Summary of Overarching Public Comments received on the Challenge substances Draft Screening Assessment Reports and Risk Management Scope documents for Batch 5

Comments on the draft screening assessment reports and Risk Management Scopes documents for Batch 5 substances to be addressed as part of the Chemicals Management Plan Challenge were provided by Learning Disability Association of Canada, Storm Coalition, CEPA ICG, and Chemical Sensitivities Manitoba and the Canadian Environmental Law Association.

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

- Risk Assessment
- Risk Management
- Vulnerable Populations
- Future Notification

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Risk Assessment	It is a concern that 17 of the 19 substances in Batch 5 identified through categorization as being high priorities are being proposed not to meet the criteria of s.64 of CEPA 1999. The scope of the Batch 5 draft screening assessments is too limited and does not incorporate a weight of evidence approach nor a precautionary approach.	The categorization of substances on the Domestic Substances List used approaches that were suitable for application to very large numbers of substances in order to identify priorities for further assessment. For health-related priorities, information gathered during categorization was based on what are now considered to be historical uses which may have changed since that time. Therefore, data on the uses or exposure of these substances may not represent the current situation. A screening assessment provides an opportunity to conduct an initial critical review and interpretation of information such as categorization results, as well as to identify further information specific to a substance, including new information submitted through the Challenge survey and questionnaire. Screening assessments provide better characterization of hazards and exposures and consider the risks that may be posed by the substances. Therefore, some substances that met the categorization criteria may be found not to meet the criteria of s.64 under CEPA, 1999. A weight of evidence approach is used in assessments conducted

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		under CEPA 1999. This approach accounts for multiple sources of information during the identification of critical values used in the assessment and considers the relative relevance, strengths and uncertainties of the various information. Multiple lines of evidence are also evaluated in determining whether a substance may pose a risk. The conclusions from the screening assessments do adhere to a precautionary approach because where there are uncertainties (such as volumes of the chemical in commerce or volumes of the chemical being released, or where computer modelling is used to predict exposure or effects), conservative/protective approaches are used.
	Quality Assurance reporting such as improved documentation of various activities and processes, including, but not limited to, peer review and stakeholder consultation would substantially improve the screening assessment documents.	The Government of Canada is committed to maintain open and transparent assessment processes and documents through its activities. All assessments are subject to a comprehensive internal review by government scientists. Areas of uncertainty identified during the assessment process and internal review are used to help focus external scientific peer review. All comments provided to the Government of Canada by peer reviewers are considered in finalizing assessment reports. The Challenge Advisory Panel also provides advice to Government on the CMP Challenge to industry and other stakeholders. The Government of Canada works with stakeholders such as the public, industry and health and environmental communities to ensure that the risks are clearly communicated and the decisions made are understood. The 60-day public comment period provides stakeholders with an opportunity to submit comments on draft screening assessment reports. Summarized comments and responses are published at the time of release of the final assessment report. Also, information and consultation sessions for stakeholders are held regularly to explain how risk assessments are conducted under CEPA.

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	The screening assessments should provide an overview of Health Canada's non-threshold carcinogenicity policy and the weight of evidence approach used by Health Canada; references to these documents should also be provided.	Screening assessment documents are based on scientific information leading to a conclusion on the toxicity of the chemicals as assessed under CEPA 1999. Any information related to the procedures, policies and decision-making processes are not part of these documents but are available through the CMP website for consultation. The overall process followed in the evaluation of existing substances is outlined in the documents located at: http://www.chemicalsubstanceschimiques.gc.ca/assess-eval/guide/index_e.html. A weight of evidence approach is used in assessments conducted under CEPA 1999. This approach accounts for multiple sources of information during the identification of critical values used in the assessment and considers the relative relevance, strengths and uncertainties of the various information. Multiple lines of evidence are also evaluated in determining whether a substance may pose a risk. The conclusions from the screening assessments do adhere to a precautionary approach because where there are uncertainties (such as volumes of the chemical in commerce or volumes of the chemical being released, or where computer modelling is used to predict exposure or effects), conservative/protective approaches are used. Consistent with the Ministers' Notice of Intent published in the Canada Gazette (December 9, 2006), Health Canada considers that evidence of genotoxicity and carcinogenicity (i.e., classification by one or more international/national agencies), without data clearly indicating how the chemical exerts its toxic effects, is sufficient to propose that there is a probability of harm at any level of exposure. Nonetheless, any subsequent risk management action would be proportional to the level of risk identified in the assessment and includes best environmental stewardship practices, technical feasibility, availability of alternatives, and economic

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		issues. Additional information regarding the assessment of carcinogenic substances under CEPA is available at: http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/approach/index-eng.php
	A re-evaluation assessment process should be included in the risk assessment documents to be consistent with Government of Canada policy.	All substances that have undergone assessment remain subject to future evaluation if new, substantive information is identified that indicates that further consideration is warranted. New information can be received through several mechanisms, some of which are defined under specific sections of CEPA 1999. Examples of such mechanisms include mandatory industry submissions, international decisions, and emerging science and monitoring. New information is reviewed and further evaluation activities, if warranted, are considered in keeping with other assessment priorities.
	The surveys under section 71 should be expanded in their scope to require the submission of all existing data, including data on hazardous properties. Respondents to the s.71 surveys should also be required to generate new data on these substances in order to fill existing data gaps.	In the Notice of Intent published in the Canada Gazette, Part 1, and the accompanying questionnaire, the Government of Canada invited industry and other stakeholders to provide specific information that may be used to inform risk assessment and to develop and benchmark best practices for the risk management and product stewardship of those substances identified as the highest priorities. This includes the provision of any available data on the substance. Under this call for information the decision to acquire new experimental data is left with the stakeholder. In the absence of submission of additional data, the Ministers are pre-disposed to conclude that there is a potential for harm, and actions may be taken that are protective of the health of Canadians and of the environment. In addition to the data collected under the section 71 surveys, the

