

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 300**

[EPA-HQ-SFUND-1983-0002; FRL-9959-04-Region 4]

**National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Perdido Ground Water Contamination Superfund Site****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule; notice of intent.

**SUMMARY:** The Environmental Protection Agency Region 4 is issuing a Notice of Intent to Delete the Perdido Ground Water Contamination Superfund Site (Site) located in Baldwin County, Alabama, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Alabama, through the Alabama Department of Environmental Management (ADEM), have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

**DATES:** Comments must be received by April 17, 2017.

**ADDRESSES:** Submit your comments, identified by Docket ID no. EPA-HQ-SFUND-1983-0002, by mail to Deborah P. Cox, PE, Remedial Project Manager, Superfund Restoration and Sustainability Branch, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Deborah P. Cox, PE, Remedial Project Manager, Superfund Restoration and Sustainability Branch, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960, phone 404-562-8317, email: [cox.deborah@epa.gov](mailto:cox.deborah@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the “Rules and Regulations” Section of today’s **Federal Register**, we are publishing a direct final Notice of Deletion of the Site without prior Notice of Intent to Delete because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the *Rules* section of this **Federal Register**.

**List of Subjects in 40 CFR Part 300**

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

**Authority:** 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601-9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Dated: September 6, 2016.

**V. Anne Heard,***Acting Regional Administrator, Region 4.*

[FR Doc. 2017-05289 Filed 3-16-17; 8:45 am]

**BILLING CODE 6560-50-P****ENVIRONMENTAL PROTECTION AGENCY****40 CFR Chapter I**

[EPA-HQ-OPPT-2016-0770; FRL-9960-09]

**Tetrabromobisphenol A (TBBPA); TSCA Section 21 Petition; Reasons for Agency Response****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Petition; reasons for Agency response.

**SUMMARY:** This document provides the reasons for EPA’s response to a petition it received under the Toxic Substances Control Act (TSCA). The TSCA section

21 petition was received from Earthjustice, Natural Resources Defense Council, Toxic-Free Future, Safer Chemicals, Healthy Families, BlueGreen Alliance, and Environmental Health Strategy Center on December 13, 2016. The petitioners requested that EPA issue an order under TSCA section 4, requiring that testing be conducted by manufacturers (which includes importers) and processors on tetrabromobisphenol A (“TBBPA”) (CAS No. 79-94-7). After careful consideration, EPA denied the TSCA section 21 petition for the reasons discussed in this document.

**DATES:** EPA’s response to this TSCA section 21 petition was signed March 10, 2017.

**FOR FURTHER INFORMATION CONTACT:**

*For technical information contact:* Virginia Lee, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-4142; email address: [lee.virginia@epa.gov](mailto:lee.virginia@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](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. General Information***A. Does this action apply to me?*

This action is directed to the public in general. This action may, however, be of interest to those persons who are or may manufacture (which includes import) or process the chemical tetrabromobisphenol A (“TBBPA”) (CAS No. 79-94-7). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

*B. How can I access information about this petition?*

The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0770, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone

number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

## II. TSCA Section 21

### A. What is a TSCA section 21 petition?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 4 or 5(e) or (f). A TSCA section 21 petition must set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or the expiration of the 90-day period.

### B. What criteria apply to a decision on a TSCA section 21 petition?

1. *Legal standard regarding TSCA section 21 petitions.* Section 21(b)(1) of TSCA requires that the petition “set forth the facts which it is claimed establish that it is necessary” to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested to evaluate this TSCA section 21 petition. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B).

2. *Legal standard regarding TSCA section 4 rules.* EPA must make several findings in order to issue a rule or order to require testing under TSCA section 4(a)(1)(A)(i). In all cases, EPA must find that information and experience are insufficient to reasonably determine or predict the effects of a chemical substance on health or the environment and that testing of the chemical substance is necessary to develop the missing information. 15 U.S.C. 2603(a)(1). In addition, EPA must find that the chemical substance may present an unreasonable risk of injury under

section 4(a)(1)(A)(i). Id. If EPA denies a petition for a TSCA section 4 rule or order and the petitioners challenge that decision, TSCA section 21 allows a court to order EPA to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence in a *de novo* proceeding that findings very similar to those described in this unit with respect to a chemical substance have been met.

## III. Summary of the TSCA Section 21 Petition

### A. What action was requested?

On December 13, 2016, Earthjustice, Natural Resources Defense Council, Toxic-Free Future, Safer Chemicals, Healthy Families, BlueGreen Alliance, and Environmental Health Strategy Center petitioned EPA to issue an order under TSCA section 4(a)(1), 90 days after the petition was filed, requiring that testing be conducted by manufacturers (which includes importers) and processors on tetrabromobisphenol A (“TBBPA”) (CAS No. 79-94-7) (Ref. 1).

### B. What support do the petitioners offer?

The petitioners state section 4(a)(1) of TSCA requires EPA to direct testing on a chemical substance or mixture if it finds the following criteria are met:

1. 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.
2. There is insufficient information and experience upon which the effects of such 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.
3. Testing is necessary to develop such information.

The petitioners assert that TBBPA “may present an unreasonable risk of injury to health or the environment” because there is substantial evidence that TBBPA may be toxic, including conclusions from:

- EPA’s TSCA Work Plan Chemical Problem Formulation and Initial Assessment (Ref. 2), which states TBBPA “can be considered hazardous to the environment” and that “there is some concern” for certain cancers and developmental effects.
- The International Agency for Research on Cancer (IARC) has identified TBBPA as probably carcinogenic to humans (Ref. 3).

- Multiple *in vitro* and animal tests, where TBBPA has been detected to cause endocrine effects, reproductive effects, neurological effects, and immunological effects (Refs. 4–9).

The petitioners also note that EPA, upon adding TBBPA in 1999 to the Toxics Release Inventory (TRI) established under the Emergency Planning and Community Right to Know Act, concluded that “TBBPA is toxic” because “[i]t has the potential to kill fish, daphnid, and mysid shrimp, among other adverse effects, based on chemical and/or biological interactions.” 64 FR 58666, 58708. The petitioners assert there is TBBPA exposure to humans and the environment based on the following conclusions.

- TBBPA has the highest production volume of any brominated flame retardant and is extensively used in consumer products, including children’s products (Ref. 2). The potential for widespread exposure is extremely high.
  - In 2012, TRI indicated that 127,845 pounds of TBBPA were released into the environment (Ref. 2). Such releases indicate the potential for widespread exposure in the population.
  - The presence of TBBPA in people and the environment (biota and environmental media) is established and affirmed in EPA’s TBBPA Problem Formulation and Initial Assessment (Ref. 2).
- With the evidence of toxicity and exposure and EPA’s addition of TBBPA to TRI (Ref. 10), the petitioners argue that TBBPA clearly meets the TSCA section 4 criteria for “may present an unreasonable risk of injury to health or the environment.”

