Summary of Public Comments Received on the Substance Hexabromocyclododecane Government of Canada Risk Management Scope and Draft Screening Assessment Report

Comments on the draft Screening Assessment Report and Risk Management Scope for Hexabromocyclododecane (HBCD) were provided by: Bromine Science and Environment Forum (BSEF), Canadian Environmental Law Association (CELA) and Chemicals Sensitivities Manitoba (CSM), Canadian Plastics Industry Association (CPIA), Crooked Creek Conservancy Society of Athabasca (CCCSA), Dow Canada Ltd. (included documents authored by: European Brominated Flame Retardant Industry Panel (EBFRIP), European HBCD Industry Working Group (IWG), Styrofoam safety assessment etc.), EPS Molders Association (EPSMA), Extruded Polystyrene Foam Association (XPSA), Inuit Tapiriit Kanatami (ITK), and Plasti-Fab Ltd.

TOPIC	COMMENT	RESPONSE
Proposed Risk Management		
Proposed Risk Management	Any risk management strategy for HBCD should include discontinuation of current uses of HBCD, progressive elimination of HBCD as a legacy substance and ongoing public education to minimize exposure.	The Government of Canada agrees that a risk management strategy for HBCD should encompass current uses, legacy issues and provide information for the public. The Government of Canada is working on ways to eliminate releases of HBCD to the environment based on the final screening assessment's conclusions. The Government of Canada is also publishing a Risk Management Approach for HBCD which will propose measures to achieve this objective.
	Risk management of HBCD should be implemented immediately.	The Government of Canada agrees that a risk management strategy for HBCD should be implemented as quickly as is practical and is developing a Risk Management Approach to do so.
	Canada should align HBCD policy with that of other jurisdictions.	The Government of Canada acknowledges the usefulness of alignment with other jurisdictions, taking into account, of course, Canadian circumstances.
	The Government of Canada should work closely with stakeholders when developing policies for HBCD.	The Government of Canada will consult stakeholders upon publication of the Risk Management Approach regarding HBCD.
	The Government of Canada should use the precautionary principle, and implement preventive measures to protect the health of Canadians.	The Government of Canada's proposed risk management activities focus on the risks identified in the screening assessment based on the information available. Screening assessments focus on information critical to determining whether a substance meets the criteria as set out in section 64 of CEPA 1999. Screening assessments examine scientific information and develop conclusions by incorporating a weight-of-evidence approach and precaution.

TOPIC	COMMENT	RESPONSE
		The screening assessment report proposes that HBCD is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. According to the screening assessment report, the margins between estimated exposures to HBCD and critical effect levels are considered adequately protective of human health.
	HBCD should be added to Schedule 1 of CEPA 1999.	The Minister of the Environment will recommend the addition of HBCD to the List of Toxic Substances in Schedule 1 of CEPA 1999.
	HBCD should be identified as meeting the criteria for virtual elimination under CEPA 1999. In addition, the manufacture, use, sale, offer for sale, import, and export of HBCD and products containing HBCD should be prohibited via a regulation under CEPA 1999.	The Government of Canada has identified HBCD as meeting the criteria for virtual elimination in the final screening assessment and the risk management will be based on the objective of eliminating the release of measurable quantities of this substance. A regulation that prohibits the manufacture, use, sale, and import of HBCD or products containing HBCD will be considered in the Risk Management Approach.
	Canada should play an important role on work being done internationally.	Issues related to the risk management of HBCD are complex and are currently being examined at the international level under the United Nations Environment Programme (UNEP) Stockholm Convention on Persistent Organic Pollutants and the Convention on Long-range Transboundary Air Pollution (LRTAP) of the United Nations Economic Commission for Europe (UNECE). Canada is actively engaged in these discussions and will seek to benefit from the experience of other jurisdictions where they are relevant to Canadian circumstances.
	The Government of Canada should discourage any requests for exemptions in the development of regulations aiming to achieve prohibitions.	The Government of Canada will give careful consideration to whether or not to grant exemptions to any prohibition of HBCD or products containing HBCD and will solicit input on this issue during public consultations on the Risk Management Approach.
	If a regulation is introduced that prohibits the manufacture, use, sale, offer for sale, import and export of HBCD or products containing HBCD (virtual elimination), industry requests an essential use exemption or permission for continued use until a more sustainable replacement is found, tested, commercialized and phased into use by the polystyrene foam insulation sector.	The Government of Canada will give careful consideration to all available relevant evidence in its decisions regarding the continued use of HBCD in polystyrene foam insulation. The Government of Canada will seek input on this issue during public consultations on the Risk Management Approach.
	HBCD should not be prohibited for use in products “currently in place” that “contain HBCD in a safe and effective manner”.	The Government of Canada will give careful consideration to all available relevant evidence in its decisions regarding the continued use of products containing HBCD. New products and products already in use present different challenges and may warrant different treatment under an HBCD risk management strategy. The Government of Canada will also seek input on this issue during public consultations on the Risk Management Approach.

