Summary of Public Comments received on the Challenge substance BHA (CAS 25013-16-5) Draft Screening Assessment Report and Risk Management Scopes for Batch 8

Comments on the draft screening assessment report for BHA to be addressed as part of the Chemicals Management Plan Challenge.

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

- Data gaps and deficiencies
- Exposure
- Risk assessment conclusion

TOPIC	COMMENT	RESPONSE
Data gaps and deficiencies	Possible endocrine disruption effects are not dealt with adequately in the Screening Assessment Report.	Possible endocrine disruption effects are now described in the Screening Assessment Report in further detail, drawing upon more studies.
	BHA should not be described as a 'suspected' endocrine disruptor. Endocrine disrupting effects should be taken into account in the ecological assessment of BHA. Endocrine disrupting substances can be addressed within the existing Canadian legislation and regulatory frameworks. Current risk assessment/management approaches in Canada can be used to identify effects produced via endocrine disrupting mechanisms.	Due to the high degree of uncertainty associated with the ecological relevance of the current endocrine disruption research on BHA and the conflicting results related to estrogenic effects, the assessment uses conventional toxicological endpoints of concern (i.e., impaired growth and mortality) together with assessment factors to protect against possible subtle effects of long-term exposure to characterize the ecological risk..
Exposure	Concentrations of BHA in water, drinking water, and soil from various Canadian locations should be established. Relying on levels found in the United States to determine exposure is not appropriate for Canada. Releases of BHA to the environment from waste disposal and other release sources needs to be established.	While there were no data on levels of BHA in Canada, exposure levels in the United States are expected to be reasonably close to those in Canada. In addition, while environmental concentrations of BHA in water bodies in United States were included in the SAR, two conservative model scenarios, one for consumer released (mega flush), and one site-specific industrial release scenario, that considered the release of BHA into the Canadian environment were also presented.
	Some margins of exposure (MOE) were low,	The margin of exposure of greater than 500 is considered to be

	specifically that for children.	conservative and sufficiently protective of human health.
	Cumulative MOEs due to drinking water intake, food, and consumer products were not calculated.	Since drinking water/ food and personal care products have different routes of exposure, the toxicities are not directly comparable and a cumulative MOE would not be meaningful.
	MOEs were calculated using mean values, not maximum values, as in other assessments.	MOEs are calculated using upper bound values (the greatest values). This is consistent in all assessments. A probabilistic exposure assessment was used to generate mean values for different age groups. The upper bound mean values were used to estimate the MOEs.
	Attention needs to be paid to determining vulnerable population exposures and effects on vulnerable populations, including fetal development.	In the exposure assessment and calculation of the MOEs, different age groups were considered and exposures to BHA for infants and young children were calculated. As well, the assessment of potential intakes incorporated contributions from food and consumer products consumed or used by children.
	Given its potential for carcinogenicity and endocrine disruption, as well as some low MOEs, BHA should be proposed as “toxic” under CEPA, 1999 on the basis of precaution, and added to CEPA Schedule 1.	Tumours were observed at the site of contact in animals following oral exposure, in a structure for which there is no counterpart in humans. The International Agency for Research on Cancer has concluded that the mechanism by which BHA induced carcinogenicity in experimental animals is not relevant to humans. Endocrine effects were secondary effects in animals, resulting from effects upon the thyroid gland and sex hormones following exposure to high doses. The margins are considered protective for human health; consequently there is no need to invoke precaution.