

Summary of Public Comments Received on the Challenge Substance DTBSBP (CAS RN 17540-75-9) Proposed Risk Management Approach/Consultation on RMA for Batch 8

Comments on the proposed Risk Management Approach (RMA) document and the Consultation Document on the RMA published for DTBSBP to be addressed as part of the Chemicals Management Plan Challenge were provided by: New Brunswick Partners in Agriculture; Canadian Environmental Law Association; Chemical Sensitivities Manitoba; Dow Chemicals; and Inuit Tapiriit Kanatami. The table contains a condensed version of each comment and a response in non-technical terms.

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

Proposed Risk Management Approach for DTBSBP:

Food Packaging
 Proposed Risk Management
 Monitoring and Surveillance
 Stakeholder Consultation and Engagement
 Confidential Business Information
 Alternatives/Substitutes
 Vulnerable Populations

Consultation Document on the Proposed Risk Management for DTBSBP:

Food packaging
 Proposed risk management

Topic	Summarized/Rolled-up Comment	Summarized/Rolled- up answer
Public Comments on the Proposed Risk Management Approach for DTBSBP		
Food packaging	Under the <i>Food and Drugs Act</i> , the Government of Canada should clearly identify through a list, all substances that are unacceptable to be used in food packaging. This list should include all CEPA toxic substances. The Government of Canada should also consider amending the <i>Food and</i>	The various materials used to package food sold in Canada must comply with safety provisions listed under the <i>Food and Drugs Act</i> and the <i>Food and Drug Regulations</i> . These provisions are intended to ensure that, when used as directed, food packaging materials are safe. Under the <i>Food and Drug Regulations</i> , there is a general prohibition on the sale of a food in any packaging material that may transfer a substance which would be considered to represent a health risk to consumers. While there

	<p><i>Drugs Act</i> to require mandatory reporting of ingredients and food packaging to the Food Directorate with respect to pre-market assessment of ingredients and packaging food materials rather than a voluntary approach.</p>	<p>is no mandatory requirement for pre-market review of food packaging materials by Health Canada, at the request of the food industry, Health Canada continues to conduct assessments of such products to determine whether they are acceptable for their intended use from a safety perspective.</p>
<p>Proposed Risk Management</p>	<p>A number of comments were received related to the proposed risk management and the objective of virtual elimination:</p> <ul style="list-style-type: none"> • To achieve virtual elimination of DTBSBP, the government should have explicit plans to adequately deal with DTBSBP and address its full life cycle. The government should ensure full recovery of DTBSBP in products, including brake fluids and other products, for the purpose of its full destruction at the end of its life cycle. Methods for recovery and destruction of DTBSBP and empty brake fluid containers that would have contained DTBSBP should include the application of Extended Producers Responsibility programs to allow for the complete destruction of DTBSBP. • The risk management objective should be revised to prevent releases and the use of DTBSBP and not only focus on minimizing releases. The risk management approach should be more preventative with a focus on the prohibition of this chemical in consumer and industrial products. 	<p>DTBSBP meets the requirements for the implementation of virtual elimination. As outlined in the Proposed Risk Management Approach, the Government of Canada considered a regulation to prohibit and/or limit the conditions under which DTBSBP may be imported, manufactured or used. Since that publication, further investigations have brought forth new information regarding the use profile and potential releases of DTBSBP.</p> <ul style="list-style-type: none"> • There has been a significant reduction trend in the use of DTBSBP due to the pro-active phase-out of DTBSBP in certain applications. There is also ongoing progress towards phasing out the use of DTBSBP in another application. • Releases of DTBSBP from the disposal of polyurethane foam products containing DTBSBP are unlikely due to its physical and chemical properties. • Based on the worst-case scenario, life-cycle losses estimated in the Final Screening Assessment Report, the only remaining potential releases of DTBSBP to the environment are likely to be from its presence in brake fluids. Releases from the disposal of brake fluids are not expected to be of concern in light of existing controls. The vast majority of brake fluid operations are performed in commercial centers which ensure that brake fluids are captured for proper treatment/disposal. These centers may either capture spent brake fluids indirectly with used oils or as hazardous waste sent to licensed facilities. Any potential releases by consumers are expected to be infrequent, widely dispersive, and to contain very small amounts of DTBSBP. <p>To complement the above-mentioned voluntary actions and existing controls, the application of the Significant New Activity provisions under</p>

