Summary of Public Comments Received on the Government of Canada's Revised Risk Management Strategy for Polybrominated Diphenyl Ethers (PBDEs) and Draft Ecological State of the Science Report on Decabromodiphenyl Ether (decaBDE) (Bioaccumulation and Transformation)

Part I
Summary of Public Comments Received on the Government of Canada's Revised Risk Management Strategy for Polybrominated Diphenyl Ethers (PBDEs).

Comments on the Revised Risk Management Strategy for PBDEs were provided by the David Suzuki Foundation, Ecojustice, Canadian Environmental Law Association (CELA), Bromine Science and Environment Forum (BSEF), Canadian Cancer Society (CCS), Canadian Partnership for Children's Health and Environment (CPCHE), MG Chemicals Ltd., Canadian Vehicle Manufacturer's Association (CVMA), Canadian Association of Recycling Industries (CARI), International Sleep Products Association (ISPA), International Electrotechnical Commission (IEC), and individual stakeholders (8).

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

- Revised Risk Management Strategy – general
- Alternative flame retardants
- Harmonization with the international community
- Proposed regulatory controls to restrict PBDEs in manufactured and imported products
- Recycled products
- Proposed Environmental Performance Agreement

TOPIC	COMMENT	RESPONSE
Revised Risk Management Strategy - general	Public awareness about indoor exposure sources and pathways for PBDEs is an important and legitimate component of a risk management strategy.	The State of the Science Report for a Screening Health Assessment of PBDEs (also referred to as the human health screening assessment) did not identify a current risk to human health from PBDEs. The Government of Canada did, however, make additional information concerning PBDE flame retardants and human health available to the public on the "it's your health" website: http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/environ/pbde-eng.php The human health screening assessment (Health Canada 2006) concluded that worst-case estimates of the exposure of Canadians to PBDEs are much lower than levels which caused adverse health effects in laboratory animals. Based on reported concentrations of PBDEs in

		ambient and indoor air, water, various foodstuffs, human breast milk and dust, along with standard reference values for six different age groups, including breast-fed infants, upper-bounding estimates of daily intake of total PBDEs (i.e., tetra- to decaBDE congeners) were calculated. Food (including breast milk) represented the principal source of exposure for the majority of the age groups (although dust was the principal source of exposure for the 0- to 6-month-old non-breast-fed age group). The control measures that the Government of Canada will be proposing to protect the environment from PBDEs are expected also to reduce human exposure.
	The Revised Risk Management Strategy fails to link any adverse effects found for PBDEs to the commercial PBDE mixtures.	PBDEs are sold and used in three commercial mixtures, PentaBDE, OctaBDE and DecaBDE, each containing two or more of the seven congener groups (see Figure 1 of the Revised Risk Management Strategy for composition of the commercial mixtures). There are no known natural sources of PBDEs and the presence of these substances in the environment results primarily from human activity and the use of the commercial mixtures. Accordingly, the assessments and the Revised Risk Management Strategy consider PBDEs found in the commercial mixtures, as effects associated with PBDEs are attributable to their use. All the documents mentioned in this response are found on the Management of Toxic Substances website at: http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=98E80CC6-1&xml=5046470B-2D3C-48B4-9E46-735B7820A444
	The Revised Risk Management Strategy for PBDEs underestimates the contribution of dust to PBDE exposure.	The contribution of dust to human PBDE exposure was included in the Human Health Screening Assessment published in 2006, which found that food (including breast milk) represented the principal source of exposure for the majority of the age groups (although dust was the principal source of exposure for the 0- to 6-month-old non-breast-fed age group). The control measures included in the final Revised Risk Management Strategy, published jointly with this table, such as regulatory controls to restrict PBDEs in manufactured and imported products will reduce PBDE exposure from dust by restricting the amount of PBDEs that are incorporated into products. The Risk Management Strategy also includes

		biomonitoring to continue to monitor the exposure of Canadians to PBDEs from all sources, including vulnerable populations such as pregnant woman and northern communities.
	The Revised Risk Management Strategy provides insufficient assurance that the monitoring to be conducted will address indoor exposures, particularly via dust.	The human health assessment (Health Canada 2006) concluded that worst-case estimates of the exposure of Canadians to PBDEs are much lower than levels which caused adverse health effects in laboratory animals. However, the Government of Canada continues to monitor PBDEs in the environment and in humans. This data will be used as performance indicators of risk management actions, and to determine whether the Risk Management Strategy is meeting its objectives.
	The potential widespread use of decaBDE in plastic pallets used to ship and store produce underscores the limitations of the Revised Risk Management Strategy, which focuses exclusively on the use of decaBDE in electrical and electronic equipment.	Ongoing assessment and management of PBDEs in Canada and other jurisdictions, in concert with the December 2009 announcement by the three largest manufacturers of DecaBDE of their intention to phase out production and import of DecaBDE for the US market by 2013 is expected to significantly decrease the use of this commercial mixture in Canada in the next few years. The Government of Canada is aware of the use of decaBDE in plastic pallets. In parallel with the findings of the State of Science Report on decaBDE, the phase-out of the decaBDE substance by industry in the United States, and the public comments received, the final Revised Risk Management Strategy for PBDEs (published jointly with this table) was revised to propose the inclusion of a broader range of control measures for PBDEs, including restrictions for decaBDE that apply to all products (not limited to electrical and electronic equipment as indicated in the March 2009 Risk Management Strategy). A consultation document on the proposed regulatory controls for PBDE containing products is currently being prepared. This document will provide a detailed outline of the proposed instrument, and will allow interested stakeholders to comment and provide feedback. This comment will be considered in the development of the proposed regulatory controls.
Alternative flame retardants	There is a need to ensure that toxic substances being regulated will not be	The Government of Canada is in agreement with the points raised and the need for an orderly transition to safer products and technology. The Government of Canada is currently undertaking screening assessments of two important alternative flame retardants,