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	Environment Canada should take a product-by-product, risk-by-risk approach with HBCD.	The Government of Canada will give careful consideration to the various products containing HBCD and the availability of alternatives. The Government of Canada will also seek input on this issue during public consultations on the Risk Management Approach.
	Substances released through uncontrolled combustion of HBCD in Expanded Polystyrene (EPS) foam should be exempt from the risk management strategies for HBCD.	Substances from incomplete combustion of HBCD, such as polybrominated dibenzo-*p*-dioxins (PBDDs) and dibenzofurans (PBDFs), will be considered when developing the risk management approach. However, these by-products will not be the primary objective of a risk management strategy for HBCD.
	Products containing HBCD should not be recycled or incinerated. The risk management approach document should place more attention on risk management of HBCD in the waste sector.	An approach for HBCD and products containing HBCD in recycle and waste streams will be incorporated in to the risk management strategy. A consultation document that considers minimizing adverse impacts of recycling in the proposed risk management approach is being prepared, and will be provided to stakeholders for comments and input. The Risk Management Approach will address this issue. The Government of Canada is developing a risk management strategy for the waste sector (i.e., landfills, incinerators and recycling facilities) that will include best management practices to minimize the release of toxic substances, like HBCD, into the Canadian environment during the recycling and disposal of products. The Government of Canada is collecting information on waste and recyclable materials processing facilities in Canada and HBCD is also being monitored across Canada in landfill leachate to determine concentrations of HBCD released from these sites. HBCD will be monitored and collected information will be used in performance measurement of risk management actions. Waste management is also under provincial / territorial jurisdiction.
	Risk management strategies for HBCD should include longitudinal monitoring programs on indoor sources of HBCD and continued monitoring of fish for the presence of HBCD, and its breakdown products, in bodies of water that are sources of food for the Canadian population.	The Government of Canada will incorporate an appropriate monitoring plan into its risk management strategy for HBCD. The Risk Management Approach for HBCD will address this issue.
	The benefits to human and environmental health of eliminating the use of HBCD should be studied through a socio-economic analysis and resulting regulation be implemented as soon as possible.	The Government of Canada will consider socio-economic factors related to the costs and benefits of removing HBCD from use and develop regulatory instruments in accordance with Cabinet Directives and Treasury Board procedures.
	Any risk management strategy for HBCD used in polystyrene foam should take account of its potential impact on non-flame retardant products.	The Government of Canada will, in its risk management strategy for HBCD, take into consideration the costs, as well as the benefits, of the various options, including the prohibition of HBCD. These matters will be addressed in the Risk Management Approach.

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	The following statement in the Risk Management Scope does not apply to polystyrene foams in their use phase: "As HBCD is not covalently bound, but is only mixed or dissolved in the product polymer, HBCD has the potential to migrate out of consumer or industrial end use products into the environment. Releases may thus occur in both indoor and outdoor environments"	The screening assessment report identifies factors that constrain HBCD release from products (such as polystyrene foam) to the environment. However, HBCD is found in the environment over wide areas, including in waste treatment facility effluents and landfill leachates, therefore HBCD migration is not always insignificant. Modifications relating to potential HBCD releases were made to the screening assessment report and risk management scope as appropriate.
	Information on the presence of HBCD in products must be made available to the general public.	The Government of Canada makes information on exposures to HBCD in products available to the public, where practical.
	Safer alternatives to HBCD should be identified and implemented.	The Government of Canada agrees that there is a need for an orderly transition to safer products and will seek to implement a risk management strategy for HBCD that carefully weighs the benefits and costs of that the strategy. The availability, cost and effectiveness of acceptable alternatives are considered as part of the risk management process while consulting with the stakeholders.
	Environment Canada should first obtain all available data on HBCD.	The Government of Canada agrees that all relevant existing information and data be considered.
	All steps required under section 65 of CEPA 1999 should be followed before declaring virtual elimination for HBCD.	The Government of Canada agrees that all relevant sections of CEPA 1999 must be followed.
	When implementing a risk management strategy for HBCD, the Government of Canada should publicly demonstrate that it is following policies in the "Cabinet Directive on Streamlining Regulation (TBS 2007)" and "Assessing, Selecting, and Implementing Instruments for Government Action".	The Government of Canada follows all relevant government policies.
	A sustainable development objective should be included in the risk management of HBCD.	The Government of Canada considers sustainable development as an important objective.
	Risk management strategies should take into account HBCD risk management plans developed by industry.	The Government of Canada acknowledges the efforts that industry applies to the responsible management of HBCD.
	HBCD does not meet the criteria for *CEPA 1999* 64c and is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.	The conclusion on human health is based upon margins of exposure (MOEs) presented in the assessment, between the estimates of exposure and critical effect levels. These MOEs address uncertainties in the health effects and exposure databases and are protective of the general and vulnerable populations in Canada.
	Adverse potential health effects are a major concern, which requires much more attention and study.	All available and relevant data on human health effects related to HBCD were considered. Any additional information that is submitted will be considered.
	Clarification or modifications are required for sections of the HBCD Risk Management Scope that refer to findings in the HBCD Screening Assessment Report. It is also requested that findings from the HBCD Screening Assessment Report be applied to HBCD in general, regardless of CAS number.	All modifications and updates to the HBCD Screening Assessment Report have been considered for the final Risk Management Scope. For the HBCD Screening Assessment Report, all available relevant data and studies that are of reliable quality were considered equally. Therefore the assessment findings and scope apply to HBCD in general and irrespective of CAS number.

