Summary of Overarching Public Comments received on the Draft Screening Assessment Reports and the Risk Management Scope Documents for Batch 6

Overarching comments on the draft screening assessment reports and risk management scope documents for Batch 6 to be addressed as part of the Chemicals Management Plan Challenge were provided by Reach for Unbleached Foundation, International Institute of Concern for Public Health and Inuit Tapiriit Kanatami, International Institute of Concern for Public Health, Dow Chemical Canada Inc., and Chemical Sensitivities Manitoba and Canadian Environmental Law Association.

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

- Categorization
- Risk Assessment
- Significant New Activity (SNAc) provisions
- Risk Management
- Consideration of Public Comments
- Risk Based approach vs. a Hazard based approach

TOPIC	COMMENT	RESPONSE
Categorization	A large proportion of the substances originally identified as high priorities through the Categorization process are being assessed now as not meeting section 64 of CEPA 1999, with no further need for risk management. Given that for many of these substances there is a lack of information on volumes and releases to the environment, and given the uncertainties associated with models used to predict ecological risk, there are concerns that this is not 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. A substance can be considered to meet section 64 of CEPA 1999 only after an assessment has been completed. A screening assessment provides an opportunity to conduct a 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 allow risks to be better characterized, and therefore some substances that met the categorization criteria may be found to not meet the criteria of section 64 under CEPA 1999.
Risk Assessment	While analogues have a use in short-term decision making, the practice of using a limited number of analogues (e.g. Disperse Orange 30, Disperse Blue	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. The process

	79 and Disperse Blue 79:1) to make decisions on many chemicals is not precautionary. The use of analogues and read-across data to assess key criteria in the current approach deters industry and government from generating new toxicity data. The government should develop an effective workplan, beyond the scope of the Challenge and DSL Inventory Update, to fill in data gaps with experimental data and in particular, to require the generation of data using section 71(1)(c) and full enforcement of section 70. The workplan should ensure full accountability to chemical users, manufacturers and those responsible for disposal (complete supply chain) in filling information gaps for all chemicals covered under the Chemicals Management Plan, including medium priority chemicals, other chemicals under the DSL and new chemicals.	being used for Challenge substances is to act on what we know now, rather than waiting until data gaps are filled. If information specific to a substance is not available, use of data for appropriate surrogate substances, or analogues, may be used. The use of analogue (or read-across) data is an internationally accepted approach. For example, the Organisation for Economic Co-operation and Development (OECD) has a working group on the use of read-across and category approaches. As well, the U.S. Environmental Protection Agency's Office of Pollution Prevention and Toxics has used an analogue approach for many years in the assessment of both new and existing substances. The information available for surrogate substances is evaluated in the same way as for substance-specific information. Structural differences between the substance being assessed and the surrogate are an additional source of uncertainty in the assessment. If new, substantive information is identified that indicates that further consideration is warranted, then that substance is subject to future evaluation. 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.
	To improve transparency in the screening assessments, the Government should clearly identify the toxicity data that is new since categorization and was considered in the assessment.	The Government is committed to improving the transparency of screening assessments and has taken steps to improve the identification of recently obtained information used in assessments. The screening assessment is based on the collective information currently available for the determination of the critical health and ecological effects. The collective information could include data collected under the section 71 surveys, available scientific data from a range of sources including published literature in scientific journals, as well as other international reviews.

