Summary of Public Overarching Comments Received on the Proposed Risk Management Approach Documents for Batch 1

Overarching comments on the proposed risk management approaches for Batch 1 to be addressed as part of the Chemicals Management Plan Challenge were provided by the Canadian Environmental Law Association, Chemical Sensitivities Manitoba, and Dow Chemical Canada.

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

Risk management action
Risk management process
Alternatives and substitutes
Further evaluation
Other jurisdictions
Information gathering

TOPIC	COMMENT	RESPONSE
Risk management action	All substances that meet the criteria under section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) should be added to the List of Toxic Substances in Schedule 1 of CEPA 1999.	When a substance is found to meet the criteria under section 64 of CEPA 1999, the Ministers of Health and the Environment can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999. The Ministers proposed to recommend the addition of all Batch 1 substances that meet the criteria under section 64 of CEPA 1999 to the List of Toxic Substances in Schedule 1 of CEPA 1999.
	The Government of Canada should not apply a significant new activity notice to substances that are carcinogenic.	Risk is a combination of both exposure and hazard. Although a hazard may be of high concern (i.e., cancer), the potential for exposure is equally important in determining risk. If current exposures are low or negligible, it may be considered appropriate to impose a condition whereby the Government is able to assess the

		risks posed by any proposed new manufacture, import or use, and would determine if the new activity requires further risk management consideration. By doing so, the government is able to ensure that the exposures remain low.
	Substances that meet the criteria under section 64 of CEPA 1999 should be added to the National Pollutant Release Inventory (NPRI) for reporting. Reporting thresholds should be lowered.	Environment Canada will consider proposing the addition of substances that meet the criteria under section 64 of CEPA 1999 to the NPRI's substances list. Substances that meet the criteria under section 64 of CEPA 1999, in particular, are given high priority in NPRI consultations. A formal NPRI consultation process is used to inform changes to the substance list. Changes may include the addition, modification or removal of substances as well as changes in the thresholds at which they must be reported.
	Risk management actions should be proportional to the established risk. There is no need for a robust instrument where there is high uncertainty that a risk actually exists.	For substances that meet the criteria under section 64 of CEPA 1999 and are added to the List of Toxic Substances in Schedule 1 of CEPA 1999, the Government of Canada must propose a regulation or an instrument respecting preventive or control actions in relation to the substance and thereby reducing or eliminating risks to human health and the environment posed by its use and/or release. As per the Government's *Cabinet Directive on Streamlining Regulation*, decisions are based on evidence and the best available knowledge and science in Canada and worldwide, while recognizing that the application of precaution may be necessary when there is an absence of full scientific certainty

		and a risk of serious or irreversible harm.
	The Government of Canada should develop regulations, instruments and tools under acts other than CEPA 1999 for managing the risks from substances in the Challenge, where appropriate.	It is the Government of Canada's goal to use the most appropriate program(s) for managing the risks of substances that are added to the List of Toxic Substances in Schedule 1 of CEPA 1999. In addition, the Government may also consider risk management measures, as appropriate, for substances not added to Schedule 1.
	Substances that meet the criteria under section 64 of CEPA 1999 used in a closed system with a destructive or consumptive end result should be exempt from risk management.	The Government of Canada considers use patterns, releases to the environment and best management practices in determining the need for and the nature of a risk management instrument.
	Regulations should include a low volume threshold, which would allow for the use of substances as analytical standards or for product evaluation at the pre-commercialization stage.	The Government of Canada will consider the use of thresholds during the risk management process. Some regulations already include such clauses.
Risk management process	The selection process for risk management instruments should include a qualitative and quantitative analysis of socio-economic factors.	Socio-economic, technical and environmental factors are considered qualitatively and quantitatively, where possible, in the regulation and instrument selection process. However, a quantitative analysis of all factors is not always possible due to the limited availability of information.
	The Government of Canada should fully disclose how it selected the risk management instruments.	As recommended by the Government of Canada's *Cabinet Directive on Streamlining Regulation* (http://www.regulation.gc.ca/directive/directive01-eng.asp) and by criteria identified in the Treasury Board Secretariat document titled *Assessing, Selecting, and Implementing Instruments for Government Action*, the risk