The petitioners also assert there is “insufficient information” on TBBPA based on EPA’s TBBPA Problem Formulation (Ref. 2), which petitioners say cited lack of data for:

- Dermal and inhalation exposures, diet and drinking water exposures, exposures to communities near facilities that manufacture and process TBBPA, exposures to communities near facilities where “e-waste” is disposed of and recycled, exposures to the workers in manufacturing, processing, disposal and recycling facilities, and exposures to degradation and combustion products.
- developmental, reproductive and neurological toxicity, endocrine disruption, and genotoxic effects.

The petitioners argue that the testing recommended in the petition is critical to address this allegedly insufficient information and for performing any TSCA section 6 risk evaluation of TBBPA, and they request EPA to not

commence the risk evaluation for TBBPA until data generated to comply with the section 4 test order requested by the petitioners have been received by EPA.

#### IV. Disposition of TSCA Section 21 Petition

##### A. What was EPA's response?

After careful consideration, EPA has denied the petition. A copy of the Agency's response, which consists of two letters to the signatory petitioners from Earthjustice and Natural Resources Defense Council (Ref. 11), is available in the docket for this TSCA section 21 petition.

##### B. Background Considerations for the Petition

EPA published a Problem Formulation and Initial Assessment for TBBPA in August 2015 (Ref. 2). As stated on EPA's Web site titled "Assessments for TSCA Work Plan Chemicals" (Ref. 12), "As a first step in evaluating TSCA Work Plan Chemicals, EPA performs problem formulation to determine if available data and current assessment approaches and tools will support the assessments." During development of the Problem Formulation and Initial Assessment document for TBBPA, EPA followed an approach developed for assessing chemicals under TSCA as it existed at that time.

Under TSCA prior to the June amendments, EPA performed risk assessments on individual uses, hazards, and exposure pathways. The approach taken during the TSCA Work Plan assessment effort was to focus risk assessments on those conditions of use that were most likely to pose concern, and for which EPA identified the most robust readily available, existing, empirical data, located using targeted literature searches, although modeling approaches and alternative types of data were also considered. EPA relied heavily on previously conducted assessments by other authoritative bodies and well-established conventional risk assessment methodologies in developing the Problem Formulation documents. Although EPA identified existing data and presented them in the problem formulations, EPA did not necessarily undertake a comprehensive search of available data or articulate a range of scientifically supportable approaches that might be used to perform risk assessment for various uses, hazards, and exposure pathways in the absence of directly applicable, empirical data prior to seeking public input. Rather,

EPA generally elected to focus its attention on the uses, hazards, and exposure pathways that appeared to be of greatest concern and for which the most extensive relevant data had been identified. (Ref. 2).

As EPA explains on its Web site, "Based on on-going experience in conducting TSCA Work Plan Chemical assessments and stakeholder feedback, starting in 2015 EPA will publish a problem formulation for each TSCA Work Plan assessment as a stand-alone document to facilitate public and stakeholder comment and input prior to conducting further risk analysis. Commensurate with release of a problem formulation document, EPA will open a public docket for receiving comments, data or information from interested stakeholders. EPA believes publishing problem formulations for TSCA Work Plan assessments will increase transparency of EPA's thinking and analysis process, provide opportunity for public/stakeholders to comment on EPA approach and provide additional information/data to supplement or refine assessment approach prior to EPA conducting detailed risk analysis and risk characterization." (Ref. 12).

EPA's 2015 Problem Formulation and Initial Assessment for TBBPA does not constitute a full risk assessment for TBBPA, nor does it purport to be a final analysis plan for performing a risk assessment or to present the results of a comprehensive search for available data or approaches for conducting risk assessments. Rather, it is a preliminary step in the risk assessment process, which EPA desired to publish to provide transparency and the opportunity for public input. EPA received comments from Earthjustice, Natural Resources Defense Council and others during the public comment period, which ended in November 2015 (Ref. 13). After the public comment period, EPA was in the process of considering this input in refining the analysis plan and further data collection for conducting a risk assessment for TBBPA.

On June 22, 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA has interpreted the amended TSCA as requiring that forthcoming risk evaluations encompass all manufacturing, processing, distribution in commerce, use, and disposal activities that the Administrator determines are intended, known, or reasonably foreseen (Ref. 14). This interpretation, encompassing "conditions of use" as defined by TSCA section 3(4), has prompted EPA to re-

visit the scoping and problem formulation for risk assessments under TSCA. Other provisions included in the amended TSCA, including section 4(h) regarding alternative testing methods, have also prompted EPA to evolve its approach to scoping and conducting risk assessments. The requirement to consider all conditions of use in risk evaluations—and to do so during the three to three and a half years allotted in the statute—has led EPA to more fully evaluate the range of data sources and technically sound approaches for conducting risk evaluations. Thus, a policy decision articulated in a problem formulation under the pre-amendment TSCA not to proceed with risk assessment for a particular use, hazard, or exposure pathway does not necessarily indicate at this time that EPA will need to require testing in order to proceed to risk evaluation. Rather, such a decision indicates an area in which EPA will need to further evaluate the range of potential approaches—including generation of additional test data—for proceeding to risk evaluation. EPA is actively developing and evolving approaches for implementing the new provisions in amended TSCA. These approaches are expected to address many, if not all, of the data needs asserted in the petition. Whereas under the Work Plan assessment effort, EPA sometimes opted not to include conditions of use for which data were limited or lacking, under section 6 of amended TSCA, EPA will evaluate all conditions of use and will apply a broad range of scientifically defensible approaches—using data, predictive models, or other methods—that are appropriate and consistent with the provisions of TSCA section 26, to characterize risk and enable the Administrator to make a determination of whether the chemical substance presents an unreasonable risk.

##### C. What was EPA's reason for this response?

For the purpose of making its decision on the response to the petition, EPA evaluated the information presented or referenced in the petition and its authority and requirements under TSCA sections 4 and 21. EPA also evaluated relevant information that was available to EPA during the 90-day petition review period that may have not been available or identified during the development of EPA's TBBPA Problem Formulation and Initial Assessment (Ref. 2).

EPA agrees that the manufacture, distribution in commerce, processing, use, or disposal of TBBPA may present an unreasonable risk of injury to health

or the environment under TSCA section 4(a)(1)(A). EPA also agrees that the Problem Formulation and Initial Assessment was not comprehensive in scope with regard to the conditions of use of TBBPA, exposure pathways/routes, or potentially exposed populations. However, the Problem Formulation and Initial Assessment was not designed to be comprehensive. Rather, the Problem Formulation and Initial Assessment was developed under EPA's then-existing process, as explained previously. It was a fit-for-purpose document to meet a TSCA Work Plan (*i.e.*, pre-Lautenberg Act) need. Going forward under TSCA, as amended, EPA will conform its analyses to TSCA, as amended. EPA has explained elsewhere how the Agency proposes to conduct prioritization and risk evaluation going forward (Refs. 15 and 16). However, EPA does not find that the petitioners have demonstrated, for each exposure pathway and hazard endpoint presented in the petition, that the existing information and experience available to EPA are insufficient to reasonably determine or predict the effects on health or the environment from "manufacture, distribution in commerce, processing, use, or disposal" of TBBPA (or any combination of such activities) nor that the specific testing they have identified is necessary to develop such information.

