Summary of Public Comments received on the Challenge substance 1,4-benzendiol (CAS RN 123-31-9) (Hydroquinone) Proposed Risk Management Approach document for Batch 1

Comments on the proposed risk management approach for 1,4-benzenediol to be addressed as part of the Chemicals Management Plan Challenge were provided by Dow Chemical Canada, the Hydroquinone Group, the Nail Manufacturers Council, the Canadian Environmental Law Association and Chemical Sensitivities Manitoba.

Comment	Response
Since hydroquinone is already subject to various federal regulations, is there a need for additional regulation under the *Canadian Environmental Protection Act, 1999* (CEPA 1999)?	While exposure to hydroquinone is low, the Government of Canada considers it appropriate to impose a condition whereby it is able to assess the risks posed by any change in the use pattern, before such a change is permitted, to ensure that exposures remain low.
Although the primary exposure route is food, the hydroquinone concentrations are extremely low and do not present a quantifiable risk.	To prevent increases in exposure of hydroquinone, the application of the Significant New Activity provisions under CEPA 1999 to this substance will be recommended. This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration.
The critical health effect for the characterization of risk to human health is carcinogenicity following oral exposure to hydroquinone. As such it meets the "toxic" criteria under section 64 of CEPA 1999. As an ingredient in topical products, repeated or prolonged dermal exposure can result in skin depigmentation, and discoloration of nails and hair. Allergic contact dermatitis has been reported at concentrations approximating 1%. Additional information is needed as to the nature of the additional restrictions proposed in the final risk management on the use of hydroquinone in cosmetic products (nail systems and hair dyes) through amendments to the Hotlist, since it is prohibited for use in cosmetics products applied on the skin or mucous membranes.	Hydroquinone is still allowed as a reactant in hair dyes and artificial nail systems. As a polymerization aid, it is consumed rapidly during use in both products. However, based on the mentioned potential health concerns, the government will further limit its use in cosmetics as a reactant to a maximum concentration of 0.3% in hair dyes and 0.02% in manicure preparations. These recommended limits are expected to provide a high level of protection to consumers. It is proposed that the Cosmetic Ingredient Hotlist be amended to reflect these recommendations. Since hydroquinone is mainly formulated and/or supplied at the proposed limits, the amendments are cost-effective to the cosmetic industry.
Consideration should be given to prohibiting the use, import, export, sale and manufacture of hydroquinone in all consumer products, and	The Government of Canada does not intend to prohibit the use of hydroquinone in consumer products as exposure modeling of the

particularly in photographic developing solutions, hair dyes, manicure products and skin lightening creams, since alternative products do exist.	appropriate use of these was calculated as being extremely low. At the same time, health warning labels are currently affixed to all consumer chemicals in accordance with the *Consumer Chemicals Container Regulations*.
There must be more aggressive action by the government to protect photographic solution users (workplace) and consumers. The onus cannot be on the user. Therefore, we continue to recommend that the use of hydroquinone be prohibited from consumer products generally, and particularly those listed in the above recommendation.	The Government of Canada has in place WHMIS (Workplace Hazardous Materials Information System) which is a hazard communications standard which provides cautionary labelling of containers of WHMIS "controlled products", the provision of material safety data sheets (MSDSs) and worker education and training programs. In addition, health warning labels are currently affixed to all consumer chemicals in accordance with the *Consumer Chemicals Container Regulations*.
To promote the use of alternatives and support increased accountability on the part of industry, the government should ensure that the alternatives for hydroquinone in consumer products are safe, and that industry supplies complete documentation to demonstrate this.	The Chemicals Management Plan does not have the mandate to assess and approve of alternative chemicals and/or processes. However where possible we take into account alternatives when developing risk management approach documents.
Risk management also included the regulation of hydroquinone-containing health products, such as a prescription drug, but criteria for this type of product should have been detailed.	The criteria for drugs and health products are governed under the *Food and Drug Regulations*. The Government of Canada will propose to regulate hydroquinone containing health products as a prescription drug. As a result, it will no longer be available in over-the-counter products (e.g., skin lightening products).
Also proposed is the creation of a provision that would require industry to notify the government if the proposed use of hydroquinone exceeds a specified level. This requires some clarification, since usage levels vary according to the type of industry. When a notification level is high, some industries would not be subject to notification requirements because of their low usage levels. We oppose the use of future notification alone as a risk management mechanism, as it entrenches a control regime and does little to promote prevention of hydroquinone use.	Hydroquinone will be added to the *Food and Drugs Regulations* so it will be regulated as a prescription drug. Additional conditions on the substance use are being applied through the Cosmetic Ingredient Hotlist. The application of the Significant New Activity provisions under CEPA 1999 to this substance will be recommended. This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration.