Ministre de l'Environnement,
du Changement climatique
et de la Nature

Minister of the Environment,
Climate Change
and Nature

Ottawa (Ontario), Canada K1A 0A6

DEC 2 9 2025

Mr. Ben Gann
Director, Chemical Products and Technology
North American Flame Retardant Alliance
American Chemistry Council
benjamin_gann@americanchemistry.com; harry.dahme@gowlingwlg.com;
cmarciano@sussex-strategy.com; bjames@sussex-strategy.com

Dear Mr. Gann:

This letter is in response to your Notice of Objection and request to establish a board of review to the publication of the proposed *Prohibition of Certain Toxic Substances Regulations, 2022* (proposed Regulations), which was received by Environment and Climate Change Canada on July 13, 2022. The proposed Regulations were published in the *Canada Gazette*, Part I, on May 14, 2022.

I have carefully considered all the issues in your Notice of Objection, including those dealing with the nature and extent of the danger posed by decabromodiphenyl ethane (DBDPE) and the other questions and considerations that you brought to my attention. In my opinion, your Notice of Objection does not raise sufficient uncertainty or doubt in the science underlying the proposed Regulations that would warrant the establishment of a board of review under subsection 333(1) of the *Canadian Environmental Protection Act, 1999*. Therefore, I am denying your request, and I will not establish a board of review. The reasons for my decision are explained below and in the Annex to this letter.

Responses to comments in your Notice of Objection related to the outcomes of the screening assessment for DBDPE, which concluded that there is a risk of harm to the environment due to the persistence and widespread occurrence of DBDPE in the environment along with the potential for bioaccumulation and toxicity of its transformation products, are provided in the Annex.

The comments in your Notice of Objection regarding the development of the proposed Regulations have been considered alongside other comments received on these regulations. The specific points you have raised on the proposed Regulations and how they will be addressed are also summarized in the Annex to

…/2

this letter. Your Notice of Objection raised specific concerns on the proposed exemptions for DBDPE, and to address these concerns, the proposed timeline of the DBDPE exemptions will be extended by an additional 10 years (i.e. extended from 5 years to 15 years for new products and from 20 years to 30 years for replacement parts) and the scope of these exemptions will be broadened to include all manufactured items and additional intermediate materials. This extended timeline will allow all stakeholders additional time for the research and development of alternatives, testing and certification, and transitioning their manufacturing and supply chains. Broadening the scope of the DBDPE exemptions will help to reduce the risk of prohibiting critical components, reduce the need to apply for permits under the proposed Regulations for non-exempted parts, and reduce compliance burden of stakeholders throughout the supply chain.

Please note that the comments on the proposed Regulations will be summarized in the Regulatory Impact Analysis Statement that will be published with the final *Prohibition of Certain Toxic Substances Regulations, 2025* (2025 Regulations) in the *Canada Gazette*, Part II, which describe how these matters have been addressed.

I appreciate your bringing your concerns to my attention. Please accept my best regards.

Yours truly,

The Honourable Julie Dabrusin, P.C., M.P.

Att.

Annex

Minister of Environment and Climate Change Canada
Detailed Responses to Notice of Objection Comments

1) The following provides a summary of comments related to "DBDPE is not CEPA Section 64 "toxic" - *The Conclusions of the Final Screening Assessment upon which the Proposed Risk Management Measures for DBDPE rely is not Supported by the State of the Science*" as provided in your Notice of Objection and the analysis of the information you have provided:

1A) In your Notice of Objection, you commented that there are no scientific studies or data upon which ECCC relies that support the use of decaBDE as an analogue to confirm the results of the modelling of DBDPE. To the contrary, all available evidence demonstrates that DBDPE behaves entirely differently than decaBDE.

The use of analogues and read-across in risk assessment, much like decaBDE is used in the DBDPE screening assessment, is well established and internationally recognized. Canada's approach to the use of analogues and read-across in risk assessment[1] is consistent with OECD Guidance[2] and the approaches used in other jurisdictions, including by the European Chemicals Agency (ECHA)[3].

DecaBDE is considered to be a suitably close analogue for DBDPE given the high degree of structural and functional similarities between the two substances, and the availability of relevant empirical information. In addition to Canada, the United Kingdom (UK) in 2007 and Sweden in 2024 utilized decaBDE as an analogue substance in their respective assessments of the target substance DBDPE[4].