The discussion that follows provides the reasons for EPA's decision to deny the petition based on the finding for each requested test that the information on the individual exposure pathways and hazard endpoints identified by the petitioners does not demonstrate that there is insufficient information upon which the effects of TBBPA can reasonably be determined or predicted or that the requested testing is necessary to develop additional information. The sequence of EPA's responses follows the sequence in which requested testing was presented in the petition (Ref. 1).

1. *Dermal and Inhalation Exposure Toxicity.* *a. Dermal toxicity.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict effects to health from dermal exposure to TBBPA. Therefore, the toxicokinetics test (Organisation for Economic Co-operation (OECD) Test Guideline 417) (Ref. 17) via the dermal route and the skin absorption: In vivo test (OECD Test Guideline 427) (Ref. 18), requested by the petitioners, are not needed. The information already available includes oral toxicity studies and oral toxicokinetic studies identified in EPA's Problem Formulation and Initial

Assessment document (Ref. 2) and the dermal toxicokinetics study identified by the petitioners (Ref. 19). These available studies are sufficient to reasonably determine the internal doses of TBBPA for purposes of route-to-route (oral to dermal) extrapolation. The 2016 Yu et al. study, cited in the petition (Ref. 1), characterizes absorption and elimination, while distribution and metabolism characterization is available from studies using intravenous dosing (Ref. 20). Furthermore, the available studies do not indicate differential distribution, metabolism, and elimination specific to skin. Therefore, the dermal toxicokinetics study requested by the petitioners is not needed to inform or refine evaluation of dermal exposures.

*b. Inhalation toxicity.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict effects to health from inhalation exposure to TBBPA. Therefore, the toxicokinetics test (OECD Test Guideline 417) (Ref. 17) via the inhalation route, requested by the petitioners, is not needed. As described in EPA's Problem Formulation and Initial Assessment (Ref. 2), EPA will use an alternative approach to evaluate risks from inhalation exposure to TBBPA. Because TBBPA is a solid, it may be reasonably predicted that particulates in the air are the primary form of TBBPA that would be inhaled. TBBPA particles in air that are inhaled are subsequently swallowed via the mucociliary escalator (Ref. 21). Once the particles are in the gastrointestinal tract, absorption can reasonably be assumed to be the same as in the oral toxicity studies and hence, oral toxicity studies can be used for risk assessment. Information is also available to estimate bioaccessibility of TBBPA from dust using an extraction test with an in vitro colon (Ref. 22). This additional information could also be considered when evaluating risks from TBBPA via the oral route. This approach would not require conducting the requested toxicokinetics test (Ref. 17).

Although a small percent of TBBPA particles may be in the respirable range and may be absorbed directly through the lungs, existing tests show that no systemic effects were observed in a 14-day inhalation toxicity study (Ref. 23). Therefore, EPA considers that assuming all inhaled particles are eventually swallowed and using existing oral toxicity data should not underestimate effects from inhaling TBBPA particles and therefore would reasonably predict such effects.

Furthermore, EPA's use of available existing toxicity information reduces the

use of vertebrate animals in the testing of chemical substances in a manner consistent with provisions described in TSCA section 4(h).

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict effects to the environment, specifically, toxicity to plants exposed to TBBPA via the air. Therefore, the early seedling growth toxicity test (OCSPP Test Guideline 850.4230) (Ref. 24), requested by the petitioners, is not needed. As previously mentioned, because TBBPA is a solid, it may be reasonably predicted that particulates in the air are the primary form of TBBPA that would exist in air. Furthermore, as stated on page 88 of EPA's Problem Formulation and Initial Assessment document (Ref. 2), "[u]ltimately air releases of TBBPA would be expected to undergo deposition to terrestrial and aquatic environments . . ." and "TBBPA tends to partition to soil and sediment . . .". These fate pathways for TBBPA are also shown in Figure 2-1 of EPA's Problem Formulation and Initial Assessment document (Ref. 2). Hence, exposure of plants to TBBPA is expected to occur primarily via soil and sediments after deposition from air, which is why EPA excluded this pathway from further assessment (Ref. 2, page 42), although EPA in the Problem Formulation and Initial Assessment document mistakenly mentioned plants in another sentence addressing "[e]xposure via *directly inhaling* [emphasis added] TBBPA," even though direct inhalation is not applicable to plants and thereby may have caused potential confusion to readers. If toxicity of TBBPA to plants were to be included in an assessment, toxicity data following exposure via soil and/or sediment exposures, not air, would be the scientifically relevant data needed. To this end, as described in EPA's Problem Formulation and Initial Assessment (Ref. 2), existing data and information on phytotoxicity of TBBPA to six plant species is available (Ref. 25). EPA's Problem Formulation and Initial Assessment document (Ref. 2) included references for and a brief description of the existing plant toxicity data (page 105). While assessment of soil-dwelling organisms is included in EPA's Problem Formulation and Initial Assessment document (Ref. 2), as depicted in Figure 2-1 and described on page 40, EPA indicated that the environmental risk assessment for the soil exposure pathway would be based on concentrations of concern derived from data for soil invertebrates (Ref. 2; Figure 2-1; Table 2-6; Page 40). Support for

EPA's selection of using species that are expected to be more sensitive to potential effects of TBBPA in soil is provided in EPA's summary of plant toxicity data, which states ". . . TBBPA is two to three orders of magnitude less toxic to terrestrial plants than to soil-dwelling organisms" (Ref. 2; Table\_Apx F-2 and text on page 106).

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict toxicity of TBBPA to avian species. Hence, inhalation toxicokinetic studies (OECD Test Guideline 417) (Ref. 17) and the acute inhalation toxicity study (OCSPP Test Guideline 870.1300) (Ref. 26) modified for birds, requested by the petitioners, are not needed. Although the Problem Formulation and Initial Assessment document states, "Exposure via directly inhaling TBBPA will not be assessed because no information is available on the toxicity of tetrabromobisphenol A to plants and other wildlife organisms (e.g., birds) exposed via the air." (Ref. 2; page 42), EPA's primary rationale for not including further elaboration of inhalation risks to avian species, as discussed in the Problem Formulation and Initial Assessment document (Ref. 2; page 32 and Appendix F) is TBBPA's low avian toxicity demonstrated in existing studies.

