Summary of Public Comments received on the Challenge substance PADMEC (CAS 65140-91-2) Final Screening Assessment Report for Batch 8

Comments on the final screening assessment report for PADMEC to be addressed as part of the Chemicals Management Plan Challenge were provided by Keepers of the Athabaska Watershed Alliance and International Institute of Concern for Public Health (IICPH).

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

- Phys-Chem Properties
- Bioaccumulation
- Inherent Toxicity and Health Effects
- Ecological Exposure Assessment
- Data Gaps and Deficiencies
- Uses
- Exposure Assessment
- Risk Assessment Conclusion

TOPIC	COMMENT	RESPONSE
Physical-Chemical Properties	The empirical values for water solubility and log D should not be included in the Physical Chemical properties table for PADMEC (Table 2) because they were deemed to be of low reliability and, therefore not acceptable. The log D value derived from the table should not be used to support the conclusion concerning log D or bioaccumulation potential.	The empirical values are included in Table 2 because they are part of the weight of evidence for this assessment. The experimental log K_{OW} is not used in any modelling. Given the shortcomings of the empirical log K_{OW} study, this value is given lower weight than the modelled data, and it is included in the discussion of the bioaccumulation potential of PADMEC.
	Why was the water solubility value selected to be used for modelling?	The empirical water solubility value has been removed from the model inputs table (Appendix I) as it was not used for modelling.
	How reliable is the modelled value for log D of PADMEC, and is it appropriate to use a single modelled value for log D to support conclusions about bioaccumulation potential?	Other estimates of log D have been added to the report for both the dissociated and non-dissociated forms of PADMEC, so now there are estimates based on EPI Suite (2008) as well as ACD Phys/Chem Suite (2009). The log D estimates and empirical value range from -1.45 to 0.83. These low predicted and empirical values of log D all support the conclusion that PADMEC has low bioaccumulation potential.

	The CAS number for the test substance in the Robust Study Summary for log D is incorrect.	This was an error in the assessment report; no CAS number was given in the study report; the substance was identified only by its trade name. This error has been corrected in the Robust Study Summary.
Bioaccumulation	The results of the empirical fish study, which are deemed not acceptable, and the Dimitrov model prediction, which is considered not reliable, should not be the basis for providing evidence that PADMEC does not meet the criterion for bioaccumulation under the *Persistence and Bioaccumulation Regulations*. In fact, they should not be used at all in this assessment, and should not appear on Tables 5a and 5b on bioaccumulation potential.	An error was made in the draft report in describing the Dimitrov model prediction as not reliable; this has been corrected in the final report. Given the shortcomings of the empirical BCF study, it is given lower weight than the modelled data, but is not discounted entirely. Both the experimental and modeled data are in agreement that PADMEC has low bioaccumulation potential.
	The initial assessment had found that PADMEC <u>did</u> meet the regulatory bioaccumulation criteria. The reason for the change in the decision on bioaccumulation appears to be based on new studies of highly questionable merit.	The initial assessment report for PADMEC, published under Batch 8 of the Challenge, was based on it having met the categorization criteria. Because PADMEC was not found to be in commerce (>100 kg/year in 2006), no further work was done for the initial draft assessment report to gather new information or use updated models available since categorization was completed, and it was proposed that the significant new activity provisions of the *Canadian Environmental Protection Act, 1999* be applied. However, new property and hazard data were submitted during the public comment period on the initial draft assessment report. The decision was therefore made to conduct a new screening assessment on this substance, following the schedule for Batch 11. The change of decision for PADMEC is based not only on the new empirical data submitted, but also on updated modelled information. The modelling that served as the basis for the categorization decision for PADMEC did not account for its ionizing properties. These were taken into consideration in the screening assessment.
	It should be noted that there are no experimental or modelled data for bioaccumulation of PADMEC in any biota other than fish, in any	It is appropriate to only consider fish if no other information is available, which is the case here, as fish are good predictors of

