Summary of Public Comments Received on the Draft Screening Assessment for Substituted Diphenylamines (SDPAs) and the Consultation Document for Benzenamine, N -phenyl-, Reaction Products with Styrene and 2,4,4-Trimethylpentene (BNST)

Public comments submitted in response to the draft screening assessment report (dSAR) for Substituted Diphenylamines to be addressed as part of the Chemicals Management Plan, and on the BNST Consultation Document were provided by: Chemistry Industry Association of Canada, American Chemistry Council, Canadian Fuels Association, Canadian Vehicle Manufacturers' Association, European Chemical Agency, Lisap Canada Inc., Prevent Cancer Now, and Chemical Sensitivities Manitoba.

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

Topic	Summarized Comment	Summarized /Response
New data and information updates	Delete the sentence in Section 10.2.4.1 because it provides ambiguous information about test material used in the two toxicity studies.	The sentence was deleted.
	Flag important changes, particularly since BNST now has a change in its bioaccumulation and toxicity finding.	New and available information showed a low potential for bioaccumulation (based on field sampling data), and none of the SDPAs assessed met any criteria set out in Section 64 of the Canadian Environmental Protection Act, 1999 (CEPA).
	Changes relating to a metabolome study were suggested for Section 10.2.4.1.	The sentence referring to toxicological mode of action was revised based on new and available information.
	Changes relating to reproductive/developmental toxicity studies were suggested for Section 10.2.6.2.	The sentence in Section 10.2.6.2 was modified.
	Various editorial comments were received with respect to referencing and repeated text.	Editorial corrections were made.
	Include a data matrix table on available aquatic toxicity data.	While available aquatic toxicity data were presented, these were not considered in the assessment due to uncertainties, and because these data do not characterize the primary route of exposure through the food chain. Additional analysis was also not included due to insufficient details in aquatic toxicity reports.
	Consider the European Chemicals Agency REACH assessment results on CAS RN 68411-46-1 which are expected by the end of 2017.	Noted. Government of Canada officials discussed with the European Chemicals Agency on this topic.
Proprietary or	Significant use of data on levels of contaminants in	In the interest of public health, public safety and

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Confidential Information	Canada, and studies related to health and safety, should not be considered confidential business information.	protection of the environment, the Government of Canada continually works with stakeholders to ensure a balance between protecting proprietary information and presenting information in the most transparent manner possible.
Methodology	The use of the assessment's uncertainty/weight of evidence analysis provides critical information that contributes to an understanding of the conclusions. However, parameters and criteria should be better defined when they are used to determine the levels of confidence in the data set and used in the weight of evidence.	The approach used to communicate levels of confidence, relevance, and weight assigned in the lines of evidence supporting the conclusions is not conducive to strict criteria because it is qualitative. Section 9.1 provides an overview to explain the analysis.

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	Chemical group assessments should identify least-toxic options based on pre-specified criteria.	SDPAs with a log K_{ow} s less than 9 are considered to have a limited bioavailability and limited bioaccumulation potential, and these are considered to be of lower ecological hazard potential.
	Concerns were expressed regarding the scientific process and the validity of data used in the assessment.	Assessments under the CMP are based on available information and use the best available estimation approaches, including application of read-across methods, and international guidelines and tools which apply both modeling and empirical data. Complementary samples were also collected by the Government of Canada to confirm SDPA levels in the environment.
	SDPAs, including BNST, could have been considered as part of a group approach for the assessment of other SDPAs to address potential substitutes and efficiencies. Indicate why this approach was not considered when BNST was originally assessed.	BNST was not initially considered in a group approach because prior to initiation of the CMP, Canada's categorization exercise identified it as a high priority for assessment. Therefore, BNST was part of the Ministerial Challenge announced by the Government in 2006 which focused on individual substances.
	The grouping should have considered other chemically-related substances, as well as similarities in physical-chemical properties. There is a need to develop and scientifically validate guidance for grouping chemicals that are to be assessed under the CMP.	International guidelines were followed for grouping substances, including SDPAs, e.g., Organisation for Economic Co-operation and Development (OECD), United States Environmental Protection Agency (US EPA). SDPAs are considered similar in terms of chemical properties, environmental fate, and toxicity.

