

Summary of Public Comments received on the Challenge substance TCEP (CAS No. 115-96-8) Draft Screening Assessment Report and Risk Management Scope for Batch 5

Comments on the draft Screening Assessment report and Risk Management Scope documents for TCEP to be addressed as part of the Chemicals Management Plan Challenge were provided by Dow Chemical Canada Inc., Canadian Vehicle Manufacturers' Association and Chemical Sensitivities Manitoba and Canadian Environmental Law Association.

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

- Risk Assessment
- Risk Management

TOPIC	COMMENT	RESPONSE
Risk Assessment	TCEP does not pose a significant cancer risk for humans as the EU classification for reproductive toxicity was more compelling for risk management purposes than the EU classification for carcinogenicity.	As a result of categorization, toxicity classifications by other national or international agencies and the potential for exposure to Canadians helped to determine TCEP's high priority for assessment. However, the conclusions regarding toxicity endpoints in the Screening Assessment are those of the Government of Canada. All relevant data were considered in developing conclusions, including the data which led to the EU classifications for carcinogenicity and reproductive toxicity.
	The declaration of unacceptable risk based on the Margin of Exposure (MOE) should be revisited, as the MOE was above 1000. Risk management applications could be challenged where the MOE is greater than 1000 as they may be considered "safe" by international standards.	In Screening Assessments prepared under the Challenge, there are no specific cut-offs for Margins of Exposure (MOEs) in determining whether the risk is unacceptable or not. The conservative MOE is considered together with the adequacy and nature of the toxicity and exposure databases to determine if it is protective of human health. In the context of the TCEP Screening Assessment, there was moderate confidence in the toxicity and exposure databases in light of the uncertainties in the databases on exposure and effects. These included the fact that increased incidences of tumours were also observed at the critical effect level for non-cancer effects in oral studies in rats (44 mg/kg-bw per day), which was the lowest dose tested (i.e., a lower bound on exposure levels associated with effects was not established). It is

		considered that estimated margins of exposure may not be adequately protective of human health.
	Overly conservative scenarios were developed and used in modeling (e.g. to develop the Predicted Environmental Concentration (PEC) for water) they are inappropriate and could cause problems with the risk management development.	The PEC for water was derived from monitoring data from the Great Lakes. The highest reported concentration was used as a conservative PEC. Because the resulting risk quotient was much smaller than 1, indicating a negligible risk, it is not necessary to consider refining the PEC. The assessment has found that TCEP is unlikely to cause harm to sensitive aquatic organisms in Canada. Therefore risk management instruments would not be needed to protect aquatic organisms.
	The Government of Canada deserves credit for conducting a limited external peer review but a more thorough peer review would meet scientific standards.	An external peer review was undertaken by experts. The draft Screening Assessment was prepared by staff in Health Canada and Environment Canada. This included a comprehensive internal science review. The internal and external science reviews are normal practices for Draft Screening Assessments.
	The possible presence of TCEP in landfill leachate was questioned if TCEP is affixed or contained within a matrix and not available to leach. The levels of TCEP in landfill leachate in Canada should be determined before moving ahead with any risk management measures.	Based on the information available, TCEP is not completely affixed or contained within a matrix. In addition, TCEP was measured in landfill leachate identified elsewhere, and based on its physical and chemical properties and use pattern, TCEP is expected to be in Canadian landfill leachate. TCEP is being considered for addition to the CMP Environmental Monitoring Program which includes monitoring of landfill leachate.
Risk Management	If, as stated in section 1.2 of the Risk Management Scope document, " <i>TCEP has no single use as a consumer product in Canada</i> " is correct, no risk management is needed for consumer products.	The sentence in the Risk Management Approach has been reworded. TCEP itself is not directly available as a consumer product, however it is an additive flame retardant that is a common component of polyurethane foam and upholstered furniture and consequently such products may be subject to risk management action.
	There is a need to demonstrate the abrasive release	It is well known that certain flame retardants found in

