

## Summary of Public Comments Received on the Government of Canada’s Draft Screening Assessment Reports and Risk Management Scope Document for BNST(CAS 68921-45-9)

Comments on the draft screening assessment report and risk management scope document for BNST to be addressed as part of the Chemicals Management Plan Challenge were provided by Chemtura Corporation, Emerald Performance Materials, Afton Chemical Corporation, Ciba Canada Ltd, CEPA ICG, Chemical Sensitivities Manitoba, and Canadian Environmental Law Association.

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

- Risk Assessment
- Peer Review
- Risk Management
- Socio-Economic Impact

TOPIC	COMMENT	RESPONSE
Risk Assessment	Given the low levels of BNST in lubricating fluids, it is expected that the toxicity characteristics would be dominated by the major component of the base product.	It is recognized that the final product contains only small amounts of BNST, however, even low amounts of a persistent and bioaccumulative substance may have an effect on organisms in the environment.
	The chief use of BNST is as an additive to a product that at the end of its useful life no longer contains BNST.	Transformation of BNST during its service life was considered in estimating releases of BNST to the environment.
	Additional information was provided on the manufacture, handling and transport, breakdown products, commercial supply and applications of BNST as they relate to the potential for industrial and environmental release. No releases of BNST were expected to occur during handling of materials in storage vessels.  Additional information on wastewater treatment and disposal practices for BNST was provided.  Further details on the life-cycle, including the	The information provided was reviewed and has been considered in finalizing the assessment. Results obtained for BNST nevertheless indicate that there is a significant potential for release to the environment at different stages of its life-cycle.

	formation of breakdown products, was provided.	
	The assessment results do not provide an accurate assessment of the fact that BNST can be found in finished imported products.	The life cycle release of BNST has been documented in the assessment using the Mass Flow Tool. The Mass Flow Tool indicates that a very large fraction of the substance is chemically transformed; this would apply to the substance which is imported and manufactured into products within Canada, or imported into Canada in finished product form.
	Import is either in drums, with the substance then heated to allow pumping into a mixing system, or by bulk transport in a formulated additive. Based on this, it is not expected that significant air emissions would occur.	The additional supply information on BNST is acknowledged and has been considered in the release estimation scenario. Based on information received during the public comment period, emissions to air are now considered negligible.
	<p>Release estimates are based on general assumptions and modeling results rather than on empirical data.</p> <p>Further details on these assumptions and processes as they pertain to application of the Mass Flow Tool is requested. Clarification is also requested on the conclusion that BNST is being released in amounts that are resulting in toxic effects.</p>	<p>In the absence of sufficient and reliable empirical data, assessments are based on the best available estimation approaches and tools. These estimation methods are based on conservative assumptions. In the case of BNST, release estimates summarized using the Mass Flow Tool were designed to provide information on potential releases throughout the entire life cycle of the substance. These release estimates were originally based on confidential business information and have now been refined based on new life cycle information received during the public comment period. The results now indicate only limited releases to soil and sewer and negligible release to air.</p> <p>When the release proportions, as estimated using the Mass Flow Tool, are considered together with the relatively large quantities being manufactured in and imported into Canada, and the dispersive uses of BNST, it is concluded that there is a significant potential for release of the substance into the Canadian environment. The available data indicate that BNST is persistent in the environment and will accumulate in organisms. Based on all these factors, the screening assessment concluded that BNST has the potential to cause ecological harm in Canada.</p>
	A 1995 Australian Institute of Petroleum survey determined that most (86%) used automotive engine	The Government agrees that the level of BNST recovery is high. However, as indicated above, the substance is determined to be

	oils is disposed of responsibly. As BNST is largely non-bioaccumulative and is destroyed during use, no further action is warranted on this substance by Environment Canada.	persistent in the environment and bioaccumulative, and therefore, even small quantities released into the environment are of concern. Additionally, due to the large quantity of BNST in commerce, even releases of a small percentage can represent significant quantity.
	A decision that would negatively impact companies would result in reduction in the work force at plants in Canada.	The Government is currently gathering additional information that will allow informed decision-making regarding risk management of BNST. Risk management control instruments will take into consideration socio-economic factors while still protecting the environment.
	Additional information relating to the chemical structure of BNST was provided.	The government acknowledges and appreciates the chemical structure information received on BNST. The range of potential structures that best represent BNST has been reviewed and two appropriate new structures have been selected for further evaluation of the substance
	Further clarification is requested on the data supporting the decision to conclude that BNST is bioaccumulative.	No empirical bioaccumulation data was available and a predictive approach based on well recognized models was used to determine the potential for accumulation in organisms. The results support a conclusion of high bioaccumulation potential for this substance. Discussion of the interpretation of these modelling results has been significantly augmented in the final assessment report.
	Further clarification is requested on the basis of the modelling used to estimate ecotoxicity.	Empirical and modelled data support the conclusion that BNST has the potential to cause harm to aquatic organisms at relatively low concentrations, for example a median lethal concentration (96-h LC <sub>50</sub> ) of 2.3 mg/L was determined experimentally using mysid shrimp. While uncertainties in the data exist, such as those relating to mixture complexities and water solubility limits, empirical and modelled values indicate a potential for acute effects to aquatic species.
	Further justification is needed regarding the validity of modeled, hazard and exposure data in the assessment. There is no discussion of uncertainty associated with the data generated by models. There is no indication that weighting was applied. As BNST is a superhydrophobic chemical,	The Government of Canada recognizes that 'uncertainty' is an important consideration in the ecological risk assessment process, and that all assessments include elements of uncertainty. In cases where empirical information specific to a substance is not available, use of modeled data or appropriately selected surrogate substances may be used. Information available for these modeled