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		screening assessments use the available scientific data from a range of sources including published literature in scientific journals and other international reviews. Respecting direction under section 76.1 of CEPA 1999, and in the absence of additional relevant information as a result of this Challenge, the Ministers are predisposed to conclude, based on a screening assessment, that this substance satisfies the definition of toxic under section 64 of CEPA 1999.
	The cumulative and synergistic effects of substances should be considered in the screening risk assessment.	Consideration of cumulative, synergistic and antagonistic effects is not precluded from a risk assessment. However, in order to be considered, sufficient information to undertake such analyses would be needed. Under the Challenge, the information typically available for assessing effects is representative only of a substance's inherent ability to elicit adverse effects.
	The identification of all possible safe alternatives should be included in all assessment documents with a proposed toxic conclusion. It is also necessary that a process under CEPA 1999 be in place to assess or screen the safety of the substitutes.	Consideration of safe alternatives is done as part of the development of instrument development. Where available and relevant to the Canadian context, information on the availability and cost of alternatives for a substance is usually included in public documents related to instrument development. For alternative substances which are new to Canada, importers and manufacturers are subject to notification and assessment under the New Substances Notification Regulations under the *Canadian Environmental Protection Act, 1999*. The Government of Canada welcomes input from stakeholders on alternatives for substances in Batch 5 of the Challenge. Stakeholders and members of the public are requested to submit such information via the Challenge questionnaire or by email to DSL.surveyco@ec.gc.ca.

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Risk Management	The risk management action of any substance found to be carcinogenic or having the potential to be carcinogenic should be that it be phased out or eliminated.	Prohibition is one of the risk management options considered for substances that meet the criteria under section 64 of CEPA 1999. However, there are situations where mutagenic or carcinogenic substances can be managed such that there is no or negligible exposures to Canadians. In these situations, the Government of Canada could choose to develop regulations or other controls to limit exposures and/or prevent any increases in exposures as a result of new or on-going uses of the substance.
	Risk management measures, other than a ban, will not provide adequate measures of protection to human health and the environment. It would be more protective for the Government of Canada to commit to an elimination strategy for all toxic chemicals.	When a substance is found to meet the criteria under Section 64 of CEPA 1999, risk managers consider a wide variety of risk management options in order to address the risk(s) identified in the screening assessment. The risk management option is selected in accordance with the Government of Canada's Cabinet Directive on Streamlining Regulation[1], using a thorough, consistent and efficient approach and taking into consideration the information available at the time. In some cases prohibition and/or virtual elimination is determined to be necessary in order to manage the risk(s) posed by the substance. In other cases, other types of risk management instruments (such as regulations, pollution prevention plans, voluntary agreements, codes of practice, etc…) are determined to provide the necessary protection in order to adequately address the risk.
	If a substance is determined to meet the criteria of persistence only, the government should undertake measures to reduce these chemicals over time. This should be done because they have the potential to affect the environment; these substances are found in many products and may be released into the environment through the degradation of these products.	All substances that have undergone assessment remain subject to additional assessment if new, substantive information is identified. All incoming information is reviewed and, if further assessment is needed, it will be conducted in keeping with other existing assessment priorities. Risk management will be initiated for substances that meet the criteria of section 64 of CEPA 1999 and are added to Schedule 1 of CEPA 1999.
	The screening assessments should take into	Extensive data is required to conduct complete life-cycle analysis,

[1] Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal."

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	consideration the full life cycle of the substance, including the disposal phase; this should include consideration of breakdown products, contaminants and metabolites.	including assessment of the breakdown products, and its collection is normally only a possibility for very detailed risk assessments, such as those that may be conducted for substances on the Priority Substances List. In screening assessments, information obtained in response to the Challenge, as well as from a range of other sources, is used to identify sources of exposure to a substance. Persistence is one factor affecting fate, transport and exposure, and is considered as part of the assessment. The assessment and subsequent management of risk then focuses on those sources that are most likely to be of concern, bearing in mind the persistence of a given substance. Regarding the potential for releases following product disposal, assessments of ecological concerns include an estimate of the quantity of the substance that may end up in landfills at the end of its life. Approaches are currently under development to identify substances for which monitoring of landfill leachates may be warranted to support risk management activities.
Vulnerable Populations	The screening assessment reports should be strengthened to consider impacts to vulnerable populations, such as people of low income, workers, people with chemical sensitivities, and aboriginal communities.	Screening assessments are science-based assessments of the available data. The various conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada including low income populations. However, if information is available which suggests that a specific sub-population would be particularly vulnerable, this information would be considered in the assessment.
Future Notification	The SNAc approach of non-toxic substances is an issue as an assessment of chemicals under the New Substances Notification Regulations will not include input from the public on assessment results.	Use of the future notification provision will ensure that further assessment of the substance is conducted if a stakeholder is interested in using it in the future. Any company or individual who plans to import or manufacture a substance subject to notification under the Regulations must provide a New Substances Notification package containing all information prescribed in the Regulations prior to import or manufacture. Through the New Substances program a joint assessment process is carried out between Environment Canada and Health Canada to determine

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		whether there is a potential for adverse effects of the substance on the environment and human health.