

Consultation Information:

TSCA Work Plan Chemical Problem Formulation & Initial Assessment and Data Needs Assessments for Flame Retardant Clusters

1. Background Information on TSCA Work Plan Chemical Assessments

As part of EPA's chemical safety program, EPA has identified a work plan of chemicals for further assessment under the Toxic Substances Control Act (TSCA). Originally released in March 2012, EPA's TSCA Work Plan helps focus and direct the activities of its Existing Chemicals Program. The Work Plan was updated in October 2014. The changes to the TSCA Work Plan reflect updated data submitted to EPA by chemical companies on chemical releases and potential exposures.

EPA develops TSCA Work Plan Chemical assessments using the best available information and approaches. Assessments focus on those TSCA uses of the chemical with significant potential for exposure to humans and/or the environment. As a first step in evaluating TSCA Work Plan Chemicals, EPA performs problem formulation and initial assessments to determine if available data and current assessment approaches and tools will support the assessments. Problem formulation and initial assessment is the analytical phase of the assessment in which the purpose for the assessment is articulated, the problem defined and a plan for analyzing and characterizing risk is determined.

EPA has recently released for comment and input problem formulation and initial assessment documents for three clusters of flame retardants: Tetrabromobisphenol A; Chlorinated Phosphate Esters; and Cyclic Aliphatic Bromides. In addition, EPA released a data needs assessment document for the Brominated Phthalates flame retardant cluster. The information provided below is provided to facilitate Tribal Consultation on these four TSCA Work Plan Chemical assessments.

1. Background on the Chemicals

A. Chlorinated Phosphate Esters Cluster

This cluster includes the following chemicals:

- Ethanol, 2-chloro-, phosphate (3:1) (TCEP, CASRN 115-96-8)
- 2-Propanol, 1-chloro-, 2, 2',2''-phosphate (TCPP, CASRN 13674-84-5)
- 2-Propanol, 1,3-dichloro-, phosphate (3:1) (TDCPP, CASRN 13674-87-8)

The chlorinated phosphate esters are chemicals that have been used as flame retardants in furniture foams and textiles.

B. Cyclic Aliphatic Bromides Cluster

This cluster includes the following chemicals:

- Hexabromocyclododecane (HBCD) (CASRN 25637-99-4)
- 1,2,5,6,9,10-Hexabromocyclododecane (CASRN 3194-55-6)
- 1,2,5,6-Tetrabromocyclooctane (CASRN 3194-57-8)

The cyclic Aliphatic Bromides are used as a flame retardant in extruded and expanded polystyrene foams (EPS/XPS) and polystyrene (PS) products.

C. Tetrabromobisphenol A (TBBPA) (Brominated Bisphenol A) cluster

This cluster includes the following chemicals:

- Tetrabromobisphenol A (CASRN 79-94-7)
- TBBPA-bis(dibromopropyl ether) (CASRN 21850-44-2)
- TBBPA-bis(allyl ether) (CASRN 25327-89-3)
- TBBPA-bis(methyl ether) (CASRN 37853-61-5)

Tetrabromobisphenol A (TBBPA), also known as Brominated Bisphenol A, is a compound commonly used as a flame retardant in plastics/printed circuit boards for electronics.

D. Brominated Phthalates Cluster

This cluster includes the following chemicals:

- **1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) esters (TBPH, CASRN: 26040-51-7)**
- **Benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl esters (TBB, CASRN: 183658-27-7)**
- 2-(2-Hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromobenzenedicarboxylate (CASRN: 77098-07-8)
- 3,4,5,6-Tetrabromo-1,2-benzenedicarboxylic acid, mixed esters with diethylene glycol and propylene glycol (CASRN: 20566-35-2)
- 1,2- (2,3-dibromopropyl) benzenedicarboxylate (CASRN: 7415-86-3)
- Chemical A – Chemical Identity claimed confidential by manufacturer
- Chemical B – Chemical Identity claimed confidential by manufacturer

The Brominated Phthalates Cluster is a group of seven chemicals at least two of which, TBB and TBPH, are found in commercial flame retardant formulations.

During problem formulation, EPA reviewed previous assessments by EPA and other organizations and additional published studies on the exposure and hazard for members of this Brominated Phthalates cluster. This review identified critical data gaps and uncertainties that limit EPA's ability to conduct a quantitative risk assessment for any of the chemicals in the Brominated Phthalates Cluster. Specifically, the review identified numerous gaps in toxicity data and exposure data; testing was conducted on limited commercial mixtures, not all constituents of mixtures; and attribution of toxicity is uncertain for commercial mixtures.

2. Reason for Publishing Problem Formulation and Initial Assessment or Data Needs Assessment Documents

Based on experience in conducting TSCA Work Plan Chemical assessments to date and public input, starting in 2015 EPA will publish a problem formulation and initial assessment or a data needs assessment, for each TSCA Work Plan assessment as a stand-alone document to facilitate public input as well as State and Tribal consultations prior to conducting further risk analysis.

EPA believes publishing problem formulation and initial assessment documents for TSCA Work Plan assessments will increase transparency about EPA's thinking and analysis process, provide opportunity for the public and States and Tribes to comment on EPA's approach, and provide EPA the opportunity to receive additional information/data to supplement or refine the assessment approach prior to EPA conducting detailed risk analysis and risk characterization.

