Summary of Public Comments received on The Challenge Substance DEHA (CAS: 103-23-1) Draft Screening Assessment Report and Risk Management Scope for Batch 11

Comments on the draft screening assessment and risk management scope for DEHA to be addressed as part of the Chemicals Management Plan Challenge were provided by AEP Industries, Canadian Environmental Law Association and Chemical Sensitivities Manitoba, Canadian Vehicles Manufacturing Association, Dow Chemical Canada, Eastman Chemical Company, and the Phthalate Esters Panel of the American Chemistry Council.

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

- Physical-Chemical Properties
- Persistence
- Aquatic Toxicity
- Exposure – Ecological
- Exposure – Human Health
- Human Health Toxicity
- External Peer Review Risk Assessment Conclusion
- Proposed Risk Management
- DSL Inventory Update
- National Pollutant Inventory Release (NPRI)

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Physical-Chemical Properties	There is generally good agreement for parameters, with the exception of vapour pressure, Henry's law constant, and water solubility. Please identify and justify the values used in the assessment.	The values used for further modelling in the assessment are indicated in the footnotes of Table 2 of the screening assessment report. Justification for the choice of water solubility was provided in the draft assessment report. Further justification has been provided in the text of the final screening assessment; in particular it is noted that experimental data of acceptable quality are preferred to data from models.
Persistence	The potential impacts of long-range transport need to be addressed in the report.	DEHA reacts rapidly with other molecules in the air (i.e., hydroxyl radicals), breaks down in sunlight (direct photolysis), and may precipitate out of the air (by wet and dry deposition); therefore, it is not expected to persist in air.

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	The need for generating modelled data should be justified when empirical data exists.	Empirical data of acceptable quality are preferred to modelled data and are given more weight when evaluating substance properties such as persistence. However, even where experimental data are available, data from predictive approaches may be considered as an additional line of evidence.
Aquatic Toxicity	The weight of evidence of available toxicity studies do not demonstrate a result below 1 mg/L (only 4 of 22 studies are below 1 mg/L).	The majority of acute toxicity studies on aquatic organisms indicate no effects at saturation. However, experimental data do indicate a concern for chronic toxicity to aquatic organisms (below 0.1 mg/L). The critical toxicity value, which is based on the acceptable chronic study by Felder et al. (1986), is also used by the Organisation for Economic Co-operation and Development (OECD) in their assessment report for DEHA, referred to as the Screening Information Data Sets (OECD SIDS 2005). The critical toxicity value is used to derive a predicted no-effects concentration (PNEC) for aquatic organisms.
	The conclusion for inherently toxic needs to be justified with respect to physical effects versus effects due to the toxic action of the chemical itself.	The critical toxicity value (CTV) in the assessment report, is based on chronic (21-day) toxicity for survival, growth and reproduction (and is also used by the OECD in their assessment report for DEHA; OECD SIDS 2005). Authors of the study did not link the results to physical effects. Since this value is within a factor of 10 of the estimated water solubility of the substance, it is acceptable for use in the screening assessment, recognizing variability and uncertainties in test procedures, and the fact that co-solvents exist in the natural environment that may ultimately affect the solubility and bioavailability of a substance. In assessing the ecological risks of a substance, other modes of action (e.g., physical effects) that could be manifested in the natural environment and be potentially harmful to the environment may also be considered. Therefore, aquatic toxicity tests that are conducted above a substance's water solubility limit may provide useful information.
	The robust study summaries for DEHA should be included in the report.	The robust study summary for Felder et al. (1986) has been included in the final report.
	DEHA is rapidly degraded, thus, acute toxicity results should be primarily considered in assessing the overall environmental effects.	Although DEHA degrades fairly rapidly (i.e., ranging from days to weeks), continuous release to the environment would result in longer-term exposures. The available information on measured and potential releases, measured concentrations in the Canadian environment, and toxicity to aquatic invertebrates indicates that chronic toxicity is the primary consideration in assessing the risk of DEHA.

