

Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Report and Risk Management Scope on 2,4,6-tri-tert-butylphenol (CAS RN 732-26-3)

Formal comments made during the 60-day public comment period that took place from May 17, 2008 to July 16, 2008 on the draft screening assessment report and risk management scope on 2,4,6-tri-tert-butylphenol, a substance included in Batch 2 of the substances to be addressed as part of the Chemicals Management Plan Challenge under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), were provided by SI Group and Albemarle Corporation.

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

- Validity of evidence
- Environmental impacts
- Economic considerations

TOPIC	COMMENT	RESPONSE
Validity of Evidence	The emission estimates in the draft screening assessment are neither well described nor verified by actual environmental monitoring data. The exposure estimates are overstated. No further action should be taken on 2,4,6-tri-tert-butylphenol or, if necessary, 2,4,6-tri-tert-butylphenol should be added to the Priority Substances List (PSL) for further assessment, particularly related to emissions and exposure.	It is true that environmental monitoring data are not available for this substance. The exposure scenario does, however represent a reasonable worst case scenario based upon the known uses, volumes and information that supports assumptions and input parameters.
	More data is required in order to conduct a risk assessment.	In the survey conducted under section 71 of CEPA and the accompanying questionnaire for the Batch, industry and other stakeholders were invited to provide specific information that may be used to inform risk assessment and risk management of any substance in the Batch. In addition to the data collected under the section 71 surveys, the screening assessments use the available scientific data from a range of sources including published literature in scientific journals and other international reviews.

		The Government of Canada has stated that the absence of new information will not preclude the Ministers from issuing a decision that safeguards human health and the environment. Thus the process being used for the Challenge substances is not to wait until data gaps are filled, but to act to protect the health and environment of Canadians.
	The water solubility for this substance is “likely at less than 1 mg/L”. There is also a question about the origin of a 35 mg/L solubility value referenced to Japan’s Ministry of International Trade and Industry (MITI).	The solubility values from OSPAR (0.512 mg/L) and the Ministry of International Trade and Industry (MITI) database (35 mg/L) referred to in the comment were included in the draft screening assessment. The 35 mg/L value originated from the Japanese Chemical Inspection and Testing Institute which is run by MITI. A sentence was added to the SAR to reflect a degree of uncertainty with the water solubility of this substance due to the difference between the estimated and experimental values. However, the experimental value will still be given a higher weight in comparison to the estimated value.
	The draft screening assessment document cites one measured study (MITI, 1992), and several modeling estimates for bioconcentration of the substance. Screening estimation methods do suggest that the substance could bioaccumulate, but should be an indication that more testing is needed to refine the assessment.	The weight of evidence strongly supports that this substance is bioaccumulative. The experimental values from the study MITI (1992), the 3 metabolism corrected bioconcentration factor (BCF) and bioaccumulation factor (BAF) values modelled using Arnot and Gobas (2003) as well as the fish BCF modelled using BBM (2008) are all above the bioaccumulation criteria (BCF, BAF $\geq$ 5000). The one model that predicts a lower value (BCFWIN) is likely due to compounds used in the model’s training set having greater metabolic potential than 2,4,6-tri-<i>tert</i>-butylphenol. The Government of Canada has stated that the absence of new information will not preclude the Ministers from issuing a decision that safeguards human health and the environment. Thus the process being used for the Challenge substances is not to wait until data gaps are filled.
	Bioaccumulation values reported in the draft screening assessment are inconsistent with other	These inconsistencies were due to differences in rounding and have been modified to be consistent with other reported values.

	published values.	
Environmental impacts	The amount of 2,4,6-tri-tert-butylphenol that would be released to the environment and thus potentially cause adverse effects is extremely limited. More studies need to be undertaken before risk management is developed that would involve virtual elimination of the substance.	The releases of 2,4,6-tri-tert-butylphenol to the environment are, indeed estimated to be relatively low. The Mass Flow Tool in the draft screening risk assessment is meant to provide a reasonable worse case scenario based upon information submitted in the Section 71 survey and other sources. The anticipated release of 2,4,6-tri-tert-butylphenol is a combination of small releases to different media (i.e. a 0.1% loss to soil, a 1.6% loss to air and a 0.8% loss to water for a total of 2.5%). These releases are anticipated to occur throughout the life cycle of the substance at different stages of use. However, while the estimated releases of 2,4,6-tri-tert-butylphenol are small, the Government of Canada has decided to manage all substances that are concluded to be persistent and bioaccumulative, and inherently toxic (PBiT) that exceed a threshold level (100 Kg) of importation or manufacture. This is because the long term risk of PBiT substances cannot be reliably predicted. Furthermore, since accumulations of such substances may be widespread and are difficult to reverse, a conservative response to uncertainty is justified.
Economic Considerations	A total ban of 2,4,6-tri-tert-butylphenol would impose hardship on the fuel additives industry and its suppliers in that coincidental formation of this substance is very difficult to suppress.	A risk management control instrument will take into consideration socio-economic factors while still protecting the environment. The Government of Canada is in the process of gathering additional information in order to make informed decisions regarding risk management.
	2,4,6-tri-tert-butylphenol is an impurity; the cost to remove the impurity varies by manufacturer but typically adds 5-10% to the cost of the production. The cost to remove this impurity exceeds the benefit from removing the impurity; thus it remains in the final antioxidant products.	This information will be considered in the development of risk management instruments.

