Response to comments received following the Publication after screening assessment of 754 low concern substances on the Domestic Substances List

A Notice was published in the *Canada Gazette*, Part 1, Volume 141, Number 25, Pages 1735-1762 dated June 23, 2007, inviting comments within 60 days after publication of the following report: *Publication After Screening Assessment of 754 Substances on the Domestic Substances List (subsection 77(1) of the Canadian Environmental Protection Act, 1999)*. Comments from the following organizations were received:

- Canadian Environmental Law Association and Ecojustice
- Brenntag Canada Inc.

Comments and responses are summarized below.

Comment	Response
Precautionary approach and use of recent data	
The submission expressed the view that the government's rapid screening tools did not follow a precautionary approach, as required under CEPA 1999, in reaching the conclusion that "no further action" was required for many of the substances evaluated. It stated support for use of the tools to reprioritize all substances addressed in this approach for further action.	A range of approaches were used to identify substances requiring further assessment. Conservative approaches were used in both identification of substances subject to the rapid screening approach and in the steps within the rapid screening approach. For example, in consideration of potential for ecological risk, various conservative exposure scenarios were applied, and a search of a broad range of information sources to identify potential concerns with the substances. Additional refinements were made between publication of the draft and the updated draft assessment, including removal of aromatic azo and benzidine based substances which have been separately identified for assessment activity. As well, the updated draft report indicates that new information obtained in the future on these substances could indicate that a substance should be considered for additional assessment. The Government of Canada considers that the approach constitutes appropriate application of precaution, as required under CEPA 1999.
The submission noted that the government's effort to review data from other jurisdictions on volume and range of uses is not sufficiently based in science, nor does such an inquiry adequately demonstrate that the substances do not pose a threat to the ecosystem based only on low volume data. It contends that the government's decision that a number of the substances do not meet the criteria for s.64 should be delayed until detailed, current data can be obtained. Data on volumes, uses at source and downstream, location of facilities using the substances, current management	It is recognized in the rapid screening documentation that the exposure scenarios are based on Canadian quantities data from 1986, which may have changed since that time. (Of note, information collected for 123 substances as part of a pilot project showed that the quantity in commerce decreased or remained fairly constant for 94% of the substances between 1986 and 2000.) In recognition of this uncertainty, these substances will be specifically addressed in an upcoming update of the Domestic Substances List. Volume data collected under a s.71 survey issued in 2009 have identified 14 substances included in the draft rapid screening assessment that were manufactured or imported at quantities greater than 1000 kg in 2008. Consequently, these 14 substances have been removed from the updated draft assessment. Conclusions resulting from application of this rapid

activities, and additional toxicity data for human and non-human organisms, should be collected through a survey under s.71 of CEPA 1999. The substances should be monitored annually through, at least, the National Pollutant Release Inventory and updating of the Domestic Substances List (DSL).	screening approach will be verified as new information on quantities and uses becomes available. Other types of information that could lead to further assessment of a substance, and mechanisms for them to be identified, are outlined in the updated draft report.
It was suggested that interim risk management strategies be put in place until sufficient information is available to conclude that the substances do not pose a risk. It was additionally suggested that, since they have met the categorization criteria, Significant New Activity (SNAc) Notices should be applied to the low concern substances to ensure that the government is notified of changes in their current status. Notifiers should be required to fulfill the most stringent data submission requirements.	Given the lack of concern identified for these substances using the currently available information, and recognizing the mechanisms in place to address areas of uncertainty in this information, it is concluded that no further action is required on these substances at this time. However, should the analysis of information in the future suggest a high hazard potential, Significant New Activity (SNAc) Notices would be applied where applicable.
Documentation of Assessment of all criteria set out in section 64 of CEPA 1999	
The submission states that the rapid screening approach expressly addresses the likelihood of meeting the criterion for being toxic as set out in s. 64 (a) of CEPA 1999 but does not address the likelihood of meeting the criterion set out in s. 64 (b) and (c). It states that once a substance has been found to meet the categorization criteria under section 73, section 74 requires an assessment of toxicity on the basis of all criteria listed within s. 64, and not simply those components of toxicity that were suggested through the categorization findings.	As indicated in the *Canada Gazette* Notice published June 23, 2007, the results of the rapid screening approach proposed that certain substances do not meet any of the criteria set out in section 64 of the Act; “With respect to the criterion set out in s. 64 (b), the information sources that were consulted (for example OSPAR list; European Union Priority Substances List; Nomination dossiers for Canada’s Priority Substances List) did not identify any likely danger to the environment on which life depends.” It was therefore proposed in the Notice that these substances do not meet the criteria set out in either paragraphs 64(a) or 64(b) of CEPA 1999. The report has been modified to indicate this. With respect to the criterion set out in s. 64 (c), in response to public comments on the draft report, the rapid screening approach for human health considerations has been more fully elaborated upon in the updated draft report. As a result, 65 substances were identified as requiring further assessment. Potential for exposure to the general population was not identified for substances remaining in the rapid screening approach and these substances are considered to be unlikely to cause harm to human health at current levels of exposure.
Consideration of human health effects information	
The submission states that the lack of consideration of human toxicity is a significant gap in keeping with both a	During categorization, all substances on the DSL were subject to the simple hazard tool (SimHaz), which enables the identification of high hazard substances