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	The statement in the Risk Management Scope that releases of HBCD to air, water, soil and sediment can contribute to the contamination of food is not supported.	The comment in the Risk Management Scope that releases of HBCD to air, water and soil and sediment can contribute to levels in food is supported by peer reviewed literature.
	The following statement in Section 1.3 of the Risk Management Scope should be clarified: "HBCD has been known to discharge to…"	The intent of this statement is that it is reasonable to expect HBCD releases to the environment are occurring, as HBCD is found in the environment over wide areas, including in waste treatment facility effluents and landfill leachates. This statement is supported by global and North American data.
	The uses of HBCD have not been consistently characterized in the Risk Management Scope document.	The characterization of HBCD use has been amended accordingly in the Risk Management Approach.
	All cited sources of information should be made available to the public for "peer review".	The Government of Canada uses of all available relevant information when formulating policy. Some of this information is "confidential business information" and cannot be shared with the public because of the terms under which it was acquired.
	Risk management measures should be tied to factual, as opposed to inaccurately identified, risks.	The Screening Assessment Report has identified factual risks posed by HBCD. The Report states that HBCD is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.
Monitoring		
Monitoring	More monitoring and biomonitoring must be done, especially in sensitive areas, including the Arctic, and for vulnerable populations.	Biomonitoring information of susceptible populations was taken into consideration as part of the risk characterization for human health. Further monitoring is underway for HBCD. HBCD is being measured in Canadians aged 6 - 79 years of age as part of a study on organohalogens in blood from the Canadian Health Measures Survey (http://www.statcan.gc.ca/survey-enquete/household-menages/5071o-eng.htm). Results of this study are expected to be available able in 2012.
	The Risk Management Scope indicates that HBCD is being monitored in the Canadian Health Measures Survey (CHMS); however it is not listed on the survey web site.	HBCD is being measured as part of an ancillary study to the CHMS which is being conducted with residual pooled blood. It is not a part of the core CHMS study.
	The CHMS website provided in the Risk Management Scope states that data will be available in 2011 compared to 2012 in the Risk Management Scope.	Due to the complexity of the laboratory analysis, CHMS results will be released in 2012.
	The Government of Canada should not use CHMS data if it is not available during risk management instrument development, for consistency with other CMP substances.	All assessed substances remain subject to future assessment if new information indicates that further consideration is warranted.
Toxicity and Quantitative Risk Assessment		

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Toxicity and Quantitative Risk Assessment	To support the conclusion that virtual elimination is required, the Risk Management Scope should make a clear statement regarding the toxicity of HBCD; in addition to stating that it is persistent and bioaccumulative.	The Screening Assessment Report shows that HBCD enters the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment. Therefore, HBCD meets one or more of the criteria set out in section 64 of the *Canadian Environmental Protection Act, 1999 (CEPA 1999)*. In addition, the Risk Management Scope also concludes that HBCD meets the criteria for persistence and bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).
	A lower maximum HBCD usage by a facility (i.e., 50 000 kg/year rather than 100 000 kg/year) would better represent a reasonable worst-case scenario in the modelled exposure exercise for the risk quotient analysis. Model assumptions and inputs also need to be justified.	The inputs and estimates used for this modeled exposure scenario have been carefully evaluated and are considered reasonable representations of "worst-case conditions" for Canada. This is based on information from the section 71 survey (Environment Canada 2001) and default emission factors recommended by the OECD and European Communities Technical Guidance Documents. Even with a maximum usage of 50 000 kg/year, as suggested in the comment, risk quotients would still exceed 1 for both pelagic and benthic organisms.
	Uncertainties associated with analytical testing procedures may be influencing risk assessment results.	While it is acknowledged that there are areas of uncertainty associated with analytical testing procedures for complex substances, in the case of HBCD, techniques have been refined over recent years and are considered well established. In order to reduce uncertainty, all studies considered in the assessment were critically reviewed and only studies deemed to be of satisfactory reliability and acceptable quality were used in the weight of evidence assessment.
	The final assessment report should be published in time for the Stockholm Convention Conference of the Parties meeting on persistent organic pollutants scheduled for May 2011.	The Government of Canada will publish the final assessment report for HBCD as soon as possible.
	A study examining potential HBCD impact on various terrestrial plants found no effects. Given some facilities in Canada are located in or adjacent to agricultural locations, the assessment should overtly recognize that HBCD does not have impact on agricultural conditions.	The assessment evaluated the potential HBCD risk to soil organisms by evaluating exposure via sewage sludge application to agricultural soils. The corresponding risk quotient analysis found that current estimated exposure concentrations of HBCD in Canadian soils are unlikely to exceed those leading to adverse effects in soil organisms.
	The assessment should review and present any potential mode of action for HBCD.	The final assessment has been updated to provide a more information on potential modes of action for HBCD.
	It appears that the Kuiper [et al.] (2007) study is not relevant enough to support ecological assessment conclusions.	The Kuiper [et al.] (2007)[1] study did not add significantly to the weight of evidence in the ecological assessment and it has been removed, and more recent and relevant studies have been added to the assessment.
	A submission with toxicity assessment results for extruded polystyrene (XPS) and expanded polystyrene (EPS) foams was provided.	The Government of Canada appreciates the submission of the safety assessment results for XPS and EPS foams. However, these data are not included in the assessment as they do not change the results.

