (anaerobic sludge and mineral salts solution at a solids level of approx. 25,000 mg/L) shall be fed on a weekly basis. Prior to mixing, approximately 75 milliliter (mL) of supernatant shall be removed from the reactor and replaced with an equal volume of digester sludge feed solution.

The solids added in this way are expected to be approximately equivalent to 10% of the total digester solids reasonably expected to be present. The amount of digester sludge feed solution added may be adjusted based on the observed level of gas production. The activity of the supernatant removed shall be measured using liquid scintillation counting (LSC).

(9) *Abiotic control.* An abiotic control shall be included. Biological activity is inhibited in the abiotic control, which is used for estimating mineralization by difference, establishing extraction efficiency and recovery of the test substance, and quantifying other loss processes such as hydrolysis, oxidation, volatilization or sorption to test apparatus. The preparation of the abiotic system is typically performed using a combination of chemical and heat sterilization. A proven approach is to add mercuric chloride (1 g/L) to the sludge, which is then autoclaved for at least 90 min. Typically the volume of medium is less than or equal to half the volume of the container being autoclaved (e.g., 500 ml sludge in a 1–L container). After cooling, the pH of the abiotic system should be measured and adjusted to match that of the biologically active system. Alternative approaches to deactivate the system can also be used.

(10) *Sample collection schedule.* Proposed sampling times are day 0 and months 1, 2, 4, 6, 8, 9, and 10, but the actual sampling times shall be documented in the study records and in the final report. The timing of the sampling may be altered at the discretion of the Study Director, and more frequent sampling may be conducted. Based on the analytical method that is selected, the minimum change in the initial concentration of the test substance that can be detected shall be estimated, then applied to help determine the sampling schedule and assess the need for additional samples. As an example, if the minimum reliably detectable change is 5% relative to the starting concentration, and if this has already occurred at the first suggested sampling time (1 month), then measurements should be made monthly up to 10 months. The solids concentration of sludge shall be measured at each sampling interval.

(11) *Evolved gas and headspace analysis.* The evolved gas and headspace of the treated systems shall be analyzed for radiolabeled mineralization products ($^{14}CO_2$ and $^{14}CH_4$). At intervals throughout the study, evolved gases shall be analyzed by passing the contents of the gas collection bags through the mineralization apparatus described in this paragraph. Reactor headspace analysis shall be performed at the end of the study. The headspace gases within the reactor shall be continuously purged with a flow of nitrogen for a minimum of 2 hours and passed through a gas collection system consisting of two sets of carbon dioxide (CO_2) traps and a combustion apparatus. The displaced gases shall initially pass through one empty bottle followed by two bottles each containing approximately 100 mL of 1.5 normal (N) potassium hydroxide (KOH) (CO_2 trapping solution) followed by another empty bottle. The gas shall be combined with a flow of oxygen and channeled through a quartz column that is packed with cupric oxide and maintained at approximately 800 °C in a tube furnace to combust methane to CO_2. The gas exiting the combustion column shall be passed through an empty bottle followed by two additional CO_2 traps.

(12) *Sample processing and analysis for total radioactivity.* (i) Treated digester sludge samples shall be analyzed using a combination of LSC and combustion followed by LSC to determine the total amount of radioactivity associated with the sludge. At each sampling interval, replicate (minimum 3) one mL aliquots of well mixed digester sludge shall be placed into microcentrifuge tubes and centrifuged at 10,000 x g for 15 min. The activity associated with the supernatant shall be measured by LSC. Solids shall be analyzed using combustion followed by LSC to determine the total amount of radioactivity associated with the sludge solids.

(ii) Digester sludge shall be extracted following methods evaluated and verified prior to the start of the study. These methods shall be able to detect and quantify parent and degradates at least as well as those reported in the literature for polybrominated diphenyl ether (PBDE) analysis. The extraction method shall be robust, for example sequential extraction by solvent washing, soxhlet extraction and supercritical fluid extraction, but shall not substantially change the test substance or degradation products, or the structure of the matrix itself. Solvent extracts and extracted solids shall be analyzed to determine total radioactivity. Untreated controls shall be extracted in the same manner as the test substance-treated systems, but will not be analyzed for radioactivity.

(13) *Characterization of extracted radioactivity.* Digester sludge extracts from the treated systems shall be analyzed for radiolabeled test substance and degradation products using high performance liquid chromatography with radiochemical detection. Methods of analysis shall be verified prior to the start of the study.

(14) *Quantification of test substance and degradation products.* (i) Digester sludge extracts from the untreated control, abiotic control and treated systems shall be analyzed for quantification of BDE–209 (decaBDE) and trace level lower brominated diphenyl ethers (BDE) including but not limited to BDE–202 (octaBDE), BDE–197 (octaBDE), and BDE–201 (octaBDE), as well as brominated dibenzofurans. (ii) Methods for analysis shall be evaluated and verified prior to the start of the study and shall reference available best practice techniques for the type of analyte. This analysis shall be conducted using gas chromatography/electron capture negative chemical ionization mass spectrometry (GC/ECNI–MS). Expected limits of detection (LOD) and quantitation (LOQ) for reasonably anticipated products shall be determined and reported to EPA prior to starting the test.

(iii) All debromination products shall be measured in each sample, including background and time zero samples, and both biotic systems and abiotic (inhibited) controls.