	medium, especially water and soil.	bioaccumulation for a water soluble chemical, such as PADMEC. This is because fish are surrounded by water-soluble chemicals in their environment and take in chemicals not only through their diet but by respiration through the gills. Therefore, fish are more exposed to water-soluble chemicals than are non-aquatic organisms. It should also be noted that the criteria in CEPA's *Persistence and Bioaccumulation Regulations* for bioaccumulation are based on the aquatic medium.
Inherent Toxicity and Health Effects	With respect to the zebra fish (Brachydanio rerio) study discussed in the report: • Why is a study that was carried out in 1988 considered new in 2010? • Why were adverse effects noted in the robust study not further pursued? • Given lack of substance information, and the fact that the test substance was described as "practically insoluble," it is impossible to tell what the test substance in the zebra fish study was. Under the circumstances, it appears that the confidence level for the zebra fish study should be classified as "unsatisfactory".	This confidential study is considered as new data since the Government of Canada did not have access to it previously. A discussion of the adverse, sub-lethal effects noted in the study has now been added to the report, and the Lowest Observed Effect Concentration (LOEC) used for calculating the Predicted No Effect Concentration (PNEC) has been changed in consideration of these sub-lethal effects. The reliability of the zebra fish study given in the robust study summary has been classified as "low reliability", due to the identity and solubility issues, as well as the lack of measured concentrations.
	Robust study summaries were not provided for the other three studies on ecotoxicity (bacteria, algae and Daphnia). This makes it impossible to assess their reliability. The validity of any of the studies used in Table 6 is highly questionable.	Robust study summaries are only prepared for those studies which are considered as "critical" to the outcome of the risk assessment. Since the other studies were not used to derive a Predicted No Effect Concentration (PNEC) value, robust study summaries were not prepared. However, a statement has been added to the assessment report which states that all of the studies summarized in Table 6 are of low reliability.
	The modelled data have been used to indicate that PAMDEC has low toxicity to aquatic organisms. The use of highly uncertain data to	The modelled data are not used as the basis of the conclusion of low toxicity for PADMEC. The Predicted No Effect Concentration (PNEC) is derived from the lowest Lowest Observed Effect

	conclude low toxicity is not scientifically acceptable.	Concentration (LOEC) from the experimental data. Upon re-examination of the data, the PNEC is now based on the LOEC for sub-lethal effects observed during the zebra fish study rather than the LOEC for zebra fish survival. Additionally, a higher safety factor has been used to better account for the limitations and uncertainties of the toxicity data.
	Health Canada has issued several letters of "no objection" for specific uses of PADMEC as a component of various food packaging materials. Is this an indication that an increase in use for this purpose is expected? If so, this "no objection" is done in light of several uncertainties as to the potential adverse health effects of PADMEC.	A safety assessment of PADMEC for use as a component of various food packaging material was conducted by Health Canada prior to issuing letters of "no objection". In this assessment, Health Canada took into consideration the potential for increased exposure to consumers via food from these potential uses and derived a conservative estimate based on a worst case scenario. A "no objection letter' means that a product has been evaluated by Health Canada and deemed acceptable from a chemical safety standpoint, for use in specified food packaging applications at a specified level, for specified use patterns. It should be noted, however, that a letter of "no objection" does not constitute an approval under the *Food and Drugs Act*
	Exposure to vulnerable populations and occupational exposure should be addressed.	The screening assessments are based on consideration of the available data and include various conservative exposure scenarios considered to account for both the general and vulnerable populations in Canada. If information was available that suggests 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, is considered in the assessments, when available. No hazard data from occupational settings were identified for PADMEC.
	Public access to information cited in Appendix III is not available due to a confidentiality statement and the quality of information cannot be independently evaluated.	Appendix III of the Screening Assessment summarizes the results of the health effects studies that were identified and used to support the assessment of PADMEC; these results are therefore publicly available. Persons who submit information to the Minister of Environment under CEPA 1999 have the right to request that it be treated as confidential. Nonetheless, the Government of Canada

		continually works with stakeholders to ensure a balance between the protection of confidential business information and the presentation of information in the most transparent manner possible.
Ecological Exposure Assessment	No data on concentrations of PADMEC have been identified. The scenarios developed in the assessment to estimate industrial and consumer product releases cannot provide valid information without any measured data and without specific information on quantities used in industry or in consumer products.	Assessments are based on available information using the current state of the science and the resulting modelled environmental concentrations are estimated conservatively to ensure that potential for exposure is not underestimated. The exposure scenario and the derivation of the Predicted Environmental Concentration (PEC) in this assessment is considered highly conservative (i.e., protective of the environment). This scenario is based on a quantity of PADMEC in commerce of 100 000 kg, which is the upper end of the range of PADMEC used in Canadian commerce in 2005 (1000-100 000 kg). The scenario assumes that this entire quantity is used at a single industrial facility, with its effluent having no dilution in the receiving water.
	The Risk Quotient determined from the exposure scenario, which indicates that harm to aquatic organisms from industrial discharge of PADMEC is unlikely, has no scientific basis.	PADMEC was not reported to be in commerce in 2006 above the 100 kg reporting threshold, and the industrial stakeholders identified in 2006 have confirmed that they are not currently (2011) manufacturing, importing or using this substance in Canada. Despite this, 100 000 kg of PADMEC, a conservative value based on 2005 import data, was assumed to be used at a single industrial site in the exposure scenario, which makes this scenario highly conservative (ie. protective of the environment). Having a relatively low risk quotient (2.1) when using such a highly conservative exposure scenario indicates low potential for harm to the environment from this substance.
Data Gaps and Deficiencies	Confidential studies that are neither published nor independently peer-reviewed have no scientific standing and do not provide a sound, reliable basis for any decisions that may have an impact on the health and well-being of the public and the environment. This is particularly true when those studies are carried out by parties (corporations) who have a vested	Critical studies, from both confidential and published reports, are reviewed to verify whether the study protocol and results are reliable. In this case, the confidential empirical studies were used in a weight of evidence approach along with modelled data, and the quality of these studies was taken into consideration in this approach. The empirical and modelled data are in agreement on the low value of the partition coefficient, and the persistence and bioaccumulation conclusions. For aquatic toxicity, the Predicted No Effect Concentration (PNEC) is based on the lowest empirical Lowest