precautionary approach and the need to assess substances with respect to all criteria under s.64 of CEPA 1999. It recommends that the authority of CEPA 1999 should be used to collect human health toxicity data for consideration in the assessments, and that all available data on human health impacts should be disclosed to promote transparency and accountability.	based on weight of evidence evaluations conducted by other national and international agencies. Endpoints considered in SimHaz are carcinogenicity, genotoxicity, developmental toxicity and reproductive toxicity. A full description of the SimHaz tool is provided in the document, "*Proposed Integrated Framework for the Health Related Components of Categorization of the DSL under CEPA 1999*" available on the Chemical Substances Web site (www.chemicalsubstances.gc.ca). Substances identified as high hazard during the categorization exercise were excluded from to the rapid screening approach. One substance included in the rapid screening approach in the draft report has recently been classified as a reproductive toxicant by the European Commission (CAR RN 14816-18-3) and this substance was removed from the approach. In addition, other substances (e.g., aromatic azo and benzidine based substances) were grouped with similar substances for assessment and removed from the rapid screening approach. The Government of Canada has recently indicated their intent to assess this class of substances (Notice of Intent published in *Canada Gazette* Part I, Vol. 144, No. 23 on June 5, 2010). Based on the public comments received, and as described above, the approach for rapid screening for human health considerations was further elaborated upon in the updated draft assessment report. Potential for exposure to the general population was not identified for substances remaining in the rapid screening approach and these substances are considered to be unlikely to cause harm to human health at current levels of exposure. As risk to human health is a function of hazard and exposure, collection of health effects data was not considered necessary for these substances. All substances remaining in the rapid screening approach are subject to further assessment in the future if information is identified that indicates that such evaluation is warranted. The hazard potential of these substances may be taken into further consideration in the development of Significant New Activity notification requirements in the future.
Prioritization of assessment activities	
The submission expresses the view that the limited government resources should be directed to substances other than those believed to be of low priority. Application of rapid screening to low concern substances at an early stage appears to favour the interests of industry in ensuring that little attention is given to these substances.	It is recognized that identification of risks that may be posed by the low concern substances are of a lower priority than for the medium and high concern substances. However, as outlined in the documentation on rapid screening, the low concern substances are being addressed at an early stage as it will facilitate the further prioritization of substances for assessment, by: • rapidly identifying those substances that require further assessment; • focusing resources on higher priority substances by rapidly identifying those that are not of concern; • facilitating planning for efficient industry

	stewardship practices; • improving the ability of government program managers to do long-term strategic planning - including identification of resource needs for risk assessment and risk management; and • rapidly providing information concerning a large fraction of substances meeting the categorization criteria, and thereby generally focusing the attention and actions of parties involved on substances likely of higher concern. The conservative approach implemented through rapid screening allowed efficient assessment of these lower concern substances without impacting resources focussed on substances of higher concern.
Assessment of Cumulative Effects of Substances	
The submission includes a list of 23 substances being addressed under rapid screening that contain bisphenol A or that may degrade into bisphenol A by-products, and recommends that the government include these in the assessment of bisphenol A that is taking place under the Challenge.	Information on the presence of bisphenol A in all substances will be used to inform ongoing risk management activities for this substance. The final assessment of bisphenol A was published in *Canada Gazette* Part I, Vol. 142 No. 42 on October 18, 2008. It concluded that bisphenol A meets one or more of the criteria set out in section 64 of the Act. On October 13, 2010, an Order adding bisphenol A to Schedule 1 of the Act was published in the *Canada Gazette* Part II, Vol. 144 No. 21. A proposed risk management approach document was also published in October 2008 for public comment to continue discussions with stakeholders regarding the risk management actions for this substance. A notice regarding one of these proposed actions, i.e., requiring the preparation and implementation of pollution prevention plans with respect to bisphenol A in industrial effluents, was published in *Canada Gazette*, Part I, Vol. 144, No. 42 on October 16, 2010
The submission recommends that assessments should consider cumulative effects of substances found to have similar endpoints. It states that the list of substances proposed for elimination from further evaluation includes more than 100 substances that are structurally similar to substances that bind to the estrogen binding site. The more than 1400 such substances that are on the DSL should be evaluated together, in keeping with the precautionary principle, in spite of the argument that the science is not mature enough to use. It is also recommended that a cumulative assessment be done for substances in rapid screening that are potential carcinogens.	It is stated in the rapid screening assessment document that all substances, including those proposed to be unlikely to cause ecological harm or harm to human health, remain subject to future evaluation if they are part of a category that may later be prioritized for 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. The information typically available for assessing effects is representative only of an individual substance's inherent ability to elicit adverse effects.
Application of Rapid Screening to Assessment of Other Substances	
The submission strongly rejects the suggestion in the screening documentation that the approach could be applied to higher priority substances.	It is stated in the technical approach document for rapid screening that a modified version of the approach may be applied to other groups of substances if judged applicable and relevant. In all cases, the assessment would be available for public comment.

Further Evaluation of Substances Identified by Mechanical Filters	
The submission recommends that substances flagged by mechanical filters should automatically receive a higher prioritization and in-depth assessment.	Substances identified for further assessment will be prioritized and scheduled for assessment together with remaining CMP priorities.
Other Mechanisms for Identification of Priorities for Assessment	
The submission questions the basis for the government's confidence that other “feeders” will capture any cases of significant risk that may not have been identified by rapid screening process.	The rapid screening documentation refers to other mechanisms that have been established to identify existing substances as priorities for assessment. These mechanisms engage a wide range of both domestic and international intelligence sources relating to identification of substances of potential concern. The government considers that these mechanisms, in combination with new information on quantities in commerce that will be obtained though activities on updating of the DSL, will be effective in identifying substances that may require further assessment.
Additional information on a substance in rapid screening	
The submission identified a substance included in rapid screening that has recently been imported by the company at a quantity greater than the 1000 kg/year level.	Following review of the information, the substance has been removed as a candidate for rapid screening in the updated draft assessment report.