		management actions outlined in the risk management approach document are selected using a consistent approach. This approach considers a number of factors including available information on alternative chemicals and substitutes, as well as information received through the Challenge and other information available at the time. The risk management approach documents provide early thinking on the proposed instrument(s). The next component of the risk management process may involve consultations on a proposed regulation or instrument for managing a substance. For regulations, disclosure about why instrument(s) are either proposed or dismissed is included in the *Regulatory Impact Analysis Statement,* which is published in the *Canada Gazette* at the same time as the proposed regulations.
	Presenting specific risk management options in the risk management scope and approach documents would expedite the stakeholder consultation process and ensure the delivery of an instrument that balances environmental and human health concerns with sustainable development.	It is the intention of the Government of Canada to provide as much detail as possible on the proposed regulations or instruments as early as possible in the risk management process. However, providing details early is not always possible due to limited availability of technical or socio-economic information.
	The Government of Canada should recognize the lack of Canadian data when selecting the risk management instrument for non-threshold carcinogens for which most of the exposure is naturally occurring.	The Government of Canada's approach to the management of non-threshold genotoxic substances, which have both natural and anthropogenic sources, is to reduce exposure from anthropogenic sources to the extent practicable. This is because anthropogenic sources are additive

		and avoidable.
	Identifying risk managers for each substance would enable discussion with stakeholders and expedite the risk management process.	The Government of Canada 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. Stakeholders may identify themselves under the section 71 survey, either by responding to the survey if they meet the criteria, responding to the Questionnaire or sending in a Stakeholder Engagement form. This will allow the risk manager to contact stakeholders.
	The Government of Canada should use a multi-stakeholder consultation process when developing regulatory actions.	The development of risk management measures may, as appropriate, involve a multi-stakeholder consultation process. Various opportunities to consult in the Challenge include public comment periods following the publication of the risk management scope document, proposed risk management approach document and proposed instrument, as well as meetings (if necessary), and potentially, additional communication and interaction during regulation or instrument development.
	New risk management instruments should have minimal paperwork, reporting and/or administrative burden.	During the risk management development phase, the Government of Canada will apply the principles contained in the *Paperwork Burden Reduction Initiative* (http://reducingpaperburden.gc.ca/eic/site/pbri-iafp.nsf/eng/Home). This means it will consider costs and impacts of regulatory compliance on small business and pursue opportunities to reduce,

		rationalize and simplify regulatory requirements.
Alternatives and substitutes	The use of safe alternatives and preventative measures such as adding substances to the *Prohibition of Certain Toxic Substances Regulations, 2005* should be supported.	The Government of Canada considers a wide variety of risk management options including prohibiting or phasing-out a substance. However, there are situations where substances can be managed such that releases to the environment and human exposure are minimal. In these situations, the Government of Canada may develop regulations (other than prohibition regulations) or instruments respecting preventive or control actions to limit releases to the environment and human exposure. Available information on alternatives and the risks of the alternatives is considered during the risk management process.
	No substitutes are available for some substances, in terms of performance and cost effectiveness.	The availability of substitutes and the socio-economic impact and benefits of substitutes will be considered during the development of risk management regulations or instruments.
Further evaluation	The Government of Canada should further evaluate the safety of substances identified as being only persistent or only bioaccumulative, even if they do meet the criteria under section 64 of CEPA 1999. These substances should be targeted for risk management.	All substances that have undergone assessment remain subject to additional, future assessment if new, substantive information is identified that indicates that a further evaluation is warranted. All incoming information is reviewed and, if further assessment is needed, it will be conducted in keeping with other existing assessment priorities. For substances that meet the criteria under section 64 of CEPA 1999 and are added to the List of Toxic Substances in Schedule 1 of CEPA 1999, the Government of Canada must

		propose, within 24 months after addition to the List, a regulation or an instrument respecting preventive or control actions in relation to the substance thereby reducing or eliminating risks to human health and the environment posed by its use and/or release.
Other jurisdictions	The Government of Canada should align regulatory limits with other jurisdictions.	Potential alignment of regulatory limits with those of other jurisdictions is considered; however, all decisions will be made within the Canadian context.
	An export exemption should exist for substances that meet the criteria under section 64 of CEPA 1999, which are used properly in other countries.	The focus of the risk management for those substances which meet the criteria under section 64 of CEPA 1999 is to minimize environmental releases or human exposures within Canada. However, CEPA 1999 provides the authority to establish an Export Control List containing substances whose export is controlled because their use in Canada is prohibited or severely restricted or because Canada has accepted, through an international agreement, to control their export. The international agreements legally obligate Canada to control exports of certain substances and, in some cases, provide information to the importing country when exporting substances subject to domestic controls that prohibit or restrict their use. Identifying that a substance can be used properly in another country does not remove these obligations.
Information gathering	The Government of Canada should establish an equivalent to the American Inventory Update Rule for Challenge substances, in consultation with stakeholders.	The Government of Canada has been engaged in mandatory information gathering for several hundred substances since the Chemicals Management Plan was launched in 2006. The Government is currently working

		with stakeholders to refine approaches for information gathering on the balance of substances identified by DSL Categorization.