Problem Formulation is the analytical phase of the assessment in which the purpose for the assessment is articulated, the problem defined and a plan for analyzing and characterizing risk is determined.

Outcomes of a problem formulation and initial assessment are:

- a) Conceptual Model – including a visual representation and written description of actual or predicted relationships between chemicals and human or wildlife;
- b) Analysis Plan – describing the intentions regarding the technical aspects of the risk assessment.

In some instances, as a result of problem formulation and initial assessment, EPA identifies data gaps (uses, exposure pathways, toxicity data) so significant as to prevent conducting a meaningful risk assessment. In these cases, EPA will publish a Data Needs Assessment document and provide opportunity for the, public, States and Tribes, as well as stakeholders to comment, identify or provide data or information that may fill identified data gaps prior to EPA pursuing data collection via TSCA authorities.

To facilitate States, Tribes, public and stakeholder input prior to conducting further risk analysis, EPA will open a public docket for receiving comments, data or information from interested stakeholders when it publishes each problem formulation and initial assessment or data needs assessment document. Following receipt of comments on the problem formulation and initial assessment and data needs assessment documents as well as consideration of any additional data or information received, EPA will initiate a risk assessment which is the process to estimate the nature and probability of adverse health and environmental effects in humans and ecological receptors from chemical contaminants that may be present in the environment.

3. Relevance to the Tribes

The EPA recognizes that the problem formulation and initial assessment and data needs assessment documents may be of particular interest to Tribes due to potential exposures to tribal populations via consumer products containing these flame retardants, or due to the fate of these chemicals in the environment.

In addition to general comments, EPA requests input on the problem formulation and the characterization of exposure scenarios relevant to tribal populations, as well as any additional information regarding monitoring of these chemicals in Indian Country.

4. Opportunity for Tribes to Participate

The tribal consultation process establishes a timeline for government-to-government consultation and coordination. In addition to the tribal consultation process, tribes may also participate in any public review and comment process.

Tribes may access related consultation information on the EPA Tribal Portal under Tribal Consultation Opportunities, located at: yosemite.epa.gov/oita/TConsultation.nsf/TC?OpenView.

More information on the flame retardant clusters can be found on the TSCA Work Plan Chemicals webpage under the “Ongoing Chemical Assessments” section at:
<http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html>

The combined goal of all these efforts is to ensure there is sufficient information for tribal officials to make an informed decision about the desire to continue with consultation and to understand how to provide informed input.

5. How to Provide Comments as Part of the Public Comment Process

Comments on the three Work Plan Chemical Problem Formulation and Initial Assessments for Tetrabromobisphenol A, Chlorinated Phosphate Esters, and Cyclic Aliphatic Bromides must be received on or before *October 19, 2015*.

Comments on the Work Plan Chemical Data Needs Assessment for Brominated Phthalates (TBB & TBPH) must be received on or before *December 16, 2015*.

When submitting your comments, please identify your correspondence with the docket identification (ID) number for the corresponding TSCA Work Plan chemical as identified in the following table (Table 3).

Table 3: TSCA Work Plan chemicals docket numbers

| Chemical Cluster | Docket Number |
|------------------------------|------------------------|
| Tetrabromobisphenol A | EPA-HQ-OPPT--2014-0730 |
| Chlorinated Phosphate Esters | EPA-HQ-OPPT2015-0068 |
| Cyclic Aliphatic Bromides | EPA-HQ-OPPT-2015-0081 |
| Brominated Phthalates | EPA-HQ-OPPT- 2014-0491 |

Comments can be submitted:

- on-line at the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments;
- by mail to the Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001;
- or special arrangements can be made for hand delivery or delivery of boxed information, by following the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

6. Additional Information

TSCA Work Plan Chemicals

<http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html>

US Environmental Protection Agency. *Significant New Use Rule for Hexabromocyclododecane and 1,2,5,6,9,10-Hexabromocyclododecane*. 77 Federal Register 58 (March 26, 2012), pp. 17386-17394.

<http://www.gpo.gov/fdsys/pkg/FR-2012-03-26/pdf/2012-7207.pdf>

US Environmental Protection Agency. 2014. *Flame Retardant Alternatives to Hexabromocyclododecane (HBCD)*. EPA Publication 740R14001. Design for the Environment, Washington, DC.

<http://www.epa.gov/dfe/pubs/projects/hbcd/hbcd-full-report-508.pdf>.

US Environmental Protection Agency. 2014. *An Alternatives Assessment for the Flame Retardant Decabromodiphenyl Ether (DecaBDE)*. Design for the Environment. Washington, D.C.

http://www2.epa.gov/sites/production/files/2014-05/documents/decabde_final.pdf

US Environmental Protection Agency. 2014. *Flame Retardants in Printed Circuit Boards: Updated Draft Report*. Design for the Environment. Washington, D.C.

http://www2.epa.gov/sites/production/files/2015-01/documents/pcb_updated_draft_report.pdf

OECD (Organisation for Economic Co-operation and Development). 2007. *SIDS Initial Assessment Profile for HBCDD*. OECD Existing Chemicals Database, Paris, France.

<http://webnet.oecd.org/HPV/UI/handler.axd?id=ea58ac11-e090-4b24-b281-200ae351686c>.