Summary of Public Comments received on Tetrabromobisphenol A (TBBPA, CAS 79-94-7), TBBPA bis(2-hydroxyethyl ether) (CAS 4162-45-2) and TBBPA bis(allyl ether) (CAS 25327-89-3), Draft Screening Assessment Report and proposed Risk Management Scope

Comments on the draft Screening Assessment Report and Risk Management Scope for Tetrabromobisphenol A (TBBPA) were provided by: the Association of Connecting Electronics Industries (IPC), New Brunswick Lung Association (NBLA), BIOTRONIK Canada Inc. (BIOTRONIK), Gurit (Canada) Inc. (Gurit), the Bromine Science and Environmental Forum (BSEF), and Canadian Vehicle Manufactures' Association (CVMA).

A summary of comments and responses is included below, organized by topic:

TOPIC	COMMENT	RESPONSE
Persistence and bioaccumulation	Environment Canada should use the experimental data for the biodegradation in sediments and soil (2006) that were analyzed in the European Union Risk Assessment Report (EU RAR). These values are preferred because they are from an actual study.	The findings from the subject sediment and soil biodegradation studies conducted by Wildlife International Ltd. (2006a, b) and those cited in the EU RAR (2008) have been added to the assessment. These studies show that TBBPA can undergo primary biodegradation, but both studies also found minimal mineralization had occurred.
	A dimethyl ether derivative of TBBPA (Me-TBBPA) is not used as a flame retardant, and the screening assessment report (SAR) inappropriately indicates that it may be more bioaccumulative than TBBPA.	The statement suggesting that Me-TBBPA may have been used as a flame retardant has been deleted. The SAR does not evaluate whether Me-TBBPA is more bioaccumulative than TBBPA—it only cites the conclusions of Watanabe et al. (1983), which indicate that while Me-TBBPA accumulation in fish and shellfish seemed negligible, it is possibly more bioaccumulative than TBBPA.
	Consideration should be given to the analysis found in the EU RAR (2008) of the bisphenol A (BPA) risk in the	The findings of the EU RAR (2008) regarding bisphenol A transformation and risk in the environment were reviewed for the SAR. Both the EU RAR (2008) and the Canadian SAR are

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	environment that results from TBBPA transformation. Based on that assessment—which concluded that there were no risks identified for soils and sediments—the risk for potential degradation of TBBPA to BPA should be reversed.	consistent in indicating transformation of TBBPA to bisphenol A in sediments and soils. The Canadian SAR, however, does not endeavour to estimate risks to the environment resulting from this process; rather, it only cites the findings of its assessment on bisphenol A that indicate that this substance meets the criteria set out in section 64 of CEPA 1999 (Canada 2008).
	The criteria for Persistence , Bioaccumulation , and Toxicity should be clarified, as should the link between persistency and long-range transport.	The Canadian criteria for Persistence and Bioaccumularion are identified in the *Persistence and Bioaccumulation Regulations* under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). Regarding persistence and long-range transport, as noted in Part 3 of the *Regulations*, "a substance is persistent when it has at least one of the following characteristics: • (*a*) in air, o (i) its half-life is equal to or greater than 2 days, or o (ii) it is subject to atmospheric transport from its source to a remote area. …" Thus, the determination of Persistence in air is judged based on whether the substance satisfies *either one* of these criteria. There are no Canadian regulatory criteria for inherent Toxicity. Some criteria were developed, however, specifically for the sole purpose of the Categorization priority setting exercise (for more information, please see http://www.chemicalsubstanceschimiques.gc.ca/about-apropos/categor/index-eng.php#b). Screening assessments do not conclude formally on inherent toxicity, but rather whether substances meet criteria under Section 64 of the Act.
	Bisphenol A is readily biodegradable, not "potentially persistent" as mentioned in the draft risk management scope.	The Canadian assessment on bisphenol A found this substance meets criteria for persistence in sediments under conditions of low or no oxygen (Canada 2008).
	It is not clear why a bioaccumulation factor (BAF) greater than one for soils is considered to be significant, particularly since a BAF of greater than 5000 is noted in the SAR.	The criteria for BAF and bioconcentration factors (BCF) (*i.e.*, 5000) specified in the *Persistence and Bioaccumulation Regulations* under CEPA 1999 (Canada 2000) are based on aquatic organisms. A BAF greater than one for soil organisms, however, is indicative of accumulation from soil and/or diet. The wording in the SAR is presented accordingly.