	replaced by equally hazardous ones. Missing from the Revised Risk Management Strategy is a mechanism to ensure that decaBDE is replaced with a safer alternative. The absence of DecaBDE from products in Canada conveys that in order to achieve the necessary level of fire resistance, other technologies and materials will be introduced, each with their own particular environmental footprint and potential risk. The Revised Risk Management Strategy pays little attention to the inherent risk posed by chemical substitution. Manufacturers should seek out their solutions, and if they find an alternative chemical, they should conduct studies to ensure it is safe.	tetrabromobisphenol A (TBBPA) and hexabromocyclododecane (HBCD). In addition, as part of the Categorization of the Domestic Substances List (DSL) that was completed in September 2006, approximately 4300 substances have been identified as requiring further action (e.g., through a process of risk assessment and risk management if needed). This group includes substances which may have application as flame retardants. The Government of Canada is currently considering ways to prioritize the assessment and management of substances remaining to be addressed. In this respect, approaches are being examined which would further consider the impacts of alternative substances.
	There will not be a suitable amount of lead time needed to develop and incorporate	The availability, cost and effectiveness of acceptable alternatives are considered as part of the risk management process in consultation with stakeholders. A consultation document on the proposed regulatory controls for PBDE containing

	a suitable alternative to decaBDE, in order to meet the regulatory requirement on flammability.	products is currently being prepared. This document will provide a detailed outline of the proposed instrument, and will allow interested stakeholders to comment and provide feedback. These comments will be considered in the development of the proposed regulatory controls, and any exemptions for critical uses will be considered.
Harmonization with the international community	Aligning Canada's Risk Management Strategy with the European Union RoHS (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment) Directive 2002/95/EC is premature and unwarranted. Aligning Canada's Risk Management Strategy with the European Union RoHS Directive is in agreement with the needs and capability of the many companies and suppliers in the Canadian electronics industry.	While the Government of Canada fully considers actions that are taking place in other jurisdictions, risk management actions are based on the findings of risk assessments undertaken by the Government of Canada. The final Revised Risk Management Strategy for PBDEs (published jointly with this table) proposes the inclusion of control measures for PBDEs in products, including restrictions for decaBDE that apply to products (not limited to electrical and electronic equipment as indicated in the March 2009 Risk Management Strategy). These revisions are broader than the restrictions currently in the European Union RoHS Directive, and were made following conclusions of the final State of Science Report on decaBDE (published jointly with this table), the public comments received during the consultation period and the voluntary phase-out by industry of the production of decaBDE substance, in the United States. A consultation document on the proposed regulatory controls for PBDE containing products is being prepared. This document will provide more details on the proposed instruments, and will allow interested stakeholders to comment and provide feedback. These comments will be considered in the development of the proposed regulatory controls, and possible exemptions for critical uses will be considered.
Proposed regulatory controls to restrict PBDEs in manufactured and imported products	The proposed regulatory controls to restrict PBDEs in manufactured and imported products do not take into consideration issues such as labelling and certification requirement.	This comment will be taken into consideration as part of the development of the proposed regulatory controls for PBDE containing products. A consultation document on these regulatory controls is currently being prepared. Stakeholders will be invited to provide further information and opinion on potential requirements concerning labelling and certification.
	As part of the proposed regulatory controls to	This comment will be taken into consideration as part of the development of the proposed regulatory controls for PBDE containing products. As above, a consultation document on

	restrict PBDEs in products, it seems unwise to allow for the re-use of non-compliant spare parts, given the environmental and health risks involved. These products should be labelled as non-compliant. The provision allowing for spare parts should sunset after a fixed period of time (e.g. 5 years).	these regulatory controls is currently being prepared. This document will provide further details on the proposed instrument, and will allow interested stakeholders to comment and provide their feedback. As for health risks, the health assessment did not identify a current risk to human health from PBDEs.
	There is concern that since the DecaBDE commercial mixture is not manufactured in Canada, the responsibility will rest on the importer rather than the manufacturer.	Consultations on proposed controls will cover where responsibility for compliance will lie for finished products imported into Canada as well as for products manufactured in Canada. The consultation document will provide further details on proposed instruments and will allow interested stakeholders to comment and provide their feedback. These comments will be considered in the development of the proposed regulatory controls.
	The proposed Product Regulations will not provide adequate measures of protection to human health and the environment. It would be more protective for the Government of Canada to commit to a full ban on PBDEs in products (including in the textile sector). A voluntary approach is the	The risk management objective for all seven groups of PBDEs that were added to Schedule 1 of CEPA 1999 is to prevent the introduction of their manufacture in Canada and to minimize their release into the environment from all sources in Canada. The health assessment did not identify a current risk to human health from PBDEs. In the final Revised Risk Management Strategy for PBDEs (published jointly with this table), the Government of Canada proposes stringent regulatory action for all sectors, including those covered by the Performance Agreement (plastics and textiles). This revision from the March 2009 Risk Management Strategy is based on the conclusions of the State of Science Report on decaBDE regarding its potential to transform into forms slated for virtual elimination (tetraBDE, pentaBDE and hexaBDE congeners), the public comments listed in this table and the announcement of the voluntary phase-out of decaBDE by industry in the United States. As such, the proposed Performance Agreement[1] is no longer deemed an effective tool to manage the use of DecaBDE at manufacturing

