Summary of Overarching Public Comments received on the Draft Screening Assessment Reports and Risk Management Scopes for Batch 8

Overarching comments on the draft screening assessment reports for Batch 8 to be addressed as part of the Chemicals Management Plan Challenge were provided by Chemical Sensitivities Manitoba and Canadian Environmental Law Association, Dow Chemical Canada, and Inuit Tapiriit Kanatami (ITK).

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

- Proposed Risk Management
- Peer Review
- Data Gaps and Deficiencies
- Risk Assessment Conclusion
- Confidential Business Information
- General

TOPIC	COMMENT	RESPONSE
Proposed Risk Management	How is the *Cabinet Directive on Streamlining Regulation* applied in the instrument selection process, and how are risk management instruments selected?	The selection team, composed of risk assessors, risk managers from implicated sectors, and internal subject matter experts from various fields including economics and enforcement, considers the full suite of available risk management instruments, identifies potentially applicable instruments, then evaluates each one against the criteria described in the *Cabinet Directive on Streamlining Regulations.* Recommendations outlining an instrument or mix of instruments are then presented to management and the final decision is published in the Risk Management Approach document for public comment, prior to actual design of the retained instrument.
	Importers as well as manufacturers should be involved in the risk management consultations.	The Government of Canada communicates with the public and with industrial and commercial associations to identify all potentially affected stakeholders. However, stakeholders who may not be subject to the section 71 Notice should ensure that the Government of Canada is aware of all relevant activities related to the substance by responding to the Challenge Questionnaire. This information will be considered in the development of the risk

		management approach, including instrument selection and design. Participation in the questionnaire will also ensure that the Government of Canada will be aware of stakeholders that should be consulted throughout the implementation of the Challenge.
Peer Review	The details of the peer-review process for the ecological portion of the assessment should be disclosed for transparency.	The Government of Canada recognises the importance of transparency in outlining the peer-review process. The screening assessment reports (and supporting documentation) undergo both internal and external peer-reviews. External reviewers are selected based on their expertise in the type of substance, or the area of uncertainty in assessment reports. External reviewers are asked to perform a critical review of the draft screening assessment reports. They are invited to provide detailed comments and recommendations relating to the science contained in the report, what (if any) critical information is missing, and whether the lines of evidence presented are weighted appropriately and support the proposed assessment conclusions. In addition to a review of the screening assessment documents, reviewers may be asked to respond to precise questions that are specific to the characteristics of the substance or to circumstances surrounding the use of and/or exposure to the substance. While external comments are taken into consideration, the final content and outcome of the screening assessments remain the responsibility of the Government of Canada.
Data Gaps and Deficiencies	Screening assessment reports represent a summary of critical information and do not represent a review of all available data pertaining to the substances. This opens the door to challenges to the assessment and/or the risk management actions.	Screening assessment reports are based on the collective information currently available for the determination of the critical health and ecological effects. Stakeholders are engaged and provide information that is helpful to the preparation of the screening assessment reports through surveys conducted under CEPA section 71 and voluntary submission questionnaires to industry. Stakeholders have been continually notified to submit this information since the CMP challenge was launched. Government scientists examine lines of evidence from stakeholder

		submissions, available scientific data from a range of sources including published literature in scientific journals, as well as other international reviews, and seek additional scientific advice and review from experts when proposing conclusions. When experimental results are available from multiple sources, greater weight is given to data that were generated following recognized protocols and standards. The Government of Canada is aware of the context and regulatory implications of using weight of evidence evaluations of hazard done by other international agencies. Draft screening assessment reports are also subject to a 60-day public comment period, which provides an opportunity to all stakeholders to submit comments or additional data or information, if available. These comments are taken into consideration in finalizing the screening assessment reports. All substances that have undergone assessment remain subject to future evaluation if new, substantive information is identified that indicates that further consideration is warranted.
	Where data gaps exist, additional empirical data from industry should be sought, rather than relying on the use of analogue data and modeling to predict persistence, bioaccumulation and toxicity.	The Government of Canada has stated that the absence of new information will not preclude the Ministers from issuing a decision that safeguards human health and the environment. Thus the process being used for Challenge substances is not to wait until data gaps are filled, but to act on what we know now. All substances that have undergone assessment remain subject to future evaluation if new, substantive information is identified that indicates that further consideration is warranted.
	The use of modeling to determine the potential for long-range transport should be accompanied by environmental monitoring data such as sampling of sediment and wildlife populations at various distances from a use facility. The lack of monitoring data to confirm the concentrations or fate of high-volume substances in the environment is concerning.	The Challenge screening assessments are based on considerations of the available data. The exposure scenarios used in the long-range transport modelling are conservative and are considered to be protective. Monitoring and surveillance for specific substances in the environment will be considered under a comprehensive monitoring and surveillance strategy under the Chemicals Management Plan (CMP). A variety of substances, including

