

Summary of Public Comments Received on the Government of Canada’s Draft Screening Assessment Report on Ethyloxirane (CAS RN 106-88-7)

Comments on the draft screening level assessment report on ethyloxirane, a substance included in Batch 1 of 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., BASF Canada and, Reach for Unbleached during the 60 day public comment period from January 19, 2008, to March 19, 2008. A summary of the comments that relate specifically to the draft assessment of ethyloxirane, along with responses, is presented in the table below. Comments related to subsequent risk management of the substance are addressed separately.

Comment	Response
A concern was expressed about the lack of detail in the documentation regarding the nature of the peer review undertaken.	Information concerning the nature of the external peer review of the sections relevant to the assessment of risk to human health will be included in the final screening assessment.
<p>An opinion was expressed that a “proper realistic worst case” exposure assessment should be conducted, despite the assessment being only screening level.</p> <p>In addition one commenter indicated that it was unrealistic to base the upper bounding estimate of exposure on the assumption that all ethyloxirane imported into Canada was released into air and water.</p>	<p>As monitoring data were not available to be used as a basis for estimating exposure, estimates were derived based on the threshold quantity for release reporting under the CEPA 1999 section 71 survey (since no releases above this quantity were reported), rather than on total import value.</p> <p>The estimation of exposure based on the assumption that all of the ethyloxirane imported into Canada was released to air and water was included in the draft screening assessment report for comparison purposes only. These values were not used in estimating of the upper bounding intake or risk characterization.</p> <p>In addition, based on the predicted very low levels of ethyloxirane in environmental media, quantitative estimates of intake were removed from the screening assessment.</p>
One commenter reiterated that products that contain ethyloxirane are used only in a closed or industrial setting and consumer exposures to ethyloxirane from these products would therefore be negligible.	It was stated in the screening assessment that ethyloxirane is mainly used for industrial applications in a closed system, and thus consumer exposure is thus expected to be negligible.

<p>The opinion was expressed that perhaps ethyloxirane should no longer be labelled an “intermediate potential for exposure” (IPE) substance</p>	<p>The determination of “intermediate potential for exposure” (IPE) for this substance refers to the results of the prioritization process for existing chemicals (categorization) which the Government of Canada completed in 2006. This determination was based on information collected during the compilation of the Domestic Substances List in the mid 1980s.</p>
<p>One commenter questioned the evidence that ethyloxirane is genotoxic <i>in vivo</i> and provided additional older references which had not been included in the draft assessment report.</p>	<p>These additional data were consulted and, as indicated in the screening assessment report, although one study (McGregor 1981) - occasionally attributed to ethyloxirane - indicates negative results for <i>in vivo</i> cytogenetic and dominant lethal assays. However, the nature of the test substance used in this study is unclear, as CAS 109-99-9 (tetrahydrofuran/ butylene oxide) was cited as the test substance in the report.</p> <p>An additional older study regarding genotoxic response in <i>D. melanogaster</i> (Vogel and Nivard 1998) has been added to the screening assessment report but does not change the overall nature of the <i>in vivo</i> data.</p> <p>McGregor DB. 1981. Tier II mutagenic screening of 13 NIOSH priority compounds: individual compound report: butylene oxide. NIOSH Report No. 28.</p> <p>Vogel EW, Nivard MJ. 1998. Genotoxic effects of inhaled ethylene oxide, propylene oxide and butylene oxide on germ cells: sensitivity of genetic endpoints in relation to dose and repair status. <i>Mutat Res</i> 405(2):259-71.</p>
<p>The opinion was expressed that the data on ethyloxirane do not support a non-threshold mode of action and that ethyloxirane is an <i>in vitro</i> mutagenic agent, but it is not an <i>in vivo</i> genotoxic or systemic carcinogenic agent.</p>	<p>It is recognized that ethyloxirane has induced non-cancer effects and tumour formation in the same “portal of entry” tissues, and that there is potential linkage between these effects. However, in the absence of a fully elucidated mode of action, it cannot be precluded that tumours observed in experimental animals resulted from direct interaction with genetic material.</p>

<p>A commenter did not support the proposed conclusion with respect to human health; i.e., that ethyloxirane be considered toxic under paragraph 64c of CEPA 1999. This comment was based on quantification of risk for non-cancer effects and suggested margins of exposure for carcinogenic effects based on a non-genotoxic mode of action for carcinogenicity proposed by the commenter. Similarly, another commenter suggested that the proposed conclusion relied too heavily on the precautionary principle and that the risk to human health seemed “exaggerated”, particularly in view of the estimated low exposure from the environment.</p>	<p>When the critical effect for a substance is believed to have no threshold of exposure for induction of effects, it is assumed that there is a probability of harm to human health at any level of exposure. Therefore, the proposed conclusion was that ethyloxirane “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.” The application of a precautionary approach is required in CEPA 1999.</p>
<p>A discrepancy in a statement between the Risk Assessment and the Risk Management scoping document regarding exposure from consumer products was noted by one commenter.</p>	<p>The discrepancy has been noted and will be revised in the risk management documentation.</p>

Summary of Public Comments Received on the Government of Canada’s Risk Management Scope Document for Batch one substance ethyloxirane [CAS 106-88-7] on the Domestic Substances List

The table below presents a summary of the comments received during the 60-day public comment period that took place from January 19, 2008 to March 19, 2008. Comments summarized below were received by one or more of the stakeholders listed.

Comments on this publication were provided by:

1. Dow Chemical Canada Inc.
2. Canadian Environmental Law Association

Comment	Response
There are no consumer products identified in the draft screening assessment report however the risk management scope identifies that options for risk management would focus on the presence of ethyloxirane in consumer products.	Information obtained during the preparation of the scope suggested the presence of ethyloxirane in some consumer cleaning products. In subsequent investigations, no consumer products were identified which contained ethyloxirane in Canada.
The government is urged to develop a CEPA Guideline for consumer products identifying conditions for which consumer products are not allowed.	No consumer products were identified which contained ethyloxirane in Canada. It is proposed to create a provision whereby any proposed use of ethyloxirane would be subject to notification of the federal government.
An instrument to ensure exposure to ethyloxirane in consumer products is not expanded into new applications at concentrations that create unacceptable risk should be accomplished through a regulation, CEPA Guideline (above), other acts or a Significant New Activity (SNAc) restriction.	Risk management being considered for ethyloxirane is a provision whereby any future use of ethyloxirane would be subject to notification of the federal government.
Prohibit all present or future use of ethyloxirane in cosmetic and consumer products.	<p>Ethyloxirane is subject to Canada's Cosmetic Ingredient Hotlist, as the substance is a prohibited ingredient not to be used in cosmetics sold in Canada.</p> <p>No consumer products were identified which contained ethyloxirane in Canada.</p> <p>It is proposed to create a provision whereby any proposed use of ethyloxirane would be subject to notification of the federal government.</p>