

Summary of Public Comments received on the Challenge substance 3-chloropropene (CAS 107-05-1) Draft Screening Assessment Report for Batch 6

Comments on the draft screening assessment report for 3-chloropropene to be addressed as part of the Chemicals Management Plan Challenge were provided by the Canadian Environmental Law Association/Chemical Sensitivities Manitoba and the International Institute of Concern for Public Health.

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

- Risk Assessment
- Significant New Activity (SNAc) provisions
- Risk Management

TOPIC	COMMENT	RESPONSE
Risk Assessment	There are uncertainties associated with the use of models to characterize the potential for ecological risk.	To ensure protection of human health and the environment, the Government has committed to promptly assess substances in the Challenge based on available information. Gaps in information are frequently addressed through the use of models and protective assumptions. It is recognized that there are uncertainties associated with results obtained from models, just as there are uncertainties with results of experimental studies. However, all results considered in the assessment, including those generated through models, are reviewed by technical experts.
	There is no basis for the assumptions used to estimate exposures of children to the substance in consumer products.	Exposure estimates were generated for adults because they were determined to be the most highly exposed subpopulations. Children use less of the same personal care products than adults. As such, at lower amount of products applied, the exposure model predicted that exposures from the products are at comparable levels or lower than that of adults.
	The literature used for the assessment was not current, and there are no data regarding environmental concentrations of 3-chloropropene in Canada.	The screening assessment is based on the collective information currently available for the determination of the critical health and ecological effects. The collective information could include data collected under the section 71 surveys, available scientific data from a range of sources including published literature in scientific journals, as well as other international reviews.

	Occupational exposures deserve more attention.	Occupational exposures are not characterized in the screening assessments, as the focus of the assessments is on general population exposures. Hazard information obtained from occupational settings, in particular data from relevant epidemiological studies, is considered in the screening assessments. The information developed through the CMP process may be used to inform decisions concerning additional actions to minimize exposure to workers. CMP is working to communicate results to appropriate occupational health and safety jurisdictions.
	Vulnerable populations were not considered.	The Challenge screening assessments are based on considerations of the available data. Exposure estimates to chemicals from environmental media (e.g., food, ambient air, soil, consumer products) are derived for various age groups of the general population. If information is available which indicates that a specific sub-population could be susceptible, this information is taken into consideration when characterizing risk.
	Based on the conclusion that epichlorohydrin was toxic under CEPA 1999, the findings of the screening assessment report of 3-chloropropene should be reconsidered as the substance is primarily used to synthesize epichlorohydrin.	3-chloropropene is used to synthesize chemical intermediates such as epichlorohydrin for downstream derivatives such as resins and polymers. While residual levels of 3-chloropropene may result as part of the production process of epichlorohydrin, due to its reactive nature, it is expected that there would be negligible levels of the substance in final consumer products as result of its use to manufacture epichlorohydrin.
	The highest reported 3-chloropropene concentration in outdoor air was not used for exposure calculations.	The maximum reported concentration of 3-chloropropene measured in Maine was not considered to be representative of the general population's exposure because it was from only two annual observations in a rural parking lot where the land was allocated for industrial use. The data has limited validity as all other ambient air monitoring data retrieved from the US EPA Air Quality System indicate 3-chloropropene concentrations to be below detection limits.
	The use of an extrapolated "dermal" LOEL value from an oral study is questionable.	The Challenge screening assessments are based on considerations of the available data. When data are not available to quantify risks for a route of exposure, available data may be used as a substitute