[1] For an archive of this proposed Performance Agreement, please refer to: http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=0B904C67-1

	most responsible means to managing decaBDE.	facilities in Canada, and will not be finalized for implementation.
	The International Electrotechnical Commission (IEC) recently developed and published an International Standard (IEC 62321) on testing for certain substances in electronic and electrical equipment (EEE) products. Does the Canadian government see a need to adopt a Canadian standard for the testing of regulated substances and in particular PBDE congeners?	A consultation document on the proposed regulatory controls for PBDE containing products is currently being prepared. This document will provide more details on the proposed instruments. This matter will be considered in the development of the proposed regulatory controls and stakeholders will be invited to provide further information and opinion on this issue.
Recycled products	If the restrictions become too stringent from the perspective of recyclers, they may stop accepting any materials containing PBDEs and this will create a disposal problem. The Revised Risk Management Strategy overlooks the risk for exposure from the waste recovery and reuse of products containing PentaBDE and OctaBDE.	The first comment will be taken into consideration while developing the regulatory controls to restrict PBDEs in products, in an effort to minimize adverse impacts of proposed controls on the recycling/refurbishment industry. A consultation document on the proposed regulatory controls is currently being prepared. This document will provide more details of the proposed regulations and will provide interested stakeholders the opportunity to provide comments and feedback on any potential adverse impacts to the recycling industry. Issues related to the recycling and reuse of products containing PBDEs are complex and are currently being examined at the international level under the 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. At the fourth Conference of the Parties (COP4) of the Stockholm Convention, the convention added provisions allowing the continued recycling and reuse of products containing the listed PBDEs (contained in the PentaBDE and OctaBDE commercial mixtures) until 2030. For more information on this

		listing decision, please consult the COP4 documents of the Stockholm Convention at: http://chm.pops.int/Convention/COP/hrMeetings/COP4/COP4Documents/tabid/531/language/en-US/Default.aspx The Government of Canada is developing a risk management strategy for the waste sector (i.e., landfills, incinerators and recycling facilities) that will include PBDE-containing products and other toxics at end-of-life. This strategy will aim to minimize the quantities of PBDEs released to the Canadian environment through the disposal or recycling of products containing PBDEs. As part of the development of one of these strategies, the Government of Canada is presently collecting information on waste and recyclable materials processing facilities in Canada. PBDE's are also included in the Chemicals Management Plan (CMP) Environmental Monitoring Program and are being monitored across Canada in landfill leachate to determine the concentration of PBDEs released from these sites. Environment Canada plans to continue to monitor PBDEs and other toxics over the next few years, and will use the information collected as a performance measure of the risk management actions implemented. Furthermore, as waste management also falls within provincial jurisdiction, many Canadian provinces have already passed province-wide legislation that requires manufacturers, importers and sellers to ensure take-back and recycling services for designated electronic products that they sell. Existing provincial programs are administered by: Electronics Stewardship Association of British Columbia (ESABC), Alberta Recycling Management Authority (ARMA), Saskatchewan Waste Electronic Equipment Program (SWEEP), Ontario Electronic Stewardship (OES), and Atlantic Canada Electronics Stewardship (ACES) for Nova Scotia. These programs continue to divert many tonnes of electronic waste from landfill to environmentally sound material recovery and recycling operations.
Proposed Environmental Performance Agreement	The proposed Performance Agreement for DecaBDE should require a progressive phase-down and be backstopped with an enforceable ban once the agreement expires.	A multi-instrument approach for the risk management of PBDEs was selected to minimize releases of PBDEs from all sources to the environment. The Performance Agreement was developed as an early action initiative of the Chemicals Management Plan and to complement regulatory instruments outlined in the Risk Management Strategy. Ongoing assessment and management of PBDEs in Canada and other jurisdictions, in concert with the December 2009 announcement by the three largest manufacturers of DecaBDE of their intention to phase out production and import of DecaBDE for the US

		market by 2013 is expected to significantly decrease the use of this commercial mixture in Canada in the next few years. The Risk Management Strategy for PBDEs has been further revised in response to these events as well as the public comments received on the March 2009 version of the Strategy. The Risk Management Strategy now proposes the inclusion of broader restrictions on PBDE containing products, including restrictions for decaBDE in a wide range of products (not limited to electrical and electronic equipment as indicated in the March 2009 Risk Management Strategy). As a result, the proposed Performance Agreement[2] is no longer deemed an effective tool to manage the use of DecaBDE at manufacturing facilities in Canada, and will not be finalized for implementation.

[2] For an archive of this proposed Performance Agreement, please refer to: http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=0B904C67-1

Part II

Summary of Public Comments Received on the Government of Canada's Ecological State of the Science Report on Decabromodiphenyl Ether (decaBDE)

Comments on the Draft Ecological State of the Science Report were provided by the David Suzuki Foundation, Ecojustice, Canadian Environmental Law Association (CELA), Bromine Science and Environment Forum (BSEF), Abermarle Corporation, Chemtura Corporation, and individual stakeholders (1).

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

- State of the Science Report -general
- Transformation, degradation and debromination in environment
- Bioaccumulation/biomagnification studies
- Metabolism/uptake
- Toxicity
- Bioaccumulation criteria outlined in the *Persistence and Bioaccumulation Regulations* under CEPA 1999
- Alternatives - decabromodiphenyl ethane
- Independent Board of review

TOPIC	COMMENT	RESPONSE
State of the Science Report - general	As a result of a long delay in releasing the draft State of the Science report on decaBDE, the information it reviews is a full year out of date and has caused timelines for the risk management of decaBDE to be pushed back.	The findings of the draft Ecological State of the Science Report on decabromodiphenyl ether (decaBDE or BDE209) have been updated further for the final report since the time of its publication in March 2009, and are considered current. The Risk Management Strategy originally published in 2006 was revised to take into consideration the results of the Ecological State of the Science Report. The final revised Strategy, published along with this table, was further revised to propose broadening the application of control measures restricting PBDEs in manufactured and imported products to include restrictions on decaBDE in a wide range of products (not limited to electrical and electronic equipment as indicated in the March 2009 Risk Management Strategy).