Halldin et al., 2001 and Berg et al., 2001 (Refs. 27 and 28) indicate no effects to egg-laying female quail nor embryos (except at very high doses). The Halldin et al. (Ref. 27) study also included toxicokinetic data indicating that TBBPA is rapidly metabolized and excreted in birds (both embryos and egg-laying females). In these studies, TBBPA was delivered by intravenous injection into females and direct injection into eggs. This dosing regimen assures full (100%) delivery of the dose into the animal, which does not occur in nature, and thus provides the most sensitive means to detect the toxicity of the TBBPA. Other routes of exposure (*i.e.*, oral, inhalation, dermal) result in incomplete absorption limiting the systematic availability of TBBPA compared to the intravenous injection (*i.e.*, less than 100% delivered dose). Hence, intravenous toxicity test designs provide a good understanding of the potential toxicity (or lack thereof) of a chemical. In addition to the low avian toxicity of TBBPA, demonstrated via intravenous injection, inhalation is not expected to be a substantial exposure pathway to wildlife for TBBPA (Refs. 29 and 30). The predominant route of exposure to terrestrial wildlife for a chemical with physical-chemical

properties (*i.e.*, Log  $K_{ow}$  = 5.90; water solubility = 4.16 mg/L) and partitioning parameters (*i.e.*, low mobility in soil) such as TBBPA is not expected to be via inhalation, but rather through ingestion because the TBBPA will predominantly partition to soils and sediments if/when released to the environment. The physical-chemical properties of TBBPA also indicate that the fate of TBBPA into water would result in preferential partitioning into sediments and biota (fish or other aquatic organism). Available monitoring data support this conclusion, with higher concentrations of TBBPA in soil and fish relative to concentrations in air.

Hence, additional toxicokinetic studies by the inhalation route is not needed to conduct a reasoned determination or prediction of TBBPA risk to birds.

Furthermore, EPA's use of available existing toxicity information reduces the use of vertebrate animals in the testing of chemical substances in a manner consistent with provisions described in TSCA section 4(h).

## 2. Diet and Drinking Water Exposures.

*a. Diet.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict effects from exposure to TBBPA via diet. Testing of food products for TBBPA contamination, such as the plant uptake and translocation test (OCSPP Test Guideline 850.4800) (Ref. 31) and modified methods for TBBPA using the Food & Drug Administration's (FDA) Drug & Chemical Residues Methods (Ref. 32), requested by the petitioners, is not necessary because existing data are available to address this exposure pathway.

While a plant uptake study combined with soil concentrations could be used to estimate dietary exposures from plants, chemicals with low water solubility and higher log  $K_{ow}$  values similar to TBBPA are less likely to bioaccumulate in plants compared to other foods, such as meats, fish and dairy products (Ref. 33). Hence, other food items, such as meats, fish and dairy products would be expected to be primary contributors to dietary exposures. Available market basket surveys for TBBPA support this, with most samples comprised of lipid-rich food groups (Ref. 34). There were 465 food samples collected in Europe between 2003 and 2010. Most of these were comprised of lipid-rich food groups; however, some vegetable and grain based food groups were sampled. All samples from this study were below the level of quantification, which was approximately <1 ng/g wet weight,

although this varied by food group (Ref. 35). To address dietary exposure from TBBPA, EPA could use a combination of approaches. First, there are existing plant uptake studies available that could be used to estimate TBBPA concentrations in plants from modeled or measured near-facility soil concentrations (Refs. 36 and 37). These studies are not cited in the petition. This approach is supported by a study, that EPA identified since the Problem Formulation and Initial Assessment document was published, that compared a wide variety of plant uptake studies with available models that estimate soil to plant uptake (Ref. 38). Any modeled estimate can be compared to available measured data and a range of values informed by both approaches could be derived. EPA could model soil concentrations from TRI data; these concentrations along with available physical-chemical properties can be used to reasonably estimate plant concentrations and associated dietary exposures. There is also an existing study that quantified soil and plant TBBPA concentrations near a facility (Ref. 39). This data can be used to supplement and/or evaluate the modeling approach. Because existing approaches exist for estimating plant concentrations of TBBPA (modeling and market basket data), the plant uptake and translocation test (Ref. 31) is not necessary.

EPA recognizes that dietary exposures come from a wide variety of sources, not just plants. Market basket surveys provide food concentrations, which can be used to estimate dietary exposure. There are market basket surveys from other countries that measured TBBPA in various food products (Refs. 40 to 42). Other studies are available that provide data on TBBPA concentrations in breast milk or edible fish (Refs. 43 to 48). Fish concentrations can also be estimated from combining modeled or measured surface water concentrations with bioaccumulation/bioconcentration factors (BAF/BCF). Ingestion from other dietary sources, in addition to fish, shellfish, and breast milk (dairy, meat, fruits and vegetables and grains), can be estimated individually and in total using existing data. It is expected that ingestion of foods with higher lipid content, such as fish and milk, will contribute more to dietary exposure (Ref. 49) than other foods, such as plants. Levels may vary based on proximity to point sources when compared to levels detected in market basket surveys, and this can be considered in developing exposure scenarios and/or background estimates.

*b. Drinking Water.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict effects from exposure to TBBPA via drinking water. Sampling of waters in the vicinity of representative manufacturing and processing facilities known to discharge TBBPA, requested by the petitioners, is not necessary because an existing approach is available to address this exposure pathway.

EPA can use release data collected under EPA's TRI program to characterize TBBPA concentrations in surface water near TBBPA manufacturing and processing facilities.

In addition, while there are no data on TBBPA concentrations in finished drinking water, EPA can use surface water monitoring data as a surrogate for finished drinking water to assess potential risks posed by drinking TBBPA-contaminated water. EPA's Office of Water routinely derives Ambient Water Quality Criteria for the Protection of Human Health (Ref. 50) using the assumption that people may ingest surface water as a drinking water source over a lifetime. There are existing data on TBBPA concentrations in surface water to conduct a drinking water exposure assessment using surface water as a surrogate (Refs. 51 to 53).

EPA believes these approaches are adequate, and likely conservative, to assess potential exposures to drinking water. First, the physical-chemical and fate properties of TBBPA, such as high sorption, low water solubility, and high  $K_{OC}$  indicate that concentrations of TBBPA in drinking water would be expected to be low prior to treatment. When sediment monitoring data is used with assumptions about  $K_{OC}$ , organic content, and density of water and sediment, surface water concentrations can be estimated to be generally low, below the highest levels reported in surface water (Refs. 54 to 56). This is supported by existing surface water monitoring data indicating the highest concentration of TBBPA in surface water is 4.87 ug/L with most data below 1 ug/L (Refs. 57 and 58). These same chemical and fate properties would indicate that drinking water treatment processes would further reduce TBBPA concentrations in finished drinking water. Overall, the contribution to exposure to TBBPA via drinking water is expected to be minimal.