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	A discussion of the proposed classification from other groups or regulatory bodies (i.e. Stockholm Convention, EU) should be included in the assessment.	Although the Government of Canada looks at all available literature when conducting an assessment, only official and final classifications and conclusions from specific regulatory bodies are considered (when available) in conducting screening assessments. Those regulatory bodies have been selected based on the rigour of their scientific processes as well as the similarity with Health Canada and Environment Canada in their regulatory mandate.
	There should be more studies on lifetime and multigenerational exposure, and the extrapolation from animal to human studies is uncertain.	Although there are uncertainties when extrapolating animal study data to human health effects is typical and thus not outlined in the assessments. Multigenerational and long term studies have been identified and are presented in the assessment.
	All types of health effects should be considered in the screening assessment rather than just the one effect identified in the risk characterization.	All available and relevant data on HBCD were considered, and the screening assessment highlights key studies that cover the health effects and other issues mentioned the public comments.
	It should be clearly indicated that HBCD in polystyrene foam is not hazardous to health because it is contained within products resulting in no exposure.	The screening assessment report describes how HBCD exposure does not occur with certain products (e.g. polystyrene foam). However HBCD is found in the environment over wide areas, including in waste streams, and these routes of exposure are reflected in the assessment.
Persistence and Bioaccumulation		
Persistence and Bioaccumulation	The designation of Persistence, Bioaccumulative and inherently Toxic (PBiT), in particular the designation of Persistence, for HBCD based on existing data is questionable. The evaluation of the bioaccumulation potential of the degradation product 1, 5, 9-cyclododecatriene (CDT) is also contested.	The screening assessment found that HBCD met the criteria for Persistence in air, water, soil and sediment as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000). This finding was based on empirical data and modeled data which support the designation. HBCD concentrations in sediment layers date back to the 1960s, indicating that HBCD can persist in the environment for decades. HBCD is also found to be present in remote sites such as the Arctic via long range atmospheric transport, and has a high potential for biomagnification. The biological break-down product CDT is also considered to be potentially bioaccumulative.
	Two studies on the differences in HBCD diastereomer degradation rates in sediment were mis-interpreted in the draft assessment. Namely EBFRIP (2004b) and Gerecke et al. (2006).	For these two studies, minor differences in degradation rates for the different isomers of HBCDs were noted. For the Gerecke et al. (2006) study, it is agreed that all diastereomers degraded quickly and that no statistically significant differences were noted. The final assessment has been modified to clarify study findings.
	Where the assessment compares two soil degradation studies for HBCD: ACCBFRIP (2003c) and EBFRIP (2004b), a key difference in the studies is that the amount of HBCD added to the soil was significantly different. The amount of a substance may influence degradation rates. Also, the first study determined rate of reaction as HBCD biodegrades and the other study was designed to identify HBCD degradation products.	The final assessment has been modified to show that the experimental design and research methods of these two studies are different. It is also noted that the amount of a chemical substance will influence how quickly it biodegrades in the environment.

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	Model estimates for persistence in air may not be accurate.	There will always be uncertainties when using modeled data. However, field data indicate that HBCD is measured in remote locations, such as the Arctic, suggesting long range atmospheric transport. It is determined that HBCD meets the persistence criterion for air, as specified in the *Persistence and Bioaccumulation Regulation* under CEPA 1999.
	It may not be necessary to generate QSARs for data rich substances such as HBCD.	QSARs should be used routinely as they lend support to experimental data and help to identify conflicts in limited experimental data. In most cases, empirical data is given more consideration than modelled data. However, results generated from computer models should also be used to support evidence on the environmental fate and effects of a substance. Reliable model results can be more credible than empirical data that is of questionable quality or relevance. In general, HBCD is 'data rich' compared to many other substances, however, there are still limited data available for certain compartments.
	Remote northern regions of Canada should be monitored for presence of HBCD in order to better understand the implications of long-range transport for this chemical.	Research and monitoring, where relevant, will support verification of assumptions used during the HBCD screening assessment and, where appropriate, the performance of potential control measures identified during the risk management phase. Northern regions of Canada will be considered for relevant monitoring.
	The Risk Management Scope lacks theoretical discussion on HBCD found in remote areas due to long range transport. Long range transport models should be considered.	In the Screening Assessment Report, it is noted that HBCD persists in air for as long as two days, and is therefore capable of remaining in the atmosphere long enough to undergo long-range transport. The long range transport behaviour of HBCD depends on the atmospheric particulates to which it attaches. The screening assessment report discusses HBCD long-range transport modelling, as well as HBCD measurement in remote areas. While it is possible that HBCD in remote areas is due to local contamination, it is likely that HBCD undergoes atmospheric transport over long distances. HBCD is considered to meet the persistence criteria of CEPA 1999 for being subject to atmospheric transport sources to remote areas.
	Fugacity modelling results should be considered in the assessment since the physical and chemical properties of HBCD suggest that it is not likely to end up in water and air.	Fugacity modelling and the physical and chemical properties of HBCD, indicate that only a small proportion of HBCD is expected to be found in air and water compared to soil and sediments. However, information and data included in the screening assessment report show that if present, HBCD can persist in air and water. Empirical and modelled data also strongly suggest that HBCD bioaccumulates in aquatic organisms and biomagnifies in aquatic food webs.
HBCD Degradation Products		
	Further consideration should be given to determine the toxicity of the various degradation products of HBCD and in particular, the final breakdown product - 1, 5, 9-cyclododecatriene (CDT).	Existing model and empirical data indicate that CDT has a high potential for toxicity to ecological organisms. The Government of Canada is interested in additional empirical data for this degradation product.

