

Summary of Public Comments Received on the Government of Canada’s Draft Screening Assessment Reports for Butane (CAS 106-97-8) containing 1,3 butadiene and Isobutane (CAS 75-28-5) containing 1,3 butadiene

Comments on the draft screening assessment reports for Butane and Isobutane containing 1,3 butadiene to be addressed as part of the Chemicals Management Plan Challenge were provided by Dow Chemical Canada, Chemical Sensitivities Manitoba, and Canadian Environmental Law Association and The Canadian Cosmetic, Toiletry and Fragrance Association

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

- Risk Assessment
- Categorization
- Consumer Products
- Concentration of 1,3-butadiene
- Petroleum stream approach

TOPIC	COMMENT	RESPONSE
Risk Assessment	This assessment does not scientifically address butane or isobutane but rather is an analysis of 1,3-butadiene contained in butane or isobutane.	The assessment was intended to focus on the scientific analysis on which its categorization as a high priority substance was based (classification for carcinogenicity by the European Commission based on the presence of 1,3-butadiene). Screening assessments of butane and isobutane themselves will be conducted in conjunction with the medium priority substances.
	It appears that the assessment proposed that both butane and isobutane, once containing 1,3-butadiene, meet the criteria of section 64 of CEPA 1999. In general terms if a "CEPA toxic" is present in another substance does this now suggest the substance itself is CEPA toxic?	The assessment did not propose butane and isobutane to be “CEPA toxic”; rather it proposed that 1,3-butadiene in butane or isobutane be considered as additional sources of exposure in the context of the risk management approach for 1,3-butadiene. Butane and isobutane themselves will be considered in the medium priority substances.
	The CMP documents stated that the European Union has classified butane and isobutane as Category 1 substances (known to be carcinogenic to humans), when this is the case only when 1,3-butadiene is present at greater than 0.1% in the butane or isobutane.	All current CMP documents (screening assessment report, public summary, etc.) qualify the classification statement to indicate that the European classification was only applicable in the presence of 1,3-butadiene.
	The government is adopting a “safe level” of 1,3-	Although the level of 0.1% 1,3-butadiene was the level for

	butadiene of 0.1% without critical review.	classification as a carcinogen by the European Commission, this classification was only used for priority setting from categorization. In the PSL assessment of 1,3-butadiene and in the screening assessment for butane and isobutane containing 1,3-butadiene, a “safe level” was not established, but risk-based upper-bounds of exposure and margins of exposure were calculated in order to provide guidance for risk management. In the case of the screening assessment, these comparisons indicate that the priority for investigations of options to reduce exposure for these particular exposure scenarios is low to moderate. The risk management strategy focus is on the reduction of 1,3-butadiene exposures through existing risk management practices.
Categorization	Why were butane and isobutene containing 1,3-butadiene included in categorization? The government should set butane and isobutane containing 1,3-butadiene aside indicating that 1,3-butadiene is already CEPA toxic and that butane and isobutane be evaluated outside of the challenge.	One of the methods used to identify substances for categorization was the classifications for carcinogenicity, genotoxicity, reproductive and developmental toxicity by other national/international agencies. This identification was done via CAS registry number matching. Although butane and isobutane were flagged, the classification by the European Commission applies only in the presence of > or = 0.1% 1,3-butadiene. Therefore, the scope of the challenge assessment was to characterize exposure to 1,3-butadiene from its presence in butane and isobutane. Butane and isobutane themselves will be considered in the medium priority substances.
Consumer Products	It should be clarified that 1,3-butadiene is not intentionally used in personal care products and that multiple use scenarios for consumer products should be considered in relation to ongoing risk management activities for 1,3-butadiene.	The assessment concluded that exposures to 1,3-butadiene from consumer products would be considered in relation to ongoing risk management activities for 1,3-butadiene. The assessment report did not identify exposure from consumer products as a significant source of exposure. The risk management objective is to continue to mitigate the risks associated with the prominent sources of exposure to 1,3-butadiene namely; vehicle and engine emissions, industrial emissions, indoor air levels and residential wood burning. Although 1,3-butadiene is not intentionally added to personal care products, as a precautionary measure it will be listed on the Cosmetic Ingredient Hotlist as a prohibited substance and its

		residual levels will be restricted to less than 0.1% in butane and isobutene.
Concentration of 1,3-butadiene	The residual concentration of 1,3-butadiene in butane or isobutane of up to < 1% w/w in some consumer products would be more accurately represented as likely to be < 0.1% w/w for cosmetics and personal care products.	Although the typical upper level for 1,3-butadiene in butane and isobutane was reported to be < 0.1% w/w for cosmetics and personal care products, reported levels did range up to < 1% w/w.
Petroleum stream approach	There has been limited information on what management activities will be undertaken through the Petroleum Sector and the impression was that this would be a non-regulatory approach. Therefore there was concern that end-use fuels containing butane/isobutane and 1,3-butadiene would not be adequately addressed under the sector approach.	The Petroleum Sector Approach will follow the CEPA framework for assessment and management of substances (e.g. draft assessments released for public comment, final assessment and risk management approach, etc.). Appropriate risk management will be taken based on the risk assessments.