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Vulnerable Populations	There is a lack of epidemiological data in Canada, particularly for the sensitive stages of human development.	Screening assessments are based on considerations of the available data. A recent cross-sectional study conducted in Belgium that examined neurobehavioural function, thyroid hormone levels, and exposure to flame retardants in 515 adolescents was considered in the screening assessment.
	There is a lack of recent Canadian biomonitoring data on TBBPA levels (or its derivatives) in human serum, specifically for the most sensitive stages of human development.	The screening assessments are based on consideration of the available data, including a biomonitoring study of pregnant women in Alberta in 2008. Another recent study by Carginan et al. (2012) examined human milk samples collected in 2004–2005 from 43 women from Boston, MA (USA). TBBPA is included on the list of chemicals planned for measurement as part of the biomonitoring component of the Canadian Health Measures Survey (Cycle 3).
	The assessment does not adequately address the potential thyroid disrupting properties of TBBPA. Similarly, preliminary evidence that TBBPA may concentrate in the fetus raises concerns about fetal exposures. Until these and other data gaps are filled, we feel that a precautionary approach limiting the importation and use of TBBPA in Canada is warranted.	The screening assessment identifies various studies that investigated potential for effects of TBBPA exposure on the thyroid (including a recent neurodevelopmental study in rats following exposure to TBBPA). The screening assessment identifies the potential of TBBPA to affect the endocrine system, including the thyroid, as an uncertainty. However, the margins of exposure between upper-bounding estimates of exposure and effect levels were considered adequate to address uncertainties in the health effects and exposure databases.
Data gaps and deficiencies	Studies sponsored by industry on *Daphnia magna*, activated sludge respiration inhibition, soil organism nitrogen transformation and chronic sediment amphipod toxicity (in *Hyalella azteca*) should be added to the SAR.	These studies have been added to the SAR.
	The assessment does not adequately consider the possibility of low-dose effects and non-monotonic dose-response curves. Some screening assessments appear to be lacking both human health studies and studies that examine toxicity at low dosages.	Screening assessments are based on considerations of the available data. The margins of exposure between upper-bounding estimates of exposure and effect levels were considered adequate to address uncertainties in the health effects and exposure databases.
	The SAR should include the review of recent and relevant studies cited in the EU RAR (2008), the opinion on the EU Risk Assessment published by the European Commission Scientific Committee on Health and Environmental Risks (SCHER, 2008), and in the recent	The reference to the 2006 WHO report is not accurate—it should reference Monrose (2006). The Monrose report (2006), where alternatives to TBBPA and hexabromocyclododecane are considered, and its findings are not based on a risk evaluation, and therefore not equivalent to those in the TBBPA assessment. The WHO (1995) report was considered and cited in the Canadian TBBPA assessment, although it did not provide any conclusions on risk to the

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	(2006) World Health Organization report.	environment. The EU RAR (2008) was considered for the production of the Canadian TBBPA assessment.
	References attributed to Great Lakes Chemical Corporation (GLCC) should be amended to reflect the appropriate ownership of the studies.	The recommended changes have been made to the referencing.
	The reported data used in the ecological effects assessment of the SAR should be performed in accordance with accepted international guidelines and good laboratory practices. Furthermore, study results with samples collected in Canada should be listed first in Tables 6 and 7, and a minimal standard for acceptance of the study results should be established prior to their inclusion.	The comment has been noted and Canadian studies are now listed first in Tables 6 and 7. All studies considered in the assessment are reviewed for quality and are considered to be acceptable for use in the weight of evidence assessment approach. Validity of studies relating to persistence, bioaccumulation and inherent toxicity in screening assessments is reviewed using an approach similar to that of Klimisch et al. (1997). This process quantitatively evaluates the reliability of the studies using a scoring system and modified robust study summary forms that are based on Organisation for Economic Co-operation and Development (OECD) templates. Robust study summaries for critical studies are included in an appendix to the assessment.
	There is no need for unit conversion from μg /L to pg/L.	620 000 pg/L was presented in parentheses to provide the original unit reported in the cited reference. No changes were made to the assessment based on this comment.
	It is difficult to comment on the screening of TBBPA and its derivatives when there are few human health studies, epidemiological or otherwise, to consider. Given the effects of chemical substances on the human body or other organisms, causation is not necessarily easy to define in the absence of appropriate studies and knowledge of physiological processes. Also, determination of subtle effects on humans—such as those resulting from epigenetic effects—may only become apparent in multi-generation human studies.	Screening assessments are based on considerations of the available data. In the case of TBBPA and the two derivatives, the screening assessment not only considered multiple lines of evidence that were available at the time of the assessment when determining whether these substances may pose a risk, but also conservative exposure estimates. The margins of exposure between upper-bounding estimates of exposure and effect levels were considered adequate to address uncertainties in the health effects and exposure databases.