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HBCD Degradation Products	Two studies: EBFRIP (2006) and Davis et al. (2006a) show that the HBCD degradation product 1,5,9-cyclododectriene (CDT) does not persist in the environment.	The lack of evidence of complete break-down of HBCD, along with other factors, supports the conclusion that it persists in sediments. The primary degradation products of HBCD (e.g. CDT) have been identified in sediments, therefore the assessment examined the limited information on these products to more fully characterize potential ecological concerns of HBCD. In EBFRIP (2006), it was demonstrated that CDT is subject to primary degradation, but there was no evidence to show that it breaks down completely. Davis et al. (2006a) also demonstrated that small amounts of CDT break down to carbon dioxide in the presence of oxygen in laboratory testing environments. However, information is not available on CDT biodegradation in low oxygen environments such as subsurface soil and sediment, where HBCD usually ends up. The final assessment has been modified to clearly reflect that CDT's stability in sediment remains uncertain due to limited information.
	The bioaccumulation potential of degradation product *1,5,9-cyclododecatriene (*CDT) should be low since it is not expected to persist in the environment.	CDT bioaccumulation estimates presented in the assessment represent measured data and results of standard modeling approaches, all of which have indicated a high potential for bioaccumulation. Therefore the Government of Canada maintains that the interpretation that CDT is potentially bioaccumulative in aquatic organisms is valid. However, it is acknowledged that depending on the stability of CDT in a given compartment, the substance may not always be stable long enough to bioaccumulate. This qualification has been added to the assessment.
Releases to the Environment		
Releases to the Environment	Stating the presence of HBCD is sometimes at "high concentrations" is relative and judgmental. High concentrations should be established relative to some accepted standard. It is suggested the text be reconsidered and simply give values and a potential comparison.	The Government of Canada agrees that "high" is a relative term; the relevant section of the Synopsis has been modified to addess this comment.
	The validity of the assertion that global usage of HBCD is on the rise is questioned. It is believed this statement is incorrect, and that usage of HBCD is declining.	While there is a growing body of research on levels of HBCD and other flame retardants in the environment, available information on industrial use of HBCD is more limited, particularly in Canada and North America. However, for the years and continents having available data since 2000, increases in the demand for HBCD have been reported.
	Differences in HBCD releases among product types is supported by the European Union (EU) risk assessment. The EU assessment noted that although polystyrene applications represented 89% of use and textiles represented 11% of use, only 14% of releases were attributed to polystyrene applications and 86% of releases were attributed to textile applications.	The Government of Canada agrees that these data are relevant to the discussion of releases in the assessment report. A description of these differences by product type and the reference (EU RAR 2008) have been added to the 'Sources of release' section of the assessment.

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	Several comments were made suggesting that HBCD's likelihood for migration from products (in particular construction material) is insignificant due to: low vapour pressure, low water solubility, high predicted organic carbon water partition coefficient, and enclosure within building products.	The assessment report describes the factors that constrain HBCD migration from a product, and recognizes the limited migration potential. However, as described in the assessment, HBCD is found in the environment over wide areas, including in waste treatment facility effluents and landfill leachates. Therefore the Government of Canada does not agree that HBCD migration is always "insignificant". Suggested additions and modifications to text relating to potential release have been made where judged appropriate.
	Comments were submitted clarifying terminology for polystyrene foam description**.**	Suggested modifications have been made to the assessment text where judged appropriate.
	It is suggested that the Draft be revised to eliminate the apparent inconsistency between the following statements: - "Uses", paragraph 1: "Foam HBCD levels in Europe are higher than used in Canada …" - "Uses", paragraph 3: "The primary uses of HBCD in Canada … are consistent with the abovenoted global and European use patterns."	The Government of Canada does not see these comments as inconsistent since the first statement refers to *level* or concentrations of HBCD in European foams, and the second statement refers to the actual uses/applications of HBCD.
	The list of activities is not accurate, in particular use of the term "improper".	The list of activities is acknowledged as representing a generic list of activities potentially associated with release of HBCD. However the subsequent sections of the report further qualify which activities/sources are most applicable to the Canadian assessment. Please note that this section of the assessment states that HBCD production 'does not' occur in Canada (see paragraph 2), and the term "improper" qualifies the activities of "handling" and "storage" only.
	In characterizing the potential sources of release of HBCD from "processing activities" in the assessment report, it is important to distinguish between processing activities involving the direct use and handling of HBCD and those activities simply employing HBCD-containing materials.	The section has been modified, as suggested, to clarify that processing involving direct handling of HBCD could be a more likely source of HBCD release than those processing activities simply employing HBCD-containing materials.
	The word "uncontrolled' should be added before "certain" so that the text reads: Combustion of HBCD under certain uncontrolled conditions may lead to production of polybrominated dibenzo-p-dioxins (PBDDs) and dibenzofurans (PBDFs).	The word "uncontrolled" has been added to this sentence in the Synopsis. This section is now consistent with the Sources of Release section of the assessment.