*3. Exposure from Manufacturing and Processing. a. Communities.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to

reasonably determine or predict exposure to TBBPA to communities near manufacturing and processing facilities. Air sampling, using methods, such as EPA Air Method Toxic Organics-9A (TO-9A, Determination Of Polychlorinated, Polybrominated And Brominated/Chlorinated Dibenzo-p-Dioxins And Dibenzofurans In Ambient Air) (Ref. 60), sampling of soils, and sampling of waters in the vicinity of representative manufacturing and processing facilities known to discharge TBBPA, as requested by the petitioners, is not necessary because EPA could use an alternative approach to evaluate exposure to TBBPA to communities near manufacturing and processing facilities. EPA could use release data collected under EPA's TRI program and a Gaussian dispersion model, such as AERMOD, to quantify air concentrations and air deposition to soil, to water bodies and to sediments near manufacturing and processing facilities. AERMOD is an EPA model that has been extensively reviewed and validated based on comparisons with monitoring data (Ref. 60). Variability and uncertainty associated with variable emission rates and degradation over time can also be characterized using modeling approaches whereas one-time or limited sampling cannot provide temporal characterizations. In addition, EPA can use monitoring data from other countries as surrogate "near-facility" monitoring data along with modeled estimates. However, the petition does not address this possibility, let alone explain why a testing order under section 4 would be necessary on this point. There are several references with sampling locations near facilities that can be considered, many of which were cited in the Problem Formulation and Initial Assessment document (Ref. 2). EPA considers this approach to be reasonable to determine exposure to communities near manufacturing or processing facilities, but may decide to pursue targeted sampling in the future near manufacturing and processing facilities to reduce uncertainty.

*b. Workers.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict exposure to TBBPA to workers in manufacturing and processing facilities.

Since publication of the Problem Formulation and Initial Assessment document, EPA identified exposure monitoring data for Europe, China and the United States for several industries (the manufacture of epoxy resins and laminates; manufacture of printed circuit boards; and compounding of

acrylonitrile butadiene styrene (ABS resin) (Refs. 61 to 66).

As discussed previously, EPA is actively developing or evolving approaches for implementing the new provisions in amended TSCA. One such approach is to perform systematic literature reviews to identify and/or develop additional available data and modeling approaches for estimating worker inhalation exposure. EPA may also assess exposure concentration in the case of conversion of compounded ABS resin to finished products based on available monitoring data for other industries, such as manufacture of epoxy resins and laminates and manufacture of printed circuit boards. Furthermore, the National Institute of Occupational Safety and Health (NIOSH) has initiated a study titled: "Assessment of Occupational Exposure to Flame Retardants" that aims to quantify, characterize occupational exposure (inhalation, ingestion, or dermal) among workers, and to compare workers' exposures to those of the general population (Ref. 67). Data generated from the NIOSH study is expected to inform occupational exposures and will be considered in an occupational assessment of TBBPA. However, the petition fails to explain how it considered these points or why a testing order under section 4 would be necessary for additional information.

EPA considers the approach considered in the previous paragraph to be reasonable to determine exposure to workers in manufacturing and processing facilities, but may decide to pursue targeted sampling in the future near manufacturing and processing facilities to supplement or refine these approaches.

*Dust.* EPA believes the approaches described earlier in this unit are sufficient to characterize exposures to workers at manufacturing or processing facilities from external doses/concentrations. Sampling of settled dust (surface wipe and bulk sampling) using the OSHA Technical Manual (Ref. 68), as specifically requested by the petitioners, is not needed. Presence of TBBPA in settled dust may indicate additional dermal and ingestion exposures are possible. However, surface wipe sampling does not provide a direct estimate of dermal or ingestion exposure. Surface wipe sampling would need to be combined with information on transfer efficiency between the surface, hands, and objects, as well as the number of events to estimate exposures from ingestion (Ref. 69). EPA notes that in the NIOSH study that is in progress surface wipe sampling is not included, which provides support for

the conclusion that settled dust is not a customary measure for occupational exposure. EPA would, however, use any information generated from the NIOSH study considered relevant for this exposure pathway.

**Biomonitoring.** EPA believes the approaches described previously are sufficient to characterize exposures to workers at manufacturing or processing facilities from external doses/concentrations. Therefore, the biomonitoring data collected following the protocols of the current NIOSH study, as requested by the petitioners, is not needed. EPA would, however, consider any data or information generated from the NIOSH study deemed to be relevant and applicable for discerning exposures from any/all exposure routes.

**4. Exposure from recycling.** The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict communities specifically located at or near and workers in facilities that recycle TBBPA-containing products. In the Problem Formulation and Initial Assessment document (Ref. 2), EPA identified three monitoring studies that describe concentrations of TBBPA in soil, sediment, and sludge near manufacturing and recycling facilities (Refs. 71, 72, 76). Since publication of the Problem Formulation and Initial Assessment document (Ref. 2), EPA has identified four monitoring studies that describe concentrations of TBBPA in soil, sediment, indoor and outdoor dust from sampling locations in and near e-waste recycling facilities in other countries (Refs. 70, 73 to 75). These data may be useful for estimating exposures at or near U.S. recycling facilities.

However, EPA intends to further assess how comparable the nature and magnitude of these types of facilities and handling of TBBPA-containing products are to facilities within the U.S. EPA may collect available information related to estimating potential extent and magnitude of exposure. For example, the following could inform development of exposure scenarios for recycling facilities within the United States:

- a. The number and location of recycling facilities in the United States,
- b. the types and volumes of products that are accepted by these sites, and
- c. the recycling and disposal methods employed at these facilities.

With such data or information, the recycling processes used in the U.S. could be compared with the processes used in the studies characterizing the foreign facilities. However, the petition

does not address this possibility, let alone explain why a testing order under section 4 would be necessary on this point. If the processes are similar, EPA could extrapolate from foreign facilities to U.S. facilities. If EPA determines these previously indicated approaches are not reasonable to determine exposures, then sampling of soils, sediments and waters in the vicinity of facilities and air to which workers may be exposed at facilities known to recycle TBBPA-containing products, as requested by the petitioners, may become necessary. EPA also notes that the NIOSH study, "Assessment of Occupational Exposure to Flame Retardants," (Ref. 67) may inform occupational exposures from recycling facilities and will be considered in an occupational assessment of TBBPA. EPA also notes that the settled dust sampling and biomonitoring data, as requested by the petitioners, may not be the most appropriate data to collect for the reasons provided previously in Unit IV.C.3.b., but that EPA would consider any data or information generated from the NIOSH study deemed to be relevant and applicable for discerning exposures from any/all exposure routes.