		some CMP substances, are monitored under the Northern Contaminants Program.
	The cumulative and synergistic effects of mixtures of substances in consumer products should be considered in the screening assessment.	Consideration of cumulative, synergistic and antagonistic effects is not precluded from a screening 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 an individual substance's inherent ability to elicit adverse effects.
	The Government should improve its assessment process to account for the exposure and release of substances throughout their life-cycle and in particular during the disposal phase (via incineration, wastewater, landfill).	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. Assessments of risk focus on those sources that are most likely to be of concern. Regarding the disposal phase, assessments based on ecological concerns include an estimate of the quantity of the substance that may end up in landfills at the end of the product life. The potential for release of a substance from a landfill due to leaching or in landfill gas is highly dependent on the nature of both the substance and the product in which it is contained. In only a very limited number of cases is sufficient information available to allow estimation of the quantity of substance released. As such, the fact that some portion of a substance is expected to end up in landfills is recognized in assessments, but releases of the specific substance from those sites are generally not quantified. Approaches are currently under development to identify substances for which monitoring of landfill leachates, of landfill gas or of emissions from incineration may be warranted to support risk management activities.
	When analogue data is used, some validation of the key conclusions should be undertaken, or a timeline established to revisit the assessment conclusion pending new data or information.	The information available for analogue substances is evaluated in the same way as for substance-specific information. Structural differences between the substance being assessed and the analogue are an additional source of uncertainty in the assessment. The availability of empirical data for an analogue is taken into consideration during the selection process for such analogues.

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Risk Assessment Conclusion	The Government should reconsider its proposal to apply Significant New Activity provisions (SNAcs) to four substances in Batch 8 (Benzene, 1,3,5-tribromo-; Benzene, 1,2,3,4-tetrachloro-5,6-dimethoxy-; Phosphonic acid, [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]-, monoethyl ester, calcium salt (2:1); and Fatty acids, C6-19-branched, zinc salts) which are hazardous, but not currently in use in Canada.	The substances Benzene, 1,3,5-tribromo-; Benzene, 1,2,3,4-tetrachloro-5,6-dimethoxy-; and Fatty acids, C6-19-branched, zinc salts had no report of import, use or manufacture for the year 2006; the potential for exposure is already very low, therefore they do not meet the criteria set out in section 64 of CEPA 1999. The application of the Significant New Activity provisions under CEPA 1999 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. Significant new scientific information on Phosphonic acid, [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]-, monoethyl ester, calcium salt (2:1) has been obtained during the public comment period. Therefore, given this new information and the aim to be transparent in the decision-making process, this substance was moved from Batch 8 to Batch 11 (the next available Batch to publish draft assessment decisions).
	With the reporting threshold for the section 71 Notices set at 100 kg/year, the surveys conducted cannot account for the number of possible users that fall below the threshold and who are not required to report to the survey.	Stakeholders not subject to the section 71 Notice (i.e., that fall below the reporting threshold for the reporting year) are strongly encouraged to inform the Government of Canada of their activities relating to substances by responding to the Challenge Questionnaire. When such information is received, it is considered in the screening assessment as well as in the development of the risk management documents.

	Toxicity information would be minimal under a Significant New Activity notification as applicants will not be required to submit data for chronic toxicity, endocrine disruption, or neurodevelopmental toxicity. Revisions to the New Substances program are needed for assessment of chemicals that are listed under the DSL and found to meet the criteria outlined for categorization.	Based on the information obtained through the Categorization process, the Government of Canada identified these substances high priorities for action and is pre-disposed to consider these substances PBiT; or presenting greatest or intermediate potential for exposure and posing a high hazard to human health. If a Significant New Activity notification was submitted, the onus would therefore be on the notifier to submit new information that indicates otherwise. The New Substances Program operates under the information requirements specified in the Significant New Activity provisions. If the information in the Significant New Activity Notification is insufficient, Section 84(1)(c) of CEPA 1999 enables the Minister of the Environment, under certain conditions, to request additional information to determine whether the substance is "toxic" or capable of becoming "toxic" under the Act. After a submission of new information, the assessment process is resumed and risk management measures can be taken. if necessary.
	The application of the Significant New Activity provisions on these substances will mean that the public will not have legal opportunities to engage in the assessment process. The public should have access to this process during the subsequent assessment conducted under the Significant New Activity Notifications, particularly as it has now been expanded to address substances that were originally on the Domestic Substances List.	Although the process is still being developed, it is the Government's intention for the public to have access during the assessment process for Significant New Activity Notifications.
	Many of the comments and concerns provided on the assessments and risk management proposals for the first seven batches released under CMP are also relevant for the chemicals listed in Batch 8. These issues have not been substantially addressed through the current government approach. Public interest groups expect the government to protect Canadians and their environment from toxic chemicals. The lack of response to the on-going issues has resulted	The Government is committed to continuing and enhancing dialogue with all stakeholders to ensure that risks posed by substances being assessed under the Challenge are reduced and managed to protect the health of Canadians and the environment. The Government of Canada considers all comments received during the public comment periods. These comments are helpful in assisting the Government to improve risk assessment processes and the development of appropriate and effective risk management instruments, as well as improving the design of risk

