Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Reports and Risk Management Scope documents for Diethyl sulfate (DES) (CAS 64-67-5) and Dimethyl Sulfate (DMS) (CAS 77-78-1)

Comments on the draft screening assessment reports and risk management scope documents for Diethyl sulfate and Dimethyl sulfate 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 STORM Coalition, and CEPA ICG.

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

- Risk Assessment
- Exposure
- Uses and Emissions
- Risk Management

TOPIC	COMMENT	RESPONSE
Risk Assessment	Two commenters noted that the assessment considers effects of the isolated chemical but should also consider possible synergistic effects when exposure is part of mixture of other chemicals.	For screening assessments, the available information on interactive effects with other chemicals is generally insufficient for risk assessment purposes. However, if available this information would be considered for use in the assessment.
	Two commenters suggested the Government should expand the scope of the assessments to consider the impacts of exposure on vulnerable sub-populations.	The Challenge screening assessments are based on considerations of the available data. The various conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada. Additionally, if information is available which suggests that a specific sub-population would be particularly vulnerable, this information would be considered in the assessment.
	New data is needed for diethyl sulfate on the inhalation route (epidemiology or animal studies) since this is the most relevant route of exposure.	The screening assessment is based on the collective information currently available for determination of the critical health effects. This information could include data collected under the section 71 surveys, publicly available scientific data from a range of sources including published literature in scientific journals, as well as 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 on what is known currently. Uncertainties in the dataset are outlined in the screening assessment and are taken into consideration when characterizing risk.
	Two commenters suggested the NPRI threshold might not be adequate to capture the releases of the substances.	Any party (person, government or organization) in Canada may submit a proposal to Environment Canada for changes to the National Pollutant Release Inventory (NPRI) program. 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.
	One commenter suggested the screening assessments do not provide references for the various Health Canada policies applied with respect to the challenge (non-threshold carcinogenicity, framework for conducting screening assessments, weigh of evidence decisions, etc.). These references should be included in the assessments.	The overall process followed in the evaluation of existing substances is outlined in the documents which are publically available. Consistent with the Ministers' Notice of Intent (December 9, 2006), Health Canada considers that evidence of carcinogenicity (i.e., classification by one or more international/national agencies), in the absence of a fully elucidated mode of action analysis, is sufficient to propose a conclusion that there is a probability of harm at any level of exposure and that the criterion in paragraph 64*(c)* of the *Canadian Environmental Protection Act, 199*9 (CEPA 1999) is met. In the consideration of subsequent risk management action, the measure of risk management proposed is proportional to the level of risk identified in the assessment. It is also important to note that factored into proposed measures are current best environmental stewardship practices, technical feasibility, availability of alternatives, and economics issues.
	One commenter noted that the screening assessments do not indicate whether new toxicity data was submitted under the section 71 survey and whether the new information was considered in the assessment. In addition, it was suggested that additional data on specific toxicity endpoints (i.e.	The screening assessments are based on the collective information currently available for determination of the critical health effects. The collective information could include data collected under the section 71 surveys, publicly available scientific data from a range of sources including published literature in scientific journals, as well as other international reviews. The Government of Canada

	neurodevelopmental toxicity and endocrine disruptions) be required in order to have a more complete data set for the assessments	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 on what we know currently. Uncertainties in the dataset are outlined in the screening assessment and are taken into consideration when characterizing risk.
	One commenter suggested that diethyl sulfate should not be considered CEPA "toxic" since there does not appear to be any exposure to Canadians.	Due to uncertainties associated with the exposure dataset for DES, the screening assessment used conservative assumptions, in accordance with the application of a precautionary approach as required by CEPA 1999. Using these conservative estimates, Canadians' exposure is expected to be low to negligible. However, the critical effect for DES is considered not to have a threshold of exposure, and in such cases, it is assumed that there is a probability of harm to human health at any level of exposure. Therefore, the screening assessment concludes that DES "may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health."
Exposure	Two commenters suggested that the assessment should consider exposure of workers in industrial facilities, wholesale operations, and trades because exposure in the workplace may be prolonged and concentrated. Risk management actions should minimize occupational exposure.	Exposure of the general population to chemicals through environmental media (e.g., food, ambient air, soil, consumer products) is taken into account in developing both the screening assessment and risk management scope documents. Other factors, such as the impact on vulnerable populations, are also considered. Hazard information obtained from occupational settings, in particular data from epidemiological investigations, is considered in the risk assessment. The information developed through the Chemical Management Plan (CMP) process may be used to inform decisions concerning additional actions to minimize exposure to workers. CMP is working to communicate results to appropriate occupational health and safety groups.
	One commenter suggested exposure data should reflect combined exposure from all sources of Diethyl sulfate.	In the screening assessment, combined exposures from multiple sources are considered in the derivation of exposure estimates from environmental media (air, soil, water, etc.)

