Summary of Public Comments received on the Challenge substance Butanone oxime (CAS 96-29-7) Draft Screening Assessment Report and Risk Management Scope document for Batch 7

Comments on the draft screening assessment report for Butanone oxime to be addressed as part of the Chemicals Management Plan Challenge were provided by Inuit Tapiriit Kanatami (ITK), Chemtura, Nuco and Honeywell.

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

- Uses
- Releases to the Environment
- Persistence and Bioaccumulation
- Ecological Toxicity
- Exposure
- Human Health Effects
- Proposed Risk Management
- Risk Management Scope

TOPIC	COMMENT	RESPONSE
Uses	The difference between the amount imported and used in one year is substantial and an explanation is needed to account for this difference.	Difference in quantities imported and used can be attributed to several factors, including: 1) different thresholds for import and use in the Notice; 2) use, as defined in the Notice, which excludes sale, distribution and repackaging of a substance, and 3) storage of a substance for later use i.e., for the following calendar year, which wouldn't be reportable.
Releases to the Environment	The amounts of butanone oxime released into the environment is virtually unknown. However, the assessment expects that the total industrial releases of butanone oxime are low. Such expectations are unfounded.	Based on the quantity of butanone oxime reported in the reporting year of 2006, the concentrations of butanone oxime in the aquatic compartment was modelled and the results indicated that the exposure potential from the environmental media was expected to be low.
	There should be further research on releases and disposal of butanone oxime.	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. The process being used for Challenge substances is to act on what we know now, rather than waiting until data gaps are filled. This does not

		preclude the government from taking action in the future based on new information.
	Releases of butanone oxime to all environmental media should be reported.	The Government of Canada will consider proposing the addition of substances that meet the criteria under section 64 of CEPA 1999 to the NPRI's substances list. Changes to the substance list result from the NPRI consultations process and may include the addition, modification or removal of substances as well as changes in the thresholds at which they must be reported.
Persistence and Bioaccumulation	The potential impact for long-range transport on communities, for example northern communities, needs to be examined.	Butanone oxime is only moderately persistent in air, and has low potential of bioaccumulation and only moderate acute toxicity to aquatic organisms. Given the moderate long-range transport potential, there is no ecological concern.
	Very limited empirical data was available to estimate approximate half-lives in these media. There were contradictions within the model predictions.	The draft assessment has acknowledged that there were contradictions within model predictions. The weight of evidence was given to the experimental and modeled data suggesting relatively rapid degradation in soil, sediment and water, but persistent in air.
Ecological Toxicity	There is a need to re-examine the ecotoxicity effects of butanone oxime, as the draft assessment was lacking in appropriate data. This would include re-assessing the findings on bioaccumulation.	Both valid empirical measures and model data for bioaccumulation and aquatic toxicity have been included in the draft assessment. They are considered to be sufficient and appropriate to conclude that bioaccumulation potential is low, and the aquatic toxicity potential of butanone oxime is low to moderate.
	There was no toxicity data for the organisms in the soil or sediment. The significance of soil and sediments as important media of exposure is not well addressed by the effects data available.	The ecological assessment has focused on the substance in the water because it is expected that concentrations in receiving waters near industrial sources, and the water compartment is potentially impacted to the greatest extent.
Exposure	Concentrations within Canadian environmental media, specific consumer products, and food should be established. The assumption that there is no exposure through food must be tested.	Based on the quantity of butanone oxime reported in the reporting year of 2006, the concentrations of butanone oxime was modelled and the results indicated that the exposure potential from the environmental media was expected to be low. Although concentrations were not identified for environmental media, information on uses and sources, and physical-chemical properties of the substance indicate that exposure of the general population form environmental media is likely to be low. Available

		information on concentrations in consumer products were reported in the assessment. Butanone oxime is found in some printing inks used in the manufacture of food packaging materials but it does not have direct contact with food. Therefore, no exposure via food is expected.
	The draft screening assessment does not take into account vulnerable populations nor does it account for occupational exposures.	The screening assessments are based on consideration of the available data. The conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada, and do incorporate specific exposure estimates for Canadians of different ages. If information were available suggesting a specific sub-population would be vulnerable, that information would be considered in the assessment. . Hazard information obtained from occupational settings, in particular data from epidemiological investigations, is considered in the assessments. The information developed through the Chemicals Management Plan may be used to inform decisions concerning additional actions to minimize exposure to workers. The Government of Canada is working to communicate results to appropriate occupational health and safety groups.
	It may be useful to consider the industrial exposure to Butanone oxime and the measurement of levels produced during the manufacture and uses stage .	Information submitted on air concentrations of butanone oxime following simulated paint scenarios have been incorporated into the screening assessment.
Human Health Effects	Additional carcinogenicity data, beyond the current inhalation carcinogenicity data, should be acquired.	The Government of Canada has stated that the absence of new information will not preclude the Ministers from taking action that safeguards human health and the environment. The available carcinogenicity data was considered adequate to characterize risk to human health. The uncertainties in the available hazard information are documented in the screening assessment. The limited information on toxicity via the oral and dermal routes in noted.
	The threshold approach for assessing carcinogenicity in the assessment should be replaced by a non-threshold approach and also exposure from other potential carcinogens should be assessed together with that of butanone oxime.	Consideration of the available information indicates that butanone oxime is not likely to be genotoxic. Accordingly, although the mode of induction of tumours is not clear, the tumours observed are not considered to have resulted from direct interaction with genetic material. Therefore a threshold approach is used to assess

		risk to human health. The proposed risk management activities focus on minimizing the risks identified in the screening assessment, based on the information available.
	The confidence in the toxicity database for butanone oxime is not low to moderate based on reproductive/developmental toxicity studies by the oral route.	The overall confidence in the toxicity database for butanone oxime is considered to be low to moderate. Although adequate reproductive/developmental toxicity studies by the oral route of exposure were available, route-specific studies for these and other endpoinds were not available and this decreased confidence in the toxicity database.
	The lack of dermal studies should not result in a low to moderate confidence of the toxicity database, as stated in the screening assessment. Toxicity following repeated dermal exposure would be expected to be similar to that observed following repeated oral and inhalation exposure.	The overall confidence in the toxicity database for butanone oxime is considered to be low to moderate. Lack of route-specific studies for several endpoints decrease confidence in the toxicity database.
Proposed Risk Management	Efforts should be made to seek potential substitution with safer alternatives.	No information on alternative technologies was submitted and no safer alternatives have currently been identified.
Risk Management Scope	The impact of the disposal of products containing butanone oxime and potential releases from disposal methods, whether through incineration or in other wastestreams should be addressed in the final assessment and in the risk management approach.	The Government's proposed risk management activities focus on minimization of the risks identified in the risk assessment based on the information available. These proposed conclusions are based on the available information supplemented by new information during the public comment period. If an identified risk cannot be discounted, a precautionary approach is taken to protect the health and environment of Canadians.