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	The value of discussing the issue of toxic by-products of the uncontrolled combustion of HBCD and HBCD-containing materials in the assessment is questioned. The study by Desmet et al. (2005) on the combustion of HBCD-containing polystyrene foam did not find the toxic byproducts themselves were produced, only potential precursors. So the suggestion that toxic by-products are formed from the uncontrolled combustion of EPS foam remains unproven. In addition, given HBCD's mode of action as a flame retardant in which the HBCD-containing EPS foam withdraws from the combustion source by melting away, it is questionable how much HBCD is actually combusted uncontrollably.	It is agreed that Desmet et al. (2005) demonstrates the production of bromophenols (rather than PBDDs/PBDFs) from HBCD products. However, other studies have demonstrated the formation of PBDDs and PBDFs from the precursor, bromophenol, and have reported that brominated phenols show a higher potential for the formation of PXDDs/PXDFs compared to their chlorinated analogue. Literature suggests insufficient combustion (e.g open fires/accidental fires, even incerneration) and pyrolysis conditions can lead to high amounts of these hazardous products via the precursor pathway. This study also discusses the likely destruction of BFRs under high efficiency and controlled combustion conditions.
	Given the lack of certainty in this area, it cannot be presumed that contamination of groundwater is low.	The Government of Canada agrees that there is some uncertainty with respect to HBCD groundwater concentrations in Canada. However, the assessment uses the most reliable available information in its evaluation of the likely fate of HBCD within all compartments. As stated, the tendency of HBCD to sorb to particulates, its limited solubility in water, and evidence that it will undergo anaerobic biodegradation all suggest that the risk to of groundwater is probably low. Future studies and monitoring may provide further information on HBCD in groundwater in Canada.
	If the landfill is operated correctly and according to provincial permit/approval standards, weathering is insignificant because waste materials must be covered and are therefore not subject to weathering. Further, leachate in a landfill is not an emission. In a properly constructed and operated landfill it is collected or prevented from being lost off site to the environment.	The HBCD screening assessment discusses potential releases from landfills due to weathering and leachate loss, but recognizes the physical- chemical factors that limit these HBCD losses, and generally describes any potential releases from landfills as 'low'.
	HBCD does not represent a technical flame retardant alternative to Polybrominated diphenyl ethers (PBDEs), particularly in polysterene foam. The sections in the assessment suggesting this should be clarified.	The final assessment report has been re-phrased to clarify that the shifting trends in HBCD and PBDE concentrations described are based on measurements in the environment rather than product-specific information.
	The purpose of HBCD as a flame retardant in EPS foam is to reduce the risk of combustion to buildings and building occupants. The potential risk of toxic by-product formation is outweighed by the enhancement in safety to buildings and their occupants.	While the importance of fire safety is recognized, an evaluation of the role HBCD plays in enhancing building and occupant safety is considered to be beyond the scope of this chemical screening assessment.
	A submission was received respecting a European Union wide industry survey of HBCD emissions**.**	The submission was reviewed and relevant information has been added to the "releases to the environment" section of the screening assessment report. Specifically, information relating to: estimates of HBCD release to land, and the decreases in HBCD release to the environment noted