	interest in the outcome of these decisions.	Observed Effect Concentration (LOEC) with an added safety factor, to account for the limitations and uncertainties of the toxicity data set.
Uses	Confidentiality is a large impediment in obtaining information about this substance, including its uses domestically and internationally.	PADMEC's uses in the U.S and internationally are provided in the report (see Uses section). It was not reported to be in commerce in Canada in 2006 above the reporting threshold of 100 kg/year. Although confidentiality was requested for some parameters by some stakeholders, pertinent information on the use pattern for PADMEC was obtained from stakeholders and has been summarized in the Screening Assessment,. The Government of Canada continually works with stakeholders to ensure a balance between protection of proprietary information and presenting information in the most transparent manner possible in the interest of public health, public safety and for the protection of the environment.
	The quantity of PADMEC in products that may be imported is not known, and therefore there is no way of determining its impact.	Although the lack of data establishing whether PADMEC is present in some imported manufactured items and/or consumer products is an uncertainty, the concern associated with this uncertainty is low based on no reported industrial activity for PADMEC in Canada in 2006.
	The public has not been made aware of the potential use of PADMEC in food packaging materials or the potential for direct exposure to PADMEC from such use.	In Canada, food packaging materials are regulated under the *Food and Drugs Regulations*. Companies may make a voluntary request to Health Canada to assess the safety of the proposed food packaging type. If Health Canada finds that the proposed use will not represent a health risk to Canadians, a letter of no objection for that specific use is issued to the company. The details of the submission are considered confidential business information and are not released; however, Health Canada and the Canadian Food Inspection Agency maintain lists of acceptable resins and food packaging types on their websites. No objection letters acknowledge that the use of PADMEC in the product is deemed to be acceptable. However, it does not constitute an approval of the product under the *Food and Drugs Act*
	The potential impact in Canada of amendments to the U.S. FDA Regulations allowing the use of PADMEC as a stabilizer for polyethylene phthalate polymers intended for use in contact	Canada and the U.S. each have their own petition requirements for companies wanting to use PADMEC. Companies may or may not file petitions to both Canada and the U.S. depending on their market predictions in each country. Although approval in another country

	with food should be addressed.	may provide some indication of the level of concern associated with a substance, an action taken in the U.S. on that substance does not constitute an action taken in Canada. Based on a full safety assessment review by Health Canada's Food Directorate, a letter of "no objection" was issued to industry for use of PADMEC as a component of polyethylene teraphthalate.
Exposure Assessment	What consumer/commercial products are considered in estimating releases to wastewater? Since the assessors assume a significant percentage of losses result from the disposal of products, certainly the public needs to be informed of these products.	The loss estimates from consumer/commercial products are not product specific, but rather are based on generic emission factors taken from the OECD's Emission Scenario Document on Plastics Additives (2009), which considers losses of plastics additives during consumer/commercial products usage from both indoor and outdoor service life.
	The report acknowledges that PADMEC can potentially leach from landfill into groundwater. This potential for leaching and contaminating groundwater has not been accounted for or even addressed.	The report has been revised to state: "…as PADMEC is expected to adsorb strongly to mineral surfaces, leaching from landfill sites or from soil is not expected to be significant."
	Releases to land and from chemical transformation were assumed to be zero because no emission factors were found. Because no factors exist, this does not preclude that there are no emissions. Furthermore, the loss to land does not include transfers subsequent to a substance's use and service life (e.g., land application of biosolids).	The releases to land are assumed to be zero because, as PADMEC is found in plastics, releases to land would be minimal. The Mass Flow Tool does not account for biosolids being applied to land, so all of the potential biosolids releases are accounted for under "losses to wastewater". The losses due to chemical transformation are assumed to be zero, which is a conservative assumption. All of the losses will then be accounted for under the various environmental compartments (i.e. air, water, etc.)
Risk Assessment Conclusion	In light of the numerous uncertainties that have been cited, particularly as they relate to the bioaccumulation potential and ecotoxicity of PADMEC, the proposed conclusions have no validity. In face of the lack of evidence, the precautionary approach has not been taken.	The derivation of the Predicted No Effect Concentration (PNEC) has been re-evaluated in light of the comments received and a new, more precautionary value has been derived. Given this, and the highly conservative predicted exposure concentration (PEC) used in this assessment, there is confidence in the assessment conclusion.