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	The approach to choosing a critical toxicity value (for derivation of a PNEC) is contrary to the Canadian Council of Ministers for the Environment's guidance for deriving water quality guidelines for the protection of aquatic life (i.e., results from aquatic toxicity tests conducted above a substance's water solubility limit should not be used).	Laboratory tests are conducted under relatively pristine conditions, and do not take into account the various co-solvents that exist in the natural environment that may influence the solubility and bioavailability of a substance. This aspect is considered in ecological risk assessments, and the critical toxicity value chosen for DEHA is within the acceptable range of values generated using water solubility lab tests for this substance.
Exposure – Ecological	The assessment has relied on exposure estimates that do not reflect realistic industrial use practices and potential discharges and which are not supported by widely representative water monitoring data.	Canadian environmental monitoring data provides the most pertinent evidence for exposure of non-human organisms in Canada. A number of municipal sewage treatment plants in Quebec provide substantial data on DEHA concentrations and releases to aquatic environments. These data provide relevant Canadian information for evaluating the potential for ecological risk in the Canadian regulatory context. Realistic worst-case scenarios were also developed for a number of industries based on data submitted under the section 71 survey notices. These scenarios provide site-specific exposure estimates based on current industry practices, which consider Emission Scenario Documents issued by the OECD.
	The US monitoring data have been ignored in assessing potential environmental effects. These data show environmental levels to be much lower than those assumed in the assessment report, despite the fact that DEHA use is greater than in Canada.	Substantial Canadian monitoring data was available. While all information was considered, the Canadian monitoring data provides the most pertinent evidence for evaluating the potential for ecological risk in the Canadian regulatory context.
Exposure – Human Health	The assessment report should recognize that Canadians expect a well balanced and nutritious food supply, and substances that enhance its delivery should be allowed. Health Canada should lead in managing the contradictory issue of using harmful substances or materials to ensure a healthy food supply.	In the screening assessment, food was identified as a higher source of exposure than environmental media in the estimate of total daily intake of the general population, but it was not the highest among all potential sources of exposure identified. Although food is the higher contributor to total intake, margins of exposure associated with this exposure source are found to be acceptable.

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	Studies conducted 15 years ago do not represent current practices. In particular, reduction in the use of plasticizers is anticipated to result in reduced environmental exposures. Related information should be obtained from manufactures.	In the exposure assessment, the most relevant data available were used, acknowledging the fact that this may provide for an over-estimate of exposure due to the age of the data. The resulting margins of exposure, however, were considered adequately protective. Health Canada is developing a survey on plasticizers in food and food packaging, including DEHA, which will be delivered in the near future.
	Exposure of the general public to DEHA is most likely underestimated due to the limitation of data availability (which indicated that higher levels of DEHA were reported in oily foods which were wrapped in food packaging containing DEHA and prepackaged foods which were not included in intake estimates).	This assessment derived upper-bounding estimates of exposure to determine the adequacy of the risk posed by DEHA to the general population. In the case of exposure from food, empirical data on concentrations of DEHA in food relevant to the Canadian context were used when available, but lack of data identifying levels of DEHA in prepared food stored in contact with plastic film is recognized as an uncertainty. However, the margins of exposure, which are based on upper bounding estimates of exposure from food, are considered adequate to account for the uncertainties in information on health effects and exposure .
	Intake estimates of DEHA for infants were provided for packaged food/formulas, but not for adults. Also, information on the presence of the substance in breast milk was not provided.	Intake estimates of DEHA were determined for all age groups including the adult population based on the available empirical data on DEHA concentration in food. No empirical data were identified for breast milk. Lack of incorporation of DEHA intake from prepared food is recognized in the assessment as an uncertainty.
	The government should work with the North American food packaging industry to eliminate the use of plasticizers such as DEHA and find safer alternatives to food packaging that contains DEHA.	Health Canada is planning to conduct a survey on plasticizers in food and food packaging, including DEHA, in 2011-2012.
	DEHA is not listed in the Canadian Cosmetic Toiletry and Fragrance Association (CCTFA) cosmetic ingredient list and there is quite a disparity in the concentrations reported by Cosmetic Ingredient Review (CIR) (2006) and the Cosmetic Notification System (CNS) database, suggesting that exposure was overestimated in 17 of the 19 personal care products and underestimated in deodorant and sunscreen. Also, the highest percentages of use in the CNS database are inaccurate and do not reflect actual use.	Notification of any cosmetic products imported or manufactured for sale in Canada is a requirement from the Food and Drug Act and Health Canada's CNS database is a relevant source of Canadian specific information on ingredients in cosmetic and personal care products available in Canada. The CCTFA database does not provide information on the concentrations of ingredients found in cosmetics, and does not include information on ingredients such as DEHA that are not "commonly" found in products. The CIR provides information on US products reported to the US Food and Drug Administration and is not considered as representative of the Canadian market as CNS. DEHA concentrations in Canadian products are reported as ranges in the CNS, and refinement of the upper range of

