Summary of Public Comments received on the Challenge substance DHNUP (CAS 68515-42-4) Draft Screening Assessment Report and Risk Management Scope Document for Batch 6

Comments on the draft screening assessment report and risk management scope document for DHNUP to be addressed as part of the Chemicals Management Plan Challenge were provided by Crooked Creek Conservancy Society of Athabasca, International Institute of Concern for Public Health, American Chemistry Council, Imperial Oil Products & Chemicals Division, Dow Chemical Canada Inc., Canadian Vehicle Manufacturers' Association and Chemical Sensitivities Manitoba and Canadian Environmental Law Association.

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

- Risk Assessment
- Risk Management

TOPIC	COMMENT	RESPONSE
Risk Assessment	The Government should add DHNUP to the List of Toxic Substances in Schedule 1 of CEPA 1999.	The Government of Canada has assessed information about the current usage and handling practices for DHNUP wastes. The final screening assessment report concludes that DHNUP does not meet any of the section 64 criteria of CEPA 1999 and does not meet the criteria for addition to schedule 1 of CEPA, 1999.
	Efforts should be made to clarify manufacture, import and use amounts. Nomenclature issues and the market-based phaseout beginning end of 2006 created further difficulties in accounting for quantities. There is uncertainty regarding whether recent decreases in quantities in commerce are permanent. Higher quantities may return in the future for electrical insulation and other applications.	Companies have been contacted to clarify current manufacture, importation and usage of DHNUP. DHNUP was proposed for inclusion in the DSL inventory update initiative where quantities in commerce will be updated periodically. The phaseout of DHNUP will likely depend upon the cost gap between linear and branched plasticizer alcohols.
	There is little evidence to support indoor air as the principal source of exposure. Exposure via drinking water should also be considered.	Potential uses of DHNUP identified after 2006 were plasticized PVC products. As high molecular-weight phthalates such as DHNUP are trapped tightly within the polymer matrix, slow off-gassing over decades of service life would lead to minimal inhalation exposure. Drinking water is not considered to be a major source of exposure due to the low "true" water solubility of high molecular weight phthalates such as DHNUP. Also, due to a

		very high log K_{oc}, DHNUP released from disposed PVC articles would exhibit poor soil mobility and therefore would be anticipated to leach minimally from a landfill to groundwater.
	Environment Canada should develop experimental data for degradation, bioaccumulation and ecotoxicity and reconsider persistence and bioaccumulation. Experimental data should be developed for key physical and chemical properties.	There is a high degree of certainty about the persistence and bioaccumulation potential of DHNUP. Some ecotoxicity information is available for the substance. Further research is not needed at the present time.
	The Government of Canada should pay attention to how waste is dealt with.	The Government obtained additional information about the handling and treatment of DHNUP waste from industry.
	The Government needs to explain how impurities in DHNUP affect risk assessment. The amount of each substance in the DHNUP mixture should be established to provide a better sense of DHNUP's contribution to the environmental concentrations of each of its individual components.	During the literature review, one review of the commercial form of DHNUP revealed an approximately equal composition mixture of the six components. No monitoring data was discovered for DHNUP itself and minimal data was discovered for one of its components, CAS RN 3648-20-2. This data was not attributed to DHNUP itself in the study and therefore was not used in the assessment. The component CAS RN 3648-20-2 is a remaining medium priority substance in the Chemicals Management Plan and will be assessed in the future.
	There is concern over the nomenclature used within the assessment since different jurisdictions may use different ones. This might have resulted in the non-evaluation of studies that could have significantly contributed to the assessment.	The Challenge screening assessments are based on considerations of the available data. Literature searches were performed for the individual components of DHNUP in addition to DHNUP itself. Common names and trade names of DHNUP were also employed in the search. No environmental monitoring data were discovered for DHNUP as a mixture. DHNUP was identified as a high priority for assessment as a mixture, not as isolated components.
	The entrapment of *Daphnia* (and insect) in the surface film of undissolved DHNUP is a well documented physical effect. It is generally agreed that it is not possible to establish a no-effect level for high molecular weight phthalate esters like DHNUP.	It is not known if the phenomenon of surface entrapment occurs in large natural waters the way it does in small containers under laboratory conditions. Even if the effects on *Daphnia* were physical, rather than physiological, DHNUP and some related phthalate esters did cause the death of organisms in laboratory studies.

	The Government did not consider occupational exposure and exposures to vulnerable populations despite high quantities in commerce. Exposures during packaging, storage and shipping should also be considered.	The screening assessments are based on consideration 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 subpopulation could be susceptible, this information is taken into consideration when characterizing risk and in the risk management scope documents. 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 risk assessment. The assessment report may be used to inform actions in occupational health and safety jurisdictions.
	The risk management discussions of a substance that is not P and not B, and only iT could be problematic. In fact it could be challenged that the substance should not be CEPA toxic and not risk managed. This consideration should be part of any action the government proposes for Risk Management.	Substances that are not persistent or bioaccumulative can still be determined to be "toxic" if they meet the criteria for "toxic" presented in Section 64 of CEPA 1999. For example, a substance can be determined to be "toxic" if its concentration in the environment is estimated to be high enough to harm organisms. If a substance is found to be toxic under section 64 of CEPA 1999, the Act mandates that risk management action in the form of a CEPA instrument must be taken in order to address the risks associated with the substance. The final screening assessment report concludes that DHNUP does not meet any of the s.64 criteria of CEPA 1999.
	The evidence on DHNUP is too limited and too weak to support a decision of CEPA "Toxic."	The final screening assessment report concludes that DHNUP does not meet any of the s.64 criteria of CEPA 1999.
	The thoroughness of the peer review process could be improved by including a variety of stakeholders with expertise in industrial and environmental areas. The current peer review process appears to be	The Government of Canada is committed to the effective use of science in the preparation of screening assessment reports. All assessments are subject to a comprehensive internal and external science review of both their human health and ecological components. Areas of uncertainty found during the assessment and

	health-based.	internal review are identified for external scientific peer review. A variety of technical expertise is the main criteria for identifying suitable external individuals, who may come from academia, industry, or consulting firms. All comments provided to the Government of Canada by peer reviewers are taken into consideration. Draft assessments are also subject to a 60-day public comment period. These comments are taken into consideration in finalizing the assessment report.
	The precautionary principle was not applied properly. It is also questioned whether further research and monitoring will support verification of assumptions in the screening assessment.	Due to uncertainties associated with the exposure dataset for DHNUP, the screening assessment used conservative assumptions, in accordance with the application of a precautionary approach as required by CEPA 1999. The proposed conclusion was based on the available information supplemented by new information received during the public comment period. Further follow-up with industry has been performed subsequent to release of the draft screening assessment report in an effort to verify the accuracy of assumptions. Release rates from containers, nomenclature issues and quantities in commerce were all subjects of inquiry during this period. Information received was considered in formulating the final conclusions of the screening assessment.
Risk Management	The Government of Canada should consider sustainable development when the risk management instrument for DHNUP is developed.	Based on available information DHNUP does not meet any of the s.64 criteria of CEPA 1999 and no further action will be taken. However, it is important to note that sustainable development is one of the guiding principles of CEPA 1999 and is considered during the selection and development of risk management instruments for all CEPA toxic substances.
	Vehicle assemblers use materials that may include DHNUP as a constituent and there is no residual waste given the state in which the material is used. Vehicle assemblers are concerned that they would inadvertently be captured in the risk management approach and request being included in the consultation process that will follow.	Based on available information DHNUP does not meet any of the s.64 criteria of CEPA 1999 and no further action will be taken. However, the Government would encourage stakeholders to continue to participate in the Challenge. Stakeholder involvement has been an essential part of the success of the Chemicals Management Plan.