**5. Exposure from disposal. a. Landfills, wastewater treatment plants, and sewage sludge.** The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict movement of TBBPA from landfills in soil columns. Leaching studies (OCSPP Testing Guideline 835.1240) (Ref. 77), requested by the petitioners, are not necessary because an existing approach is available to address this fate pathway. Studies measuring the sorption of TBBPA to soil, sand columns, and sediment are available as discussed in Appendix C of the Problem Formulation and Initial Assessment document (Ref. 2). Larsen et al. (2001) reported negligible leaching potential of TBBPA applied to soil and sand columns. (Ref. 78). The adsorption of TBBPA to sediment has been reported (Ref. 79) and suggest low mobility in soil and partitioning to sediments. Data from these existing studies can also serve as input to soil transport models to estimate mobility.

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict transformation processes of TBBPA, which would be episodically and/or continuously released to wastewater. The simulation tests to assess the primary and ultimate biodegradability of chemicals discharged to wastewater

(OPPTS Test Guideline 835.3280) (Ref. 80), requested by the petitioners, is not needed because primary degradation and major transformation products can be determined from existing studies on the ultimate biodegradability of TBBPA in aerobic and anaerobic sludge. One of the studies (Ref. 81) was discussed in Appendix C of EPA's Problem Formulation and Initial Assessment (Ref. 2). Two additional studies (Refs. 82 and 83) were identified after publication of EPA's document (Ref. 2). Li, et al. (2015) (Ref. 82) studied TBBPA transformation in nitrifying activated sludge (NAS). TBBPA transformation was accompanied by mineralization. Twelve metabolites, including those with single benzene ring, O-methyl TBBPA ether, and nitro compounds, were identified during the study. Potvin et al. (2012) (Ref. 83) measured the removal of TBBPA from influent to conventional activated sludge, submerged membrane and membrane aerated biofilm reactors. Removal of TBBPA from these wastewater treatment systems was found to be due to a combination of adsorption and biological degradation. Nyholm, et al. 2010 (Ref. 81) reported transformation as biodegradation half-lives for TBBPA in aerobic activated sludge, aerobic digested sludge, and anaerobic activated sludge amended soils.

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict effects from dietary exposure to crops where TBBPA contaminated sewage sludge is applied. A plant uptake and translocation test (OCSPP Test Guideline 850.4800) (Ref. 31), requested by the petitioners, is not necessary because existing data are available to address this fate pathway. As explained in the dietary exposure section, there are existing plant uptake studies available (Refs. 36 and 37). These data are also available to be used to estimate plant concentrations of agricultural crops where TBBPA-containing sewage sludge is applied. While a plant uptake study combined with sewage sludge concentrations could be used to estimate dietary exposures from plants, chemicals with low water solubility and higher log  $K_{ow}$  values similar to TBBPA, are less likely to bioaccumulate in plants compared to other foods, such as meats, fish and dairy products (Ref. 33). Hence, other food items, such as meats, fish and dairy products, would be expected to be primary contributors to dietary exposures. Available market basket surveys for TBBPA support this, with most samples comprised of lipid-

rich food groups (Ref. 34). To address dietary exposure from TBBPA, EPA could use a combination of approaches as described in the dietary exposure section. EPA believes this approach can provide a reasonable estimate of plant concentrations of agricultural crops grown where TBBPA-containing sewage sludge was applied.

*b. Incineration.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict communities specifically located near facilities that incinerate TBBPA or TBBPA-containing products.

Electronic waste can be sent to waste-to-energy incinerators (Ref. 84). EPA's Problem Formulation and Initial Assessment for TBBPA (Ref. 2) included a study that measured TBBPA emissions (0.008 ng/L to air) from a mixed household and commercial waste incinerator in Japan (Ref. 85). These data may be useful for estimating exposures at or near U.S. facilities that incinerate TBBPA or TBBPA-containing products.

EPA intends to further assess these facilities and could use an approach that combines existing data to estimate the amount of combustion products at incineration facilities that could have formed from incinerating products that contain TBBPA. Such an approach could combine information on:

- i. The types of by-products using data from EU (2006) (Ref. 62) and U.S. EPA (Ref. 87);
- ii. information regarding types of consumer waste that contains TBBPA and may be sent to incinerators;
- iii. information on the concentrations of TBBPA in various types of consumer waste; some of these data are available (Refs. 86 to 91);
- iv. Toxics Release Inventory data on emissions of the dioxin, furan and polycyclic aromatic hydrocarbons (PAH) by-products from incinerators.

The emissions of dioxins, furans and PAHs could then be modeled using EPA's AERMOD air dispersion model (Ref. 60) and the amount of these by-products that might be attributed to TBBPA could be determined.

Another approach that EPA could take is to estimate exposures near facilities by grouping all near-facility data for a variety of facilities (manufacturing, processing, e-waste, disposal) to estimate a generic "near-facility" exposure. By estimating exposure in this manner, EPA could take advantage of the larger number of monitoring studies or modeled estimates.

However, EPA intends to further assess how comparable locations around

incineration sites would be to those around manufacturing, processing, e-waste, and other disposal facilities. There are factors that may either increase and decrease emissions and potential concentrations around these facilities. For example, elevated temperatures are likely to eliminate some amount of possible TBBPA and its combustion products which could reduce overall exposures. The waste stream and content of TBBPA in materials as part of this waste stream are likely to be highly variable and could result in emissions that are higher or lower than those in manufacturing and processing facilities. Comparison of facility specific information could inform which categories of incineration may be sufficiently different from manufacturing and processing facilities to potentially warrant environmental sampling.

Therefore, to complement the existing data, EPA could collect available information related to estimating potential extent and magnitude of exposure (for example, the number and location of incineration facilities in the U.S. and the types and volumes of products that are accepted by these sites). Waste disposal by incineration as used in the United States could be then compared with the processes used in the studies assessing the foreign facilities. However, the petition does not address this possibility, let alone explain why a testing order under section 4 would be necessary on this point. If the processes are similar, EPA could extrapolate from foreign facilities to U.S. facilities. If EPA determines these previously indicated approaches are not reasonable to determine exposures, then sampling of soils, sediments and waters in the vicinity of facilities and air to which workers may be exposed at facilities known to incinerate TBBPA or TBBPA-containing products, as requested by the petitioners, may be necessary, but could be more strategic and better targeted when based on deliberate evaluation of available existing data and information.

*6. Exposure to degradation by-products. a. Degradation in water or soil.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict degradation of TBBPA in water by direct photolysis. Studies identifying photodegradation products of TBBPA formed by direct photolysis in water under laboratory conditions (Ref. 92) were identified after the Problem Formulation and Initial Assessment document was published. Therefore, the photodegradation in water test (OCSPP

Test Guideline 835.2240) (Ref. 93), requested by the petitioners, is not needed.