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		in 2009, has been added.
	Two studies (Ismail et al. 2009; Law et al. 2008) have identified declines in HBCD in the environment over a short time. It would seem likely that industry's product stewardship activities contributed to the positive result. The assessment should reflect that HBCD in the environment may not be continually increasing, but rather that industry product stewardship activity may have a measurable and positive impact.	While data presented in the assessment indicate that HBCD usage and presence in the environment have been generally increasing, it is acknowledged that recent European industry's efforts to improve their handling of HBCD, (documented in the VECAP Progress Report 2009), suggest that industry product stewardship may have a measurable impact on reducing HBCD emissions. Recent European Industry Survey findings have been added to the "sources of releases" section of the assessment. Future research and monitoring may clarify the recent trends.
	Comments were made regarding a lack of Canadian HBCD data post-year 2000, including: source data, import data, use data, release data etc.	The data included in the assessment represent the most recent data available to the Government of Canada, including HBCD data for the Canadian Arctic, and are considered sufficiently current for risk analysis.
	The synopsis should clarify that release of HBCD from EPA foam is unlikely as it is protected during use.	The sentence is a general statement within a synopsis and does not specifically refer to foam, but rather covers all end-use products.
	Two submissions were provided for analysis of XPS and EPS foams. One was an analysis on 'exposure to light" and one was an analysis on exposure to water for XPS and EPS foams.	The Government of Canada appreciates the submission of the analysis for XPS and EPS foams that are exposed to water and light. The results of these studies are generally consistent with findings reported in the screening assessment report, and therefore, do not change its conclusions. However modifications relating to the limited potential for HBCD release from foam products have been made to the screening assessment report text where appropriate.
Exposure		
	Caution must be exercised in extrapolating any European HBCD data to North America as it may over estimate.	There is some uncertainty with respect to how current trends in usage of HBCD between Europe and North America compare. Within the assessment, Canadian and North American data have been used wherever possible in scenarios for predicted exposure concentrations (PECs) for Canada. For risk quotient analysis, Canadian and North American data were used for the soil organism and wildlife PECs, while pelagic and benthic organism PECs were determined with data considered relevant to Canadian HBCD exposure.
	The Screening Assessment Report presents considerable data from beyond Canada. There is a lack of data for addressing the effect of HBCD on Canadians and the Canadian environment. This information should be analyzed in a context relevant to Canadian situations.	Canadian and North American data were used where available, especially for determining the HBCD exposure concentrations for Canada. However data from other countries provides insight into persistence, transport, and bioaccumulation of HBCD; data from regions with conditions similar to Canada (e.g. countries with Arctic regions) are of particular interest. There is some uncertainty on how current levels compare, however earlier data indicate that HBCD usage in European was higher than in Canada and North America.
	HBCD is well studied, therefore data likely exists for wastewater treatment plant effluents in North America.	Information from a recent study on a North American waste treatment plant was added to the final assessment, and provides measurements of sludge from secondary treatment, but not on effluent concentrations.

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	The uncertainty with sediment dating interpretation for HBCD in the environment should be addressed through additional discussions on interpreting sediment dates. Also the time period should be confirmed for the Remberger et al. 2004 study that is cited in the assessment.	The Remberger et al. (2004) finding on HBCD associated with pre-1960's sediment is questionable. Therefore, the assessment has been modified to include the authors' description of potential sources of error in sediment dating for this study.
	Findings from several additional studies should be added to the Temporal Trends section, including: Vorkamp KM et al. (2005), Ismail et al. (2009), Law et al (2006d) and Law et al (2008).	Findings from these studies have been added to the Temporal Trends section of the assessment where appropriate, with a focus on Canadian and North American data, or more recent data.
	Since HBCD is detected widely in humans and the environment, further research on human health impacts and ongoing monitoring of vulnerable ecosystems should be conducted. More clarity is also required on exposure from oral textiles for infants and toddlers, specifically relating to release rates from Canadian and European assessments. A rationale should be provided for the use of TCEP as a substitute for HBCD in the oral exposure from mouthing scenario because these are very different molecules.	Further monitoring is underway for HBCD for those aged 6 - 79 years as part of a study on organohalogens in the Canadian Health Measures Survey (http://www.statcan.gc.ca/survey-enquete/household-menages/5071o-eng.htm). Results of this study should be available in 2012. The exposure from the textiles scenario has been updated in the screening assessment report, and two approaches for characterizing potential exposure via the oral route from the mouthing scenario are presented.
	The use of extreme ambient air and dust concentrations in the exposure assessment is too conservative.	Appropriately conservative assumptions were used in the screening assessment report in order to be protective of human health.
Arctic and Vulnerable Populations		
Arctic and Vulnerable Populations	Exposure to Canadian Arctic residents should be addressed specifically. Gaps in Canadian exposure database for HBCD, including levels in Arctic human milk, wildlife consumed in Arctic diets and human adipose tissue should be filled.	The human health exposure characterization in the assessment incorporates data from the Canadian North. The assessment considered HBCD blood levels from people living in Nunavut and NWT, Northern air concentration data and HBCD concentration levels in fish reflecting levels found in the Canadian Arctic.
	Dietary exposure for Northern populations related to consumption of traditional food may be underestimated.	HBCD blood levels from people living in Northern Canada are presented in the assessment and are in the same range as dietary exposure estimates derived for the general population. This indicates that exposure is not underestimated for Northern populations.
	The Government of Canada should consider HBCD a potential concern for human health effects, and take measures to reduce exposure to vulnerable populations such as pregnant women, children and northern and coastal communities that depend on local fish and wildlife.	Based on available data, the various conservative exposure scenarios are considered to be protective of susceptible populations in Canada and do incorporate exposure estimates for Canadians of different ages. Consideration is given to different stages in selection of critical effects for the characterization of risk to human health. If information that identifies a specific sub-population is susceptible, it is considered in the assessment.