(15) *Treatment of results.* Total mass balance of radioactivity shall be calculated at each sampling interval. Results shall be reported as a percentage of added radioactivity. Regression analysis of the percentage of test substance and major metabolites as a function of time shall be performed and the time for 50% degradation (D_T50) and the time for 90% degradation (D_T90) of the test substance and major metabolites shall be calculated, when appropriate. The ratio of BDE–197 (octaBDE) to BDE–201 (octaBDE) shall be determined, if present.

(f) *Records to be maintained.* Records to be maintained shall include, but are not limited to, the following:

(1) The original signed protocol and any amendments.

(2) Identification and characterization of the test substance as provided by sponsor.

(3) Experiment initiation and termination dates.

(4) Stock solution concentration calculations and solution preparation.

(5) Inoculum source and pretreatment data.

(6) Results of LSC and/or other (e.g., GC/ECNI–MS) analyses.

(7) Temperature data recorded during test period.

(8) Copy of final report.

(g) *Final report.* A final report of the results of the study shall be prepared by

the testing facility. The final report shall include, but is not limited to the following, when applicable:

(1) Name and address of facility performing the study.

(2) Dates on which the study was initiated and completed.

(3) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(4) Identification and characterization of the test substance as provided by Sponsor.

(5) A summary and analysis of the data and a statement of the conclusions drawn from the analysis.

(6) A description of the transformations and calculations performed on the data.

(7) A description of the methods used and reference to any standard method employed.

(8) A description of the test system.

(9) A description of the preparation of the test solutions, the testing concentrations, and the duration of the test.

(10) A description of sampling and analytical methods, including level of detection, level of quantification, and references.

(11) A description of the test results including measured values for individual PBDE congeners and polybrominated dioxin/furan (PBDF) homolog group.

(12) A description of all circumstances that may affect the quality or integrity of the data.

(13) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel involved in the study.

(14) The signed and dated reports of each of the individual scientists or other professionals involved in the study, if applicable.

(15) The location where the raw data and final report are to be stored.

(16) A statement prepared by the Quality Assurance Unit listing the types of inspections, the dates that the study inspections were made and the findings reported to the Study Director and Management.

(17) A copy of all raw data including but not limited to chromatograms, lab notebooks, and data sheets etc.

(h) *Changes to the final report.* If it is necessary to make corrections or additions to the final report after it has been accepted, such changes shall be made in the form of an amendment issued by the Study Director. The amendment shall clearly identify the part of the study that is being amended and the reasons for the alteration. Amendments shall be signed and dated by the Study Director and Laboratory Quality Assurance Officer.

(i) *Changes to the protocol.* Planned changes to the protocol shall be in the form of written amendments signed by the Study Director and approved by the sponsor's representative and submitted to EPA using procedures in 40 CFR 790.50. Amendments shall be considered as part of the protocol and shall be attached to the final protocol. Any other changes shall be in the form of written deviations signed by the Study Director and filed with the raw data. All changes to the protocol shall be indicated in the final report. Changes to the test standard require prior approval from EPA using procedures in 40 CFR 790.55.

(j) *Good laboratory practices.* This study shall be conducted in accordance with GLPs for EPA and shall be consistent with the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice. Each study conducted by the testing facility shall be routinely examined by the facility's Quality Assurance Unit for compliance with GLPs Standard Operating Procedures (SOP), and the specified protocol. A statement of compliance with GLPs shall be prepared for all portions of the study conducted by the testing facility. The sponsor is responsible for compliance with GLPs for procedures that may be performed by other laboratories (e.g., residue analyses). Raw data for all work performed at the testing facility and a copy of the final report shall be filed by project number in archives located on the facility's site or at an alternative location to be specified in the final report.

(k) *Literature cited in this section.*

(1) Gerecke, A.C.; Hartmann, P.C.; Heeb, N.V.; Kohler, H–P.E.; Giger, W.; Schmid, P.; Zennegg, M.; and Kohler, M. Anaerobic degradation of decabromodiphenyl ether. *Environmental Science & Technology*. 39:1078–1083. 2005.

(2) Gerecke, A.C.; Giger, W.; Hartmann, P.C.; Heeb, N.V.; Kohler, H–P.E.; Schmid, P.; Zennegg, M.; and Kohler, M. Anaerobic degradation of brominated flame retardants in sewage sludge. *Chemosphere.* 64:311–317. 2006.

(3) EPA. OCSPP Series 835—Fate, Transport and Transformation Test Guidelines. OCSPP Test Guideline 835.3280—Simulation Test to Assess Primary and Ultimate Biodegradability of Chemicals Discharged to Wastewater (see the Mineralization and Transformation in Anaerobic Digester Sludge unit). 2008.

6. Add § 795.65 to subpart B to read as follows:

§ 795.65 Photolytic degradation in the indoor environment of decabromodiphenyl ether.

(a) *Source.* EPA, based on a method in an article entitled ''Photodegradation of Decabromodiphenyl Ether in House Dust by Natural Sunlight'' by Stapleton and Dodder reported in *Environmental Toxicology and Chemistry*. 27:306–312. 2008.

(b) *Introduction.* Recent studies have found elevated levels of polybrominated diphenylethers (PBDEs) in indoor air and house dust, suggesting the presence of indoor sources. It has also been observed that photolytic degradation of BDE–209 (decabromodiphenyl ether (decaBDE)) can take place in house dust when exposed to sunlight, forming debrominated products. It is not well understood, however, how PBDEs are transferred from the sources to indoor media (e.g., house dust) and whether photolytic degradation can occur under indoor lighting conditions. Most Americans spend over 85% of their time indoors. Elderly and young children tend to stay indoors even longer. Therefore, understanding indoor exposure is a key to exposure assessment and risk reduction. This guideline describes test methods to characterize potential sources of these emerging contaminants in the indoor environment.