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		these concentrations was incorporated whenever possible. However, estimates of exposure from the use of cosmetics and personal care products are based on conservative assumptions, in order to take into account uncertainties associated with exposure database limitations.
	Skin absorption of DEHA through potential exposure from the use of personal care and consumer products was significantly overestimated, and not specific to DEHA.	Considering physical and chemical properties of DEHA, the value for dermal absorption (10%) used in the assessment is considered adequately conservative and is supported by the preliminary results of a Health Canada dermal absorption study conducted in 2010 which showed low dermal absorption but high levels of skin bound residues.
	The estimates of DEHA exposure generated by Health Canada grossly exceed those derived from a biomonitoring study conducted by the European Plasticised PVC Film Manufacturers' Association (EPFMA)) by Zeneca's Central Toxicology Laboratory in the late 1990s	The EPFMA Survey took place in Europe 10 years ago and is not considered appropriate to represent current consumption patterns and levels of exposure to DEHA for the general population of Canada. In addition, the survey did not include female participants who may use products containing DEHA differently from men
Human Health Toxicity	An assessment should not automatically accept the classification of carcinogenicity from other agencies without further investigation. Is the non threshold policy of Health Canada applicable and should DEHA have been assessed as a priority under the Challenge?	DEHA was identified as a high priority for assessment of human health risk because of its potentially high level of exposure for Canadians, and was classified by other agencies on the basis of carcinogenicity at the time of categorization. The relevance of this classification was then investigated in the draft Screening assessment. The classification of DEHA by the International Agency for Research on Cancer and the United States Environmental Protection Agency was noted in the draft SAR as "not classifiable" and a "possible" carcinogen, respectively. Based on further information, the assessment concludes that the issue of carcinogenicity of DEHA was not relevant to humans, and that the non-threshold policy was not applicable.
External Peer Review	The Government of Canada is encouraged to get involved in international programs and to use the data and information generated to complete an inclusive assessment for DEHA.	The draft screening assessment is based on all data and information currently available including information and data from the OECD Chemical's program and the United States High Production Volume (US HPV) program. The critical eco-toxicological endpoint used in the draft screening assessment risk characterization is the same as the critical endpoint recommended by OECD SIDS.
Risk Assessment Conclusion	DEHA is not a Persistent, Bioaccumulative, and Inherently Toxic (PBiT) substance, and local impacts were examined using a questionable Predicted No Effect Concentration (PNEC).	Concluding on P, B, and iT during categorization triggered the requirement for assessment. However, a substance does not have to be a PBiT to be listed on Schedule 1. Substances may be added to Schedule 1of CEPA if they are shown to meet the criteria in Section 64 of the Act. In addition to further evaluation of P, B, and iT characteristics, risk evaluations can examine potential impacts at various sites based on available information. The study used to