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	Not all vulnerable populations were considered in the assessment including those unintentionally exposed to HBCD through long-range transport, use, disposal and incineration.	The screening assessments are based on considerations of the available data. Upper bounding estimates of daily intake incorporate measured concentrations of HBCD in environmental media, which includes presence resulting from long-range transport, use, disposal and incineration.
	Use of the detection limit for non-detectable values in the dietary assessment is overly conservative (Appendix D). Half the detection limit should be used.	Appropriately conservative assumptions were used in order to be protective of human health.
Other (Weight of Evidence, Peer Review Transparency, Cumulative/Synergistic Effects, Tables, RSS, etc.)		
Other (Weight of Evidence, Peer Review Transparency, Cumulative/Synergistic Effects, Tables, RSS, etc.)	The criteria for weight of evidence and precaution should be disclosed. Understanding the criteria would assist to comprehend the judgments in the assessment. Further, given the weight of evidence approach; it is unclear in this screening assessment what data is considered by the government. Full understanding and disclosure would be helpful	A weight-of-evidence approach is applied to substance assessments conducted under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). This approach accounts for multiple lines of evidence in the identification of issues in determining whether a substance may have harmful properties or pose a risk. More details on the use of weight of evidence in chemical assessments can be found at the Chemical Substances portal and in the "Overview" guidance document. Please see the following links: http://www.ec.gc.ca/lcpe-cepa/documents/substances/eas_overview-eng.pdf, and/or http://www.chemicalsubstanceschimiques.gc.ca/about-apropos/assess-eval/guide/guide-ecologi-eng.php Ecological data used in the assessment is provided in tables at the end of the report and described in the text of the report. While the various sources of data and evidence are discussed throughout the report, the 'Potential to Cause Ecological Harm' section summarizes the weight of evidence evaluation. Furthermore, specific tables, such as Table 17, highlight key studies that were used to determine toxicity of the substance. Finally 'Robust Study Summaries' for the key studies on persistence, bioaccumulation, and inherent toxicity, which provide a critical review of a given study, are included in an appendix to the assessment, making the evaluation of the data transparent to the reader. Further information on the precautionary approach to decision making, is described in *A Framework for the Application of Precaution in Science-Based Decision Making About Risk* (Government of Canada). Please see the following link: http://www.pco-bcp.gc.ca/index.asp?lang=eng&page=information&sub=publications&doc=precaution/precaution-eng.htm
	Normally more informative discussion of the peer review would be presented. It is suggested in the publication of the formal assessment, more information be disclosed e.g. the peer review be	All assessments are subject to a comprehensive internal peer review by government scientists. Additionally, all assessments are subject to external peer-review/peer-consulation as outlined in the Introduction. Specifically, areas of uncertainty identified during the assessment and internal review

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	expanded and include analysis to illustrate that scientific standards have been met and transparency is evident in the scientific community and with other stakeholders.	are a focus of external scientific peer review. Technical expertise is the main criteria for identifying suitable individuals. All comments provided to the Government of Canada by peer reviewers are taken into consideration. Draft assessments are also subject to a 60-day public comment period. These comments are taken into consideration in finalizing the assessment report. The process followed in the evaluation of existing substances is outlined in the documents located at: www.chemicalsubstanceschimiques.gc.ca
	The issue of exposures from multiple sources and the potentially synergistic effects of chemical mixtures need to be examined, given that exposure to HBCD can occur in conjunction with exposure to several other potentially toxic chemicals.	Multiple sources of exposure are taken into consideration in the assessment. Consideration of cumulative and synergistic effects is not precluded from a risk assessment. However, in order to be considered, sufficient information to undertake such analyses would be needed. The information available for assessing effects is representative only of HBCD's inherent ability to elicit adverse effects.
	The screening assessment report should indicate which value of a property in Table 2 (Physical and Chemical Properties) was used in the assessment and the rationale - either in the body of the report or as footnotes on the table.	Values used in the screening assessment report have been identified as footnotes in the relevant Tables 2, 6, 16, and Appendices A and B. Additionally, a new table (Appendix F) has been added to more clearly identify inputs used for modelling.
	In Table 3, it is not evident why the half-life is "expected" (Column 4). The model outputs should be represented more positively; as the result or output. Therefore it is suggested the column be titled "Half Life".	The term has been modified to reflect the current standard term for use in ecological assessments: "extrapolated half life".
	Environment Canada is complimented for including the Robust Summaries for Key HBCD Studies in the draft Assessment (Appendix C). We encourage Environment and Health Canada to continue this practice in the future.	The support for including ecological Robust Study Summaries is acknowledged.

[1] Kuiper RV, Cantón RF, Leonards PEG, Jenssen BM, Dubbeldam M, Wester PW, van den Berg M, Vos JG, and Vethaak AD. 2007. Long-term exposure of European flounder (Platichthys flesus) to the flame-retardants tetrabromobisphenol A (TBBPA) and hexabromocyclododecane (HBCD), Ecotoxicol Envrio Saf 67(3): 349-360.