



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Ethanol, 2-(2-methoxyethoxy)

(DEGME)

Chemical Abstracts Service Registry Number (CAS RN):
111-77-3

Environment Canada
Health Canada

March 2009

CanadaThe wordmark for Canada, with a small red maple leaf icon integrated into the letter 'a'.

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This proposed risk management approach document builds on the previously released risk management scope document for DEGME, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations*, and “inherently toxic” (iT) to humans or other organisms; or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets the definition of “toxic” set out in section 64 of CEPA 1999.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comment, profiles of batches containing 15 to 30 high-priority substances.

In addition, the information-gathering provisions under section 71 of CEPA 1999 are being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance Ethanol, 2-(2-methoxyethoxy), Chemical Abstracts Service Registry Number (CAS RN)¹ 111-77-3, referred to throughout this document by “DEGME,” was included in Batch 3 of the Challenge under the Chemicals Management Plan.

¹ CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior written permission of the American Chemical Society.

1.2 Final Screening Assessment Report Conclusion for DEGME

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for DEGME on March 7, 2009, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that DEGME is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Based on the information presented in the final screening assessment (Canada 2009), it is proposed that DEGME is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.

Based upon the potential inadequacy of the margins of exposure between conservative estimates of exposure to DEGME during use of consumer products via dermal contact and critical effect levels, particularly for developmental toxicity, in experimental animals, it is concluded that DEGME be considered as a substance that is 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.

It is therefore concluded that DEGME does not meet the criteria in paragraphs 64(a) or 64(b) of CEPA 1999, but it does meet the criteria in paragraph 64(c) of CEPA 1999.

The final screening assessment report also concluded that DEGME does not meet the criteria for persistence and does not meet the criteria for bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of DEGME in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for DEGME, refer to the final screening assessment report, available at www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_3_e.html

1.3 Proposed Measure

Following a screening assessment of a substance under section 74 of CEPA 1999, a substance may be found to meet the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Ministers proposed to recommend the addition of DEGME to the List of Toxic Substances in Schedule 1 of CEPA 1999. As a result, the Ministers will develop a regulation or instrument respecting

preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

The final screening assessment report did not conclude that DEGME meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, DEGME will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach, to prevent or minimize its release into the environment.


2. BACKGROUND

2.1 Substance Information

DEGME is part of the chemical grouping organics and the chemical sub grouping glycol ethers.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for DEGME.

Table 1. Identity of DEGME

Chemical Abstracts Service Registry Number (CAS RN)	111-77-3
DSL Name	Ethanol, 2-(2-methoxyethoxy)-
National Chemical Inventories (NCI) names²	Ethanol, 2-(2-methoxyethoxy)- (TSCA); 2-(2-Methoxyethoxy)ethanol (EINECS)
Other names	Diethylene glycol monomethyl ether; 2-(2'-Methoxyethoxy)ethanol; 2-(2-Methoxyethoxy)ethan-1-ol; 2-Hydroxyethyl 2-methoxyethyl ether; Diethylene glycol methyl ether; Diethylene glycol monoethyl ether; Diglycol monomethyl ether; Dowanol DM; Ektasolve DM; Ethanol, 2,2'-oxybis-, monomethyl ether; Hicotel CAR; Hisolve DM; Methyl Dioxitol; Methyl diethylene glycol
Chemical group (DSL stream)	Organics
Chemical sub-group	Glycol ethers
Chemical formula	C ₅ H ₁₂ O ₃
Chemical structure	
SMILES	O(CCOC)CCO

² (Toxic Substances Control Act Chemical Substance Inventory); ASIA-PAC (Combined Inventories of Asia-Pacific Region); NZIoC (The New Zealand Inventory of Chemicals).

National Chemical Inventories (NCI). 2007: AICS (Australian Inventory of Chemical Substances), ECL (Korean Existing Chemicals List), EINECS (European Inventory of Existing Chemical Substances); ENCS (Existing and New Chemical Substances); PICCS (Philippine Inventory of Chemicals and Chemical Substances); TSCA (Toxic Substances Control Act Chemical Substance Inventory); ASIA-PAC (Combined Inventories of Asia-Pacific Region); NZIoC (The New Zealand Inventory of Chemicals).

Molecular mass	120.15 g/mol
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3. WHY WE NEED ACTION