		The timeline for risk management actions outlined in the final revised Strategy follows the regulatory process under the *Canadian Environmental Protection Act, 1999* (CEPA 1999).
	Conclusions within the State of the Science report are subjective, not based on strong and transparent scientific criteria, and unsubstantiated based on the weight of scientific evidence. The subjective approach to risk management contained in the proposed State of the Science report contradicts Canada's well-respected process for chemical evaluation. There is no scientific basis for proposing a ban on the use of decaBDE in electrical and electronic equipment. There is not enough information linking decaBDE to increases in risk or impacts to the environment. Further study on decaBDE is needed prior to taking action.	The conclusions of the Ecological State of the Science Report are based on published findings which are reviewed in the context of a weight of evidence evaluation. The evaluation is not a risk assessment and does not provide a detailed critical review of all studies considered. However, the quality of the included studies was reviewed and uncertainties were noted and considered in the production of the conclusions. A weight-of-evidence approach is standard for chemical evaluations 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. In the case of decaBDE an in-depth analysis relevant to bioaccumulation and transformation was conducted. The quality and quantity of available scientific evidence, determination of the adequacy and/or limitations of studies and a qualitative weighting of all relevant data, taking into account factors such as rigour, consistency and plausibility of observed outcomes, was applied. With regards to bioaccumulation, factors such as low assimilation efficiency and potentially metabolic transformation appear to be important determinants of accumulation of decaBDE in organisms. Several studies indicate that decaBDE is clearly available for uptake and has potential to accumulate in biota to levels which we consider to be high, although uptake observed under laboratory settings is generally shown to be low and subject to rapid excretion. As such, the available data do not show that decaBDE meets the numeric criteria for bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations* under CEPA 1999. The evaluation also shows that it is reasonable to conclude that decaBDE may contribute to the formation of lesser brominated PBDE products in organisms; potentially those which are bioaccumulative. Laboratory

		studies relevant to environmental conditions also indicate that decaBDE may transform via processes of photolysis and biodegradation to products (both PBDE and other products) which may be bioaccumulative.
	Health Canada needs to update their State of the Science report on PBDEs as it underestimates the contribution of dust to PBDE exposure in humans.	The contribution of dust to human PBDE exposure was included in the human health screening assessment published in 2006, which found that food (including breast milk) represented the principal source of exposure for the majority of the age groups (although dust was the principal source of exposure for the 0- to 6-month-old non-breast-fed age group). The human health screening assessment concluded that estimates of the exposure of Canadians to PBDEs are much lower than levels which caused adverse health effects in laboratory animals. Due to its risk of causing harm to the environment, action is being taken to control releases to and their presence in the environment. These actions will also serve to reduce human exposure.
	It is inappropriate and insupportable to evaluate PBDEs as a group, or to group certain PBDE compounds together and evaluate them as the same substance.	In the 2006 ecological screening assessment, PBDEs were assessed as a group, but consideration was also given to the commercial products and to the individual congeners. The rationale for conducting a class assessment for PBDEs included: that their constituents had an identical base structure; as commercial mixtures, there was overlap with respect to their constituents; there was evidence suggesting that under some circumstances higher brominated PDBEs may debrominate to form lower brominated PDBEs in the environment and in biota; and that historically, these products were used concurrently, they co-occur in the environment and any environmental risk would result from their combined presence in the environment. The Ecological State of the Science Report on decaBDE, focused on decaBDE alone, in order to provide an in-depth analysis and clarify the status relevant to bioaccumulation and transformation of this specific congener.
Transformation, degradation, and debromination in	Monitoring studies and some laboratory studies referenced in the SOS report lack specificity (e.g. detection of	Uncertainties relevant to the analysis of decaBDE have been considered for the Ecological State of the Science on decaBDE and have been reflected in the discussions of studies and overall conclusions. There is recognition that

the environment	bromine ion (m/z 79, 81; or 408 and 488, presumably coupled with retention time) since these do not monitor the molecular ion of decaBDE. Therefore the method cannot definitively detect the congener in environmental samples (e.g. sediment/soil/ and biota).	both false positive and negative errors could result from analytical methods used for the PBDEs. Over the past decade, however, there has been an improvement in the accuracy of laboratory ability to analyse decaBDE in environmental samples. For instance, Leonards and Duffek (2008), based on the results of a recent interlaboratory study respecting the analysis of decaBDE in dust and sediments, indicate that routine laboratories were able to detect and measure decaBDE in environmental samples with acceptable accuracy when special attention is given to quality analysis/quality control. This was in contrast to the results from the first interlaboratory comparison on the PBDEs (de Boer and Cofino 2002) which concluded that the reported analytical data on decaBDE was highly variable, and that the analytical results were inconsistent among the participating laboratories. It is recognized that despite recent improvements in the analysis of decaBDE, there is still potential for analytical error in environmental sampling studies. However, it cannot be assumed that each of these studies is in error due to the analytical methodology used. With this understanding, the studies included in the report are considered valid for consideration in the context of the reported methodology.
	Although sediment and soil are the major environmental compartments for BDE209, there is no evidence of decaBDE biodegradation in Swiss sediment buried 30 years, or photolytic/bacterial decaBDE biodegradation in Swedish soils treated decaBDE sewage sludge, or BDE209 bacterial degradation in 4 year Spanish soil study with treated BDE209 sewage sludge.	The Ecological State of the Science Report summarizes the findings showing that decaBDE is extremely persistent without obvious transformation in environmental media such as sediments or soils over a span of several years. However, this does not preclude the potential for transformation in the environment. Laboratory studies confirm that biodegradation half-lives of decaBDE in sediments appear very slow and may range from approximately 6 -50 years. However, a study examining historic levels of PBDEs in sediment cores taken from a Swiss Lake show that despite the high persistence observed in the levels of decaBDE, environmental debromination of decaBDE is a relevant issue, as shown by analyses of congener patterns, and the occurrence of PBDE congeners such as BDE202 which is usually not present in the commercial DecaBDE and OctaBDE products. Laboratory-based photolysis studies also demonstrate transformation to lower brominated PBDEs, as well as to other transformation products like polybrominated dibenzofurans (PBDFs) and unidentified substances. As noted in the Ecological State of the Science report, one would expect only

