Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Report on 1,4-Benzenediol (hydroquinone) (CAS RN 123-31-9)

Comments on the draft screening assessment report on 1,4-benzenediol (hydroquinone), 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., the Hydroquinone Group, Kodak Canada, Rhodia Group, Chemical Sensitivities Manitoba (CSM), Reach for Unbleached, and the Canadian Council of Grocery Distributors as well as a number of private citizens during the 60-day public comment period that took place from January 19, 2008 to March 19, 2008. A summary of the comments that relate specifically to the draft assessment on 1,4-benzenediol, along with responses, is presented in the table below. Comments related to subsequent risk management of the substance are addressed separately.

Comment	Response
An opinion was expressed that the weight of evidence approach was not appropriately or reasonably applied when the draft conclusions in the screening assessment were made because not all of the information submitted by industry and stakeholders was appropriately considered.	Health hazard information is based principally on the weight of evidence based assessments of other agencies. The Government of Canada considers all information submitted by stakeholders and its inclusion in the screening assessment is based on factors such as its relevance to the screening assessment and confidential business information (CBI) status.
A commentator suggested that the European Commission's (EC's) classification of 1,4-benzenediol as a Group 3 carcinogen and mutagen was misinterpreted in the draft screening assessment report. As well, a commentator indicated that development of tumours following exposure to 1,4-benzenediol is species-specific and that the weight of evidence shows that 1,4-benzenediol is not a genotoxic carcinogen.	According to the European Commission's summary report, 1,4-benzenediol was originally proposed as a Category 2 carcinogen based on the evidence of development of kidney adenomas and mononuclear cell leukemia in rats and liver adenomas in mice. However, the majority of European Commission's experts agreed to classify it as a Category 3 carcinogen as only benign tumors were produced following exposure to this substance in experimental animals. Uncertainties in evaluation of risk to human health following exposure to 1,4-benzenediol (e.g. species specific effects) have been acknowledged in the screening assessment document. See comments below regarding 1,4-benzenediol as a potential genotoxic carcinogen.
A commentator did not agree with the Health Canada's precautionary principle approach under which 1,4-benzenediol may be considered a genotoxic carcinogen. Also, the commentator mentioned that a published mode of action review for 1,4-benzenediol was ignored in the draft assessment report. This review also concluded that 1,4-benzenediol is not a genotoxic carcinogen.	For the Challenge screening assessment, the assessment of carcinogenicity was based principally on the conclusions of the European Commission. A mode of action for 1,4-benzenediol has not been fully elucidated. The Health Canada screening assessment did not identify 1,4-benzenediol as a genotoxic carcinogen; 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. A discussion of McGregor et al. (2007) was added to the screening assessment. It is also possible that this chemical may act through indirect mechanism(s) of carcinogenicity or genotoxicity (e.g. induction of aneuploidy, oxidative stress, inhibition of DNA synthesis or cytotoxicity) for which a threshold level may exist. In addition the application of a precautionary approach is required by CEPA.
A concern was expressed that the classification of 1,4-benzenediol as a toxic substance will destroy black and white photography as an art form, and that the risk associated with the use of 1,4-benzenediol as a photo developer can be significantly or completely reduced by using proper safety equipment and working in a ventilated area. Other commenters expressed the opinion that the consumer product scenario for photo developers was too conservative, and they provided information to improve consumer product scenario modelling for this use. One commenter also gave the opinion that photo developers should not be the subject of a risk management action.	Based on a better understanding of the photo development process following the public comment period, it was decided that the original scenario used to estimate exposure to 1,4-benzenediol in photo developers resulted in a significant overestimate. . This scenario has been modified to make it more realistic, taking into account such factors as solution concentration, dermal uptake and skin surface area exposed. Furthermore, consideration was given to the fact that labelling instructions on the product clearly indicate that proper protective equipment should be used during handling and that hazard warnings for the product are clearly marked.
The commenter suggested that since the cited exposures (the largest of which was 393.45 µg/kg-bw/day) were all much less than the most sensitive critical threshold value (CTV) of 15 mg/kg-bw/day, the risk had not been adequately quantified.	The exposure of 15 mg/kg-bw/day is the lowest oral No Observed Effect Level (NOEL) identified for non-cancer effects. Derivation of a margin of exposure to the upper-bounding estimates of exposure was not considered meaningful, as the predominant source of exposure is through the naturally occurring presence of 1,4-benzenediol in food and beverages and incremental exposure and risk associated with 1,4-benzenediol from manufacturing and industrial uses is considered to be negligible.
One commenter expressed the concern that in the estimate of exposure to 1,4-benzenediol through the use of manicure preparations or hair dye, the assumed absorption for 1,4-benzenediol have rates have been incorrectly cited and significantly contribute to an overestimate of the potential exposure to 1,4-benzenediol.	The consumer product scenarios for manicure preparations and hair dye have been modified in the final screening assessment report.