	phenomenon of TCEP prior to risk management.	polyurethane foams, upholstered furniture and automotive cushioning may be released upon abrasion and blooming and may consequently be identified, e.g. in car interiors and house dust.
	The Risk Management Scope document offered generalities and does not offer defined risk management actions.	The Risk Management Scope document provides a preliminary outline of the risk management options that may be examined based on the proposed conclusion of the draft Screening Assessment report. The Risk Management Scope documents are intended to provide the Government of Canada's initial thinking, and act as a catalyst for consultation with the implicated sectors. The Risk Management Approach document outlines in more detail the proposed risk management actions based on the final Screening Assessment report.
	Stakeholders should be included in the development of the risk management approaches.	The Government of Canada finds the input of stakeholders to be fundamental in the development of risk management instruments.. The risk management approach document is a manner to launch a process that will involve and engage stakeholders as this process is undertaken.
	The residue data from foods used in the assessment may not be appropriate to influence risk management options since, based on the study used, TCEP is rarely found in foods.	No specific risk management actions are proposed for foods at this time.
	There were concerns with footnotes 10 and 13 in Appendix 1 of the Screening Assessment (i.e., TCEP in indoor air and dust), as they indicate the use of foreign data in the estimate of daily intake. The validity of relying on foreign data and maximum values reported in foreign data to support potential risk management for TCEP in indoor air, soil or sediments is questioned.	In cases where appropriate data from Canada are not available, relevant quality data from other jurisdictions with similar life styles, geography, climate, etc., such as the United States and European countries, are considered. This approach is consistent with Screening Assessments for other substances listed under the Challenge program.

	<p>One of the references used was not appropriate and the link to the webpage was no longer active.</p>	<p>The reference has been removed from the Risk Management Approach document as confirmation has been received that TCEP is not currently used as a flame retardant for mattresses supplied in Canada by the company referred to in the reference.</p>
	<p>There are concerns with air emissions or impacts being the focus of any potential risk management instruments when modelling shows that it is not a significant release and that there is no Canadian air data available to confirm the presence of TCEP in air.</p>	<p>Based on the available literature, TCEP is present in indoor air in several countries with much smaller quantities, if any, in ambient air. Table 3 in the Screening Assessment shows the results of fugacity modelling related to an outdoor setting and not the indoor scenario.</p> <p>When Canadian data are not available, quality data from other jurisdictions with similar geography, climate, population lifestyles, etc., are used. Consideration of the possible differences, such as amounts of TCEP in products in other countries, is taken into account. This approach is consistent with Screening Assessments for other substances listed under the Challenge program.</p>
	<p>What is the relevance of using foreign data related to the presence of TCEP in consumer products? Canadian specific information should be used if risk management will be undertaken for consumer products.</p>	<p>It is noted that having Canadian specific data related to TCEP in consumer products would give greater confidence when determining potential risk management measures. Given today's global markets and the lack of Canadian specific data, assuming that Canadian products are similar to those found in the US and Europe is considered reasonable in the screening context. This approach is consistent with Screening Assessments for other substances listed under the Challenge program.</p> <p>In the development of a risk management instrument, consideration will be given to developing Canadian product specific data on the content of TCEP.</p>
	<p>When the Risk Management Approach is published, it should clearly state where the greatest risk is and what action is recommended to address.</p>	<p>All available, relevant information is taken into account when preparing the Screening Assessment report and the risk management documents to identify pertinent sources of exposure. Proposed risk management actions are explained in the Risk Management Approach document.</p> <p>The Government of Canada is recommending a prohibition</p>

		<p>relating to the presence of TCEP in products and materials. Additional engagement with stakeholders, including the 60 day comment period, will help determine the extent of the prohibition required to most effectively minimize exposure to Canadians.</p>
	<p>The draft Screening Assessment provides no details on the future risk management actions for TCEP.</p>	<p>The Risk Management Scope for TCEP was published concurrently with the draft Screening Assessment. Proposed risk management actions are reported in the Risk Management Approach which is published on the Government of Canada's Chemical Substances website (http://www.chemicalsubstanceschimiques.gc.ca) at the same time the Final Screening Assessment is published on this website.</p>