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		determine the PNEC is considered to be of high reliability (as indicated in the robust study summary in Appendix 1 of the screening assessment) and has also been used in the OECD SIDS assessment report for DEHA.
	Information on rapid degradation and low bioaccumulation potential of DEHA has not been adequately incorporated into the final conclusions of risk.	Evidence of relatively rapid degradation and low potential for bioaccumulation is considered in the risk assessment. The conclusion that DEHA is potentially harmful to the environment is based on quantity and frequency of releases, concentrations in Canada, and potential for recurring harm to aquatic organisms. The conclusion that DEHA is potentially harmful to the environment is based on its potential impacts to aquatic life.
	Although the non-threshold policy should not be applied to DEHA, the conclusion could be considered marginal, and should be reviewed for robustness.	Range of exposure estimates are based on the available Canadian information where it is clearly indicated that exposure from use of some products containing DEHA is not considered adequate to be protective of the general population.
Proposed Risk Management	The Pest Management Regulatory Agency (PMRA), Health Canada is strongly urged to consider the prohibition of DEHA as a formulant – a non-active ingredient, in pesticide products. Any replacement should be assessed by the government and be safer than DEHA.	DEHA is registered for used as a plasticizer in cattle ear tags and in one insecticide strip. PMRA has completed a reassessment and determined that the use of DEHA in cattle ear tags is acceptable at current concentrations. For the insecticide strip, the registrant will need to replace the formulant or submit additional data to support continued use.
	The Government is urged to prohibit DEHA as a non-medicinal ingredient in sun-block for both adults and children, as a precautionary measure. The Government should use the precautionary principle to seek a complete prohibition on the use of DEHA in all cosmetics and personal care products, and should not list DEHA on the Licensed Natural Health Products Database (LNHPD).	DEHA is not a non-threshold genotoxic carcinogen or a persistent, bioaccumulative and inherently toxic substance; therefore, other measures are considered more appropriate than complete prohibition. DEHA is a formulant (non-active ingredient) that is permitted based on the current knowledge of its risk to human health. Details of the risk management instrument will be developed in consultation with stakeholders in the near future

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	Environmental Emergency Regulations should apply to all facilities that release, use, dispose, sell or import DEHA, and they should be required to prepare Environmental Emergency plans regardless of volume use thresholds or releases. Careful consideration should be given to the proposed CEPA-toxic designation of DEHA and its potential to be toxic to aquatic organisms, when determining the parameter upon which to base an environmental emergency plan.	In the Environmental Emergency Regulations, the substance thresholds listed are determined based on an assessment of several factors and represent the quantity at which the substances pose an environmental emergency threat if accidentally released. For quantities used below the regulated thresholds, Environment Canada encourages the voluntary preparation of environmental emergency plans. Assessment of the emergency hazard potential of a substance includes consideration of aquatic toxicity, as well as flammability and inhalation hazards. The emergency hazard characteristics differ slightly from Canadian Environmental Protection Act, 1999 (CEPA) section 64 toxicity characteristics. Therefore CEPA based conclusions may not be comparable to emergency hazards under the Environmental Emergency Regulations.
	Implementation and phase in timelines for the proposed approaches need to take into account technical and feasibility considerations. As noted in the proposal, there are challenges with seeking and using alternative chemicals and substitutes for these substances.	The selection of the appropriate regulatory (or non-regulatory) initiative takes into account technical and socio-economical factors. In addition, the proposed risk management approach document will be subject to a 60-day public comment period.
	Uses that are identified as having acceptable risk should not be subject to risk management, and a public declaration should be issued for those uses. However, DEHA should be listed as a substance that is under consideration for addition to the Environmental Emergencies Regulation.	The draft SAR indicates the uses which were assessed, uses which were found acceptable and the ones which present risks. The government is considering the addition of DEHA to the Environmental Emergency Regulations under CEPA 1999, including P2 Plans.
	Pollution Prevention plans should be required for facilities where the risk is unacceptable. Also, Sustainable Development Objectives should be built into the risk management instruments.	The Government of Canada selects risk management instruments using a thorough, consistent and efficient approach and takes into consideration information received through the Challenge and other available information. Socioeconomic factors are considered in developing the instrument for managing the risks.
DSL Inventory Update	DEHA should be targeted for update under the Domestic Substances List (DSL) Inventory Update.	As captured in the synopsis of the screening assessment, DEHA will be considered for inclusion in the Domestic Substance List inventory update initiative.
National Pollutant	The NPRI reporting threshold is inadequate, and an investigation of	Any party (person, government or organization) in Canada may submit a proposal to

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Inventory Release (NPRI)	releases to water bodies by all facilities using DEHA should be undertaken.	Environment Canada for changes to the NPRI program. Changes to the substance list result from the NPRI consultations process and may include the addition, modification or removal of substances as well as changes in the thresholds at which they must be reported under section 46 of CEPA 1999. Canadian importers or manufacturers of DEHA are subject to section 71 reporting requirements (reporting threshold of 100 kg per year), which includes a requirement to disclose releases to air, land and water.