3.1 Characterization of Risk

Based principally on the weight-of-evidence classification of DEGME by the European Commission as a Category 3 substance due to its developmental toxicity (ESIS 2007) and an assessment prepared by the European Union (EURAR 2000), and on consideration of the available relevant data, the critical effects for characterization of risk to human health for DEGME are developmental and reproductive toxicity and hematological effects. Therefore, margins of exposure are derived between lowest exposure levels associated with induction of these effects and conservative estimates of population exposure to DEGME. The principal source of exposure to DEGME in the general population is expected to be through inhalation and dermal contact during the use of products containing the substance. The main use of DEGME, however, is in jet fuel, and exposure from this source is estimated to be negligible. The maximum concentration of DEGME measured in indoor air considered appropriate for use as a basis for characterizing risk was $39 \mu\text{g}/\text{m}^3$, based on monitoring data collected in Germany between 1989 and 1999 (Schleibinger et al. 2001). Modelling-based estimates of inhalation exposure during use of consumer products containing DEGME are much greater. The conservative upper-bounding estimate of airborne concentration during use of paint remover or stripper is $588 \text{ mg}/\text{m}^3$. In experimental animal studies, no effects were observed in rats exposed to the highest concentration tested of $1060 \text{ mg}/\text{m}^3$ for 90 days (Miller et al. 1985) and no mortality was observed in rats exposed to $200\,000 \text{ mg}/\text{m}^3$ for 1 hour or at a saturated atmosphere of DEGME for up to 8 hours (MB Research Laboratories Inc. 1977a; BASF AG 1960). A comparison between the concentration at which no effects were observed of $1060 \text{ mg}/\text{m}^3$ in a subchronic study and the measured indoor air concentration of $39 \mu\text{g}/\text{m}^3$ results in a large margin of exposure of about 28 000. While using some consumer products containing DEGME could result in peak levels of exposure to airborne DEGME within short time periods, there is a lack of inhalation exposure data associated with developmental toxicity, which appears to be the most sensitive effect. As such,, data are considered inadequate to characterize the risk to health associated effects with exposure to DEGME via inhalation while using products containing this substance.

Dermal contact also contributes significantly to exposure to DEGME during use of some consumer products. Comparison of the highest exposure estimate of the substance for non-cosmetic products used frequently ($0.19 \text{ mg}/\text{kg}\text{-bw}/\text{day}$ from use of floor cleaners used twice a week) to a “marginal” dermal lowest-observed-effect level (LOEL) of $40 \text{ mg}/\text{kg}\text{-bw}/\text{day}$ (EURAR 2000) for minimal effects observed in a 13-week study in guinea pigs (Hobson et al. 1986) results in a margin of exposure of about 210. For floor cleaners, less frequent use would result in lower chronic daily exposure. If the effect level for developmental toxicity is considered—i.e., lowest-observed-(adverse)-effect level, or LO(A)EL, of $250 \text{ mg}/\text{kg}\text{-bw}/\text{day}$ in a short-term study in rabbits (Scortichini et al. 1986)—and compared to the acute per-event exposure ($0.68 \text{ mg}/\text{kg}\text{-bw}$ per event), the margin of exposure for use of floor cleaners would be 370. For some other types of products used less frequently, the margins between the upper-bounding exposure estimates of DEGME (i.e., $11 \text{ mg}/\text{kg}\text{-bw}$ per event for use of floor

sealer) and the LO(A)EL of 250 mg/kg-bw/day for developmental effects from short-term studies is approximately 23. For cosmetic products, based upon available data, modelled exposure estimates for use of multiple products containing the substance could reach 0.27 mg/kg bw/day (Appendix 2). Comparison of this exposure range to the “marginal” LOEL of 40 mg/kg-bw/day or the LO(A)EL of 250 mg/kg-bw/day for developmental toxicity results in margins of exposure of approximately 150 and 925, respectively. In summary, the margins for dermal exposure during use of various consumer products (i.e., floor cleaners, floor sealer, latex wall paint, paint remover or stripper, caulking/sealant, floor polish and cosmetic products) may not be adequately protective to human health in light of the uncertainties in the exposure and hazard databases and the serious nature of the health effects associated with exposure to this substance (i.e., developmental toxicity).

With respect to oral exposure to DEGME, as levels in drinking water and food are expected to be very low, based on available information on its properties as well as its uses and releases, margins between predicted oral intakes in drinking water and the critical effect level in studies in orally exposed experimental animals would be very large (i.e., more than five orders of magnitude). Therefore, potential oral exposure to DEGME from environmental media in Canada is not expected to be of concern (Canada 2009).

4. CURRENT USES AND INDUSTRIAL SECTORS

Based on a survey conducted under section 71 of CEPA 1999, no Canadian companies reported manufacturing DEGME in a quantity greater than or equal to the 100-kg reporting threshold in 2006. However, results from the same survey and from voluntary data submitted by industry indicated that the total quantity of DEGME imported into Canada in 2006 ranged from 1 000 000 to 10 000 000 kg (Environment Canada 2008).

According to responses to a survey under section 71 of CEPA 1999 (Environment Canada 2008), DEGME is mainly used as an additive in jet fuel. It is also a formulant in pest control products for various applications, particularly those used in the pulp and paper industry (Environment Canada 2008; PMRA 2007). DEGME is used as a solvent in floor finishes, in various cleaners and degreasers, and in paints and paint removers (Environment Canada 2008). DEGME is used in some hairsprays, skin creams and cleansers (CNS 2008), and is a fragrance ingredient (CTFA 2008). In addition, this substance may be used as a solvent in the manufacture of inks and can end coatings used in food contact applications. However, the potential daily intake from this latter use is considered to be negligible as the coating is cured, resulting in evaporation of the solvent (e-mail 2008 from Health Canada, Food Directorate, Food Packaging Materials and Incidental Additives Section sent to Health Canada, Existing Substances Bureau, unreferenced). According to the same source, DEGME has been used in cleaners used in the food industry; however, the surfaces that come into direct contact with food must be thoroughly rinsed with potable water; as well, non-food contact surfaces (e.g., floors) must be cleaned under well-ventilated conditions. Thus population exposure from this use is also expected to be negligible. DEGME is additionally used in other applications and settings which are not expected to result in the exposure of the general population of Canada.