	<ul style="list-style-type: none"> • A regulatory approach should be used to achieve virtual elimination through specific regulations to prohibit the use, manufacture, sale, disposal, import and export of DTBSBP, and cover both industrial uses and consumer products. The approach should also include a prohibition on export of the chemical or products that may contain this chemical. In the development of these regulatory measures, the government is urged not to grant exemptions to facilities or sectors. • The Government of Canada should provide additional details as to what regulatory controls are being considered to achieve virtual elimination of the releases of DTBSBP to the environment. 	<p>section 81(3) of CEPA 1999 is proposed to ensure that any future uses are subject to assessment to determine whether additional risk management is required.</p> <p>The environmental objective for DTBSBP remains virtual elimination, and the risk management objective remains minimizing releases of DTBSBP to water and soil to the greatest extent practicable. However, in light of the new information and the current actions, pursuing a prohibition regulation at this time is not warranted.</p> <p>The Government of Canada will continue to evaluate the situation, and may take additional risk management measures in the future if there is insufficient progress towards meeting the environmental objective.</p> <p>For more information, please refer to the Consultation Document on the Proposed Risk Management for DTBSBP, which can be accessed at http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0D0BCDA2-1</p>
	<p>Releases from brake fluids containing DTBSBP do not cause an unreasonable risk to the environment, brake fluids are vital to society, and replacements are not readily available. As a result, the Government of Canada should prohibit DTBSBP in all applications except its use as an antioxidant in brake fluids where it should be allowed to continue to be used in concentrations less than 1 %.</p>	<p>At this time, the definition of a significant new activity in the proposed significant new activity provisions for DTBSBP would not apply to an activity related to its use as an antioxidant and/or corrosion inhibitor in brake fluid at a concentration less than or equal to 1 % by weight. However, the Government of Canada will continue to evaluate the situation to determine if additional actions are required to meet the environmental objective.</p>
	<p>A number of comments were received specifically related to the development of a Level of Quantification (LOQ), including:</p> <ul style="list-style-type: none"> • Support for the government’s proposal for virtual elimination of DTBSBP, but 	<p>As DTBSBP meets the requirements for the implementation of virtual elimination (VE), it will be considered for addition to the VE list. Socioeconomic and technical factors will be considered during this process. Stakeholders will have the opportunity to comment on the proposed addition of substances to the VE list and Limit of</p>

	<p>not for the determination of an LOQ as it does not effectively achieve virtual elimination.</p> <ul style="list-style-type: none"> • Social, economic and technical considerations should be taken into account in the establishment of a LoQ. • Effort should be made to obtain data on uses of DTBSBP and release levels to all media in order to derive quantitative estimates of releases and for the determination of an LoQ. 	<p>Quantification as part of the consultation process.</p>
	<p>The addition of DTBSBP to the <i>Environmental Emergency Regulations</i> of CEPA 1999 is warranted, however, additional training and communication with workers and communities are required to understand contingency plans in the event of an accident. Management measures should include destruction and management measures for potential stockpiles of this substance. Another stakeholder suggested that the <i>Environmental Emergency Regulations</i> would not likely apply to DTBSBP because it is present only at low volumes and concentrations at facilities in Canada.</p>	<p>DTBSBP has been assessed against the criteria set out in section 200 of CEPA 1999 in the event that it was to enter the environment as a result of an environmental emergency, and it has been determined that it does not meet these criteria. As such, it will not be considered for addition to the <i>Environmental Emergency Regulations</i>.</p> <p>For additional information, visit the following link: http://www.ec.gc.ca/ee-ue/.</p>
	<p>The Government of Canada should fully disclose publicly how the <i>Cabinet Directive on Streamlining Regulation</i> and the Treasury Board document <i>Assessing, Selecting, and Implementing Instruments for Government Action</i> were complied with for DTBSBP in order to increase transparency.</p>	<p>The criteria described in the <i>Cabinet Directive on Streamlining Regulations</i> was used by the selection team, composed of risk assessors, risk managers from implicated sectors, and internal subject matter experts from various fields including economics and enforcement, to evaluate each potentially applicable risk management instrument. . The instrument choice framework used for DTBSBP, including the criteria considered, is outlined in Annex A and B of the Treasury Board document entitled “Assessing, Selecting, and Implementing Instruments for Government Action”. The data considered, analysis, and conclusions</p>