	in very few regulatory actions aimed to eliminate chemicals of concern.	assessment/risk management programs.
	Why are risk quotients not calculated for persistent and bioaccumulative substances?	When risks for persistent and bioaccumulative (P & B) substances are estimated using standard methods, the risks may be underestimated. Although conservative approaches (e.g., additional assessment or uncertainty factors) may be used to address these shortcomings, there are uncertainties associated with resulting risk estimates. To ensure protection of human health and the environment, a substance that is persistent and bioaccumulative, and has potential to cause adverse effects to organisms and for release to the environment, is concluded to meet the criteria under paragraph 64(a) of CEPA 1999.
Confidential Business Information	The citing of confidential business information (CBI) on use and volume of chemicals should be reviewed with an aim to reduce claims for CBI. Stakeholders are not able to appropriately comment on the assessments without access to that information. CBI restrictions should be reconsidered by the government when there are public health and environmental impacts.	Persons who submit information to the Minister of Environment under CEPA 1999 have the right to request that it be treated as confidential. Nonetheless, the Government of Canada continually works with stakeholders to try to ensure a balance between protection of proprietary information and presenting information in the most transparent manner possible in the interest of public health, public safety and for the protection of the environment.
General	There is little emphasis on elimination or reduction of CEPA toxic substances at the source. Current risk management options generally maintain the status quo in the use of substances or lead to a slight reduction in release to the environment – they do not address production, sale and use of toxic substances. One example is the insufficient use of Pollution Prevention Plans.	Prohibition and pollution prevention are among the risk management options considered for substances added to the List of Toxic Substances. It should be noted, however, that there are situations where mutagenic or cancer causing substances can be managed such that there is not expected to be exposure to Canadians. In these situations, the Government of Canada will develop regulations or other controls to limit exposures and/or prevent any increases in exposures as a result of new uses of the substance, or complimentary measures to address sources of release or exposure that are addressed by existing measures.
	The Government of Canada should develop a federal toxic chemical substitutions and green chemistry strategy.	Although a formal strategy is not currently in place, consideration of safe alternatives is done as part of the 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 proposed risk management approach documents and documents related to public consultations during instrument development. The Government of Canada will take into consideration the recommendation to develop a strategy for chemical substitutions and green chemistry.
	The current approach for gathering information, assessing risks and developing RM strategy is inadequate, particularly as it relates to vulnerable populations and occupational exposures.	The Challenge screening assessments are based on considerations of the available data. The various conservative exposure scenarios used are considered to be protective of both the general and vulnerable populations in Canada and do incorporate specific exposure estimates for Canadians of different ages. However, if information is available which suggests that a specific sub-population would be particularly vulnerable, this information would be considered in the assessment. Hazard information obtained from occupational settings, in particular data from epidemiological investigations, is considered in the assessments, when available. The information developed through the Chemicals Management Plan may be used to inform decisions concerning additional actions to minimize exposure to workers. The Government of Canada is communicating results to appropriate occupational health and safety groups.
	Socio-economic considerations made in developing Risk Management Approach documents are weak and the socio-economic information is not made available to the public.	Socio-economic information presented in the Risk Management Approach document is public and does not contain any confidential business information. It provides preliminary, high-level information of the sectors identified in the Risk Management Approach document, which could ultimately be used when the risk management instruments are developed. Where the Government decides to manage the risk posed by a substance through regulation, a more in-depth socio-economic analysis will be presented in the Regulatory Impact Analysis Statement (RIAS), the depth of which is dictated by the expected impact of the regulations. The analysis is based on collected information and stakeholder submissions.