

Summary of Public Comments received on the Challenge substance DEGME (CAS RN 111-77-3) Proposed Risk Management Approach document for Batch 3

Comments on the Proposed Risk Management Approach document for DEGME to be addressed as part of the Chemicals Management Plan Challenge were provided by Dow Chemical Canada, the Canadian Environmental Law Association, Chemical Sensitivities Manitoba, Radiator Speciality Company, Learning Disabilities Association of Canada, and Canadian Vehicle Manufacturers Association. The table contains a condensed version of each comment and a response in non-technical terms.

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

- [Alternatives](#)
- [Risk management](#)
- [Instrument development](#)
- [Exposure risks](#)

TOPIC	COMMENT	RESPONSE
Alternatives	It should not be assumed that substitutes are available until a comprehensive alternatives assessment is conducted.	Proposed risk management approaches consider alternative technologies, methods, and substances through consultation with affected stakeholders.
	The government should send out a call to identify alternatives and develop an assessment process to find effective, safe, and available alternatives.	Information on alternatives was requested through the Challenge Questionnaire, and may be submitted during public comment periods. Risk Management Approach documents also contain available information on alternatives. Further consideration of alternatives will occur as needed during the instrument development process.
	Restrictions on use of DEGME may increase use of 2-ethoxyethanol acetate (2-EAA), a more harmful substance that is not regulated under section 64 of the CEPA. DEGME had previously replaced 2-EEA.	The risk assessment concluded that DEGME is entering the environment in such a way that it may be a danger to human life or health in Canada. It was determined that DEGME (in Batch 3) does not enter the environment such that poses a danger to human life or health in Canada. The Significant

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		New Activity provisions of CEPA have been applied to DEGME, therefore a Significant New Activity Notification will be required for any new uses of DEGME to address changes or increases in future uses.
	The government should phase out DEGME in industrial applications, food contact packaging & materials, cleaners, consumer products, and cosmetics.	Risk management of DEGME is based on the Screening Assessment Report. The Government of Canada has added DEGME to the <i>Cosmetic Ingredient Hotlist</i> to address its use in cosmetics, which is an administrative tool that provides guidance as to which substances are subject to the cosmetic safety provisions of Section 16 of the <i>Food and Drugs Act</i> .
Risk management	What will be the <i>de minimis</i> threshold for DEGME if it is added to the <i>Cosmetic Ingredient Hotlist</i> ?	The Government of Canada has added DEGME to the <i>Cosmetic Ingredient Hotlist</i> to address its use in cosmetics, which is an administrative tool that provides guidance as to which substances are subject to the cosmetic safety provisions of Section 16 of the <i>Food and Drugs Act</i> .
Instrument Development	Risk management instruments should be tailored to the needs of individual product groups, such as cosmetics, latex paints, paint remover, etc.	The Government of Canada works to develop risk management options specific to particular product groups and sectors. Risk management options vary among sectors.
	Proposed risk management of DEGME is conducted under the <i>Food and Drug Act</i> and the <i>Hazardous Products Act</i> . Therefore, why should it be added to Schedule 1 of CEPA 1999?	For Substances categorized under section 73 and assessed under section 74 of CEPA 1999, if it is concluded that the substance meets one or more criterion under Section 64 of the Act, it may be recommended for addition to the List of Toxic substances in Schedule 1 as outlined in s77 (2)(c) of the Act. Each substance is then risk managed under the Act or Acts that are most appropriate for that substance, which may include Acts other than CEPA 1999.

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	Certain Canadian risk management actions listed in section 6.1 in the Risk Management Approach should be considered as instruments for DEGME.	The actions listed in Section 6.1 of the risk management approach as well as additional risk management of DEGME are both required for adequate protection of human health in Canada.
	DEGME risk management should emulate the approach in the <i>2-butoxyethanol Regulations</i> , i.e. concentration limits in various commercial and consumer products designed for indoor use.	A number of risk management tools will be considered in the instrument development process, including regulations similar to those developed for the risk management of 2-butoxyethanol under CEPA 1999.
	There should be an exemption from regulation for all uses of DEGME that involve outdoor use or use where the chemical is introduced into fuel and combusted.	Any exemptions, where appropriate, will be considered during the development of the risk management instrument.
Exposure risks	Information on harmful substances found in direct-contact food packaging should be provided by the food packaging industry. It should be determined if DEGME is present in food packaging before the Government implements action in this sector.	The Risk Management Approach requests data on DEGME residuals found in direct food contact packaging submissions. In the absence of information on the presence of DEGME in direct-contact food packaging ink, it is expected that most, if not all of it will evaporate as it dries. As such, exposure risks are very low since residuals of DEGME are negligible. Levels of DEGME in food packaging continue to be monitored.
	Canada should consider the effects of DEGME use in the pulp and paper industry, and establish maximum permissible limits for presence in water and food, similar to those used in the Netherlands.	Information shows that there are low volumes of products containing DEGME in Canadian pulp and paper facilities. Therefore release of DEGME in effluent from Canadian pulp and paper facilities is negligible. The quality of effluents from all Canadian pulp and paper facilities are regulated under the <i>Canadian Pulp and Paper Effluent Regulations</i> .
	The government should take action to eliminate DEGME in jet fuel.	DEGME is used as an anti-ice additive in aviation turbine fuel and is fully combusted in jet engines. Therefore release of DEGME from this use is not a significant source of human exposure and does not require risk management actions.

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	<p>The margins of exposure from the Screening Assessment Reports are large enough to be deemed adequately protective.</p> <p>This could prompt the regulated community to question the need for a risk management instrument.</p>	<p>DEGME may potentially impact the pre-natal and post-natal development of children; therefore, a precautionary approach is deemed appropriate. The Government concluded that DEGME enters the environment in such a way that it may be a danger to human life or health in Canada.</p> <p>Studies conducted on the absorption of DEGME through the skin indicate developmental toxicity in animals. Margins of exposure during regular use of consumer products may be greater than anticipated in lab studies; therefore, a measure of precaution is appropriate when using such data to decide upon risk management to protect human health.</p>