Structural and functional similarities between substances have typically translated to similarities in environmental fate, behaviour, and other properties. It is noted that some differences in molecular makeup, dimensions, and configurations exist between DBDPE and decaBDE that may affect the manner in which these molecules interact with their environment; however, these differences are well within what is typical for analogue - target differences found in regulatory risk assessments.

The abundance of empirical data on decaBDE also factored into its selection as the most appropriate analogue for DBDPE. Expert judgement is applied in this process, where chemical properties, fate, or behaviour of decaBDE is read-across to DBDPE on a case-

[1] https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/analogues-read-across-risk-assessment.html.
[2] OECD, *Guidance on Grouping of* Chemicals, 2d ed., 13 April 2017: https://www.oecd.org/en/publications/guidance-on-grouping-of-chemicals-second-edition_9789264274679-en.html.
[3] ECHA, Read-Across Assessment Framework (RAAF), 2017: https://echa.europa.eu/documents/10162/17221/raaf_en.pdf/614e5d61-891d-4154-8a47-87efebd1851a.
[4] Environmental risk evaluation report: 1,1'-(Ethane-1,2-diyl)bis[penta-bromobenzene] by United Kingdom Environment Agency (2007) and Substance Evaluation Conclusion and Evaluation Report for 1,1'-(ethane-1.2-diyl)bis[pentabromobenzene] (DBDPE) by Sweden (2024).

by-case (e.g., per endpoint or property) basis rather than in an absolute manner, and by taking into consideration the suitability and comparability of these attributes.

1B) In your Notice of Objection, you referenced 50 studies provided during the assessment process and new studies (i.e. 336-hour study modelling the photolytic degradation of DBDPE within high impact polystyrene ("HIPS") in the Canadian environment and 2,000-hour study extending the modelling of the photolytic degradation of DBDPE within HIPS and polypropylene (PP) along with associated independent expert opinion confirming that the proper methodology was followed) generated since the publication of the screening assessment which you stated that either does not support the conclusion of the assessment or provides sufficient justification to reconsider its conclusion.

All additional experimental studies submitted (including the 50 studies provided during the assessment process), aside from the 336-hour and 2,000-hour photodegradation study (reported in May 2021 and February 2022, respectively with the latter study published in 2023, all following the publication of the screening assessment), were considered in development of the screening assessment by weighing their reliability and relevance. Those studies that were reliable and relevant to evaluating the risks posed by DBDPE to the environment were included as outlined in the final screening assessment. Thus, the information presented in these 50 studies was either considered in the final screening assessment or has no impact on the regulatory conclusion reached in the final screening assessment for DBDPE.

With regards to the 336-hour and 2,000-hour photodegradation studies, while the applied weathering conditions appear reasonable for simulation of environmental conditions and the quality of the 2,000-hour study was deemed sufficient by a submitted data quality evaluation report, these studies represent only one specific type of release scenario with limited relevance to overall DBDPE environmental release and fate. DBDPE has been found in the Canadian environment and around the world. Evidence from studies with DBDPE adsorbed to solid matrices such as soil or sediment are most relevant to the fate of the substance in the natural environment. As an additive brominated flame retardant that is blended with the polymer product (rather than a reactive flame retardant chemical bonded to the polymer product), there is the possibility of release of DBDPE from these products to the environment. In addition, DBDPE may be released to air or dust by volatilization or abrasion of product containing the substance and then deposited to soil or water. Thus, the information presented in these photodegradation studies with DBDPE present within a polymer matrix has no impact on the regulatory conclusion reached in the DBDPE screening assessment.

Annex

Minister of Environment and Climate Change Canada
Detailed Responses to Notice of Objection Comments

1C) In your Notice of Objection, you provided a third-party review in 2020 by Dr. Gobas (the "2020 Gobas Review"), updated in 2022 (the "2022 Updated Gobas Review"), on the available scientific reports relating to DBDPE, as well as the draft and final screening assessments for DBDPE.

You stated that the 2020 Gobas Review concluded that:

i) decaBDE is not a good read-across substance for the purpose of estimating the rate of potential debromination of DBDPE;

ii) guidelines and recommendations for applying a read-across approach exist but were not adequately followed by ECCC in the screening assessment;

iii) the screening assessment does not include evidence to substantiate that lower-form DBDPE products enter the environment in a quantity or concentration that have or may have an immediate or long-term harmful effect.