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict reactions resulting from chemical or electronic excitation transfer from light-absorbing humic species rather than from direct sunlight for TBBPA. A study identifying indirect photodegradation products of TBBPA formed by indirect photolysis in water under laboratory conditions (Ref. 94) was identified after the Problem Formulation and Initial Assessment document was published. Therefore, the indirect photolysis in water test (OCSPP 835.5270) (Ref. 95), requested by the petitioners, is not needed.

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict degradation of TBBPA in soil by photolysis. Photolysis of TBBPA deposited on soil or applied to soil with sludge is a possible fate pathway, which could involve different pathways and mechanisms other than photolysis in water. Existing aqueous photolysis studies and/or predictive models can be used to reasonably predict the degradation products of TBBPA. Environmental transport and exposure modeling could be conducted using available measured or estimated physical-chemical properties to estimate exposure of degradation products. This approach has been used by others (Ref. 96) to estimate PBT properties for degradation products. Therefore, the photodegradation in soil test (OCSPP Test Guideline 835.2410) (Ref. 97), requested by the petitioners, is not needed.

*b. Microbial degradation.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict microbial degradation of TBBPA in soil in aerobic and anaerobic conditions. EPA has identified existing studies/data describing aerobic and anaerobic biodegradation pathways of TBBPA in both soil samples potentially pre-exposed and not pre-exposed to TBBPA. Some studies are discussed in Appendix C of EPA's Problem Formulation and Initial Assessment document (Refs. 81, 98 and 99). EPA identified two additional studies after publication of the Problem Formulation and Initial Assessment document that also address this endpoint (Refs. 82 and 100). These studies allow EPA to reasonably determine transformation products and

predict relative rates from aerobic and anaerobic microbial degradation in soil. Therefore, the aerobic and anaerobic transformation in soil test (OECD Test Guideline 307) (Ref. 101) and terrestrial soil-core microcosm test (OCSP Test Guideline 850.4900) (Ref. 102), requested by the petitioner, are not needed.

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict aerobic aquatic biodegradation of TBBPA. Studies are available (Refs. 103 and 104) to reasonably determine aerobic aquatic biodegradation pathways and products as discussed in Appendix C of EPA's Problem Formulation and Initial Assessment document (Ref. 2). Therefore, the aerobic mineralization in surface water-simulation biodegradation test (OCSP Test Guideline 835.3190) (Ref. 105), requested by the petitioner, is not needed.

As noted in the exposure from disposal discussion, the petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict degradation processes of TBBPA, which would be episodically and/or continuously released to wastewater. The simulation tests to assess the primary and ultimate biodegradability of chemicals discharged to wastewater (OPPTS Test Guideline 835.3280) (Ref. 80), which the petitioner cited in the discussion about exposure to degradation by-products, is not needed.

*c. Combustion products.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict potential combustion products of TBBPA. The reference to combustion testing cited by the petitioners and others is available (Refs. 62 and 106). However, knowledge of the types and volumes of TBBPA-containing products is needed to use this data to estimate potential exposures to combustion products. As stated in the Problem Formulation and Initial Assessment document (Ref. 2; page 91), “. . . contribution of TBBPA to combustion byproducts is not possible to determine.” However, EPA could acquire this information from recycling and incineration facilities using approaches described in Units IV.C.4. and IV.C.5.b. The petition does not address this possibility, let alone explain why a testing order under section 4 would be necessary on this point.

*d. Toxicity of degradation products.* The petition does not set forth facts

demonstrating that there is insufficient information available to EPA to reasonably determine or predict characterization of TBBPA degradation products, and, as stated in Units IV.C.5.a, IV.C.6.a, and IV.C.6.b., EPA has an understanding of the products potentially formed from TBBPA degradation (*e.g.*, tri-, di-, and monobromobisphenol A, bisphenol A, TBBPA—bis(methyl ether), isopropyl dibromophenols). EPA can use predictive models (*e.g.*, EPA's EPISuite models (Ref. 107) to estimate the key physical-chemical properties of these degradants. EPISuite models have been validated and peer reviewed, and TBBPA degradates are chemicals for which EPISuite models are suitable for estimating (*i.e.*, are within applicability domains of EPISuite models). EPISuite has been used for estimating chemical properties in risk assessments conducted by the USEPA, the EU, and Canada. Therefore, the use of the EPA series 830 Group B testing guidelines (Ref. 108), requested by the petitioners, is not needed.

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict toxicity effects of TBBPA degradation products to mammals and birds. The petition did not reflect a comprehensive search and review for existing toxicity data on potential degradation products, and EPA's Problem Formulation and Initial Assessment document (Ref. 2) did not purport to represent such a comprehensive search for degradation products. To address the need for mammal or avian toxicity under EPA's current approach, EPA would conduct a comprehensive literature review to identify existing data for these chemicals or for analogs. Following identification and review of existing data, if EPA deemed specific testing necessary to fill identified data gaps, EPA would consider testing according to EPA series 850 Ecological Effects Test Guidelines (Ref. 109), EPA series 870 Health Effects Test Guidelines (Ref. 110), or appropriate OECD Guidelines.

The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict the toxicity effects of TBBPA degradation products to aquatic organisms. The petition did not reflect a comprehensive search and review for existing toxicity data on potential degradation products, and EPA's Problem Formulation and Initial Assessment document (Ref. 2) did not purport to represent such a comprehensive search. To address the need for aquatic toxicity under EPA's

current approach, EPA would conduct a comprehensive literature review to identify existing data for these chemicals or for analogs. EPA also believes there are alternative approaches available to EPA regarding ecological effects of TBBPA degradation products on aquatic organisms. EPA could use EPA's ECOSAR (Ref. 111) to estimate the aquatic toxicity of these degradants. ECOSAR is an expert system and collection of models (*i.e.*, Quantitative Structure Activity Relationships) that estimate toxicity from structure and physical-chemical properties of a chemical. The models incorporated into ECOSAR have been validated and peer reviewed. ECOSAR models are suitable for estimating toxicity of potential TBBPA degradates (*i.e.*, TBBPA degradation product chemicals are within the applicability domains of ECOSAR models). Therefore, the use of the EPA series 850 testing guidelines (Ref. 109), requested by the petitioners, is not needed for aquatic organisms.

Furthermore, EPA's use of available existing toxicity information and modeling approaches reduces the use of vertebrate animals in the testing of chemical substances in a manner consistent with provisions described in TSCA section 4(h).

