Summary of Public Comments received on the Challenge substance Isophorone (CAS 78-59-1) Draft Screening Assessment Report for Batch 7

Comments on the draft screening assessment report for Isophorone to be addressed as part of the Chemicals Management Plan Challenge were provided by International Institute of Concern for Public Health (IICPH) and Dow Chemical Canada Inc.

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

- Exposure
- Experimental Data
- Conclusion

TOPIC	COMMENT	RESPONSE
Exposure	80 000 kg was reportedly imported in the year 2000 (Statistics Canada 2009), however, there is no mention of the amount of isophorone used in that same year.	Use quantities for the year 2000 are unavailable. CEPA 1999, section 71, data is for the year 2006 and Statistics Canada only provides international trade data, not domestic use quantities.
	There is a lack of environmental media monitoring data and mandatory reporting of environmental isophorone levels to arrive at a meaningful conclusion.	There is recent Canadian data on isophorone levels in drinking water, indoor air and agricultural soil, and this information has been incorporated in the final screening assessment.
	Data gaps and uncertainty in isophorone exposure should result in applying a precautionary approach to the isophorone assessment and consider the substance “toxic” under Section 64(c) of CEPA.	Data gaps and uncertainties have been considered when concluding that isophorone does not meet the criteria of section 64 of CEPA, 1999.
	The lack of regulations could lead to unregulated use in foods.	The safety of all materials used for packaging foods is controlled under the *Food and Drug Regulations*, which essentially prohibit the sale of a food in a package that may impart a harmful substance to its contents. For most flavours, including isophorone, there are no provisions in the *Food and Drug Regulations* that control their addition to foods, although such use must not result in a violation of the *Food and Drugs Act*.

		In the case of isophorone, the screening assessment did not identify any health risks for which risk management measures would be required.
	The *Food and Drug Regulations* do not include any provisions to control the addition of flavours to foods. There is insufficient data on isophorone in food packaging for the assessors to determine if isophorone intake from food packaging is negligible.	The *Food and Drug Regulations* do not require that food flavouring agents undergo a premarket review by the Government of Canada. However, the Regulations prohibit a number of substances from being present in or added to food, including several agents that might otherwise be used for flavouring food. Isophorone intake from food packaging is negligible as its use in food packaging is limited to the manufacturing of some tin can linings.
	Should all packaging material containing isophorone, including food packaging, be sent to hazardous waste facilities, similar to how industry disposes of isophorone?	Consumer products and packaging materials may contain trace, residual levels of isophorone and do not need to be disposed of in hazardous waste facilities, based on isophorone content.
	The Screening Assessment did not adequately consider occupational exposure.	Exposure to the general population through environmental media and consumer products was taken into account. Hazard information obtained from occupational settings, in particular epidemiological information, is considered in screening assessments. The information developed through the Chemicals Management Plan may be used to inform decisions concerning additional actions to minimize exposure to workers. The Government of Canada is working to communicate results to appropriate occupational health and safety groups.
	Some animal studies found some harmful health effects in adult female animals and in their offspring following isophorone exposure, while the screening assessment indicated that isophorone is not considered to be a developmental or reproductive toxicant.	A critical evaluation of available studies did not identify developmental or reproductive endpoints as critical effects for characterization of risk to human health.
	The determination of Margin Of Exposure (MOE) was limited, as only one MOE was calculated.	A margin of exposure was derived to characterize risk from oral exposure. A margin was not derived for inhalation exposure as the route of exposure was considered to be negligible.
	There is a need for a clear explanation for taking a	Although the mode of induction of tumours is not fully elucidated,

	threshold approach to the effects of isophorone.	the tumours observed are not considered to have resulted from direct interaction with genetic material. Therefore, a threshold approach is used to assess risk to human health.
	One commenter suggested that vulnerable population were not considered.	The Challenge screening assessments are based on considerations of the available data. The various conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada and do incorporate specific exposure estimates for Canadians of different ages. If information were available suggesting a specific subpopulation would be vulnerable, that information would be considered in the assessment.
	There is some confusion as to whether there are any developmental or neurological effects from exposure to isophorone.	A critical evaluation of available studies did not identify developmental endpoints as critical effects for characterization of risk to human health. The large margin of exposure to the effect level from animal studies used to characterize risk to human health is protective of potential neurological effects.
Experimental Data	When multiple physical-chemical properties are available, the assessors should identify which data point is used, for what purpose and a rationale for selection.	When multiple physical-chemical properties were available, the assessors identified which data points were used, and have now added a purpose and a rationale for selection in the screening assessment.
Conclusion	The substance should be declared toxic so that risk management strategies can be developed and monitoring and mandatory reporting data of releases are required.	The screening assessment report concludes that current levels of exposure are determined not to pose a risk to the general population, therefore no risk management strategy will be developed.