You stated that the 2022 Updated Gobas Review confirms his prior conclusions and offers the following conclusions:

iv) A substance with a long record of safe use and which has been subjected to many toxicological studies, is considered to be toxic by ECCC in absence of any evidence of toxicity;

v) ECCC struggles to make evidence-based decisions for DBDPE. Despite a thorough compilation of the results from many scientific studies that accompanies the assessment, ECCC relies on questionable theories and an inappropriate use of the precautionary principle in situations where there is no evidence of threats of serious or irreversible damage;

vi) The rationale for determining that DBDPE meets the criteria set out in paragraph 64(a) of the Canadian Environmental Protection Act (CEPA 1999), i.e., "*that DBDPE is expected to transform to lower brominated products in a manner similar to decaBDE* (p. 32).", and that "*DBDPE may contribute to the formation of persistent, bioaccumulative and inherently toxic transformation products, such as lower brominated (B)DPEs in the environment*" is seriously flawed and should be revisited to reach an accurate environmental assessment of DBDPE. A Board of Review is a logical step towards that.

Regarding **conclusions i)**, **ii)** and **vi)**, please refer to the responses to points 1A (above) and 2A (below).

In response to **conclusion iii)**, ECCC acknowledges that the parent structure DBDPE is highly persistent, highly insoluble in water, and highly sorptive to particulate matter

while also having the potential to cause reproductive effects at high concentrations to earthworms as well as effects on plant survival and growth. As a result of these properties, DBDPE will accumulate in the environment and become a significant source of lower brominated transformation products, which have properties that suggest they are more bioaccumulative and hazardous than the parent structure DBDPE itself. Modelled aquatic toxicity data for potential DBDPE debrominated transformation products suggest effects at low concentrations in the range of water solubility of these transformation products. In addition, the presence of DBDPE debromination products in wastewater treatment system pond sediments near a DBDPE manufacturing plant in the U.S have been confirmed. Considering DBDPE is a high-volume substance in Canada and that its levels are known to be increasing in the environment (as seen in Great Lakes sediment), and that DBDPE in aqueous solutions or adsorbed to solid surfaces such as sand, sediment, or dust is susceptible to various naturally occurring debromination processes, the pool of potential lower brominated transformation products are environmentally significant. Therefore, it is concluded that DBDPE meets the criteria set out under paragraph 64(a) of CEPA as 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 harmful effect on the environment or its biological diversity.

In response to **conclusion iv)**, neither what is referred to as a "history of safe use" nor past toxicological studies showing no adverse effects to certain organisms precludes a determination under CEPA that DBDPE is toxic. With respect to DBDPE there is expected to be a slow buildup of harmful transformation products in the environment over time. The substance was concluded based on available information to meet the criteria set out under paragraph 64(a) of CEPA.

For **conclusion v)**, there was no struggle to make evidence-based decisions for DBDPE. All sources of information were cited and rationale as to how studies were used in terms of their reliability, relevance and overall contributions to weight of evidence are provided in the final screening assessment report. In particular, sections 9.3.2 "Consideration of lines of evidence and conclusion" and 9.3.3 "Uncertainties in evaluation of ecological risk" clearly communicate on the lines of evidence and the specific rational for the application of precaution in the overall conclusion. On the basis of the information available, it was concluded that DBDPE met the criteria as set out under paragraph 64(*a*) of CEPA.

1D) In your Notice of Objection, You also provided a third-party opinion of Dr. Solomon regarding the 2022 Updated Gobas Review (the "2022 Solomon Opinion"). You stated that the 2022 Solomon Opinion concluded that:

Annex

Minister of Environment and Climate Change Canada
Detailed Responses to Notice of Objection Comments

i) **ECCC incorrectly used read-across data on decaBDE to extrapolate the potential for DBDPE to undergo photolysis to form potentially toxic products, such as brominated furans;**

ii) **there is no evidence to show that DBDPE breaks down in the environment and forms potentially toxic products in a similar way to decaBDE;**

iii) **DBDPE does not meet the criteria set out under paragraph 64(a) of the Canadian Environmental Protection Act (CEPA 1999). DBDPE is essentially unreactive and, even under photolysis, will not form potentially toxic substances. Photolysis is also not expected in plastic products containing DBDPE and these plastics are usually formulated with UV absorbers to protect against environmental degradation of the plastic polymer;**

iv) **DBDPE is of low toxicity to mammals and aquatic organisms. This is consistent with a lack of absorption in the gut of mammals and *de minimi*s bioavailability in water because of low solubility;**

v) **while DBDPE might reach soil or surface water it will adsorb strongly to particulate matter and sediments thereby further reducing the potential for exposure of biota in the environment. This adsorption will further minimize exposures to solar radiation and reduce photolytic breakdown; and**

vi) **there is no evidence to show that DBDPE and products containing this material present a risk to the environment and human health in Canada.**

Regarding the **conclusions i), ii), iii), v),** and **vi),** please refer to responses to points 1A (above) and 1C iii) (above).