		a very small proportion of the decaBDE reservoir in the environment to be susceptible to photolytic debromination, and that biodegradation appears possible but at a very slow rate. Thus, one may expect subtle indications of transformation of decaBDE in the environment which may be masked by the current congener patterns which are dominated from the use of the commercial Penta- and OctaBDE formulations. As well, the infrequent analysis of higher brominated PBDEs like octa- and nonaBDEs would make it difficult to detect or confirm transformation to these PBDEs.
	Recent Norway studies indicate declining levels of lower brominated PBDEs coinciding with continued commercial DecaBDE use. Patterns of lower brominated congeners found in the environment are consistent with PentaBDE which is no longer in use, suggesting that degraded commercial DecaBDE is not the source of these lower congeners in the environment.	The Ecological State of the Science Report on decaBDE recognizes studies that suggest that declining levels of lower brominated PBDEs coincide with continued commercial DecaBDE use. Such a trend suggests that the predominating congener pattern in the environment could be mainly a result of the commercial Penta- and OctaBDE products whose manufacture has ceased in North America and Europe. The available science suggests that decaBDE may transform to lower brominated PBDEs, and while it is strongly suspected that decaBDE is contributing to the formation of low brominated PBDEs in the environment, the overall importance of environmental transformation of decaBDE as a contributor of these PBDEs is not known. Various reviewed studies show that decaBDE will transform to some degree under certain conditions which are relevant to the environment.
	Air and water are minor environmental compartments for decaBDE. Predominant loss of decaBDE in air is via processes other than production of lower brominated diphenyl ethers (e.g. via wet and dry deposition). Dust photolysis studies demonstrate a decrease in total PBDE content including lower brominated diphenyl ethers with exposure to sunlight.	The Ecological State of the Science Report agrees that partitioning to water and air appear to be minor components for decaBDE in comparison with other environmental compartments like sediments and soil. In air and water, decaBDE would be adsorbed to particulates. A number of laboratory-based photodegradation studies having relevance to environmental conditions were reviewed in the Ecological State of the Science Report. Some of these indicate that decaBDE adsorbed to dust can transform rapidly to several PBDE congeners (including potential formation of tetra-, penta- and hexaBDE congeners) as well as possible formation of polybrominated dibenzofurans (PBDFs) (many of which could also be bioaccumulative as shown by predictive modelling summarized in the Report) and other unidentified products. Although not conclusively determined in the environment, the available data indicate that decaBDE likely forms some persistent and bioaccumulative products due

		to transformation. Since these products could be considered persistent and bioaccumulative, if formed in the environment in very small quantities, this would be a concern given the overall reservoir of decaBDE available for transformation. Transformation to bioaccumulative products of even very small percentages can represent significant quantities.
	Long-range atmospheric transport of decaBDE is not expected.	Issues relevant to long range atmospheric transport were considered outside of the scope of the Ecological State of the Science Report on decaBDE: however, were considered in the 2006 screening assessment for PBDEs. The purpose of the Ecological State of the Science Report on decaBDE was to focus on studies and analysis related to bioaccumulation and transformation of decaBDE.
	A number of studies that are cited by EC as evidence for abiotic debromination used methodology that would be unlikely in a natural setting – e.g., photolysis in lab with solvent mixture, dust particulates not exposed to solvent, and no data to confirm photolysis of decaBDE in dust to the brominated BDEs found in biota, how photolysis applies to soil and sediment in natural environment etc. What triggers decaBDE debromination in the lab may not apply to environment. Data generated by laboratory studies, while important indicators for guiding future research, do not represent real world evidence and need to be substantiated by environmental field data.	The Ecological State of the Science evaluation also considers laboratory photolysis studies which expose decaBDE while dispersed in solvent to natural or artificial sunlight unrepresentative of conditions for transformation in the environment. This review and the final PBDE Ecological Screening Assessment noted that a number of these studies showed transformation to the tetra-, penta-, and hexaBDEs. However, laboratory-based photodegradation studies which expose decaBDE adsorbed to particulates in air, water or dispersed natural solvents like humic and fulvic acids (not concurrently in solvents) relevant to environmental conditions, provide a useful indication of the potential for transformation in the environment. Under natural conditions, it is expected that decaBDE will be found primarily bound to solids in air, on the surface of soils or other substrates, or in water. Some of these studies also demonstrate transformation by photodegradation of hexaBDEs, as well as possible formation of tetra- and pentaBDEs at trace levels. The report recognizes that only a very small proportion of all decaBDE in the environment would be available for photolytic transformation. Furthermore, studies showing biodegradation of decaBDE, for instance in activated sludge or soil, are considered to be relevant to the environment. The evaluation recognizes the uncertainty relevant to the extrapolation of laboratory results to the environment, but considers studies simulating environmentally relevant processes and conditions to be indicative of