	Two commenters suggested that exposure data for dimethyl sulfate should reflect cumulative exposure and include emission from oil-fired power plant	Currently available data do not permit quantification of emission from this sector.
	One commenter noted that the reporting threshold for dimethyl sulfate on manufacturing quantity may be too high.	This manufacture reporting threshold of 100 kg is the same as that established for the creation of the Domestic Substances List under CEPA.
Uses and Emissions	Due to the multitude of uses of these substances in the fabrication of various industrial and consumer products, releases may occur to waste streams and to all media. It was noted that there was no mention in the assessment of DES and DMS levels in waste streams.	DES and DMS are used principally as intermediate agents, which implies that they are transformed in order to manufacture other products. Therefore, little to no amount of these substances is expected to be found in these products. Any potential residual amount which may find its way into the environment or waste streams will likely be quickly hydrolyzed as illustrated by very short half-lives in both air and water.
	There is no data on emissions to waste streams or effluent. Monitoring data is needed to track releases and disposal of these substances to the environment.	The assessment is based on currently available information using the current state of the science. No data on emissions to waste streams or effluent were identified. The National Pollutants Release Inventory is the principal source of data regarding the release and disposal of DES and DMS in the environment at this time.
	More empirical information on the presence of these substances in the environment is needed before concluding whether it is toxic to aquatic organisms.	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 environments. Thus the process being used for the Challenge substances is not to wait until data gaps are filled, but to act on what we know currently. The assessment is based on available information using the current state of the science. No relevant empirical information on the presence of DES or DMS in the environment was identified. The assessment's conclusion on potential harm to aquatic organisms is based on the expectation that DES and DMS undergo rapid hydrolysis in the environment and have low inherent aquatic toxicity. .
	Monitoring data are needed to track releases and disposal of these substances to the environment.	The assessment is based on currently available information using the current state of the science. Categorization was completed in 2006. Further research done during the subsequent screening assessment phase indicated that theses substances are not

		persistent in air due to rapid hydrolysis, and therefore are not candidates for long-range transport.
	The conclusion regarding the bioaccumulation potential of the substance was based solely on modelled data.	The assessment is based on available information using the current state of the science. Since there was no experimental data available, models were used to evaluate this characteristic.
	No evaluation of the potential effects on non-aquatic organisms has been conducted.	No relevant toxicity data regarding non-aquatic organisms was identified. However, non-aquatic organisms are not expected to be at risk due to rapid hydrolysis of the substances in air and water which limits exposure.
Risk Management	The risk management scope should articulate more definitive action for management of DES. The government should suggest a few risk management instruments and initiate early stakeholder dialogue.	The risk assessment concluded that exposure of Canadians to DES is expected to be negligible. Therefore , the appropriate management of this substance is for the government to be informed of any proposed future uses, as stated in the scope.
	Health Canada should regulate DES under existing departmental regulations.	As noted above, the risk assessment concluded that exposure of Canadians to DES is expected to be negligible. Therefore , the appropriate management of this substance is for the government to be informed of any proposed future uses, as stated in the scope. As a precautionary measure, DES and DMS will also be consideration for listing as prohibited substances to the Cosmetic Ingredient Hotlist.
	There are no data on releases to waste streams or effluents, but consideration should be given to disposal of many products containing DES or DMS as these products contain other toxics.	Because the presence of DES or DMS in finished products is expected to be minimal and due to the fact that it is anticipated to hydrolyse rapidly in aqueous media, waste streams would be an unlikely source of exposure to DES or DMS. Potential exposure to other toxic substances in finished products is beyond the scope of the current exercise.
	There is concern that potential releases of DMS from fossil-fuel power plants may be a source of population exposure.	There are no data available to support his supposition, and newer technology employed in power plants plus the rapid hydrolysis of DMS in the air, would render exposure from this source unlikely.
	The Government of Canada should prohibit the presence of DES and DMS in consumer products, cosmetics, pesticides, agricultural products, natural health products, and pharmaceuticals. The Government of Canada should also minimize the	Based on the absence of data indicating the presence of these substances in these products, and also the circumstances of their use in manufacturing these products, exposure to these substances is anticipated to be negligible. However, as a preventative measure, DES and DMS are being considered for addition to the

	presence of these substances in and investigate alternatives for dyes and textiles.	Cosmetic Ingredient Hotlist.
	Because DES and DMS are carcinogens, there should be no threshold for reporting their releases under the NPRI.	With some exceptions, the NPRI specifies release-reporting thresholds for all categories of toxic substances, including carcinogens. Those subject to lower or no thresholds for reporting are deemed so because of properties that enhance their probability to cause harm.
	Occupational exposure limits for DES and DMS should be reviewed and subject to government management.	Exposure of the general population to chemicals through environmental media (e.g., food, ambient air, soil, consumer products) is taken into account in developing both the screening assessment and risk management scope documents. Other factors, such as the impact on vulnerable populations, are also considered. Hazard information obtained from occupational settings, in particular data from epidemiological investigations, is considered in the risk assessment. The information developed through the CMP process may be used to inform decisions concerning additional actions to minimize exposure to workers. CMP is working to communicate results to appropriate occupational health and safety groups.
	Ambient air limits should be set for DES and DMS.	In the absence of measured ambient data in Canada or elsewhere and indications that industrial releases would be negligible for these substances, a requirement for ambient air limits is not evident.
	Material Safety Data Sheets (MSDS) should disclose the presence of these substances regardless of concentration, and they should reflect government assessment work.	Material Safety Data Sheets are in place for both DES and DMS which incorporate recent toxicological data. The *Controlled Products Regulations* established under the *Hazardous Products Act* requires dimethyl sulfate and diethyl sulfate to be disclosed on the Material Safety Data Sheet that must accompany workplace chemicals when they are present at a concentration of 0.1% or greater as specified on the Ingredient Disclosure List