Summary of Public Comments received on the Challenge substance TCEP (CAS RN 115-96-8) Proposed Risk Management Approach document for Batch 5

Comments on the proposed risk management approach document for TCEP to be addressed as part of the Chemicals Management Plan Challenge were provided by Canadian Vehicle Manufacturers Association, Dow Chemical Canada, Chemical Sensitivities Manitoba, Canadian Environmental Law Association and Inuit Tapiriit Kanatami. The table contains a condensed version of each comment and a response in non-technical terms.

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

TOPIC	COMMENT	RESPONSE
Risk management	The Government of Canada should phase-out and prohibit the use of TCEP, and TCEP should be substituted with safer substitutes.	The Government of Canada considers a wide variety of risk management options including prohibiting or phasing-out a substance. It should be noted; however, that there are situations where hazardous substances can be managed such that there is no, or negligible, exposure to Canadians. In these situations, or when phase out or prohibition is not possible, and exposure risks are low, the Government of Canada develops regulations to control sources and limit releases of substances in order to protect the environment and human health. Proposed risk management approaches consider alternative technologies, methods, and substances through consultation with affected stakeholders. The Government of Canada is recommending a prohibition relating to the presence of TCEP in polyurethane foam products intended for children.
	Existing products and materials containing TCEP	Based on information indicating a decline in the market place for

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	are not addressed in the proposed risk management approach.	TCEP, the Government of Canada plans to implement Significant New Activity provisions under CEPA 1999. This would require that any proposed manufacture, import or use be subject to assessment, and would determine if the new activity requires further risk management consideration. The Government of Canada is recommending a prohibition relating to the presence of TCEP in polyurethane foam products intended for children. A market surveillance program will be designed to collect information on imported products that may contain TCEP. Further risk management activities may be considered pending results of this activity. Existing products and materials containing TCEP will gradually decline through disposal at end of life.
	Disposal of products with TCEP is not addressed in the proposed risk management approach.	The Government of Canada strives to take into consideration recycling activities and resulting potential releases to the Canadian environment. Where appropriate, risk management measures for the potential release of chemicals to wastewater sewer systems would be implemented at the source. The assessment for TCEP based on ecological concerns includes estimates of the quantities of the substance that may end up in landfills or incinerators at the end of their lives. These releases were not found to present a risk to the environment, and so no risk management was warranted.
	It is questioned if there will be limits for TCEP set for indoor air, as in other jurisdictions, given that the predominant sources of exposure to TCEP occur from indoor air and dust.	Limits for indoor air concentrations were not considered to be the most appropriate risk management measure for TCEP. Based on information identifying changes to the market place for TCEP, the Government of Canada plans to implement Significant New Activity provisions with no exclusions under CEPA 1999. This would require that any proposed manufacture, import or use

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		be subject to further assessment, and would determine if the activity requires further risk management consideration. The Government of Canada is recommending a prohibition relating to the presence of TCEP in polyurethane foam products intended for children. A market surveillance program will be designed to collect information on imported products that may contain TCEP. Further risk management activities may be considered pending results of this activity.
	The Government of Canada's activities should remain focused on materials used in the indoor or house-related applications only as currently proposed in the risk management document.	The proposed risk management activities for TCEP focus on the risks identified in the screening assessment report. The Government of Canada is recommending a prohibition relating to the presence of TCEP in products containing polyurethane foam intended for children. In addition, the Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to TCEP. This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration.
	It is questioned why the Margins of Exposure (MOE) - all above 1000 in the case of TCEP - are considered unacceptable for TCEP whereas other substances with similar MOEs did not require Risk Management.	In screening assessments reports prepared under the Challenge, there are no specific cut-offs for MOEs in determining whether the risk is acceptable 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 report, there was moderate confidence in the toxicity and exposure databases in light of the uncertainties in the databases on exposure and effects. It was considered that estimated MOEs may not be adequately protective of human health; therefore, risk management was required.

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Data gaps	It is questioned how socioeconomic factors were considered because of the lack of a definitive instrument, lack of data, and no consultation to dialogue and collect detailed data and information. The Government of Canada should expand its efforts to identify safe alternatives to TCEP.	Where available and relevant, socioeconomic data and information on the availability and cost of alternatives for a substance used in Canada, including the economic, social, health and environmental implications, will be considered in the development of risk management tools. Information on these impacts may be generated from a number of sources, including direct engagement with stakeholders. When a regulation is developed, the full analysis will be made available in the Regulatory Impact Assessment Statement. The Government of Canada is exploring a risk assessment approach for some groups of chemicals which could lead to the concurrent assessment of potential alternatives. In North America and Europe, TCEP has been replaced by Tris (1-chloro-2-propyl) phosphate (TCPP), CAS RN 13674-84-5 for many applications. TCPP is a mixture of four isomers. In Canada, TCPP has not yet been evaluated in an assessment to determine whether it meets the criteria under section 64 of CEPA 1999. TCPP is a medium-priority substance for assessment under the Chemicals Management Plan, and will be assessed as a potential alternative to TCEP for certain applications.
Vulnerable populations	The management regime for TCEP should ensure that vulnerable populations are effectively protected from exposure to TCEP.	Risk assessments are science-based assessments of the available data. Various exposure scenarios are used that are protective of vulnerable populations in Canada. When risk assessments identify a risk to a particular population, actions to protect that population are included in the risk management.
	The fact that occupational health and safety are not addressed under CEPA 1999 is seen as a major gap in the Chemicals Management Plan Challenge.	While the scope of screening assessment reports under CEPA 1999 are focused on the potential risks to the general Canadian public, occupational exposures are considered with respect to the potential health effects associated with a substance. In terms of risk management, the focus is on protecting the health of the

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		Canadian general population. However the detailed scientific information within the screening assessment reports are shared with officials at the federal and provincial levels responsible for occupational health and safety, including the Chief Medical Officers of Health, and they may subsequently consider additional action with respect to protecting workers.
Exposure	There is a need for the government to look beyond the home for daily exposures to TCEP.	The Government's proposed risk management activities focus on minimization of the risks identified in the risk assessment based on the information available. If an identified risk cannot be discounted, the application of precaution is taken to protect the health and environment of Canadians.
	The screening assessment report has not considered the cumulative and synergistic effects of chemicals.	Consideration of cumulative, synergistic and antagonistic effects is not precluded from a risk assessment. However, in order to be considered, sufficient information to undertake such analyses would be needed. Under the Challenge, the information typically available for assessing effects is representative only of an individual substance's inherent ability to elicit adverse effects.
	Releases to water/wastestreams and other media may present a route of exposure that has not been factored.	The Government of Canada strives to take into consideration recycling activities and resulting potential releases to the Canadian environment. Where appropriate, risk management measures for the potential release of TCEP to wastewater sewer systems would be implemented at the source. Other measures may be implemented to address the risks posed by TCEP from wastewater effluents and sludge if determined necessary. The assessment of TCEP includes estimates of the quantities of the substances that may end up in landfills or incinerators at the end of their lives.