(c) *PBDE off-gassing and photolytic degradation*—(1) *Objectives.* The objectives of this first part of the investigation are to determine:

(i) If PBDEs can migrate out of plastics/fabrics by volatilization.

(ii) Determine if photolytic degradation can take place on the surfaces of plastics and fabrics and quantify these processes.

(2) *Experimental design.* Accelerated aging tests shall be conducted in an environmental chamber. PBDE off-gassing will be determined by taking integrated air samples and potential photolytic degradation by taking wipe samples on the surface of test specimens. The chamber system must meet the following criteria:

(i) It has uniform ultraviolet A (UV–A) light irradiation sources.

(ii) The light intensity is no less than 5 Watts per square meter (W/m^2) incident to the test specimen.

(iii) The chamber has a constant air flow to allow air sampling.

(iv) The moisture content in the air flow is no less than 10 gram/meter cubed (g/m^3) (i.e., 50% relative humidity at 23 °C).

(v) The light source shall be operated according to ASTM G 151–09, Standard

Practice for Exposing Nonmetallic Materials in Accelerated Test Devices that Use Laboratory Light Sources.

(vi) Window-filtered sunlight shall be simulated according to ASTM D 4459–06, Standard Practice for Xenon-Arc Exposure of Plastics Intended for Indoor Applications. ASTM D 4459–06 is intended to simulate the effects produced by exposure to solar irradiation through glass. A chamber system conforming to ASTM D 4459–06 can provide spectral irradiance of approximately 0.3 W/m²/nanometer (nm) at 340 nm (i.e., peak emission) when operated in the continuous light-on mode without water spray. This light source satisfies the light intensity requirement of 5 W/m² as specified in paragraph (c)(2)(ii) of this section.

(3) *Materials and methods*—(i) *Test specimens.* (A) The test specimens shall include BDE–209-containing high impact polystyrene (HIPS) coupons and commercial fabric swatches. HIPS coupons shall be prepared using typical commercial extrusion and injection molding conditions for the manufacture of HIPS television cabinet backs. High purity (99% or greater) BDE–209 shall be used in making the coupons. The high purity will assist in detection of any lower brominated diphenyl ethers (BDEs) formed as degradants. The coupons shall be manufactured using high impact polystyrene resin, BDE–209 (12% by weight (wt)), antimony oxide (4% by wt), and the typical additives of television cabinet backs (UV inhibitors, antioxidants, colorants, etc.). A total of 36 coupons shall be prepared for tests listed in Table 1 of paragraph (c)(3)(ii) of this section. Each coupon shall have an area of at least 100 centimeter squared (cm²) (one-side).

(B) Fabric swatches shall be obtained from a commercial source, depending on availability, or manufactured using 99+% BDE–209 as the flame retardant. A total of 36 swatches shall be prepared for tests listed in Table 1 of paragraph (c)(3)(ii) in this section. Each swatch shall have an area of at least 100 cm² (one-side).

(ii) *Test matrix.* A total of six tests listed in Table 1 of this paragraph shall be conducted.

TABLE 1—TEST MATRIX FOR POLYBROMINATED DIPHENYLETHER (PBDE) OFF-GASSING AND PHOTOLYTIC DEGRADATION

Test No.	Material	Ultraviolet (UV) light	Durations (hours)
1	High Impact Polystyrene (HIPS) coupons	on	300, 600, 900
2	HIPS coupons	on	300, 600, 900
3	HIPS coupons	off	300, 600, 900
4	Fabric swatches	on	300, 600, 900
5	Fabric swatches	on	300, 600, 900
6	Fabric swatches	off	300, 600, 900

(iii) *Test procedure.* (A) Prepare 12 identical coupons (or swatches) for an aging test.

(B) Put aside 3 coupons (or swatches) for taking wipe samples. These wipe samples represent no-exposure conditions. To take a wipe sample of fabric, use the California roller method per Ross, *et al.* (1991) in paragraph (j)(5) of this section.

(C) Clean the chamber by wiping the interior surfaces with ethanol-soaked paper towel.

(D) Take two wipe samples for chamber walls (100 cm² area each).

(E) Place three passive air samplers (PUF disks) on supporting cradle about half chamber height and away from inlet air.

(F) Place the remaining 9 coupons (or swatches) on chamber floor or rack, depending on the type of chamber used.

(G) Close chamber door and, for light-on tests, turn on the UV light, and start the test.

(H) At 300 elapsed hours, turn off the UV light and then open the chamber door.

(I) Remove three coupons (or swatches) from the chamber for taking wipe samples.

(J) Remove one PUF disk for determination of time-integrated air concentrations of BDE–209, lower PBDE congeners, and polybrominated dibenzofurans (PBDFs).

(K) Close chamber door and turn on the UV light.

(L) At 600 elapsed hours, turn off the UV light and then open the chamber door.

(M) Remove three coupons (or swatches) from the chamber for taking wipe samples.

(N) Remove one PUF disk for determination of time-integrated air concentrations of BDE–209, lower PBDE congeners, and PBDFs.

(O) Close chamber door and turn on the UV light.

(P) At 900 elapsed hours, turn off the UV light and then open the chamber door.

(Q) Remove the last three coupons (or swatches) from the chamber for taking wipe samples.