	Volume criteria used in risk assessments should be considered to have a high margin of error because, in most cases, they do not include the volume of chemicals contained in imported products.	All available sources of information are taken into consideration in determining the quantities of substances in commerce in Canada. Direct information on volumes of a substance contained in imported products may not be available; however, an effort is made to fill these data gaps. The Government of Canada has a variety of means to gather information on this, including surveys conducted under section 71 of CEPA 1999 and voluntary submission questionnaires to industry. When no or limited relevant information is obtained and data gaps remain, estimation methods may be used to account for these volumes. It is recognized that volumes of substances contained in imported products may represent an uncertainty in the assessments.
	Exposure conditions (such as duration and longevity of exposure) and specific population characteristics all have tremendous impact on the effects of chemicals both on human and on non-human populations. These exposure conditions should be considered for vulnerable groups such as workers, aboriginal populations and those with chemical sensitivities.	Exposure of the general population to chemicals through environmental media (e.g., food, ambient air, soil, consumer products) is taken into account in developing both the screening assessment and risk management scope documents. The Challenge screening assessments are based on considerations of the available data. The various conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada. 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 epidemiological information, is considered in the risk assessment. The information developed through the CMP process may be used to inform decisions concerning additional actions to minimize exposure to workers. CMP is working to communicate results to appropriate occupational health and safety groups.
	The cumulative and synergistic effects of substances should be considered in risk assessment and management within the Chemicals Management Plan.	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 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 (including breakdown products) throughout their life-cycle. In particular, exposure to humans and the environment from the recycling and disposal processes as well as recycled products should be considered.	Extensive data is required to conduct complete life-cycle analysis, including assessment of the breakdown products, and its collection is normally only a possibility for very detailed risk 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. Approaches are currently under development to identify substances for which monitoring of landfill leachates may be warranted to support risk management activities. Breakdown products are addressed in screening assessments if sufficient information is available and there is an indication that these products are hazardous. A more systematic approach to the identification of potentially hazardous degradation products is being developed. The Government of Canada strives to take into consideration recycling activities and resulting potential releases to the Canadian environment. Risk management measures will be implemented to address the risks posed by individual substances in the Challenge throughout their lifecycles.
	The screening assessment reports should identify the levels of chemicals that result from incineration, if applicable. Chemicals that are harmful to human health such as dioxans, furans and heavy metals result from incineration and the lack of information on incineration practices hinders the complete understanding of a chemical's fate.	The Government of Canada recognizes that other potentially harmful substances may be present or formed during the processing, use and disposal of products. Assessments of substances in the Challenge on the basis of ecological concerns include an estimate of the quantity of the substance that may end up in landfills or incinerators at the end of its life. Breakdown products are addressed in screening assessments if sufficient information is available and there is an indication that these products are hazardous. Consequently, risks posed by breakdown products can influence the conclusion on whether the subject substance meets the criteria under section 64 of CEPA 1999.

	The screening assessments should consider if chemicals have the potential for long-range transport.	The long range transport potential of a substance is addressed during assessment, when applicable.
	The cut-off values for determining whether a substance has the potential to bioaccumulate in the *Persistence and Bioaccumulation Regulations,* 2000 should be re-examined. Even if a substance does not meet these specific criteria, one cannot necessarily infer that the substance does not bioaccumulate. If substances are not properly identified as persistent or bioaccumulative, the appropriate actions for these substances under CEPA 1999 will not be taken.	The persistence and bioaccumulation characteristics of a substance are important factors in an assessment, and are considered regardless of whether the criteria from the *Persistence and Bioaccumulation Regulations* are met. Conclusions on whether the substance meets section 64 of CEPA 1999 are not predicated on having the substance meet the persistence and bioaccumulation criteria. The determination that a substance meets section 64 of CEPA 1999 is the finding which results in the development of a risk management strategy. Regardless of whether the criteria in the *Persistence and Bioaccumulation Regulations* are met, the full range of risk management measures can be considered, including prohibition when appropriate.
	The Government of Canada should disclose the nature of the peer-review process and should consider a more extensive peer-review process.	The Government 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. The external reviewer is 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 assessment remain the responsibility of Health Canada and Environment Canada