Furthermore, in response to **conclusion i)**, this statement is incorrect as the screening assessment report for DBDPE did not extrapolate that brominated furans could be formed by photolysis of DBDPE.

Additionally, regarding **conclusion iii)**, in response to the statement that "[p]hotolysis is also not expected in plastic products containing DBDPE and these plastics are usually formulated with UV absorbers to protect against environmental degradation of the plastic polymer", this statement only reflects one aspect of product lifecycle for DBDPE. There are other potential sources of release during its lifecycle, such as from industrial facilities during a formulation process in which DBDPE will not be bound and is readily subject to photolysis. In addition, there are mechanisms other than photolysis (e.g., biodegradation) that may also play an important part in the transformation of DBDPE and other substances in the environment.

In response to **conclusion iv)** that DBDPE is of low toxicity to mammals and aquatic organisms, and that this is consistent with a lack of absorption in the gut of mammals and de minimis bioavailability in water because of low solubility, ECCC recognizes that once released into the environment, DBDPE is found mainly in sediment and soil. The results of risk assessment indicate that the potential for ecological harm in Canada is mainly related to the potential of DBDPE to form lower brominated diphenyl ethanes in the environment. Therefore, the lower impact that DBDPE itself may have on mammals and aquatic organisms may be of less relevance.

Furthermore, in response to **conclusion vi)**, the DBDPE screening assessment did not conclude that DBDPE presents a risk to human health in Canada.

1E) In your Notice of Objection, you referenced new information generated since the publication of the screening assessment, a National Academy of Sciences, Engineering, and Medicine report (the "NAS" Report), that suggests that decabromodiphenyl ether (decaBDE) is not an appropriate analogue for decabromodiphenyl ethane (DBDPE).

With regards to comments pertaining to the NAS Report, please refer to the response to point 1A (above) on the suitability of decaBDE as an analogue for DBDPE.

In addition, the physical-chemical and toxicological information presented in the NAS Report suggests that there are substances, other than DBDPE (e.g., pentaBDE and octaBDE), that are more comparable to decaBDE with respect to a particular set of properties considered by NAS, but it does not suggest that DBDPE is incomparable to decaBDE, nor does it suggest that some metabolites formation processes between these two substances are significantly different. It is also worth noting that these subclasses of organic flame retardant substances were developed by NAS for the purposes of assessing risk to human health, and therefore, may not have considered the behaviour of these substances in the environment when forming the subclasses. Thus, the NAS Report finding does not directly apply to the use of decaBDE for read-across to DBDPE in the screening assessment.

As mentioned in the response to point 1A (above), it is noted that some differences in molecular makeup, dimensions, and configurations exist between DBDPE and decaBDE that may affect the manner in which these molecules interact with their environment, however, these differences are well within what is typical for analogue – target differences found in regulatory risk assessments as evidenced by three different jurisdictions making this choice (i.e., selecting decaBDE as a suitable analogue for

DBDPE) in their 2007 (UK), 2019 (Canada) and 2024 (Sweden) evaluation reports on DBDPE.

1F) In your Notice of Objection, you referenced new information generated since the publication of the screening assessment, a GreenScreen Risk Assessment for DBDPE, that suggests that decaBDE is not an appropriate analogue for DBDPE.

In regards to the comment on the GreenScreen Risk Assessment for DBDPE, the report indicates that the structural differences between DBDPE and decaBDE may lead to biological/metabolic differences between the two substances, leading to different GreenScreen scores for certain toxicological endpoints (e.g., developmental neurotoxicity – human health). This report does not consider the potential to use decaBDE as an analogue to support debromination pathways of transformation in the environment. Thus, the GreenScreen Risk Assessment for DBDPE report findings do not contradict the use of decaBDE for read-across to DBDPE as was done in the screening assessment.

Please also refer to the response to point 1A (above).

1G) In your Notice of Objection, you referenced the ECCC report "Polybrominated Diphenylethers in Fish and Sediment: Canadian Environmental Sustainability Factors" and state:

i) DBDPE does not meet the criteria for listing under Schedule 1 of CEPA due to the lack of established long-term trends for decaBDE.

