

July 13, 2022

The Honourable Steven Guilbeault
Minister of the Environment
c/o Christina Paradiso
Executive Director Chemicals Management, Environmental Protection Branch
Department of the Environment
351 Saint-Joseph Boulevard, Gatineau, Quebec K1A 0H3
Email: ec.interdiction-prohibition.ec@ec.gc.ca

Re: Notice of Objection and Request for Board of Review in relation to proposed regulations prohibiting the manufacture, use, sale and import of decabromodiphenyl ethane (DBDPE, CAS Registry Number 84852-53-9) and polybrominated diphenyl ethers (PBDEs) while providing exemptions to the prohibitions, Canada Gazette, Part I, Volume 156, Number 20 – May 14, 2022: Prohibition of Certain Toxic Substances Regulations, 2022.

Dear Minister Guilbeault:

SANYU REC CO.,LTD writes to express our formal objection to the above-referenced regulatory proposal.

Our products are used as insulating resins for electronic materials and play a role in preventing the failure of cars and home appliances. DBDPE, which was listed as a prohibited substance this time, is used as a flame retardant and is used for the purpose of preventing fires. DBDPE has excellent flame retardancy, and no replacement has been found. In addition, car-related products take time to evaluate, so even if they are found, they will need a long time.

As provided for by section 332(2) of CEPA 1999, SANYU REC CO.,LTD is filing this Notice of Objection and respectfully request that a Board of Review be established, pursuant to section 333 of CEPA 1999, to “inquire into the nature and extent of danger” posed by DBDPE and PBDEs for the reasons set out below.

Proposed Risk Management Measures May Lead to Severe Risk to Public Health and Safety

DBDPE performs a valuable function by reducing the flammability of the products where it is used. Those products include not just consumer devices and appliances, but also include airplanes and motor vehicles. In the absence of alternatives, the prohibitions pose a genuine risk of increasing flammability of those products therefore creating a severe risk to public health and safety.

Proposed Risk Management Measures for DBDPE are Not Aligned with Other Regulatory Agencies or Agreements

The proposed risk management measures as set out in the proposed Prohibition of Certain Toxic Substances Regulations, 2022 (the “draft Regulation”) for DBDPE are an outlier globally. No regulatory authority in the world has proposed risk management measures as sweeping as those set out in the draft Regulation. Canada is acting alone to prohibit DBDPE. By way of example, the United States Environmental Protection Agency (U.S. EPA) is not currently conducting a risk evaluation for DBDPE and is not contemplating risk management measures.

ECCC has noted that Canada is a party to the Stockholm Convention on Persistent Organic Pollutants (POP), and that the proposed risk management measures would allow Canada to meet “its international commitments implementing amendments to the Stockholm Convention.” Yet, DBDPE is not listed as a POP under the Stockholm Convention. ECCC also cites meeting the goals of the Great Lakes Water Quality Agreement as a justification for its proposed risk management measures, even though DBDPE is not listed as a Chemical of Mutual Concern as part of the agreement. Accordingly, neither rationale justifies the proposed risk management measures.

Last, the Final Screening Assessment of DBDPE (the “Final Screening Assessment”) published in the May 11, 2019 Canada Gazette, Part I, as well as the Proposed Order to add the substance to Schedule 1 of the Canadian Environmental Protection Act, 1999 published in the June 29, 2019 Canada Gazette, Part I Notice, and the subsequent draft Regulation are inconsistent with the U.S.-Mexico-Canada Agreement (USMCA), which requires a risk-based approach to chemical regulations.

Any risk management measures for DBDPE need to align with other national and international regulatory bodies and with international agreements to avoid potential unintended consequences that could negatively affect Canadian consumers and businesses operating in Canada.

Proposed Risk Management Measures May Lead to Supply Chain Disruptions

Product manufacturers operate in a global regulatory environment and must take into account a broad range of product safety and design factors. This includes considerations related to product certification, performance, use and end of life, and even chemical registration. These regulatory, design, and performance requirements are addressed through a complex global supply chain for components and subcomponents.

A 2020 socioeconomic study commissioned by ECCC on DBDPE in the Canadian market noted that “at this time, effective fully tested alternatives are not currently known for many critical applications.” ECCC suggests that its consultations with industry stakeholders have helped it develop permits and exemptions to address the lack of available alternatives to DBDPE. However, these permits and exemptions are insufficient in addressing the lack of available alternatives for DBDPE. ECCC notes several times during the draft Regulation that there is a lack of data and certainty regarding cost and availability of alternatives to DBDPE for some critical applications, and consequently that compliance costs have not been estimated for proposed risk management measures affecting wire and cable, automotive products, and other applications.

The engineering and certification of products is a time-consuming process that can take years, and there are considerable financial costs involved in this effort. SANYU REC CO.,LTD members design products to meet relevant safety standards and to be safe when used as intended. Given the lack of available alternatives for DBDPE and unknown costs of compliance with the regulatory proposal, ECCC must revise its approach in regulating DBDPE to avoid disruptions to an already overburdened supply chain.

Especially when considering the automotive relationship, our evaluation of the parts using our products, the evaluation of the car using the parts using the parts and the evaluation period considering the safety aspect require a long time.