	The chosen risk management instrument for DHNUP should be a CEPA Code of Practice or a Pollution Prevention Plan (P2 Plan). A P2 Plan could also be used for a more targeted approach at specific facilities with unacceptable risks. The latter option would deliver greater results with the expenditure of fewer resources. Consideration should also be given to involving the substance manufacturers and suppliers as they are intimately involved in container management.	Based on available information DHNUP does not meet any of the s.64 criteria of CEPA 1999 and no further action will be taken. However, it is important to note that for substances that are found to meet the s.64 criteria of CEPA 1999, these types of considerations are made during the instrument selection and instrument development process.
	The Risk Management Scope document for DHNUP (and the RM Scope documents for other substances) should provide a more specific potential instrument or list of potential instruments in order to solicit stakeholder feedback earlier in the process; however, it would be important to communicate clearly that these would be proposals and not final decisions.	The level of detail provided in the Risk Management Scope document on the risk management options being considered is dependent on the quality and amount of information that is available at the time that the document is drafted. In the case of DHNUP, the commercial status of DHNUP had changed significantly in recent years and there was uncertainty associated with the data that was available at the time the Risk Management Scope was drafted. As a result, it was not possible to provide more specific information on potential risk management options. There is no Proposed Risk Management Approach document for DHNUP since DHNUP has been found to not meet the section 64 criteria under CEPA 1999. However, for substances that do meet the s.64 criteria under CEPA 1999, the Proposed Risk Management Approach document outlines in more detail the proposed risk management actions, including the proposed choice of instrument. Both the Risk Management Scope and the Risk Management Approach documents for all substances clearly state that the risk management options being examined are proposed and not final decisions.
	The Risk Management Scope does not provide a justification for the risk management option being	Based on available information DHNUP does not meet any of the s.64 criteria of CEPA 1999 and no further action will be taken. However it is important to note that at the time of the publication

	considered. The risk management option being considered is limited to addressing the risk of releases due to the rinsing of containers and should be broader in order to manage risks adequately.	of the Risk Management Scope document, the risk management option under consideration was the risk of releases from containers storing and/or transporting DHNUP because this was the primary source of risk identified in the draft Screening Assessment report.
	Efforts should be made to replace DHNUP with safer alternatives and risk management must be expanded to better address current and future uses.	Based on available information DHNUP does not meet any of the s.64 criteria of CEPA 1999 and no further action will be taken. However it is important to note that the Proposed Risk Management Approach document for substances that are found to meet the s.64 criteria under CEPA 1999 includes a section on alternatives, and the instrument selection and development process provides for consideration of alternatives.
	The uncertainties related to use and exposure associated with DHNUP should be addressed in the Risk Management Scope document.	Risk managers and risk assessors have gathered more information related to use and exposure on DHNUP in order to address the uncertainties in use and exposure and to better characterize the changes in use patterns of DHNUP since 2006.
	Risk management should address the long-term effects of DHNUP on the environment, and the effects of DHNUP on vulnerable populations and workers, and not just address handling practices.	Based on available information DHNUP does not meet any of the s.64 criteria of CEPA 1999 and no further action will be taken. However it is important to note that for substances that meet the s.64 criteria under CEPA 1999, consideration is given to the impact of a substance on vulnerable populations and the potential long-term effects of a substance on the environment during the instrument selection and development process.
	The Risk Management Scope document should be broadened to include addition to the Cosmetics Ingredient Hotlist and include labelling of consumer products..	Based on available information DHNUP does not meet any of the s.64 criteria of CEPA 1999 and no further action will be taken. However it is important to note that the draft Screening Assessment report states that “DHNUP is not anticipated to be present in cosmetic products in Canada, as it is not listed as an ingredient in the Cosmetic Notification System database. There is no evidence that DHNUP is used in cosmetics products. As a result, at the time of the publication of the Risk Management Scope document, it was not anticipated that the addition of DHNUP to the Cosmetic Ingredient Hotlist would address the sources of risk identified in the draft Screening Assessment report.

		The labelling of consumer products was not identified as a risk management option in the Risk Management Scope document for DHNUP because releases of DHNUP from consumer products was not identified as a significant source of risk in the draft Screening Assessment report.