(R) Remove one PUF disk for determination of time-integrated air concentrations of BDE–209, lower PBDE congeners, and PBDFs.

(S) Take two wipe samples for chamber walls (100 cm² area each).

(iv) *Sampling and analytical methods*—(A) *Surface sampling for HIPS coupons.* ASTM D 6661–10, Standard Practice for Field Collection of Organic Compounds from Surfaces Using Wipe Sampling, or an equivalent method, shall be used for surface sampling on HIPS coupons. The wipe samples shall be extracted (Stapleton *et al.* (2008) in paragraph (j)(6) of this section) and then analyzed for BDE–209, lower PBDE congeners, and PBDFs.

(B) *Surface sampling for fabric swatches.* A modified ASTM D 6661–10 method, as described in this paragraph, shall be used for surface sampling on fabric swatches. Modified procedure: Use 10×10 cm² heavy filter paper instead of cotton gauze pad; place the fabric swatch on pre-cleaned flat surface; place the solvent-wetted filter paper on the fabric swatch; place a 10×10 cm² stainless steel (or aluminum) plate on the paper filter; add additional weights on the plate such that the total weight is 2 pounds (lb); wait for 5 minutes; remove plate and weights; extract the paper filter.

(C) *Air sampling.* Time-integrated air samples shall be collected by using passive air samplers (PUF disks; see Harrad, et al, 2006 (in paragraph (j)(4) of this section) and references therein).

(D) *Analytical method.* High sensitivity is a key factor in selecting the analytical method. A method based on chromatography/mass spectrometry in electron capture negative ionization mode (GC/MS–ECNI) shall be used. The analytes shall include BDEs and PBDFs as listed in Bezares-Cruz *et al.* 2004 in paragraph (j)(2) of this section; Stapleton and Dodder 2008 in paragraph (j)(7) of this section; and Geller *et al.* 2006 in paragraph (j)(3) of this section.

(d) *Accelerated aging tests for HIPS coupons and fabric swatches with house dust*—(1) *Objectives.* The objectives of this, second part of the investigation are to determine:

(i) If PBDEs or PBDF can migrate from plastics/fabrics to settled house dust by direct partitioning.

(ii) If the particle-bound PBDEs are subject to photolytic degradation and quantify these processes.

(2) *Experimental design.* (i) HIPS coupons and used TV cabinets shall be subjected to accelerated aging in a test chamber in the presence of standard house dust, National Institute of Standards Technology, Standard Reference Material 2583 (NIST SRM 2583), free of BDE–209. The requirements for the test chamber are the same as described in paragraph (c)(2) of this section, unless indicated otherwise. This investigation shall be performed as described in paragraph (c) of this section with the exception of the addition of pre-cleaned house dust to the surface of the HIPS coupons and fabric swatches. Accelerated aging under simulated sunlight and fluorescent lighting, exposure durations, and sample collections shall be identical to those described in paragraph (c) of this section, with the addition of collection and analysis of the added house dust. This experiment requires that the coupons are sufficiently large (500 cm^2 or larger) that there is enough house dust for sampling while the dust layer is not too thick.

(ii) The house dust can be deposited on test specimens by using a separate dust deposition chamber or spiked manually on test specimens (Ashley *et al.,* 2007 in paragraph (j)(1) of this section). The test samples and dust shall then be exposed to accelerated aging for 300, 600, and 900 hours, the dust collected by vacuum, and analyzed for content of BDE–209, lower BDEs, and PBDFs.

(3) *Materials and methods*—(i) *Test specimens.* (A) HIPS coupons and used TV cabinets shall be used in this investigation. The procedure for preparing HIPS coupons described in paragraph (c)(3)(i)(A) of this section shall be followed except that the size of the coupon shall be at least 500 cm^2, such that an adequate amount of house dust can be spiked on the surface without forming a thick layer of dust. The target dust load is between 0.5 and 1 milligram (mg)/cm^2 coupon.

(B) Two used TV sets shall be vacuumed and the dust analyzed for PBDEs and PBDFs with the methods described by Takigami, *et al.* (2008) in paragraph (j)(9) of this section. Samples of the backcover shall be analyzed by Fourier transform infrared spectroscopy (FT–IR) to identify the plastic and the flame retardant. Ground samples shall be prepared for determination of PBDE and PBDF content.

(ii) *Test matrix.* A total of seven tests listed in Table 2 of this paragraph shall be conducted.

TABLE 2—TEST MATRIX FOR PBDE MIGRATION FROM SOURCE TO HOUSE DUST AND PHOTOLYTIC DEGRADATION

Test No.	Material	Ultraviolet (UV) light	Durations (hours)
1	High impact polystyrene (HIPS) coupons	Off	300, 600, 900
2	HIPS coupons	Off	300, 600, 900
3	HIPS coupons	On	300, 600, 900
4	TV cabinet 1a	Off	600
5	TV cabinet 1b	On	600
6	TV cabinet 2a	Off	600
7	TV cabinet 2b	On	600

(iii) *Test procedure for HIPS coupons.* (A) Prepare HIPS coupons.

(B) Determine PBDE content in test specimens by preparing and analyzing ground samples.

(C) Evenly spike approximately 0.25 to 0.5 gram (g) NIST standard house dust, SRM 2583, on each of the six HIPS coupons. This can be done either manually (Ashley *et al.* 2007 in paragraph (j)(1) of this section) or in a particle deposition chamber. The targeted dust load is between 0.5 and 1 mg/cm^2 coupon.

(D) Clean the test chamber by wiping the interior surfaces with ethanol-soaked paper towel.

(E) Take two wipe samples from chamber walls (100 cm^2 area each); the PBDE and PBDF content shall be below the method detection limit.

(F) Open the chamber door, place six coupons on chamber floor (or rack), and close the door.

(G) Set the chamber temperature at 55 °C and air change rate between 0.3 to 0.5 air changes per hour, or the lowest air change flow the chamber system allows.

(H) Close chamber door and start the test.

(I) At 300 elapsed hours, remove 2 coupons for dust sampling, restart chamber.

(J) Repeat the above step at 600 and 900 elapsed hours.

(iv) *Test procedure for used TV cabinets.* (A) Open the TV set and collect settled dust from the interior surfaces (see Takigami *et al.* (2008) in paragraph (j)(9) of this section).

(B) Determine the PBDE and PBDF content in the settled dust.

(C) Clean the backcover by soft cloth and air jet; do not clean it with solvents.

(D) Determine PBDE and PBDF content in test specimen by preparing and analyzing ground samples.

(E) Divide the backcover evenly into two pieces (designated a and b in Table 2 of paragraph (d)(3)(ii) of this section), one for test with light and the other without light.

(F) For each half, cut flat areas into rectangular panels for testing; the total area of the flat panels shall be no less than 1,000 cm^2.

(G) Evenly spike NIST standard house dust, SRM 2583, on the interior side of the backcover panels for a targeted dust load between 0.5 to 1 mg/cm^2.

(H) Clean the test chamber by wiping the interior surfaces with ethanol-soaked paper towel.

(I) Take two wipe samples from chamber walls (100 cm^2 area each); the PBDE and PBDF content shall be below the method detection limit.

(J) Open the chamber door, place the half backcover with NIST standard house dust, SRM 2583, on chamber floor (or rack).

(K) Set the chamber temperature at 55 °C and air change rate between 0.3 to 0.5 air changes per hour, or the lowest air change flow the chamber system allows.

(L) Close chamber door and start test.

(M) At 600 elapsed hours, remove the backcover panels from chamber, collect and extract dust samples.

(v) *Sampling and analytical methods.* Dust samples shall be collected by micro-vacuuming (Ashley *et al.* (2007) in paragraph (j)(1) of this section or ASTM D 7144–05a (2011)). The method described by Stapleton and Dodder

(2008) in paragraph (j)(7) of this section shall be used to determine the PBDE content in dust samples. Wipe and air sampling methods are described in paragraph (c)(3)(iv) of this section.

(e) *Records to be maintained.* Records to be submitted to EPA shall include, but are not limited to, the following:

(1) The original signed protocol and any amendments.

(2) Identification and characterization of the test substance as provided by Sponsor.

(3) Experiment initiation and termination dates.

(4) Stock solution concentration calculations and solution preparation, if applicable.

(5) Results of liquid scintillation counter (LSC) and high performance liquid chromatography (HPLC) and/or other analysis (e.g., gas chromatography (GC) or GC/ECNI–MS).

(6) Data on temperature, air flow and inlet air moisture content.

(7) Copy of final report.

(f) *Final report.* A final report of the results of the study shall be prepared and submitted to EPA. The final report shall include, but is not limited to the following, when applicable:

(1) Name and address of facility performing the study.

(2) Dates on which the study was initiated and completed.

(3) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(4) Identification and characterization of the test substance as provided by sponsor.

(5) A summary and analysis of the data and a statement of the conclusions drawn from the analysis.

(6) A description of the transformations and calculations performed on the data.

(7) A description of the methods used and reference to any standard method employed.

(8) A description of the test system and test chamber(s), including chamber type, dimensions and light source; and spectral irradiance inside the chamber if applicable.

(9) A description of the preparation of the test solutions, the testing concentrations, and the duration of the test.

(10) A description of sampling and analytical methods, including level of detection, level of quantification, and references.

(11) A description of test specimens and test matrix.

(12) A description of the test results including measured values for individual PBDE congeners and PBDF homolog group for each matrix, exposure condition, and exposure duration.

(13) A description of all circumstances that may affect the quality or integrity of the data.

(14) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel involved in the study.

(15) The signed and dated reports of each of the individual scientists or other professionals involved in the study, if applicable.

(16) The location where the raw data and final report are to be stored.

(17) A statement prepared by the Quality Assurance Unit listing the types of inspections, the dates that the study inspections were made and the findings reported to the Study Director and Management.

(18) A copy of all raw data including but not limited to chromatograms, lab notebooks and data sheets, etc.

(g) *Changes to the final report.* If it is necessary to make corrections or additions to the final report after it has been accepted, such changes shall be made in the form of an amendment issued by the Study Director. The amendment shall clearly identify the part of the study that is being amended and the reasons for the alteration. Amendments shall be signed and dated by the Study Director and Laboratory Quality Assurance Officer.

(h) *Changes to the protocol.* Planned changes to the protocol shall be in the form of written amendments signed by the Study Director and approved by the sponsor's representative and submitted to EPA using procedures in 40 CFR 790.50. Amendments shall be considered as part of the protocol and shall be attached to the final protocol. Any other changes shall be in the form of written deviations signed by the Study Director and filed with the raw data. All changes to the protocol shall be indicated in the final report. Changes to the test standard require prior approval from EPA using procedures in 40 CFR 790.55.

