Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Report and Risk Management Scope on Epichlorohydrin (CAS 106-89-8)

Formal comments made during the 60-day public comment period that took place from May 17, 2008 to July 16, 2008 on the draft screening assessment report and risk management scope on epichlorohydrin, a substance included in Batch 2 of the substances to be addressed as part of the Chemicals Management Plan Challenge under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), were provided by Dow Chemical Canada Inc., Reach for Unbleached! and Crofton Airshed Citizens Group.

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

- Human Exposure
- Effects on Human Health
- Food & Consumer Products
- Releases to the Environment
- Modelling

TOPIC	COMMENT	RESPONSE
Human Exposure	The screening assessment for epichlorohydrin does not clearly demonstrate any exposure to Canadians. Therefore, this substance should not be found toxic and should not be placed on Schedule 1 of CEPA.	Due to uncertainties associated with the exposure dataset for epichlorohydrin caused by information gaps, the screening assessment used conservative assumptions, in accordance with the application of a precautionary approach as required by CEPA, 1999. Using these conservative estimates, Canadians' exposure is expected to be low to negligible. However, the critical effect for epicholohydrin is considered not to have a threshold of exposure, and in such cases, it is assumed that there is a probability of harm to human health at any level of exposure. Therefore, the screening assessment concludes that epichloroydrin "may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health."
Food & Consumer Products	Epichlorohydrin should not be permitted in food packaging as it is a genotoxic carcinogen.	Risk management of epichlorohydrin will require that the Government be notified of any new use in order to determine whether or not the new use is acceptable. Submissions for the use of epichlorohydrin in epoxy linings will be scrutinized to determine whether residual levels in finished materials are as low as possible, and whether the potential migration of epichlorohydrin into food is negligible.
	Epichlorohydrin is a synthetic chemical that is	The screening assessment concluded, based on information

	manufactured for use in making other chemicals. It is imported into Canada but not manufactured in Canada and is used in the production of a variety of food and consumer products.	obtained through a survey under section 71 of CEPA, 1999, that there was no manufacture or importation of epichlorohydrin in Canada in 2006 above the reporting threshold of 100kg. However, internationally, epichlorohydrin is used to produce a wide range of chemical products, including consumer products.
Releases to the Environment	The conclusion that epichlorohydrin is not toxic with respect to the environment cannot be established without further investigation into the levels found in imported products, potential releases during disposal and recycling, and, particularly, through the application of recycled pulp mill sludge.	Epichlorohydrin is not bioaccumulative, is moderately dangerous to aquatic organisms, and is persistent in air, but not in water, soil, and sediment due to fast hydrolysis and biodegradation. If epichlorohydrin enters the environment through migration to environmental media through disposal or the application of pulp mill sludge on agricultural lands, concentrations are expected to be low. In addition, any released epicholohydrin is expected to be relatively quickly degraded both abiotically (average half-life of 6 days) and biologically (up to 68-97% degradation within 2-30 days). In the case of paper sludge, because it is applied to soils only once per year or less often (i.e., not continuously), it is not expected to reach concentrations in amended soils or groundwater that could constitute a danger to soil organisms or agricultural plants. Therefore, epichlorohydrin is unlikely to be causing harm to the environment and further investigation of epichlorohydrin is not required at this time.
	Epichlorohydrin is not likely to cause ecological harm in Canada due to reported low industrial releases.	The screening assessment concluded that “epichlorohydrin is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends”.
	The reporting threshold of the National Pollutant Release Inventory (NPRI) – 10 tonnes manufactured, processed or otherwise used - should be re-evaluated as it may not be appropriate to capture the release to air and disposal. For example, the current threshold level indicates no releases of epichlorohydrin from the Pulp and Paper Industry.	Environment Canada will make a decision on whether or not to change the NPRI reporting thresholds. Changes to the Inventory may include the addition, modification or removal of substances as well as changes in the thresholds at which they must be reported. This will be discussed during the risk management phase of the CEPA process. For further details on NPRI, please see: http://www.ec.gc.ca/pdb/npri/npri_home_e.cfm.

Modelling	Instead of assuming 100% migration of epichlorohydrin from paper into food, 50% migration should be considered as a reasonable or sufficient worst case scenario.	In the absence of data on migration of the chemical, a worst-case scenario of 100% migration is assumed. If a study on epichlorohydrin had been available where investigators did not detect the substance, the detection limit of the applied method would be used as a worst-case scenario for exposure calculation. Using the conservative 100% migration of epichlorohydrin from paper into food, oral exposure of epichlorohydrin for the general population is still expected to be low.
	The assumption that there is 0.1% residual epichlorohydrin in epoxy resins could be an overestimation of actual levels. This overestimation may have occurred because 0.1% is the legal limit for disclosure of hazardous substances on Material Safety Data Sheets (MSDSs) so companies may include this level to be conservative and ensure they are in compliance. Fifty percent of this 0.1% value should be used in the modeling or laboratory analysis of epichlorohydin residues in epoxy resins should be obtained.	In the absence of measured data for residual epichlorohydrin in epoxy resins in consumer products, 0.1% provides a conservative, upper limit of exposure. Using this conservative assumption in the screening assessment, margins of exposure for non-cancer effects are sufficiently large and lowering the residual level by 50%, to 0.05%, would have little impact on the final conclusion related to non-cancer effects. However, the wording in the screening assessment has been modified to indicate that exposures are likely to be below the estimates calculated using 0.1%. In terms of obtaining laboratory analysis of epichlorohydrin, 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 is not to wait until data gaps are filled, but to act on what we know now.