*7. Hazard endpoints. a. Reproductive toxicity, developmental toxicity and neurotoxicity.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict reproductive, developmental and neurotoxicity of TBBPA. Therefore, the reproductive/developmental toxicity screening test (OECD Test Guideline 421) (Ref. 112), NTP's Modified One-Generation Reproduction Study (Ref. 113) and the complementing Developmental Neurotoxicity Study (OECD Test Guideline 426) (Ref. 114), requested by the petitioners, are not necessary. EPA has identified 15 reproductive/developmental toxicity tests conducted by the oral route of which some include evaluation of neurotoxicity endpoints. The available studies include: A one-generation reproduction toxicity test (Refs. 115 and 9); two 2-generation reproduction tests (Refs. 116 to 118); four prenatal developmental toxicity tests, including a developmental neurotoxicity test (Refs. 119 to 122); and six postnatal developmental toxicity tests, with some that also include a prenatal component (Refs. 123 to 128). All of these studies, except Hass et al. (2003) (Ref. 119) and Kim et al. (2015) (Ref. 126), were described in Appendix G of the published Problem Formulation and Initial Assessment document for TBBPA

(Ref. 2). These studies are either equivalent or superior to the methods used in the reproductive/developmental toxicity screening test (OECD Test Guideline 421) (Ref. 112) and the NTP Modified One-Generation Reproduction Study (Ref. 113).

For developmental neurotoxicity, a study for this endpoint by the oral route is available (Ref. 119), and EPA would consider the results of this study when evaluating risks from TBBPA. Although the study was conducted when the Developmental Neurotoxicity Study OECD Test Guideline 426 (Ref. 114) was a draft guideline, the study is adequate for consideration as part of a weight-of-evidence analysis along with the results of a 2-generation reproduction toxicity study that included a neurotoxicity component (Ref. 121).

Furthermore, EPA conducted an in-depth review of the existing dataset of reproductive and developmental toxicity studies identified, as well as additional animal and human data that evaluated neurotoxicity endpoints (Refs. 131 and 116) following the publication of the Problem Formulation and Initial Assessment document (Ref. 2) and determined that the developmental, reproductive and neurotoxicity endpoints are adequately addressed. Therefore, EPA could use this body of existing data in selecting studies for use in risk evaluation.

Furthermore, EPA's use of available existing toxicity information reduces the use of vertebrate animals in the testing of chemical substances in a manner consistent with provisions described in TSCA section 4(h).

*b. Amphibian endocrine system.* The petition does not set forth facts demonstrating that there is insufficient information available to EPA to reasonably determine or predict adverse endocrine-related effects from exposure to TBBPA. Therefore, the larval amphibian growth and development assay (LAGDA) (OCSP Test Guideline 890.2300) (Ref. 132) is not necessary. Data are available that address thyroid effects of TBBPA for both bioactivity and dose response (Refs. 57 and 133 to 139). These data include mixed results in amphibians and more consistent results in mammals indicating that changes in thyroid hormones are associated with developmental effects (specifically neurobehavioral effects). Given the weight-of-evidence, EPA does not believe that the LAGDA would significantly change this conclusion. Furthermore, EPA's use of this available existing toxicity information reduces the use of vertebrate animals in the testing of chemical substances in a manner

consistent with provisions described in TSCA section 4(h).

8. *EPA's conclusions.* EPA denied the request to issue an order under TSCA section 4 because the TSCA section 21 petition does not set forth sufficient facts for EPA to find that the information currently available to the Agency, including existing studies (identified prior to or after publication of EPA's Problem Formulation and Initial Assessment) on TBBPA and analogs, as well as alternate approaches for risk evaluation, is insufficient to permit a reasoned determination or prediction of the health or environmental effects of TBBPA at issue in the petition nor that the specific testing the petition identified is necessary to develop additional information, as elaborated throughout Unit IV of this notice.

Furthermore, to the extent the petitioners request vertebrate testing, EPA emphasizes that future petitions should discuss why such testing is appropriate, considering the reduction of testing on vertebrates encouraged by section 4(h) of TSCA, as amended.

## V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Earthjustice, Natural Resources Defense Council, Toxic-Free Future, Safer Chemicals, Healthy Families, BlueGreen Alliance, Environmental Health Strategy Center; Eve Gartner, Earthjustice; and Veena Singla, Natural Resources Defense Council to Gina McCarthy, Administrator, Environmental Protection Agency. Re: Petition to Order Testing of Tetrabromobisphenol A (CAS No. 79-94-7) under Section 4(a) of the Toxic Substances Control Act. December 13, 2016.
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3. World Health Organization International Agency for Research on Cancer. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. 2014. (retrieved on February 4, 2017) <https://monographs.iarc.fr/ENG/Publications/internrep/14-002.pdf>.
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Brominated Flame Retardants. *Toxicological Sciences*. 92:157. 2006.

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11. EPA. Response to Petition to Order Testing of Tetrabromobisphenol A (CAS No. 79-94-7) Under Section 4(a) of the Toxic Substances Control Act. 2017.
12. EPA. Assessments for TSCA Work Plan Chemicals. <https://www.epa.gov/assessing-and-managing-chemicals-under-tasca/assessments-tasca-work-plan-chemicals> (retrieved on February 21, 2017).
13. EPA. Work Plan Chemical Problem Formulation and Initial Assessment and Data Needs Assessment Documents for Flame Retardant Clusters. 2015. <https://www.epa.gov/assessing-and-managing-chemicals-under-tasca/tasca-work-plan-chemical-problem-formulation-and-2>.
14. EPA. Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act; Proposed Rule. **Federal Register** (82 FR 7565, January 19, 2017) (FRL-9957-75). <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0001>.
15. EPA. Procedures for Prioritization of Chemicals for Risk Evaluation under Toxic Substances Control Act; Proposed Rule. **Federal Register** (82 FR 4826, January 17, 2017) (FRL-9957-74). <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0001>.
16. EPA. Docket EPA-HQ-OPPT-2016-0654. 2016. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0001>.
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#### List of Subjects in 40 CFR Chapter I

Environmental protection, Flame retardants, Hazardous substances, tetrabromobisphenol A.

Dated: March 10, 2017.

**Wendy Cleland-Hamnett,**

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

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 217

[Docket No. 161216999–7232–01]

RIN 0648–BG50

### Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Commercial Fireworks Displays at Monterey Bay National Marine Sanctuary

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS has received a request from the Monterey Bay National Marine Sanctuary (MBNMS or Sanctuary) for authorization to take marine mammals incidental to commercial fireworks displays permitted by the Sanctuary in California, over the course of five years (2017–2022). As required by the Marine Mammal Protection Act (MMPA), NMFS is proposing regulations to govern that take, and requests comments on the proposed regulations.

**DATES:** Comments and information must be received no later than April 17, 2017.

**ADDRESSES:** You may submit comments on this document, identified by NOAA–NMFS–2017–0017, by any of the following methods:

- *Electronic submission:* Submit all electronic public comments via the federal e-Rulemaking Portal. Go to [www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2017-0017](http://www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2017-0017), click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910.

*Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will