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Ecological Assessment	The downtrend in usage of BNST is likely a result of the phase-out planned for this chemical. If the phase-out is reversed, usage is also expected to be reversed.	The potential replacement of SDPAs with BNST was considered, and it was recognized that all SDPAs in the assessment (including BNST) are potential replacements for each other, and that changes in product compositions could occur.
Human Health Assessment	We do not agree that there is little concern for human exposure to BNST and other SDPAs.	Since the current screening assessment concludes that current levels of exposure do not pose a risk to the general population, there is still little concern for human health exposure to BNST.
	Endocrine disruption was not assessed.	Review of the effects data indicated that endocrine effects were not identified for the SDPAs.
	Make a change to Section 10.4 of the Screening Assessment, regarding uncertainties associated with developmental and reproductive toxicity studies.	The content of Section 10.4 was not modified because it notes a high level of uncertainty regarding weight of evidence for developmental and reproductive toxicity.
	Add broader scenarios in the exposure assessment for products containing SDPAs, such as occupational settings and children mouthing plastics.	Although determination of occupational exposure scenarios is beyond the scope of the CMP, hazard information from occupational settings is considered in the screening assessment, where available and appropriate. A footnote was added to the Screening Assessment report regarding potential exposures for children that mouth plastics.
Risk Characterization	The assessment of unknown or variable composition, complex reaction products, or biological materials, otherwise known as UVCBs, may pose a challenge as chemical structural descriptions and compositions of UVCBs are not well defined.	Although the assessment of UVCBs may pose challenges, the chemical structure compositions for SDPA UVCBs as presented in the assessment were reviewed by experts. Using representative structures in the assessment improved consistency with analytical data required for the risk characterization.

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	Measured physical-chemical parameters should be required for high volume chemicals. These could contribute to the ongoing validation of the modeled values. In particular, vapour pressure is calculated from the Henry's Law Constant and solubility.	Key physical-chemical parameters, both modelled and empirical, were used to evaluate SDPAs. These parameters, including vapour pressure, were generated using robust and internally consistent physical-chemical estimation approaches.
Conclusion	Conclusions are supported based on availability of new data, weight of evidence, and risk-based approach.	Noted.
	There is limited confidence in the reversal of the BNST conclusion and bioaccumulation designation.	Based on the concentrations measured, current levels of total SDPAs in the environment are not expected to result in adverse effects on human health or the environment.
Risk Management	Ensure that the process to 'de-list' a substance from Schedule 1 is robust, allows the opportunity to offer comments, and is as conspicuous as the process to add a substance.	The process to delete a substance from Schedule 1 is provided in the CEPA. Stakeholders are notified, when a proposed order is published in the Canada Gazette. This is always followed by a 60-day public comment period.

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	It may not be possible to track the use of the SDPAs unless environmental monitoring is done.	Exposure to SDPAs found in the environment is not of concern at current levels. However, some of the representative chemical structures of SDPAs are considered bioavailable, and if their levels of exposure increase, these may pose an environmental concern. Follow-up activities to track changes in exposure and commercial use patterns are being considered.
	Prohibition of BNST is a concern for the automotive industry. If the SDPAs do not meet any of the criteria set out in Section 64 of CEPA, it is necessary to finalize the risk assessment and promptly remove BNST from the Prohibition of Certain Toxic Substances Regulations (PCTSR) and the List of Toxic Substances to minimize impacts to the industry.	The proposed amendments resulted in the removal of BNST from the PCTSR.
	Future plans for continued environmental monitoring, assessment of endocrine disruption, and timelines, should be specified and justified for SDPAs. This should include the investigation and possible verification of questionable recent confidential data, and the investigation of a broad range of cellular signaling possibilities.	Screening assessment conclusions adhere to a precautionary approach by applying conservative measures in the event of uncertainties. Given the uncertainties in the assessment, surveillance activities are considered to keep SDPAs as candidate substances for future studies.
Public Consultation and Stakeholder Engagement	Provide the opportunity to be involved in upcoming consultations regarding the risk management of BNST.	Stakeholder consultations are an essential part of the risk management process. The Government of Canada has considered stakeholders comments received in response to the proposed amendments published in the Canada Gazette Part I, as well as

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		those received in response to the consultation document in making the final amendments to the Prohibition Regulations. The Government of Canada always seeks stakeholder input throughout the risk management process.