It is not clear how the lack of established long-term trends for decaBDE is relevant to the determination that DBDPE meets the criteria for toxicity set out in section 64 of CEPA. Monitoring data, including established long-term trends if available, may be a line of evidence, among several, in the characterization of exposure in the risk assessment of a substance. However, long term trends are not part of the criteria for toxicity as set out in section 64 of CEPA and are not required to determine whether a substance meets these criteria.

If DBDPE were truly degrading in the environment, relevant monitoring data for the compounds analyzed would be expected to demonstrate the increasing presence of substances of concern in the environment.

The substances of concern that were mentioned in the DBDPE screening assessment include products of debromination from DBDPE, namely polybrominated diphenyl ethanes with <10 bromines. These substances have not been subject to targeted

surveillance and monitoring under the Chemicals Management Plan (CMP). However, the lack of surveillance and monitoring cannot be taken as an indication that they do not occur in the Canadian environment. When measured, the presence of such DBDPE debromination products has been confirmed, for example, in wastewater treatment system pond sediments near a DBDPE manufacturing plant in the U.S.

2) The following provides a summary of comments related to "Final Screening Assessment for DBDPE Ignores the Weight of the Evidence" as set out in your Notice of Objection and the analysis of the information you have provided:

2A) The conclusion reached in the Final Screening Assessment that DBDPE has the potential to transform into lower brominated products that could pose a risk to aquatic organisms conflicts with the proper application of the weight of evidence approach and has not been substantiated.

The DBDPE screening assessment draws on the available empirical, modelling, and scientific information for DBDPE. In the absence of certain data on DBDPE, information on its close analogue, decaBDE, was used to evaluate certain properties of DBDPE and its potential to cause adverse effects in the environment including breaking down to lower brominated products. A weight of evidence approach is applied with consideration of multiple lines of evidence, and some uncertainty associated with data gaps in the assessment warranted application of precaution. Thus, weight of evidence, precaution and impact of uncertainty have all been considered in decision-making.

2B) DBDPE is very different scientifically and structurally than decaBDE. Thus, the use of decaBDE as a proxy for DBDPE in computer modelling to draw this conclusion of potential breakdown products in the absence of any supporting studies is not appropriate and based on faulty assumptions given their different molecular structures.

Please refer to the response to point 1A (above).

3) The following provides a summary of comments related to "<u>Proposed Risk Management Measures set out in the draft Regulation are Unnecessary and Unreasonable - *Proposed Risk Management Measures May Lead to Severe Risk to Public Health and Safety*</u>" as set out in your Notice of Objection and the analysis of the information you have provided:

3A) In your Notice of Objection, you commented that DBDPE is used as a flame retardant to meet critical flammability standards and safety requirements in products including consumer devices, appliances, airplanes, motor vehicles and electronic and electrical equipment.

Flame retardant substances are generally used to meet performance-based flammability requirements. These requirements do not specify what chemical flame retardants need to be used; rather they may require a product or component to pass a laboratory test such as a cigarette smolder or open flame ignition test (ASTM 2014). Using chemical flame retardants such as DBDPE in products is one of the ways by which companies can meet flammability requirements for their products. Alternate substances as well as non-chemical-based alternatives may also be used to replace the use of DBDPE as a flame retardant in various applications.

In addition to the concerns you have raised in your Notice of Objection, a number of similar comments were received during the public comment period for the proposed Regulations. To address these concerns, the proposed timeline of the DBDPE exemptions will be extended by an additional 10 years (i.e. extended from 5 years to 15 years for new products and from 20 years to 30 years for replacement parts) and the scope of the DBDPE exemptions will be broadened to include all manufactured items and additional intermediate materials. This extended timeline will allow all stakeholders additional time for the research and development of alternatives, testing and certification, and transitioning their manufacturing and supply chains. Broadening the scope of the DBDPE exemptions will help to reduce the risk of prohibiting critical components, reduce the need to apply for permits under the Regulations for non-exempted parts, and reduce compliance burden of stakeholders throughout the supply chain.

3B) In your Notice of Objection, you provided comments that due to the lack of available alternatives for DBDPE in some products and that without suitable alternatives, increased flammability of products will create health and safety risks and socioeconomic impacts.

Please refer to the response to point 3A (above) respecting the extended timeline for, and broadened scope of the DBDPE exemptions.