		contain confidential business information as well as advice to Cabinet and therefore cannot be publicly disclosed.
	The Government of Canada should obtain actual information and data on where and when releases and emissions occur and use this information to inform the risk management actions.	<p>The Final Screening Assessment Report summarizes available data on the sources of exposure and release of DTBSBP to the environment. In addition, following the publication of the Final Screening Assessment Report and Proposed Risk Management Approach, the Government of Canada collected further data on releases of DTBSBP to the environment through follow up with industry and a recent study..</p> <p><i>For additional details, please refer to the Consultation Document on the Proposed Risk Management for DTBSBP, which can be accessed at http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0D0BCDA2-1, or see the response to the comment on “proposed risk management and the objective of virtual elimination” above.</i></p>
Monitoring & Surveillance	The Government of Canada should generate environmental monitoring data to identify the sources of unacceptable risk for DTBSBP and then develop appropriate risk management instrument(s) to address these sources of unacceptable risk. Results from monitoring programs should be made available to the public in a format that is easily understood for increased	<p>Surveillance for DTBSBP in the environment (e.g., along transportation corridors) is being considered under a comprehensive monitoring and surveillance strategy under the Chemicals Management Plan.</p> <p>For additional information, visit the following link: http://www.ec.gc.ca/Publications/default.asp?lang=En&xml=F48952A0-3F54-4D76-BAA6-EA6CF5529590</p>
Stakeholder Consultation and Engagement	The Government of Canada should ensure that there is extensive consultation with all implicated stakeholders and should broaden its stakeholder engagement activities related to DTBSBP, including engaging importers of products containing DTBSBP, to ensure that the views of all stakeholders are represented. Due to the fact that DTBSBP meets the virtual elimination criteria, it will be important for the Government of Canada	<p>Consultation with stakeholders is an important part of the risk management process. For DTBSBP there have been 60-day public comment periods following the publication of the following documents: the draft Screening Assessment Report, the final Screening Assessment Report, the Risk Management Scope, the Proposed Risk Management Approach, the Consultation document on the Proposed Risk Management for DTBSBP, published in December 2011 which outlined the change in the proposed risk management for DTBSBP. There is also a 60 day public comment period following the publication of, and the <i>Notice of intent to amend the Domestic Substances List to apply</i></p>

	to consult extensively with all the affected stakeholders.	<p>Significant New Activity (SNAc) provisions. Stakeholders are encouraged to participate and provide feedback at all stages of the risk management process.</p> <p>To subscribe to receive the latest news on actions being taken by the Government of Canada to assess and manage chemical substances under the Chemicals Management Plan via email, visit the following link:</p> <p>http://www.chemicalsubstanceschimiques.gc.ca/listserv/index-eng.php</p>
Confidential Business Information	There is a lack of public transparency on uses for DTBSBP that are identified as confidential business information; this issue should be brought to the attention of the CMP Stakeholder Advisory Council.	<p>Persons who submit information to the Government of Canada under CEPA 1999 have the right to request that it be treated as confidential. Nonetheless, the Government of Canada continually works with stakeholders to try to ensure a balance between protection of confidential business 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. Members of the CMP Stakeholder Advisory Council are invited to bring forward any topics for discussion.</p> <p>For additional information on the CMP Stakeholder Advisory Council, visit the following link:</p> <p>http://www.chemicalsubstanceschimiques.gc.ca/plan/council-conseil/index-eng.php</p>
Alternatives/Substitutes	The process for assessing the safety of potential substitutes for DTBSBP should be rigorous and transparent. The Government of Canada should require the development of an inventory of all possible alternatives to DTBSBP as part of the risk management process. An assessment of all alternatives for DTBSBP should be completed to determine the safety of substitutes and should be hazard-based rather than risk-based.	<p>Consideration of safe alternatives is done as part of the risk management process. Where available and relevant to the Canadian context, information on the availability and cost of alternatives for a substance is usually included in public documents related to instrument development.</p> <p>For alternative substances which are new to Canada, importers and manufacturers are subject to notification and assessment under the New Substances Notification Regulations under the <i>Canadian Environmental Protection Act, 1999</i>.</p>