(i) *Good laboratory practices.* This study shall be conducted in accordance with Good Laboratory Practice Standards (GLPs) for EPA and shall be consistent with Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice. Each study conducted by the testing facility shall be routinely examined by the facility's quality assurance unit for compliance with GLPs, Standard Operating Procedures (SOP), and the specified protocol. A statement of compliance with GLPs shall be prepared for all portions of the study conducted by the testing facility. The sponsor is responsible for compliance with GLPs for procedures that may be performed by other laboratories (e.g., residue analyses). Raw data for all work performed at the testing facility and a copy of the final report shall be filed by project number in archives located on the facility's site or at an alternative location to be specified in the final report.

(j) *Literature cited in this section.*

(1) Ashley, K.; Applegate, G.T.; Wise, T.J.; Fernback, J.E.; and Goldcamp, M.J. Evaluation of a standardized micro-vacuum sampling method for collection of surface dust. *Journal of Occupational and Environmental Hygiene.* 4:215–223. 2007.

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PART 799—[AMENDED]

7. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

8. Add § 799.5350 to subpart D to read as follows:

§ 799.5350 Certain polybrominated diphenylethers.

(a) *What mixtures will be tested under this section?* The chemical mixtures that must be tested under this section are three representative commercial forms of pentabromodiphenyl ether (pentaBDE), octabromodiphenyl ether (octaBDE), and decabromodiphenyl ether (decaBDE). The test sponsor(s) must identify the percentage of each of the seven polybrominated diphenylether (PBDE) congeners present in each of the representative commercial mixtures that will be tested.

(1) Commercial pentabromodiphenyl ether (c-pentaBDE), whose predominant components are tetrabromodiphenyl ether (tetraBDE) (CASRN 40088–47–9; benzene, 1,1′-oxybis-, tetrabromo deriv.), pentaBDE (CASRN 32534–81–9; benzene, 1,1′-oxybis-, pentabromo deriv.), and hexabromodiphenyl ether (hexaBDE) (CASRN 36483–60–0; benzene, 1,1′-oxybis-, hexabromo deriv.),

(2) Commercial octabromodiphenyl ether (c-octaBDE), whose predominant components are heptabromodiphenyl ether (heptaBDE) (CASRN 68928–80–3; benzene, 1,1′-oxybis-, heptabromo deriv.), octaBDE (CAS No. 32536–52–0; benzene, 1,1′-oxybis-, octabromo deriv.), and nonabromodiphenyl ether (CASRN 63936–56–1; benzene, pentabromo (tetrabromophenoxy)-).

(3) Commercial decabromodiphenyl ether (c-decaBDE), whose component with the highest percent composition is decaBDE (CASRN 1163–19–5; benzene, 1,1′-oxybis [2,3,4,5,6-pentabromo-), aka BDE–209.

(b) *Am I subject to this section?* (1) If you manufacture (including import) or process c-pentaBDE, c-octaBDE, or c-decaBDE for any use including in articles at any time after December 31, 2013, until the end of the test data reimbursement period as defined in 40 CFR 791.3(h), you are subject to this section with respect to that mixture. You are also subject to this section if you manufacture (including import) or process c-pentaBDE, c-octaBDE, or c-decaBDE for export from the United States. For this section, importers of articles containing c-pentaBDE, c-octaBDE, or c-decaBDE are considered manufacturers and are subject to this section.

(2) If you do not know or cannot reasonably ascertain that you manufacture or process a mixture listed in paragraph (a) of this section during the time period described in paragraph (b)(1) of this section (based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), you are not subject to this section with respect to that mixture.

(c) *If I am subject to this section, when must I comply with it?* (1)(i) Persons subject to this section are divided into two groups, as set forth in Table 1 of this paragraph: Tier 1 (persons initially required to comply) and Tier 2 (persons not initially required to comply). If you are subject to this section, you must determine if you fall within Tier 1 or Tier 2, based on Table 1 of this paragraph.

TABLE 1—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2

Tier 1 (persons initially required to comply)	Tier 2 (persons not initially required to comply)
Persons who manufacture (as defined at TSCA section 3(7)), or intend to manufacture, a test rule mixture and who are not listed under Tier 2. Importers of articles containing PBDEs are considered manufacturers.	A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a test rule mixture solely as one or more of the following: —As a byproduct (as defined at 40 CFR 791.3(c)); —As an impurity (as defined at 40 CFR 790.3); —As a naturally occurring chemical substance (as defined at 40 CFR 710.4(b)); —As a non-isolated intermediate (as defined at 40 CFR 704.3); —As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i)); —In amounts of less than 500 kg (1,100 pounds (lb)) annually (as described at 40 CFR 790.42(a)(4)); or —In small quantities solely for research and development (R and D) (as described at 40 CFR 790.42(a)(5)). B. Persons who process (as defined at TSCA section 3(10)) or intend to process a test rule mixture, including in articles (see 40 CFR 790.42(a)(2)).

(ii) Table 1 of paragraph (c)(1)(i) of this section expands the list of persons in Tier 2, that is those persons specified in 40 CFR 790.42(a)(2), (a)(4), and (a)(5), who, while legally subject to this section, must comply with the requirements of this section only if directed to do so by EPA under the circumstances set forth in paragraphs (c)(4), (c)(5), (c)(6), (c)(7), and (c)(10) of this section.

(2) If you are in Tier 1 with respect to a mixture listed in paragraph (a) of this section, you must, for each test required under this section for that mixture, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after the effective date in paragraph (k) of this section.