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Releases to the environment	The actual releases to the environment from industrial use reported in Table 8 of the SAR should be based on the parent (neat) TBBPA imported into Canada rather than on what is present in finished products. It should also specify if the amount imported is pure or “neat,” as this will affect the predicted environmental concentrations in Canada and the subsequent risk quotients (found on page 31). Ultimately, predicted Canadian environmental concentrations should be compared to those in the EU.	The releases estimated to the environment from industrial uses were based on the parent (neat) quantities presented in Table 8 of the SAR. This has been clarified in the text of the SAR. The predicted environmental concentrations that are reported in the Canadian assessment have been estimated from available information, including estimated substance quantities in use, estimated release rates and characteristics of the Canadian receiving environment. These inputs and estimates have been carefully evaluated and are considered to be reasonable representations of conservative conditions for Canada.
Exposure	The statement in the SAR that TBBPA binds to the lipid fraction of biota should be reversed because studies have demonstrated that it has a low systemic bioavailability as a parent molecule.	It is possible for a substance to have low bioavailability, and yet still be absorbed in small amounts by the organism and have an affinity to bind to lipid. Therefore, no changes to the SAR have been made based on this comment.
	The input value of 0.2% used for TBBPA loss to wastewater from industrial releases (before wastewater treatment)—the value that was used for estimating industrial releases of TBBPA—is overestimated in instances where there is no contact between product and water during the production process.	Revisions have been made to generic scenario #1 in the assessment according to the updated information provided by the industrial user. Additional input was received to characterize the use and releases for generic scenario #2 by a second industrial user. Based on information received, the PECs for water were revised to show that risk is unlikely for pelagic and benthic organisms.
	The industrial scenario that assumes zero removal of TBBPA by wastewater treatment is not realistic.	This scenario—including the assumption of zero removal of TBBPA from wastewater treatment—was revised based on further information that was received.
	TBBPA and TBBPA bis(allyl ether) should not be discussed together because their uses are different. In fact, the three chemicals should be assessed individually to prevent confusion for the reader.	Known sources of exposure to TBBPA for the general population are anthropogenic and include environmental media, household dust, indoor air, human breast milk, food, and products treated with TBBPA for its flame retardant properties. While TBBPA bis(2-hydroxyethyl ether) and TBBPA bis(allyl ether) can have different uses, the sources of exposure for the two derivatives are also anthropogenic and are considered to be similar to those of TBBPA. Given these similarities—and the chemical similarities between TBBPA and its derivatives—it is defensible to have the three chemicals discussed and assessed together.

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	TBBPA is not used in building insulation.	This comment is noted and a change has been made to the assessment.
Proposed risk management	Since TBBPA is contained in components and handled in closed loop systems at vehicle assembly facilities, the use and handling of the substance should not be subject to any risk management activities.	The final assessment report concluded that TBBPA does not meet the criteria under section 64 of CEPA 1999. Accordingly, no risk management measures will be developed at this time.
	With regards to the risk management of TBBPA and its derivatives, there are concerns about the toxic effects on aquatic organisms, particularly on the thyroid. When there is clearly an effect on non-human organisms, a precautionary approach should be taken with human exposure to a substance.	With respect to the human health risk assessment, the conclusions from the screening assessments adhere to a precautionary approach, using conservative approaches where there are uncertainties. The margins of exposure between upper-bounding estimates of exposure and effect levels were considered adequate to address uncertainties in the health effects and exposure databases.
Risk management scope	Units for the global production of TBBPA in section 1.3 of the risk management scope need to be revised.	Units were revised from “kg” to “tonnes” in section 1.3 of the risk management scope.
	The availability of updated information on European risk management initiatives was raised, particularly regarding the registration of TBBPA under Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) and the most recent Voluntary Emissions Control Action Programme (VECAP) report.	The comment has been noted, and updated information on international risk management initiatives on TBBPA will be referenced as they become available.
	Criteria for listing chemicals on the Convention for the Protection of the marine Environment of the North-East Atlantic (OSPAR Convention) lists are different than the ones used for Canada or REACH.	The comment has been noted. Section 2.2 of the risk management scope, however, was to illustrate international assessment or risk management initiatives that are underway for any substance that is subject to risk assessment and potential risk management (in this case, TBBPA).
	It is unclear if there is a process that justifies decisions regarding the necessity or effectiveness of flame retardants in a given product.	It is not the role of Government to evaluate or determine the effectiveness of flame retardants. The decision on how to meet the regulatory requirements that may be set by the Government of Canada is made by the manufacturer or importer. When required, risk management measures are developed in response to a number of issues, including the toxicity, persistence and bioaccumulation potential of a substance, as well as emission sources, the availability of alternatives, and the technical and economic challenges of

