Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Reports for PBTBO (CAS 62625-32-5), Clomipramine hydrochloride (CAS 17321-77-6), Xylenol Blue (CAS 125-31-5), Bromcresol Purple (CAS 115-40-2), Bromophenol Blue (CAS 115-39-9), ATACP (CAS # 79357-73-6), and ATAEP (CAS # 68308-48-5)

Comments on the draft screening assessment reports for PBTBO, Clomipramine hydrochloride, Xylenol Blue, Bromcresol Purple, Bromophenol Blue, ATACP, and ATAEP to be addressed as part of the Chemicals Management Plan Challenge were provided by Dow Chemical Canada, Chemical Sensitivities Manitoba, and the Canadian Environmental Law Association. The comments have been compiled as most comments addressed many different substances.

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

- Risk Assessment
- Transparency
- Risk Management

TOPIC	COMMENT	RESPONSE
Risk Assessment	The exposure scenario used is not "reasonable" but rather a very conservative scenario constructed from extreme assumptions.	For efficiency in conducting assessments, an iterative approach is used in the development of exposure scenarios where relevant. If highly conservative or upper bound estimates of release and exposure do not indicate levels of potential concern, then refinement of the scenarios is unnecessary. Conservative assumptions are used to address gaps or uncertainties in information. It is recognized that the scenarios used in these assessments were based on conservative assumptions. The term "reasonable worst case" has been removed and replaced by either "conservative" or "highly conservative" depending on the cases.
	The screening assessment reports do not explicitly document the new data that was gathered and considered by the government that lead to changes in PBiT categorization decision for these chemicals.	The Departments are committed to improving the transparency of screening assessments. As such, the final reports were amended to identify the new information considered in the risk assessment, to the extent that is practical.
	The extensive use of modeling in the assessments to	When empirical data is lacking, assessments are based on the best

	make decisions on persistence and bioaccumulation should not be relied on due to the uncertainties associated with the derived data.	available estimates. The use of models to assess biodegradation and to conclude on persistence was appropriate. These models are structure-based which means that they provide reliable results for those substances for which chemicals of structural comparability are contained in their training sets. Whenever the results obtained using predictive QSAR (Quantitative structure-activity relationship) models were found to be unreliable, they were either not presented in the report, or they were presented along with an explanation as to why the results were not reliable.
	The precautionary principle was not fully applied even though many substances retained their persistence designation.	When a substance does not meet both the persistence and bioaccumulation criteria, environmental exposure is characterized and quantified, and it is compared to a PNEC (Predicted No-Effect Concentration) in a risk quotient (RQ) analysis. In the case of these substances, this analysis indicated a low potential for ecological harm.
	There is a lack of consistency in the approach to addressing discharge of effluents from sewage treatment plants (STP). Assessment reports assume or do not provide adequate rationale to demonstrate that treatment plants treat or remove all chemicals they receive and therefore effluent or sludge produced will have no impact to the receiving environment. They also do not provide information on level and type of sewage treatment applied. The assessment reports should include better analysis of the fate and impact of chemicals treated by STP. The Government must also recognize the limitations of these facilities and apply a preventative approach to the use of toxic substances.	A standard analysis approach is applied to each screening assessment in order to identify potential exposure routes of the substance to the environment. If the analysis identifies release into wastewaters with subsequent transport to sewage treatment plants (STP) to be a significant exposure route, potential release quantities from this source are estimated. In cases where measured release data are not available, an STP removal model may be used to provide these release estimates. Modelled data can also be used to support measured STP release concentrations. Information relating to the modelling approach used in an assessment, including model selection, model input data and assumptions, is available upon request. Limitations inherent in the use of modelled data in the assessment are recognized by the application of conservative assumptions in the modelling and precaution in the assessment conclusions.

	PBiT designation should be retained and substances should be declared CEPA toxic due to absence of data from industry and uncertainties in model-derived data.	Additional empirical and modeled information that was not available or that was beyond the scope of that considered at the time of categorization was incorporated into the screening assessment. Based on new information for these substances, the designation of these substances has been adjusted to provide a more accurate description of the potential hazard for the environment. This has resulted in a change in the conclusion about the bioaccumulation potential and inherent toxicity of these substances. The overall assessment conclusions were based on several lines of evidence suggesting that the ecological risk posed is low. These include results from the conservative risk quotient calculations indicating a low risk, the substances' low bioaccumulation potential and their very low to moderate predicted toxicity, and the limited quantities present in Canadian commerce.
Transparency	There is uncertainty as to why the government accepts the use of a substance to be confidential business information.	Under section 313 of the *Canadian Environmental Protection Act, 1999*, respondents to the Section 71 survey can request confidentiality on data submitted in order to protect sensitive business information. However, this does not prevent the information from being taken into consideration in the assessment process.
Risk Management	Reduction strategies should be implemented for all these substances based on their persistence.	Examinations of the potential for risk to the environment were conducted which included a consideration of persistence. This examination concluded that no or minimal risks to the environment were present due to use of these substances.