		transformation in the environment.
	The commenter does not agree with the assertion that decaBDE is a significant source through debromination of the lower congeners found in the environment.	The Ecological State of the Science report does not quantify the extent to which decaBDE may transform in the environment to lower brominated PBDEs. However, the report considers a variety of laboratory-based studies indicating that decaBDE may transform to lower brominated PBDEs (including those which are considered bioaccumulative and/or potentially bioaccumulative) to have relevance to the environment. Since many identified transformation products (lower brominated PBDEs and other products) could be considered persistent and bioaccumulative, the formation of even very small quantities would be a concern. Given the large quantities of decaBDE in use, transformation to bioaccumulative products of even very small percentages of this substance can represent a significant quantity in a national or global context.
	Comments were received recommending the addition of various studies to the State of the Science Report (e.g;, Riu et al. (2008), Bustnes et al. (2007), Kunisue et al. (2008), Helgason et al. (2008), Stapleton et al. (2009) and Yoccoz et al. (2009), and others) .	These studies have been reviewed and cited if appropriate in the Ecological State of the Science Report on decaBDE. An evaluation of studies relevant to toxicity and human health was considered outside of the scope of this evaluation. In addition to considering the studies identified during the Public Comment period, a search of the scientific literature was performed for material published to August 2009. New studies not considered in the draft Ecological State of the Science Report on decaBDE were added if their findings were considered significant to the evaluation.
Bioaccumulation/ Biomagnification Studies	Environment Canada is correct in concluding that decaBDE does not have significant potential to bioaccumulate / biomagnify, based on lab and field studies of decaBDE. Background levels of decaBDE in biological samples appear to be 2 ng/g lw. The congener decaBDE has no particular affinity to lipids**.**	The analysis in the Ecological State of the Science Report on decaBDE concludes that decaBDE is not meeting the criteria for bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations*. The evaluation also acknowledges uncertainty with respect to decaBDE's affinity for lipids, and the potential for nonspecific binding. It also notes that lower decaBDE tissue concentrations may be influenced by the organism's capacity to metabolically transform decaBDE.
	An addition should be made to the summary of the State of the Science Report stating that consideration should	The available science does not preclude the possibility that PBDEs resulting from the transformation of decaBDE will accumulate in biota. Such a statement is not supported within the context of the available

	be given to the fact that PBDEs will not continue to accumulate in biota, since studies show that levels in the environment have been reducing since production of OctaBDE and PentaBDE stopped in 2004, and that these substances are no longer being released to the environment.	science on the transformation of decaBDE and is not added to the Ecological State of the Science Report.
	In the 3rd paragraph of the Background section, Health Canada and Environment Canada have concluded to take action against PBDEs including decaBDE. Please reference what actual data are available that demonstrate known levels or total body burden of specific PBDE congeners which are responsible for contributing to an adverse impact on human health and/or quality of life. Otherwise, it appears that both Health Canada and Environment Canada are convinced by the assumption that decaBDE, which is specifically under evaluation in this document is currently causing harm.	In July 2006, the Government of Canada released the final Screening Assessment Reports for Polybrominated Diphenyl Ethers (PBDEs). It was concluded that PBDEs (i.e., tetraBDEs to decaBDE), which are found in commercial PentaBDE, OctaBDE and DecaBDE technical formulations, are 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, and thus meet the criterion set out in Paragraph 64*(a)* of CEPA 1999. As such, and as stated in the *Ecological State of the Science Report on Decabromodiphenyl Ether (Bioaccumulation and Transformation),* ecological considerations rather than those relating to human health are presented.
	The conclusion that evidence has shown that decaBDE is bioaccumulative and/or biomagnifying in food chains, is not supported by the evidence presented in the report that decaBDE has limited bioaccumulation potential due to low dietary assimilation efficiency and metabolism. Characterizing the levels of potential for accumulation in biota as “high” is	Although there are no available measured or experimental evidence to support that decaBDE, as the parent compound, meets the numeric bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations*, several studies nevertheless indicate that the substance is available for uptake and has potential to accumulate in biota to levels considered high by the authors.

	purely subjective and considered inappropriate unless it is put into context.	
	The State of the Science Report reflects a more up to date review of the scientific evidence for decaBDE in concluding that decaBDE is bioavailable and may accumulate rapidly to potentially high and problematic levels in certain species, and that it contributes to the formation of bioaccumulative / potentially bioaccumulative transformation products (e.g. lower brominated BDEs) in organisms and the environment.	The purpose of the present report is to provide an updated analysis of bioaccumulation and transformation of decaBDE, by summarizing evidence considered in the original PBDE Ecological Screening Assessment (Canada 2006, Environment Canada 2006), and in addition, examining the related new science published up to 25 August 2009.
Metabolism/Uptake Studies	Lab studies corroborate poor decaBDE uptake, circulation, systemic distribution and elimination mainly as the parent molecule. Reports of extensive metabolism in rats are not based on structural identification of products of Phase 1 and Phase 2 metabolism, poor parent molecule recovery and/or lack of recognition of fecal binding. Long term dose studies in rodents show a lack of toxicity. Lifetime (2 year) studies show no evidence of toxic or bioaccumulative metabolites. Such studies should be added to the State of the Science Report. Recent in vitro studies show no	The Ecological State of the Science report describes typically low uptake of BDE209 and rapid elimination of the parent molecule. Where appropriate, the Report recognizes the uncertainty in rat studies showing extensive metabolic transformation. For instance, with respect to Mörck et al. (2003) it notes that the analysis for hydroxyl- and hydroxymethoxyBDEs was qualitative and their identification was inferred. Nevertheless, one cannot discount that the metabolites could have been formed as reported in the subject study. The formation of such metabolites has also been shown in other studies reviewed in the report, adding support for their formation in mammalian systems. An evaluation of decaBDE toxicity was considered beyond the scope of The Ecological State of the Science Report. In July 2006, the Government of Canada published its final screening assessment on polybrominated diphenyl ethers (PBDEs). The environmental screening assessment examined various supporting information and developed conclusions based on a weight-of-evidence approach as required under subsection 76.1 of CEPA 1999 and concluded that all assessed PBDEs (tetra- to decaBDEs) were entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect

	microsomal metabolism of decaBDE.	on the environment or its biological diversity and thus meet the criterion under paragraph 64*(a)* of CEPA 1999. The Ecological State of the Science Report recognizes that there is variability and uncertainty in the findings of some metabolic transformation studies; however, the report also finds that some in vitro studies (e.g., utilizing fish liver microsomes*)* have shown rapid and substantial (e.g., up to 65% over 24 h) transformation of decaBDE to lower brominated PBDEs including hexaBDE. This is also considered evidence of microsomal metabolism of decaBDE in wildlife.
	Recent BDE 209 studies are not capable of attributing changes in trace levels to metabolism since they didn't include trace composition of the test article.	The Ecological State of the Science Report on decaBDE acknowledges uncertainties such as the potential contamination of lower brominated PBDEs in decaBDE metabolic transformation studies. However, congener patterns observed in tissues following dosing with decaBDE, which can sometimes be considered inconsistent with potential contamination or with the composition of the prevailing commercial PBDE products, have been determined in various studies. These studies also suggest that metabolic transformation of decaBDE may be occurring in organisms. Further evidence is indicated by in vitro studies showing rapid and significant transformation of decaBDE by liver microsomes. Therefore, there is a body of evidence to support the occurrence of biotransformation.
	Reductive debromination of decaBDE appears to be minimal. Studies using mixtures make it impossible to determine debromination of any individual congeners.	The Ecological State of the Science Report indicates that overall uptake of decaBDE in fish and mammals generally appears to be low and the formation of lower brominated PBDEs also appears to be a fraction (typically on the order of a few percent) of the total amount of decaBDE administered to the organism. But, some rodent studies have made inferences respecting the formation of bound and/or hydroxylated and hydroxymethoxylated PBDE metabolites which may account for a potentially larger proportion of decaBDE dosed to organisms (potentially up to approximately 45 – 65% of the total dose of decaBDE). These findings are considered significant given the potential for the formation of bioaccumulative transformation products *in vivo*. Studies utilizing mixtures were considered appropriate to consider; however, uncertainties in the findings were noted where appropriate.
	Relative potential for metabolism by	The Ecological State of the Science Report on decaBDE finds that both

	non-mammalian species is expected to be lower and/or slower, therefore fish/birds are expected to be less able to biotransform decaBDE and other PBDEs.	fish and mammals have a capacity to take up and metabolize at least some portion of BDE209. This evaluation does not rule out the potential for metabolic transformation in birds and considers evidence suggestive of their ability to metabolically transform decaBDE. Overall, the dataset is considered insufficient to undertake a comparison of the rates of decaBDE metabolism among mammals and non-mammals.
Toxicity	NPRI data, as well as environmental monitoring results in Canada indicate that decaBDE is not being released in Canada in amounts that could have immediate or long-term harmful effects.	An evaluation of decaBDE releases was considered out of the scope of the Ecological State of the Science Report. In July 2006, the Government of Canada published its final screening assessment on polybrominated diphenyl ethers (PBDEs), including decaBDE. This 2006 assessment considered use and potential release of decaBDE to the environment. The evidence provided in the PBDE Screening Assessment (2006) is consistent with paragraph 64*(a)* of the CEPA 1999[1]. [1] Paragraph 64*(a)* of CEPA 1999 states that "…it is entering or may enter the environment in a quantity or concentration or under conditions that… have or may have an immediate or long-term effect on the environment or its biological diversity…"
Criteria outlined in the *Persistence and Bioaccumulation Regulations* under CEPA	There is concern with the limited ability of the Persistence and Bioaccumulation Regulations and CEPA 1999 to address substances, such as decaBDE, that biomagnify and bioaccumulate in terrestrial species and through terrestrial food chains. There is concern that despite the report findings that decaBDE is bioavailable and may accumulate to potentially high levels in certain species, and contribute to the formation of bioaccumulative /potentially bioaccumulative transformation products, the report does not find that decaBDE meets the thresholds in the *Persistence and Bioaccumulation Regulations*. This also highlights a more far-reaching problem	Although the *Persistence and Bioaccumulation Regulations* under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) do not explicitly refer to measures of biomagnification or measures of bioaccumulation in terrestrial species and food chains, concerns of very bioaccumulative substances, including those which biomagnify, are captured by the Toxic Substances Management Policy (TSMP), a Government of Canada policy. Criteria in *the Persistence and Bioaccumulation Regulations* are based on those in the Policy that guide the Government of Canada in determining whether substances should be identified for virtual elimination, or life cycle management. In keeping with this policy direction, actions may be taken to control substances which are shown to biomagnify, or accumulate from sources other than those which are aquatic based. This policy also provides latitude for the federal government to take action on a substance should it be shown to transform in the environment to forms which are bioaccumulative. The Ecological State of the Science Report finds that decaBDE does not specifically meet the criteria for bioaccumulation under the *Persistence and Bioaccumulation Regulations* and also does not find unequivocal evidence