4) The following provides a summary of comments related to "*Proposed Risk Management Measures for DBDPE are Not Aligned with Other Regulatory Agencies or Agreements*" as provided in your Notice of Objection and the analysis of the information you have provided:

4A) In your Notice of Objection, you noted that the proposed risk management measures for DBDPE as set out in the draft Regulation are an outlier globally. No other regulatory authority in the world has proposed risk management measures for DBDPE as sweeping as those set out in the draft Regulation.

Annex

Minister of Environment and Climate Change Canada
Detailed Responses to Notice of Objection Comments

Canada has been one of the first countries to lead action on flame retardants and was the first country to complete a risk assessment and propose risk management of DBDPE; however, Canada is not alone and since then international action for DBDPE has been underway or has been finalized.

In March 2023, the European Union (EU), under the European Chemicals Agency (ECHA) published their Regulatory strategy for flame retardants, which has a focus on brominated flame retardants and their prioritization for restriction, including DBDPE. This document noted that:

> *For decabromodiphenyl ethane (EC 284-366-9, DBDPE) data was requested regarding potential bioaccumulation under substance evaluation and has been assessed by the PBT expert group. The available data, including field studies, appear to confirm the Persistent, bioaccumulative and toxic (PBT) properties of the substance.*

Furthermore, on October 31, 2024, ECHA updated the substance evaluation status for DBDPE as '*Concluded*' published a Substance Evaluation Conclusion and Evaluation Report that considers DBDPE to meet the Regulation on the registration, evaluation, authorisation and restriction of chemicals (REACH) Annex XIII very persistent and very bioaccumulative criteria, wide dispersive use and high aggregated tonnage concerns and the need for follow-up regulatory action at the EU level. The report notes the restriction of aromatic brominated flame retardants as proposed in ECHA's Regulatory strategy for flame retardants appears as a logical continuation following a formal hazard identification as very persistent and very bioaccumulative for DBDPE.

On June 27, 2025, ECHA published a proposal for identification of DBDPE as a substance of very high concern (SVHC) on the basis of the criteria set out in REACH Article 57. A REACH Annex XV report was prepared by Sweden to support the proposal for identification of DBDPE as a SVHC.

In the United States (US), DBDPE is listed as a new chemical and is subject to a Significant New Use Rule, which requires manufacturers and processors to notify the US Environmental Protection Agency (EPA) before a new use for the manufacture, import or processing of DBDPE begins. In June 2021, the EPA made DBDPE subject to a Final Health and Safety Data Reporting rule pursuant to the *Toxic Substances Control Act* (TSCA) as part of a grouping of 30 organohalogen flame retardants being evaluated for risks by the Consumer Product Safety Commission (CPSC). In January 2024, the CPSC published Organohalogen Flame Retardant Scope Document: Polyhalogenated Benzene Aliphatic and Functionalized Subclass report (the PHBzAF subclass, which includes DBDPE) which concludes that "the PHBzAF subclass has sufficient data to proceed with

risk assessment". Furthermore, DBDPE is restricted in some consumer products under general flame retardant restrictions in some states, such as California, Maine, and New Hampshire.

In August of 2021, Australia published their assessment of DBDPE and found that DBDPE:

> *meets the persistence, bioaccumulation, adverse effects in aquatic and terrestrial organisms and long-range transport criteria of Annex D of the Stockholm Convention on Persistent Organic Pollutants. Therefore, on the basis of the current hazard information available, the assessed chemical could pose an unreasonable risk to the environment.*

The Australian report also recommended control measures be developed under the *Industrial Chemicals Environmental Management (Register) Act 2021*.

On June 26, 2025, the Australian government finalized its risk management for DBDPE after publishing a statutory public consultation on the proposed risk management for DBDPE in April 2025. The Industrial Chemicals Environmental Management Standard for decabromodiphenyl ethane (DBDPE) is a final scheduling decision to list DBDPE to Schedule 6 of the *Industrial Chemicals Environmental Management (Register) Instrument 2022*. Schedule 6 of this instrument lists "Relevant industrial chemicals that are likely to cause serious or irreversible harm with essential uses" and specifies the risk management measures, including prohibitions and restrictions, that apply to the relevant industrial chemical or a mixture or article containing such a chemical (Australia, 2025).

Canadian risk management for DBDPE takes into consideration actions taken in jurisdictions, including the EU and the US, with the possibility of aligning where appropriate.

4B) In your Notice of Objection, you noted that DBDPE is listed as neither a Persistent Organic Pollutant under the Stockholm Convention, nor a Chemical of Mutual Concern (CMC) under the Canada- U.S. Great Lakes Water Quality Agreement (GLWQA) and that neither rationale justifies the proposed risk management measures and that DBDPE was not listed as a priority chemical by the Minnesota Department of Health.