	<p>bioaccumulation /bioconcentration and exposure based toxicity data are unreliable.</p> <p>Further discussion of the uncertainty and confidence of the risk assessment outcome is needed. There is no evidence of a sensitivity analysis to measure the impact of uncertainty, and as the data set is poor, the consideration of the possible influence of uncertainty is particularly important.</p>	<p>or surrogate substances is evaluated using expert interpretation and weighting of all information. In the case of modeled data, the determination that the modeled data is within the domain of the model is key. BNST was considered within the domain of the bioaccumulation models used and therefore predictions were considered reliable. Discussion of model applicability has been augmented in the final assessment report.</p> <p>For the BNST assessment, a quantitative uncertainty analysis and sensitivity analysis were not possible; therefore a qualitative uncertainty analysis was undertaken. Please refer to the “Uncertainty” discussion in the Screening Assessment Report.</p>
	<p>Further discussion and justification is needed for: data collection, the lack of measured data, and the selection of critical values.</p>	<p>The Government of Canada is committed to the use of effective science in the preparation of screening assessment reports. At the time of publication of the draft screening assessment, only modeled data were available for BNST. Data submitted through the public comments have been considered for the final risk assessment report. Refer to the uncertainty discussion in the Screening Assessment Report.</p> <p>The determination of critical values for Persistence and Bioaccumulation are based on those values set out in CEPA 1999 <i>Persistence and Bioaccumulation Regulations</i> (Canada 2000).</p>
	<p>The actual test data provided should be considered in the final evaluation of this substance.</p>	<p>The Government of Canada considers all information submitted in the development of the assessments, although the level to which any individual piece of information is used in an assessment is based on its scientific value. Consistent with normal assessment practice, quality experimental data typically carry greater weight than estimated values. Key studies considered have been identified in the screening assessments.</p>
Peer Review	<p>Due diligence should be used for assuring quality, reliability, objectivity, and integrity of science and scientific advice (including peer review) in decision</p>	<p>The Government of Canada is committed to the effective use of science in the preparation of screening assessment reports. All assessments are subject to a comprehensive internal and external</p>

	<p>making.</p> <p>There is no indication in the assessment that an external review was undertaken.</p>	<p>science review. Areas of uncertainty found during the assessment and internal review are identified for external scientific peer review. Technical expertise is the main criteria for identifying suitable external individuals, who may come from academia, industry, or consulting firms. All comments provided to the Government of Canada by peer reviewers are taken into consideration. Draft assessments are also subject to a 60-day public comment period. These comments are taken into consideration in finalizing the assessment report.</p>
	<p>Public access to findings and advice of scientists earlier in the assessment process is requested, as well as early, ongoing stakeholder consultation. The risk assessment report does not clearly indicate that there has been stakeholder involvement for BNST.</p>	<p>Release of the substance Profile for BNST was followed by a possible six month period for stakeholder submission of information. The draft Screening Assessment Report on BNST was made available to the public followed by a 60-day comment period. All data and comments were taken into consideration in developing and finalizing the assessment report.</p> <p>Stakeholder requests for additional discussion are considered on a case-by-case basis, depending on the topics and timing of the proposed discussion.</p>
	<p>Most aquatic toxicity data presented is above water solubility level; this appears to be a superhydrophobic chemical and therefore bioaccumulation/bioconcentration and exposure based toxicity estimates are unreliable. The absence of technical references makes it difficult to judge the adequacy of data.</p>	<p>For this substance, observed effects from empirical studies with BNST and close analogues show effects above the predicted water solubility, which suggests significant uncertainty with the estimated water solubility. Many of the modelled results were well within solubility limits. Applicability and uncertainties associated with the use of models to estimate toxicity and bioaccumulation are described in the final assessment report.</p>
Risk Management	<p>It was recommended that BNST should be prohibited without exemption, and that the use of safe alternatives should be promoted.</p>	<p>The environmental objective for substances added to Schedule 1 of CEPA 1999 that also meet the criteria for persistence and bioaccumulation is virtual elimination. The intent of this objective is to achieve the lowest level of release to the environment which is technically and economically feasible. It is proposed that BNST be added to the <i>Prohibition of Certain Toxic Substances Regulations, 2005</i> which could prohibit the manufacture, import,</p>

		use, sale and offer for sale of BNST in Canada. Alternatives are investigated, where possible, during the risk management process.
	It was noted that environmental monitoring has not been undertaken for this substance.	Environmental monitoring of BNST in wastewater, sediment and biota will be included in the monitoring program established under the Chemicals Management Plan.
	Information on actual releases in Canada and details on mechanisms of release is requested. If regulations are proposed, it is important to understand how the releases of concern are occurring so that the regulation could focus on the specific mechanism of those releases.	Release estimate proportions, as determined using the Mass Flow Tool, have been revised based on information received during the public comment period. The final screening assessment report provides further details on environmental releases. Significant releases of BNST occur during use and improper disposal of lubricants, as indicated in the Risk Management Approach document. In order to eliminate these uncontrollable releases, the proposed risk management measure would prohibit BNST in lubricating oils used in Canada.
Socio-Economic Impact	Prohibiting the manufacture of BNST would result in a reduction in work force at plants in Canada.	The Government is currently gathering additional information that will allow informed decision-making regarding risk management of BNST. Socio-economic factors will be considered during development of the proposed instrument.
	Socioeconomic issues should not be a consideration in managing this substance.	As part of the <i>Cabinet Directive on Streamlining Regulation</i> , a cost benefit analysis is conducted for regulatory measures such as the proposed prohibition of BNST. This work is done during the risk management development stage in consultation with stakeholders. This will include taking into consideration any comments received following the 60-day public comment period on the Risk Management Approach.