	with this CEPA regulation relying too heavily on out of date scientific criteria, which this commenter believes the Government of Canada has acknowledged (joint EC/HC response to 2008 Petition). The bioaccumulation analysis of decaBDE has highlighted the limitations with CEPA's provisions regarding bioaccumulation and the need for a thorough assessment of the thresholds and procedures used to analyze bioaccumulation under CEPA.	that the substance is subject to biomagnification in aquatic or terrestrial food chains. There is further supporting evidence indicating a limited potential for uptake and some metabolism of decaBDE in organisms; these attributes would limit bioaccumulation and biomagnification in wildlife. However, the report also concludes that decaBDE may transform in the environment (e.g., by processes of photodegradation, metabolic transformation and biodegradation) to products which may be bioaccumulative. Thus, the findings of the Ecological State of the Science report on decaBDE guided by the policy direction provided under the current provisions of the TSMP provide justification for expanded risk management of decaBDE.
	The *Persistence and Bioaccumulation Regulations* were said to be under review by Environment Canada and the commenter would like to know the status of this review.	The science-based approach taken for risk assessments conducted under CEPA 1999 ensures that advances in science can be taken into consideration in our regulatory decision-making. Based upon developments in other jurisdictions and a better understanding of the science relevant to bioaccumulation and biomagnification, Environment Canada will be initiating, in 2010-11, changes to the Bioaccumulation provisions of the *Persistence and Bioaccumulation Regulations*.
	Despite the fact that the evidence presented in the State of the Science Report indicates that decaBDE "is bioavailable and may accumulate rapidly to high and potentially problematic levels in certain species" the substance does not meet the regulatory threshold criteria for bioaccumulation. It would be appropriate under the circumstances to defer to the log K_{ow} value (6.27 to 9.97) as the measure of bioaccumulation, which does meet the regulatory	There is no regulatory obligation to base a decision on bioaccumulation using log K_{ow} determinations. Professional judgment should be applied to evaluate the intrinsic properties of the substance and ecosystem under consideration. While log K_{ow} is well known to be an indicator of the potential for bioaccumulation based on passive diffusion, its application requires substantial professional judgment due to various inherent limitations when used for this purpose. Although a log K_{ow} value may meet the numeric criterion identified in the *Persistence and Bioaccumulation Regulations,* the substance may not bioaccumulate significantly due to such factors as metabolic transformation and/or poor uptake efficiency. This approach is consistent with guidance identified in the Toxic Substances Management Policy (Government of Canada 1995a, b) which provides discussion of the uncertainties relating to the use of K_{ow}

	threshold for "bioaccumulative".	for making conclusions on bioaccumulation. For decaBDE, the available science reviewed in the Ecological State of the Science Report on decaBDE does not support a conclusion that this substance meets the bioaccumulation criteria set out in the *Persistence and Bioaccumulation Regulations.* Although a substance, such as decaBDE, may be measured in the tissues of wildlife at levels which we consider to be high, this does not necessarily mean that it should be considered bioaccumulative. In fact, such concentrations may be reflective of high environmental exposure resulting in low ratios of exposure concentrations to tissue concentrations. The intent of the Ecological State of the Science Report on decaBDE was to flag this issue since high substance concentrations in tissues could be problematic from other perspectives (e.g., greater availability of the substance for potential metabolic transformation to potentially bioaccumulative and persistent substances).
	There is concern that the report's bioaccumulation interpretation based on ratio analysis is not consistent with the original intent of the 1995 Toxic Substances Management Policy (TSMP) for bioaccumulation, which indicated the potential of a substance to bioaccumulate "can be expressed" by ratios, not that they are the only way to determine bioaccumulation. The comment notes that EC documentation calls for "expert opinion" to be considered, in addition to bioaccumulation criteria. The comment concludes that apparent uncertainties and measurement difficulties with decaBDE are not a reason to narrow the definition of	There is recognition that other evidence may be used to make inferences respecting a substance's potential for bioaccumulation, and for this reason, the Ecological State of the Science Report also considered biota concentrations as well as metabolism and uptake studies in addition to the ratio based analysis of bioaccumulation data. The Ecological State of the Science Report found that there are various attributes which support a decision that decaBDE does not meet the criteria for bioaccumulation in the *Persistence and Bioaccumulation Regulations*. For instance, the available evidence indicates that the substance is typically shown to have low uptake efficiency and may be metabolized to some extent in wildlife. Although some studies show that decaBDE may accumulate in wildlife to concentrations considered to be high, most available surveillance data indicate that decaBDE is found at much lower concentrations in organisms, and frequently at non-detectable levels. Even tissues from the same species taken from similar locations do not consistently show that decaBDE is accumulating to higher concentrations. In consideration of the weight of evidence, which is consistent with the interpretation of how to apply the TSMP and the *Persistence and Bioaccumulation Regulations,* it is concluded that decaBDE is not

	bioaccumulation to a ratio based analysis – that this misconstrues the meaning of bioaccumulation under the TSMP.	sufficiently bioaccumulative in wildlife to satisfy the criteria in the *Persistence and Bioaccumulation Regulations*.
Alternatives-Decabromodiphenyl ethane	Concerned about State of the Science Report statement that there is further need to understand the potential environmental risks and capacity of decaBD ethane (a potential alternative to decaBDE) to bioaccumulate, rather than a precautionary response to prohibit this potential substitute.	There is insufficient understanding respecting the ecological risk of decabromodiphenyl ethane, and thus, a precautionary response to prohibit its use is considered unsubstantiated. For this reason, the Ecological State of the Science Report flags a need to evaluate this substance in order to understand its potential risk to the environment because of apparent similarities between decaBDE and decabromodiphenyl ethane with respect to their chemical and physical and chemical properties.
	The reference to decabromodiphenyl ethane should be removed from the final report since speculation on its properties based on "minor structural differences" between this substance and decaBDE are unfounded. This reference should be replaced by a more general requirement that potential alternatives to DecaBDE (commercial mixture) be well understood so that substitutions are made on informed basis.	It is considered appropriate to flag the potential similarities between decaBDE and its replacement decaBD ethane along with the need to further understand the potential risks from decaBD ethane in the environment and its capacity to accumulate in wildlife and transform to potentially bioaccumulative products. However, it is agreed that there is a general need to understand potential risks from alternatives so that substitutions are made on an informed basis. A statement has been added to the Ecological State of the Science Report to reflect this suggestion.
Independent board of review	A Board of Review would be beneficial to resolve outstanding issues with respect to the scientific review of environmental bioaccumulation of decaBDE, the toxicity and fate of decaBDE breakdown products and the accuracy of information on human exposure. As well, broader issues, such as the process to evaluate substitutes replacing toxic substances and the	A decision respecting the establishment of an independent Board of Review will be based on consideration of the conclusions of the finalized Ecological State of the Science Report on decaBDE and all public comments submitted.

	criteria under the *Persistence and Bioaccumulation Regulations* would benefit from a Board of Review.	

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