The Regulatory Impact Analysis Statement (RIAS) published with the proposed Regulations did not indicate that DBDPE was listed to the Stockholm Convention. The RIAS also noted that not all substances that are prohibited under the current Regulations are listed to the Stockholm Convention. With respect to the GLWQA, the RIAS stated that "the parties have currently designated PFOS, PFOA, LC-PFCAs, HBCD

and PBDEs, among other substances, as CMCs". It was not stated in the RIAS that DBDPE is listed as a CMC under the GLWQA.

Instead, the drivers to regulate DBDPE are the conclusion of the DBDPE screening assessment, and the related risk management objective outlined in the risk management approach for DBDPE: to achieve the lowest level of release of the substance into the Canadian environment, taking into account social, economic and technical matters.

4C) In your Notice of Objection, you commented that the proposed risk management measures for DBDPE were unnecessary and unreasonable and that the U.S.-Mexico-Canada Agreement (USMCA) requires a risk-based approach to chemical regulations.

The DBDPE screening assessment concludes that DBDPE is toxic, persistent and results predominantly from human activities and that DBDPE is expected to contribute to the formation of persistent, bioaccumulative and inherently toxic transformation products, such as lower brominated diphenyl ethanes, in the environment. As such, at the time the risk management approach for DBDPE was published, DBDPE met the criteria outlined in the Government of Canada's Toxic Substances Management Policy for virtual elimination from the environment (Canada, 1995).

Upon the coming into force of the *Strengthening Environmental Protection for a Healthier Canada Act* (S.C. 2023, c. 12) in June 2023, the virtual elimination provisions of CEPA were replaced with a new regime that remains risk based. In developing a proposed regulation or instrument respecting preventive or control actions in relation to substances added to Part 1 of Schedule 1 of the Act, priority will be given to the total, partial or conditional prohibition of activities in relation to the substance or of releases of the substance into the environment. For substances added to Part 2 of Schedule 1, priority will be given to pollution prevention actions, which may include prohibition, when managing risks posed by those substances.

An Order adding DBDPE to Part 2 of Schedule 1 to the *Canadian Environmental Protection Act, 1999* was published in the *Canada Gazette*, Part II, on February 26, 2025.

As indicated in the risk management approach for DBDPE, the environmental objective for DBDPE is to reduce its concentrations in the Canadian environment to the greatest extent practicable, and the risk management objective for DBDPE is to achieve the lowest level of release of the substance into the Canadian environment, taking into account social, economic and technical matters.

The high importation volumes of DBDPE into Canada, along with information on its uses, indicate potential for widespread release into the Canadian environment. Aquatic

exposure to DBDPE is expected through activities such as formulation, either directly to receiving surface water or to a wastewater treatment system that discharges its effluent to a receiving surface water body. In addition, products containing DBDPE have the potential to release DBDPE at various stages of their lifecycle, including use (see house dust studies referred to in Section 10.1.1.2 and Appendix D of the DBDPE screening assessment) and disposal. Once released into the environment, DBDPE will be found mainly in sediment and soil, where it may persist for long periods of time, resulting in DBDPE build-up, as seen by rapid doubling times in sediment in the Great Lakes.

Given the above, a regulatory prohibition is the best approach to meet the risk management objective for DBDPE, which is to achieve the lowest level of release of the substance into the Canadian environment, taking into account social, economic and technical matters.

Furthermore, there is nothing in the 2025 Regulations that contravenes the USMCA Agreement given that the addition of DBDPE to the Regulations reflects a risk-based approach based on the conclusion of the screening assessment of DBDPE.

5) The following provides a summary of comments related to "*Proposed Risk Management Measures May Lead to Supply Chain Disruptions*" as provided in your Notice of Objection and the analysis of the information you have provided:

5A) In your Notice of Objection, you provided comments that global product manufacturers take into consideration regulatory, design, and performance requirements which are addressed through a complex global supply chain for components and subcomponents and significant time and costs are associated with switching to alternatives which require research and development, prototyping, performance testing, manufacturing retooling, and regulatory compliance certification. Furthermore, you commented that you disagree with the RIAS that the proposed permits and exemptions are sufficient for stakeholders due to the lack of available alternatives for DBDPE in some products and unknown costs throughout the global supply chain. You also commented that the unique to Canada proposed exemption for DBDPE may result in increased costs.