(3) If you are in Tier 2 with respect to a mixture listed in paragraph (a) of this section, you are considered to have an automatic conditional exemption and you will be required to comply with this section with regard to that mixture only if directed to do so by EPA under paragraphs (c)(5), (c)(7), or (c)(10) of this section.

(4) If no person in Tier 1 has notified EPA of its intent to conduct one or more

of the tests required by this section on any mixture listed in paragraph (a) of this section within 30 days after the effective date in paragraph (k) of this section, EPA will publish a **Federal Register** document that would specify the test(s) and the mixture(s) for which no letter of intent has been submitted and notify manufacturers in Tier 2A of their obligation to submit a letter of intent to test or to apply for an exemption from testing.

(5) If you are in Tier 2A (as specified in Table 1 in paragraph (c) of this section) with respect to a chemical substance listed in paragraph (a) of this section, and if you manufacture, or intend to manufacture, this chemical substance after the effective date in paragraph (k) of this section, or within 30 days after publication of the **Federal Register** document described in paragraph (c)(4) of this section, you must, for each test specified for that chemical substance in the document described in paragraph (c)(4) of this section, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after publication of the **Federal Register** document described in paragraph (c)(4) of this section.

(6) If no manufacturer in Tier 1 or Tier 2A has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in paragraph (a) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(4) of this section, EPA will publish another **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter of intent has been submitted, and notify processors in Tier 2B of their obligation to submit a letter of intent to test or to apply for an exemption from testing.

(7) If you are in Tier 2B (as specified in Table 1 in paragraph (c) of this section) with respect to a mixture listed in paragraph (a) of this section, and if you process, or intend to process, this mixture after the effective date in paragraph (k) of this section, or within 30 days after publication of the **Federal Register** document described in paragraph (c)(6) of this section, you must, for each test specified for that mixture in the **Federal Register** document described in paragraph (c)(6) of this section, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after publication of the **Federal Register** document described in paragraph (c)(6) of this section.

(8) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the mixtures listed in paragraph (a) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(6) of this section, EPA will notify all manufacturers and processors of those mixtures of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter of intent has been submitted. This letter or **Federal Register** document will additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and will give the manufacturers and processors of the mixture(s) an opportunity to take corrective action.

(9) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the mixtures listed in paragraph (a) of this section within 30 days after receipt of the certified letter or publication of the **Federal Register** document described in paragraph (c)(8) of this section, all manufacturers and processors subject to this section with respect to that mixture who are not already in violation of this section will be in violation of this section.

(10) If a problem occurs with the initiation, conduct, or completion of the required testing or the submission of the required data with respect to a mixture listed in paragraph (a) of this section, under the procedures in 40 CFR 790.93 and 790.97, EPA may initiate termination proceedings for all testing exemptions with respect to that mixture and may notify persons in Tier 1 and Tier 2 that they are required to submit letters of intent to test or exemption applications within a specified period of time.

(11) If you are required to comply with this section, but your manufacture or processing of, or intent to manufacture or process, a mixture listed in paragraph (a) of this section begins after the applicable compliance date referred to in paragraphs (c)(2), (c)(5), or (c)(7) of this section, you must either submit a letter of intent to test or apply to EPA for an exemption. The letter of intent to test or the exemption application must be received by EPA no later than the day you begin manufacture or processing.

(d) *What must I do to comply with this section?* (1) To comply with this section you must either submit to EPA a letter of intent to test, or apply to and obtain from EPA an exemption from testing.

(2) For each test with respect to which you submit to EPA a letter of intent to test, you must conduct the testing specified in paragraphs (h) and (i) of this section and submit the test data to EPA.

(3) You must also comply with the procedures governing test rule requirements in 40 CFR part 790, as modified by this section, including the submission of letters of intent to test or exemption applications, the submission of study plans prior to testing, the conduct of testing, and the submission of data; 40 CFR part 792—Good Laboratory Practice Standards; and this section. The following provisions of 40 CFR part 790 do not apply to this section: Paragraphs (a), (d), (e), and (f) of § 790.45; § 790.48; paragraph (a)(2) and paragraph (b) of § 790.80; paragraph (e)(1) of § 790.82; and § 790.85.

(e) *If I do not comply with this section, when will I be considered in violation of it?* You will be considered in violation of this section as of 1 day after the date by which you are required to comply with this section.

(f) *How are EPA's data reimbursement procedures affected for purposes of this section?* If persons subject to this section are unable to agree on the amount or method of reimbursement for test data development for one or more mixtures included in this section, any person may request a hearing as described in 40 CFR part 791. In the determination of fair reimbursement shares under this section, if the hearing officer chooses to use a formula based on production volume, the total production volume amount will include amounts of a mixture manufactured and processed as impurities and amounts imported in articles.

(g) *Who must comply with the export notification requirements?* Any person who exports, or intends to export, a mixture listed in paragraph (a) of this section is subject to 40 CFR part 707, subpart D, except when the mixture is in articles.

(h) *How must I conduct my testing of c-pentaBDE and c-octaBDE?* The tests that are required for c-pentaBDE and c-octaBDE and the test methods that must be followed are listed in paragraphs (h)(1) through (11) of this section. All tests must be conducted in accordance with the requirements described in 40 CFR part 792—Good Laboratory Practice Standards.

(1) Toxicity to freshwater invertebrates of sediment-associated contaminants conducted in accordance

with ASTM E 1706–05e1 and following the guidance of ASTM E 1391–03.

