

Summary of Overarching Public Comments received on the Draft Screening Assessment Reports and Risk Management Scope on the Challenge substances in Batch 10

Overarching comments on the draft screening assessment reports for Batch 10 to be addressed as part of the Chemicals Management Plan Challenge were provided by the International Institute of Concern for Public Health (IICPH) & Crooked Creek Conservancy Society of Athabasca (CCCSA), Canadian Nuclear Safety Commission, Chemical Sensitivities Manitoba, Nova Scotia Power Inc. and Dow Chemical Canada.

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

- Vulnerable Populations
- Mixtures
- Environmental Monitoring
- Significant New Activity Provisions
- Peer Review
- Public Comment Process

TOPIC	COMMENT	RESPONSE
Vulnerable Populations	Vulnerable populations, including communities in the vicinity of high pollution, occupational groups, northern and aboriginal communities, pregnant women, foetuses, and people with chemical sensitivities, may be significantly impacted by exposure to pollution, including toxic substances in consumer or industrial products, and should be considered in the screening assessments.	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. 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 also considered.
Mixtures	The potentially synergistic effects of chemical mixtures need to be examined given that there is exposure to several chemicals simultaneously.	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 a substance's inherent ability to elicit adverse effects.

Environmental Monitoring	The exposure estimates need to be more thorough, using information derived through environmental monitoring. Similarly, in assessments where there is a high degree of reliance on modelling rather than empirical data, long term monitoring data should be used to validate the conclusions.	The Challenge screening assessments are based on considerations of the available data. Canadian monitoring data is often not available for substances at the time of assessment. However, when monitoring data is available, this information is considered in determining exposure estimates. In addition, future monitoring may be used to support verification of assumptions used during the screening assessment. 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).
Significant New Activity Provisions	The Government should reconsider its proposal to apply Significant New Activity provisions (SNACs) to the substances in Batch 10 that are hazardous, but not currently in use in Canada (Resin acids and Rosin acids, fumarated, barium salts (RFBS) and Nickel BHMB). These substances should be instead designated as meeting the criteria set out in section 64 of CEPA 1999. Also, the SNAC will mean that the public will not have opportunities to engage in the assessment process following a notification.	These substances had no report of import, use or manufacture for the year 2006; the potential for exposure is 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. Although the process is still being developed, it is the Government's intention for the public to have access to the assessment reports for these substances when processing Significant New Activity Notifications.
	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 respond 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, regardless of quantities involved. When such information is received, it is considered in the screening assessment as well as in the development of the risk management documents. The threshold of 100 kg is consistent with requirements under the new substances notification regulations.
	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	If a Significant New Activity notification was submitted, the onus would be on the notifier to submit new reliable/credible information that indicates that it is not harmful to human health or the environment. The New Substances Program operates under the

	neurodevelopmental toxicity. Revisions to the New Substances program are needed for the assessment of chemicals that are listed under the Domestic Substances List (DSL) and found to meet the criteria outlined for categorization.	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 harmful to human health or the environment or capable of becoming harmful. After a submission of new information, the assessment process is resumed and appropriate risk management measures can be taken, if necessary.
	The application of Significant New Activity provisions to (Resin acids and Rosin acids, fumarated, barium salts (RFBS) and Nickel BHMB would provide an inadequate framework to consider impacts to vulnerable populations (e.g. developing fetuses and children, workers, indigenous communities including Inuit communities and First Nations, people of low income and people with chemical sensitivities) in an assessment following a notification.	As in the Challenge, an assessment following a notification would include various conservative exposure scenarios considered to be protective of both the general and vulnerable populations in Canada and would incorporate specific exposure estimates for Canadians of different ages. If information was available that suggested 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, would be 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.
Peer Review	Only peer reviewers are identified for the human health portions of the screening assessments, but not for the ecological portions. The ecological reviewers should be identified, in the interests of transparency, acceptability to the regulated community and meeting government policy and meet current scientific standards. Improvements to the peer review process could include using global expertise, regardless of where they reside in the spectrum of stakeholders, be incorporated in the peer review process. Conflict of interest safeguards would need	Transparency in outlining the peer-review process is important and valuable expertise may be found in all stakeholder groups. All assessments are subject to a comprehensive internal science review. Issues or areas of uncertainty identified during the completion of an assessment and internal review are used to identify the expertise most suitable to provide external science review. Technical expertise is the main criteria for identifying suitable reviewers, who may come from academia, industry, consulting firms, or government. All comments provided to the Government of Canada by peer reviewers are considered in

	to be in place for expert reviewers from the private sector.	finalizing assessment reports.
Public Comment Process	The time allowed to the public to comment on the screening assessment documents is not sufficient and may give the impression that the findings of these assessments are of low concern.	The Government of Canada is committed to maintaining open and transparent assessment processes and feedback during the public comment period is useful in helping Government to strengthen its screening assessments. Given the tight timelines of the Challenge, it would be difficult to extend the 60-day public comment period. However, this does not preclude the public from providing comments at a later date if a new assessment is warranted. 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 is reviewed and further evaluation activities, if warranted, are considered in keeping with other assessment priorities.