An opinion was expressed that information on consumer use of identified products was not sought from users, manufacturers or importers of this substance. The default values were then used to calculate chronic (daily) dermal exposure values that are highly problematic because they assume that very brief exposures to low concentrations of 1,4-benzenediol are biologically equivalent to the long term high dose exposures used in animal cancer bioassays.	Industry and interested stakeholders were asked to submit information (by responding to a mandatory survey notice, if applicable, and/or a voluntary questionnaire) that could be used to inform risk assessment and to develop and benchmark best practices for risk management and product stewardship. In the absence of further information on consumer use patterns, default consumer product scenarios were used to calculate upper bounding estimates of exposure from consumer products. Estimates were then compared to the dermal NOAEL for non cancer effects. These scenarios have been refined in the assessment report.
The comment was made that, despite the significant progress that has been made in controlling chemical releases and exposure of the Canadian environment and population to chemicals, the government is changing its definition of human exposure by creating theoretical scenarios that depend on default numbers that exaggerate potential exposures. Are Canadians really exposed to 1,4-benzenediol to any significant extent except through their consumption of normal healthful food? The commenter agrees with the finding in the draft assessment that they are not.	Exposure scenarios have been refined in the screening assessment report.

Summary of Public Comments Received on the Government of Canada's Risk Management Scope Document for Batch one substance 1,4-Benzenediol, CAS 123-31-9 (hydroquinone) 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. Hydroquinone group
3. Private Citizen
4. Kodak Canada
5. Reach for Unbleached
6. Canadian Environmental Law Association
7. Rhodia Group

Comment	Response
Exposure through industrial and commercial uses is negligible.	It is indicated in the assessment that the releases from industrial and commercial uses of hydroquinone are negligible compared to natural sources.
Potential exposure for photographers is covered by product warning.	No additional risk management actions are proposed for the photographic sector other than encouraging users to follow the safety instructions on the label.
Skin Lighteners are already subject to stringent controls. Further Risk management measures will not significantly impact the potential exposure as the exposures are already well controlled.	Risk management regulations, instruments and / or tools for skin lighteners are discussed in the Risk Management Approach document.
Risk management should focus on the cosmetic and pharmaceutical uses of de-pigmenting creams and film developer chemicals. Prohibition of its use in cosmetic products such as depigmenting creams should be enacted and enforced.	Risk management for cosmetics and de-pigmenting creams are discussed in the risk management approach document. No additional risk management actions are proposed for the photographic sector other than encouraging users to follow the safety instructions on the label.
The risk management approach should also examine the potential for release and exposure during recycling of paper products and disposal of paper recycling sludge.	Recycling of paper products and disposal of paper recycling sludge was not identified as a major source of exposure in the assessment.
Alternative skin lighteners exist, though their relative safety needs to be ensured.	All medicinal skin lighteners are evaluated under the Foods and Drugs Act

Comment	Response
Safer alternative products and technologies for this substance, in consumer and cosmetic products as well as in the digital photography industry should be identified, assessed for their safety and, if safe, promoted.	Essential uses of the substance and alternatives will be considered in the risk management process.
The management plan for hydroquinone should ensure that appropriate disposal methods are followed for products containing hydroquinone. This plan should not consider incineration an appropriate disposal method since other toxic byproducts may be produced and released.	The Screening Assessment Report did not identify waste disposal as a source of exposure to hydroquinone, therefore, the risk management approach does not propose any risk management actions for waste disposal.
Any controls, particularly at a non-threshold level, create an internal contradiction for substances like Hydroquinone which are naturally present in foods – for if the substances in question are indeed genotoxic – any exposure to them will create the risk of danger	For all exposure scenarios, hydroquinone is considered to be a non-threshold carcinogen. While it is understood that exposure to hydroquinone does occur through foods, there is no evidence to indicate that hydroquinone in foods poses a health risk to Canadians or that Canadians should avoid foods containing hydroquinone. It is also noted that exposures from anthropogenic sources are additive and avoidable. Therefore, it is considered prudent to take actions to reduce anthropogenic exposure to hydroquinone to the extent practicable.