	<p>The use of BHT as an alternative to DTBSBP should not be permitted because it is a possible human carcinogen.</p>	<p>The Proposed Risk Management Approach for DTBSBP and Consultation Document on the Change in Proposed Risk Management for DTBSBP indicate that in some instances DTBSBP has been used to replace the antioxidant butylated hydroxytoluene (BHT, CAS RN 128-37-0) in several of the non-food applications. The Government of Canada encourages industry to voluntarily phase out the remaining uses for DTBSBP that have not already been phased out, and is not suggesting that DTBSBP continue to be used as a substitute for BHT. BHT was also found to meet the Government of Canada categorization criteria as a result of the categorization of the Domestic Substances List, and has been identified as a priority for assessment under the Chemicals Management Plan. This factor should be taken into consideration when evaluating potential alternatives for DTBSBP.</p>
Vulnerable populations	<p>The Government of Canada's approach does not take measures to protect children from exposure to DTBSBP and additional regulatory action is warranted. The government should use the full scope of its authority to collect data on the impacts to children's health from this chemical. Specifically it should utilize CEPA Section 71(1)(c), to seek mandatory toxicological data from industry focused on exposure to children's health. Similarly, the risk management proposals should also recognize and take action to protect other vulnerable sub-populations of society such as people of low income, workers, people with chemical sensitivities, communities located in remote northern regions, and aboriginal communities.</p>	<p>The Government of Canada considered, where available, information relevant to exposure of DTBSBP to children and other vulnerable populations to this substance in the risk management process. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, it is proposed that no risk management actions to specifically protect children and other vulnerable populations are required for this substance at this time. It should also be noted that DTBSBP did not meet the paragraph 64 (c) criteria, i.e. was not found to pose a risk to human health including children's health.</p>
<p>Public Comments on the Consultation Document on the Proposed Risk Management for DTBSBP</p>		
Food Packaging	<p>There should be mandatory, periodic pre-</p>	<p>The chemical safety of all food packaging materials is regulated under</p>

	market assessments and testing of food packaging.	Division 23 of the <i>Food and Drugs Act and Regulations</i> . Particularly, Section B23.001 prohibits the sale of foods in packages that may impart harmful substances to their content. Under these regulations, the responsibility lies clearly with the food seller (i.e. manufacturer, packager, distributor, etc.) to ensure that materials used in contact with foods are safe. Health Canada does evaluate food packaging submissions upon request and offers letters of opinion on the safety of these materials. The Canadian Food Inspection Agency enforces the compliance with Section B23.001.
	Suggest working more closely with the Food Directorate at Health Canada due to the potential use of DTBSBP in food packaging.	Health Canada's Food Directorate has been involved in the assessment of DTBSBP. As with other substances used in food packaging, Health Canada conducts pre-market review of food packaging materials to determine whether they are acceptable for their intended use from a safety perspective. These reviews take into account any known toxicity and exposure data including assessments conducted under CEPA 1999.
Proposed Risk Management	The application of Significant New Activity (SNAc) provisions for DTBSBP may not be sufficient to address the risks. Stricter controls should be put in place.	<i>Please see response to the comments on "proposed risk management" above.</i>