Significant New Activity (SNAc) provisions	Applying Significant New Activity (SNAc) provisions to substances which are hazardous, but not in Canadian commerce as per reporting requirements are not sufficient to prevent the entry of these substances into Canada. Future assessment of chemicals under the New Substances Notification Regulations would not include input from the public on assessment results and do not have strict enough data requirements.	Significant new activities are those new activities, which fall outside of the risk scenarios evaluated in a screening assessment but may result in the substance posing a risk to human health or the environment. Use of the Significant New Activity (SNAc) provision will ensure that further assessment of the substance is conducted if a stakeholder is interested in undertaking a new activity. A new activity may include importing/manufacturing the substance in excess of the reporting threshold and is defined in the SNAc Notice for each substance. Any company or individual must provide all information set out in the notice prior to undertaking the new activity. Through the New Substances program, a joint assessment is conducted by Environment Canada and Health Canada to determine whether the new activity would result in the substance meeting section 64 of CEPA 1999. If so, an appropriate risk management strategy will be developed.
Risk Management	Risk management scope documents should include consideration of alternatives to the chemicals or the products the chemicals are contained in.	Alternatives are considered as part of the development of the proposed risk management approaches documents and instruments and tools. The Government of Canada welcomes input from stakeholders on alternatives for substances in Batch 6 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.
	The suggested action regarding use-pattern change and notification has been put forth in a number of Chemicals Management Plan substances found to meet section 64 of CEPA 1999; yet dialogue and consultations have not yet occurred on development or implementation. The actions to implement, whether that be a future use notification, a regulation or some other instrument, will be precedent setting and the implementation has the potential to have significant negative impact on	The Government of Canada is committed to continuing and improving dialogue and consultation 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 development of all risk management instruments and tools includes a consultation process and consideration of socio-economic factors.

	society - depending on the socio-economic factors.	
	Any instrument developed should strive to deliver a Sustainable Development Objective - meeting societal demands for protection and products, ensuring an economical or affordable lifestyle and delivering real, tangible improvements to the environment or human health.	The Government of Canada recognizes that environmental or health risks and social, economic and technical matters are to be considered in the process of making decisions relating to the protection of the environment and human health.
	Presenting a single instrument or list of specific risk management options in the risk management scope document would expedite the stakeholder consultation process and help to produce cost-effective, quality results.	It is the intention of the Government of Canada to provide as much detail as possible on the proposed risk management regulations or instruments as early as possible in the risk management process. However, the details on the proposed risk management actions contained in these documents are dependent on the quantity and quality of the information available at the early stage of the process.
Consideration of Public Comments	The draft/final screening assessment reports have not addressed issues raised in the past by the public on the limitations observed in the screening assessment reports.	The government is committed to continuing and improving 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. In particular, dialogue that ensures that submitted information is appropriately interpreted can facilitate the assessment process. The Government of Canada considers all comments received on risk assessment and management documents.
	The Government of Canada should disclose the nature of the peer-review process and should consider a more extensive peer-review process.	The Government 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. The external reviewer is 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 assessment remain the responsibility of Health Canada and Environment Canada
Risk Based approach vs. a Hazard based approach	The lack of data on exposure sources has made it difficult for the public to demonstrate the need for elimination of some substances found to have impacts on human health and the environment. Rather than using a risk-based approach to assessment and management, the Government should use a hazard-based approach and develop an elimination strategy for high volume chemicals proposed to be harmful.	In order to determine whether a substance meets the criteria set out under section 64 under CEPA 1999, a risk-based approach is used which embodies the concept that harm is a function of both the intrinsic toxicity (i.e., toxicity in the traditional sense) and the extent of exposure. However, substances with high intrinsic toxicity to human health (e.g., those that cause cancer through direct interaction with genetic material) are also considered harmful under CEPA 1999. Prohibition is one of the risk management options considered for substances that meet any of the criteria set out in section 64 of CEPA 1999. However, there are situations where substances found to have impacts on human health or the environment can be managed such that there is no or negligible exposure. In these situations, regulations or other controls may be developed to limit exposures and/or prevent any increases in exposures as a result of new activities of the substance.