Please refer to the response to point 3A (above) respecting the extended timeline for, and broadened scope of the DBDPE exemptions.

With respect to the estimated cost for transitioning to alternatives, it is acknowledged that the analysis does not monetize the full impact of the 2025 Regulations due to the limited information available on these substances and their possible alternatives. In response to these comments, a sensitivity analysis was done in the RIAS accompanying the 2025 Regulations to consider higher costs based on available information.

5B) In your Notice of Objection, you commented that alternative risk management measures not resulting in virtual elimination would be sufficient to address DBDPE risk of harm. Furthermore, you commented that alternative risk management measures could be proposed for DBDPE resins to contain UV stabilizers and to issue approvals for the import, manufacture and use of DBDPE in Canada.

Please refer to the response to point 4C (above) in respect to the risk management rationale for DBDPE, the amendments made to CEPA by the *Strengthening Environmental Protection for a Healthier Canada Act* (S.C. 2023, c. 12) and relevant CEPA provisions respecting toxic substances specified on Part 1 and Part 2 of Schedule 1.

With respect to the suggestion that risk management measures be implemented for DBDPE resins to contain UV stabilizers: during a product's lifecycle, any DBDPE released from UV-stabilized resin would not be protected from UV light. Furthermore, once released into the environment DBDPE will be found mainly in sediment and soil, where it may persist for long periods of time resulting in DBDPE build-up, as seen by rapid doubling times in sediment in the Great Lakes.

With respect to the suggestion that risk management measures employ an approval process for import, manufacture and use, the risk management approach for DBDPE outlines the environmental objective for DBDPE, which is to reduce its concentrations in the Canadian environment to the greatest extent practicable, and the risk management objective for DBDPE, which is to achieve the lowest level of release of the substance into the Canadian environment, taking into account social, economic and technical matters.

Given the above, a regulatory prohibition that includes exemptions for DBDPE with extended timelines and a broadened scope for those exemptions is the best approach to meet the risk management objective for DBDPE.

5C) In your Notice of Objection, you commented that the proposed permitting system is not suitable for stakeholders due to uncertainty with respect to timing.

The permit process is intended to deal with unforeseen challenges, following the coming into force, with respect to activities that are not covered by an exemption. Where there are known challenges, exemptions have been provided under the Regulations. Permits are not required for activities that are exempted following the coming into force of the 2025 Regulations and are not intended to extend the time-limited exemptions that were provided for in the proposed Regulations.

To address your concerns related to the permit process, the proposed timeline of the DBDPE exemptions will be extended by an additional 10 years (i.e. extended from 5 years to 15 years for new products and from 20 years to 30 years for replacement parts)

and the scope of the DBDPE exemptions will be broadened to include all manufactured items and additional intermediate materials. This extended timeline will allow all stakeholders additional time for the research and development of alternatives, testing and certification, and transitioning their manufacturing and supply chains. Broadening the scope of the DBDPE exemptions will help to reduce the risk of prohibiting critical components, reduce the need to apply for permits under the Regulations for non-exempted parts, and reduce compliance burden of stakeholders throughout the supply chain.

6) **The following provides a summary of comments related to "*Proposed Risk Management Measures for Polybrominated Diphenyl Ethers (PBDEs) do not Align with Global Regulations and Restrictions*" as provided in your Notice of Objection and the analysis of the information you have provided:**

In your Notice of Objection, you commented that the proposed concentration thresholds for incidental presence of PBDEs could put Canada at odds with some of its largest trading partners and consideration should be given to global regulatory alignment.

The incidental presence concentration threshold values in Schedule 3 of the proposed Regulations endeavored to align with those of other jurisdictions. The concentration thresholds for PBDEs (10 mg/kg (0.001 percent by weight) in a product that is a commercial grade substance, mixture, polymer or resin; and 500 mg/kg (0.05 percent by weight) for all other products are aligned with the concentration thresholds for PBDEs in Annex I of the European Union's Regulation (EU) 2019/1021 of 20 June 2019 on persistent organic pollutants (EU's POPs Regulation). However, the EU's POPs Regulation derogates (or exempts) electrical and electronic equipment (EEE) within the scope of the European Union's Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EU RoHS Directive) which has a higher incidental presence concentration threshold of 1,000 mg/kg (0.1 percent by weight) for PBDEs.

To support international alignment with the EU RoHS Directive, the proposed incidental presence concentration threshold for PBDEs will be modified to align in specific EEE of 1,000 mg/kg (0.1 percent by weight).