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		addressing identified risks.
	Holistic approaches should be taken in the risk assessment and risk management of flame retardants, and those approaches should cover the class of substances.	The Government of Canada is working to address flame retardants in a holistic manner as much as possible. The Substance Groupings Initiative, launched in 2011, includes a grouping for Certain Organic Flame Retardant Substances that will be assessed concurrently. The substances in this grouping are potential alternatives for substances that are currently subject to controls (or that are considered for controls) in Canada and internationally. Risk assessments for these alternatives will assist with informed substitution. For example, potential risk management efficiencies would be achieved through the engagement of stakeholders in a discussion on several flame retardants at once. This would result in improved compliance, informed substitution and less duplication of effort.
Overarching comments	Environment Canada's proposed conclusion that TBBPA meets the harmful substances criteria in section 64 of CEPA 1999, contradicts the recent findings of the European Union (EU) and World Health Organization (WHO), and it undermines the scientific credibility of the Chemical Management Plan (CMP).	The draft conclusion that TBBPA meets the criteria in section 64 of CEPA 1999, is not considered inconsistent with the findings of the European Union (EU RAR 2008) or the World Health Organization (WHO 1995) report. These are different programs with different mandates, and thus differences in outcomes may occur. Based on consideration of additional information received, however, the final assessment concludes that TBBPA does not meet the criteria for harm under section 64 of CEPA 1999.
	The parameters of the screening assessment are unclear, as is the process for determining not only what information is included in the risk management decision, but how much information is sufficient to support a conclusion. The role of industry in this process (if any) also should be indicated.	All assessments are subject to internal and external peer review/consultation and a public comment period. This takes into account the quality and quantity of available scientific evidence, the adequacy and limitations of studies, critical toxicological endpoints and exposure routes, sources and pathways, and the assessments and conclusions of other jurisdictions that all information is part of the decision. Ultimately, this approach considers multiple lines of evidence in determining whether a substance may pose a risk. The Government of Canada is committed to maintaining open and transparent assessment processes and feedback during the public comment period is useful in helping the Government to strengthen its screening assessments. The Government of Canada also continues to work with industry and our international partners, and makes information on chemicals publicly available.
	The proposed conclusion in the SAR that TBBPA meets one or more of the criteria set out in section 64 of CEPA 1999 should be reversed to conclude TBBPA is safe for human health or the environment.	Current available scientific evidence was used to support its conclusion on TBBPA. Based on the available information, it is concluded that TBBPA poses a low risk of harm to organisms (pelagic, benthic, soil organisms or wildlife) or the broader integrity of the environment. Based on the adequacies of the margins between upper bounding estimates of exposure to TBBPA and critical

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	TBBPA also should not be included for further assessment under the Chemicals Management Plan.	effect levels, it is proposed to conclude that TBBPA is a substance that is not entering the environment in a quantity, concentration or manner that constitutes (or may constitute) a danger in Canada to human life or health. Based on these proposed conclusions, risk management actions to reduce human exposure to TBBPA, TBBPA bis(allyl ether), and TBBPA bis(2-hydroxyethyl ether) are not required and there are presently no plans to include this substance for further assessment under the Chemicals Management Plan.
	Risk assessment and risk management should be coordinated internationally.	Canada is actively involved in international risk assessment and risk management initiatives on substances of concern (including flame retardant substances), most notably under the Stockholm Convention on Persistent Organic Pollutants (POPs), and the Protocol on POPs under the Convention on Long-range Transboundary Air Pollution. Canadian risk management measures under the Chemicals Management Plan are harmonized with international risk management measures to the greatest extent possible.

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