(2) Laboratory soil toxicity and bioaccumulation tests with the lumbricid earthworm *Eisenia fetida* and the enchytraeid potworm *Enchytraeus albidu* conducted in accordance with ASTM E 1676–04 and following general guidance in ASTM E 1391–03.

(3) Toxicity to polychaetous annilids of sediment-associated contaminants conducted in accordance with ASTM E 1611–00 and following the guidance of ASTM E 1391–03.

(4) Laboratory soil toxicity to nematode *Caenorhabditis elegans* conducted in accordance with ASTM E 2172–01 and following guidance for collecting laboratory soil in ASTM E 1676–04, and following general guidance in ASTM E 1391–03.

(5) Toxicity to estuarine and marine invertebrates of sediment-associated contaminants conducted in accordance with ASTM E 1367–03 and following the guidance of ASTM E 1391–03.

(6) Prenatal developmental toxicity in rabbits conducted in accordance with 40 CFR 799.9370.

(7) 2-Generation reproductive toxicity with a satellite group for body burden determinations conducted in accordance with 40 CFR 799.9380.

(8) Immunotoxicity conducted in accordance with 40 CFR 799.9780.

(9) Neurotoxicity screening battery, acute and subchronic, conducted in accordance with 40 CFR 799.9620.

(10) Developmental neurotoxicity conducted in accordance with 40 CFR 799.9630.

(11) Chronic toxicity/carcinogenicity conducted in accordance with 40 CFR 799.9430.

(i) *How must I conduct my testing of c-decaBDE?* The tests that are required for c-decaBDE and the test methods that must be followed are listed in paragraphs (i)(1) through (4) of this section. The use of the term ''test substance'' in the guidelines listed in paragraphs (i)(2) through (4) of this section, should be understood to mean c-decaBDE or test mixture where appropriate. All tests must be conducted in accordance with the requirements described in 40 CFR part 792—Good Laboratory Practice Standards.

(1) The tests and test methods listed in paragraphs (h)(1) through (10) of this section.

(2) Anaerobic aquatic metabolism conducted in accordance with 40 CFR 795.25.

(3) Biodegradation in anaerobic digester sludge conducted in accordance with 40 CFR 795.30.

(4) Photolytic degradation of decaBDE in the indoor environment in accordance with 40 CFR 795.65.

(j) *Reporting requirements.* For c-pentaBDE and c-octaBDE or c-decaBDE a final report for each specific test for each subject mixture must be received by EPA by the number of months designated for that test in this paragraph after December 31, 2013, unless an extension is granted in writing pursuant to 40 CFR 790.55. A robust summary of the final report for each specific test shall be submitted electronically in addition to and at the same time as the final report. The term ''robust summary'' is used to describe the technical information necessary to adequately describe an experiment or study and includes the objectives, methods, results, and conclusions of the full study report which can be either an experiment or in some cases an estimation or prediction method. Guidance for the compilation of robust summaries is described in a document entitled ''Draft Guidance on Developing Robust Summaries'' which is available online at: *http://www.epa.gov/chemrtk/pubs/general/robsumgd.htm.*

(1) The final report on toxicity to freshwater invertebrates of sediment-associated contaminants shall be received by EPA by (12 months after the effective date in paragraph (k) of this section).

(2) The final report on laboratory soil toxicity and bioaccumulation tests with the lumbricid earthworm *Eisenia fetida* and the enchytraeid potworm *Enchytraeus albidu* shall be received by EPA by (12 months after the effective date in paragraph (k) of this section).

(3) The final report on toxicity to polychaetous annilids of sediment-associated contaminants shall be received by EPA by (12 months after the effective date in paragraph (k) of this section).

(4) The final report on toxicity to nematode *Caenorhabditis elegans* of sediment-associated contaminants shall be received by EPA by (12 months after the effective date in paragraph (k) of this section).

(5) The final report on toxicity to estuarine and marine invertebrates of sediment-associated contaminants shall be received by EPA by (12 months after the effective date in paragraph (k) of this section).

(6) The final report on prenatal developmental toxicity in rabbits shall be received by EPA by (12 months after the effective date in paragraph (k) of this section).

(7) The final report on 2-generation reproductive toxicity with a satellite group for body burden shall be received by EPA by (29 months after the effective date in paragraph (k) of this section).

(8) The final report on immunotoxicity shall be received by EPA by (12 months after the effective date in paragraph (k) of this section).

(9) The final report on the neurotoxicity screening battery, acute and subchronic, shall be received by EPA by (21 months after the effective date in paragraph (k) of this section).

(10) The final report on developmental neurotoxicity shall be received by EPA by (21 months after the effective date in paragraph (k) of this section).

(11) The final report for the chronic toxicity/carcinogenicity test shall be received by EPA by (60 months after the effective date in paragraph (k) of this section).

(12) The final report for anaerobic aquatic metabolism shall be received by EPA by (60 months after the effective date in paragraph (k) of this section).

(13) The final report for biodegradation in anaerobic digester sludge shall be received by EPA by (24 months after the effective date in paragraph (k) of this section).

(14) The final report for photolytic degradation of c-decaBDE in the indoor environment shall be received by EPA by (24 months after the effective date in paragraph (k) of this section).

(k) *Effective date.* This section is effective after December 31, 2013, for manufacturers (including importers) and processors of c-pentaBDE, c-octaBDE, and c-decaBDE for any use, including in articles.

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