Final Screening Assessment for DBDPE Ignores the “Weight of the Evidence”

Section 76.1 of Canada Environmental Protection Act (CEPA) requires equal weight in the application of both the weight of evidence and the precautionary principle in conducting the evaluation of the scientific evidence relating to any particular substance. Section 76.1 does not give precedence to either of these two principles. The application of the precautionary principle is not stated or intended to govern decision-making.

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. ECCC reached its conclusion regarding the potential for breakdown of DBDPE based on a theory that the DBDPE would behave in the same way as another flame retardant, decabromodiphenyl ether (decaBDE). That conclusion is inconsistent with the available evidence on DBDPE.

The approach taken by ECCC is contrary to the statutory requirement to apply the weight of evidence approach. 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.

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

ECCC notes for the Final Screening Assessment that “given the available information on potential human health effects, DBDPE is not a concern for human health.”¹ A comprehensive list of 50 analytical, toxicological, environmental, and pharmacological studies were conducted on DBDPE to evaluate its safety and to register as appropriate in other jurisdictions. These studies were provided to ECCC through the assessment process to assist in the evaluation of this substance. The state of the science as demonstrated by these studies does not support a conclusion that would justify the proposed risk management measures.

¹ ECCC, Decabromodiphenyl Ethane (DBDPE) – Information Sheet, <https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/chemicals-glance/decabromodiphenyl-ethane.html#a5.1>.

In addition to the studies discussed above, there is new scientific information since publication of the Final Screening Assessment in May 2019 that was not available and therefore not evaluated by ECCC or HC during the Screening Assessment. This additional scientific information provides a sufficient justification for the Minister to reconsider the conclusion reached in the Final Screening Assessment that DBDPE is “toxic” under CEPA.

First, in November 2020, an independent third-party review was provided to ECCC of the available scientific reports, as well as the draft and final screening assessments, for the purpose of providing an opinion on the validity of the approach taken and conclusions reached by ECCC with respect to DBDPE. Below are several of the conclusions from the independent review:

- DecaBDE is not a good read-across substance for the purpose of estimating the rate of potential debromination of DBDPE;
- Guidelines and recommendations for applying a read-across approach exist but were not adequately followed by ECCC in the Final Screening Assessment; and,
- The Final 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.

Second, the National Academy of Sciences, Engineering, and Medicine (“NAS”) published a study report² in May 2019 to determine if organohalogen flame retardants (“OFRs”) – which includes DBDPE – could be divided into subgroups based on similar chemical structures or physicochemical properties for the purposes of further assessment. NAS recommended dividing 161 OFRs into 14 subclasses. It is noteworthy that in the study, NAS grouped DBDPE and decaBDE into separate subclasses. This finding further supports the position that it is not appropriate to use decaBDE as a surrogate for DBDPE to draw any conclusion regarding potential breakdown products in the absence of supporting studies.

Third, the results of a 2,000-hour study modelling the photodegradation of DBDPE within high impact polystyrene (HIPS) and polypropylene (PP) in the Canadian environment has been shared with ECCC. Conclusions from that study are that DBDPE has a long half-life under realistic photodegradation conditions, any formation of lower brominated products from DBDPE is negligible and are not the species of concern expressed by ECCC, and lower form brominated products can be prevented with the help of ultraviolet absorption and light stabilizers.

The 50 studies previously shared with ECCC, along with new information that has been shared with ECCC since publication of the Final Screening Assessment, does not support either the finding that DBDPE is “toxic” under CEPA or the proposed risk management measures.

² National Academies of Sciences, Engineering, and Medicine. 2019. A Class Approach to Hazard Assessment of Organohalogen Flame Retardants. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/25412>.

Proposed Risk Management Measures for PBDEs do not Align with Global Regulations and Restrictions

As mentioned earlier for DBDPE, it is also important that risk management measures for other substances align with global agreements and regulations. That is true for PBDEs, a group of flame retardants which have largely been phased out in Canada and around the world and are no longer being produced. At present, Canada already prohibits the manufacture, use, sale, offer for sale, and import of PBDEs, including decaBDE, and all products that contain PBDEs except for manufactured items. Canada's current regulations for PBDEs are largely consistent with international regulations for PBDEs.

ECCC proposes eliminating the exemption allowing the manufacture, use, sale and import of manufactured items containing PBDEs with a few exceptions. In addition, the presence of each PBDE congener (e.g., decaBDE, octaBDE, etc.) in a substance, mixture, polymer, or resin is proposed to be incidental at a concentration less than or equal to 10 parts per million (ppm). The presence of PBDE congeners in all other products is proposed to be incidental when the total concentration of all congeners is less than or equal to 500 ppm.

In contrast, the European Union's Restriction on Hazardous Substances (RoHS) requires electrical and electronic products to contain less than 1,000 ppm or 0.1% of PBDEs. Further illustrating the complexity in finding alternatives for some substances, although five PBDEs are listed as POPs by the Stockholm Convention, all of them still have some specific exemptions on a time-limited basis. U.S. EPA is also considering additional risk management measures for decaBDE, with a proposal for a new rulemaking expected in Spring 2023.

The proposed risk management measures for PBDEs could put Canada at odds with some of its largest trading partners and consideration should be given to global regulatory alignment, circularity goals, and potential disruptions to critical sectors in the country.

Based upon the facts and arguments set out above we ask the Minister to appoint a Board of Review to "inquire into the nature and extent of danger" posed by DBDPE and PBDEs.

Sincerely,

Name Koichiro Nagai



Title CEO

Company/Organization SANYU REC CO.,LTD