		if considered appropriate as a means to establish a worst case estimate of a LOEL for potential effects following oral exposure. The uncertainties associated with the approach are recognized and are taken into consideration in interpretation of the adequacy of the margin of exposure to protect human health.
	More recent exposure studies and toxicology studies with relevant routes of exposure should be conducted. For example, carcinogenicity studies should be conducted with animals and recent Canadian monitoring data must be used.	In the Notice of Intent published in Canada Gazette, Part 1, the Government of Canada invites industry and other stakeholders to provide specific information that may be used to inform risk assessment and to develop and benchmark best practices for the risk management and product stewardship of those substances identified as the highest priorities. This would include available toxicology and monitoring data. In addition to the data collected under the section 71 surveys, the screening assessments use the available scientific data from a range of sources including published literature in scientific journals and other international reviews. The Government of Canada has stated that the absence of new information will not preclude the Ministers from issuing a decision that safeguards human health and the environment. Thus the process being used for the Challenge substances is not to wait until data gaps are filled, but to act on what we know now.
	3-chloropropene should be designated “toxic” under CEPA 1999 based on its inherent hazard properties, evidence of genotoxicity and the level of uncertainty.	The Government of Canada conducts science-based screening assessments. Risk to human health is characterized by taking into consideration both hazard and exposure. The evidence for carcinogenicity is considered to be weak for 3-chloropropene, as recognized in the classifications by other regulatory agencies. 3-chloropropene also consistently tested negative in a range of <i>in vivo</i> mutagenicity assays. Based on consideration of this information, it was considered more appropriate to characterize risk to human health in Canada based on a margin of exposure approach for the non-cancer effects.

		On such basis, the margins of exposure between levels associated with health effects and exposures to the general population through the environment and from consumer products were considered to be adequately protective for Canadians.
Significant New Activity (SNAC) provisions	There are various tools under CEPA to ensure that future uses of substances are not permitted in Canada that should be implemented for 3-chloropropene.	It is proposed that 3-chloropropene be subjected to the Significant New Activity (SNAC) provisions specified under subsection 81(3) of CEPA 1999. This would ensure that the Government of Canada is notified of any new manufacture, import or use of 3-chloropropene and it will undergo ecological and human health risk assessments, as specified in section 83 of the Act, prior to its introduction into Canada. A SNAC will also allow the Government to be notified of future potential changes in the use-pattern for 3-chloropropene so that exposures remain low.
	We do not support the application of SNAC provisions for 3-chloropropene since data required by government under the New Substances Notification Regulations (NSN) Schedule 6 is limiting.	It is proposed that 3-chloropropene be subjected to the Significant New Activity (SNAC) provisions specified under subsection 81(3) of CEPA 1999. This would ensure that the Government of Canada is notified of any new manufacture, import or use of 3-chloropropene and it will undergo ecological and human health risk assessments, as specified in section 83 of the Act, prior to its introduction into Canada. A SNAC will also allow the Government to be notified of future potential changes in the use-pattern for 3-chloropropene so that exposures remain low. This also ensures that the criteria for these SNAC's will be consistent with the accepted protocols for existing substances. Information requested to evaluate a SNAC is equivalent to the most comprehensive schedule of information required for New Substances (i.e. Schedule 6) unless equivalent information is readily available to the program area responsible for the assessment
Risk Management	There is no information on the potential issues caused by the disposal of products containing 3-chloropropene .	The assessment did not identify health risks associated with the disposal of products that may contain traces of 3-chloropropene. 3-chloropropene did not meet the criteria for persistence or bioaccumulation. On the basis of its relatively low ecological hazard, the low concentrations measured historically in Canadian surface water and effluents, and the low quantity currently in

		commerce in Canada, it is proposed that 3-chloropropene is not harmful to the environment or human health. Therefore, it does not meet the criteria of section 64 of CEPA, 1999. In addition, due to its use as a chemical intermediate in captive reactions, and its very low concentration in certain consumer products, releases of 3-chloropropene to the ambient environment are expected to be low.
	Given its probable presence in various consumer products, it should be listed on the Cosmetic Ingredient Hotlist, the PMRA Registered Product Database; the Drug Product Database; and the Nonmedicinal Ingredient Database, and the Natural Health Products Ingredients Database or the Licensed Natural Health Products Database.	3-Chloropropene may be present in certain cosmetic products as an impurity. It is not found in the Natural Health Products Ingredient Database (NHPID), a list of approved medicinal and non-medicinal ingredients, nor in the Licensed Natural Health Products Database (LNHPD). Therefore, it is unlikely that a natural health product would contain this substance as a medicinal ingredient or as a non-medicinal ingredient. It also is not listed in the Drug Products Database (DPD) as a non-medicinal ingredient and therefore is unlikely to be present in pharmaceutical products. 3-chloropropene might be present in natural health products at residual levels, as it may be used in the manufacture of some substances that may be used as ingredients. Also, a Significant New Activity provision will allow the Government to be notified of future potential changes in the use-pattern for 3-chloropropene so that exposure remains low.