Internationally, DEGME is used as a chemical intermediate (Lewis 2007); a metal solvent for mineral oil-soap and mineral oil-sulfonated oil mixtures; a solvent for dyes, nitrocellulose, resins

and lacquers; for setting the twist and conditioning of yarns and cloth (EURAR 2000); as a component of hydraulic fluids (Verschuere 2001; Lewis 2007); as a solvent for solvent-based silk-screen printing inks, stamp pad inks, ballpoint and felt tip writing pen inks; in pastes used in printing cellulose acetate and polyester fabrics; and as a solvent and coupling agent for vat dyeing fabrics, rust removers, aluminum brighteners, and paint and varnish removers (Dow 2004; EURAR 2000). DEGME is used in water- and solvent-based paints and varnishes and as a component of floor cleaners, sealants, polishes, and in windshield washer fluid (EURAR 2000; HPD 2008). It is also used as a coupling agent for making miscible organic-aqueous systems and as a raw material for plasticizers (EURAR 2000). Finally, DEGME is used as a deactivator and stabilizer for agricultural formulations used before crops emerge from the soil (Dow 2004; US EPA 2006); and as a solvent for pharmaceutical manufacturing (EURAR 2000; Canada 2009).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

Information reported under section 71 of CEPA 1999 indicated that between 10 000 and 100 000 kg of DEGME were released into water in 2006. The same range (10 000 to 100 000 kg) was released to air (Environment Canada 2008). Most of the releases into air come from diffuse sources rather than from a single point source. Dispersive releases may also occur as a result of consumer and commercial use of the substance.

Releases of DEGME are not currently reported to the National Pollutant Release Inventory (NPRI 2006) or to the United States' Toxics Release Inventory (TRI 2006).

5.2 Exposure Sources

No measured concentrations of DEGME were available for environmental media in Canada. While DEGME was detected in drinking water in the United States, no concentration data were available (US EPA 1984). Therefore, the model ChemCAN was used to predict concentrations of DEGME in ambient air, water and soil. Modelling was based on data submitted by industry through a section 71 survey (Environment Canada 2008). Data from an indoor air study in Berlin, Germany, were used as a basis for estimating exposure of the Canadian population to DEGME in indoor air (Schleibinger et al. 2001). The upper-bounding estimate of daily intake for the general Canadian population ranges from 6.8 µg/kg-bw (kilogram of body weight) per day for seniors (aged 60 years old and older) to 20.5 µg/kg-bw per day for toddlers (aged 6 months to 4 years old). Intake from indoor air is the predominant source of exposure. The indoor air exposures likely arise as a result of the use of consumer products containing DEGME inside the home. Exposures from ambient air, water and soil are considered negligible in comparison.

DEGME is found in the following consumer products: paint, sealants and caulking, brake fluid, skin cream, skin cleanser, hairspray, paint remover, floor cleaner, floor sealant and floor polish, as well as others listed in Section 4 (Environment Canada 2008; HPD 2008; GE 2003). For products used infrequently, exposure to DEGME through dermal contact is predicted to range up to approximately 11 mg/kg-bw/day per event (for floor sealer), while airborne concentrations

during application could be as high as 588 mg/m³ (for paint stripper/remover). For products used more frequently, such as floor cleaners, dermal exposure is modelled to be approximately 0.19 mg/kg-bw/day, while airborne concentrations are predicted to be about 9 mg/m³. Aggregate dermal exposure to cosmetic products was estimated to total about 0.27 mg/kg-bw/day. The margins for dermal exposure during the use of certain consumer products may not be adequately protective of human health. These products may include paint, sealants and caulking, paint remover, floor cleaner, floor sealant, floor polish and cosmetics, although industry responses to the section 71 survey (Environment Canada 2008) did not confirm all suspected uses of DEGME in consumer products.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

DEGME is subject to

- the *Controlled Products Regulations* established under the *Hazardous Products Act*, requiring any chemical ingredient on the Ingredient Disclosure List to be disclosed on the Material Safety Data Sheet that must accompany workplace chemicals if present above a certain prescribed concentration (Canada 1988)
- the *Pest Control Products Act* List of Formulants, List 2 (Canada 2007a)

Products containing DEGME are subject to

- the *Consumer Chemicals and Containers Regulations, 2001* established under the *Hazardous Products Act*, requiring a consumer chemical product to be classified against criteria based on short-term exposure situations, with the results determining the appropriate product labelling and packaging requirements (Canada 2001)

DEGME is also impacted by the proposed Volatile Organic Compound (VOC) Concentration Limits for Certain Products Regulations (Canada 2008a) and the proposed Volatile Organic Compound (VOC) Concentration Limits for Architectural Coatings Regulations (Canada 2008b). In Ontario, the point of impingement guideline for DEGME is 800 µg/m³ (half hour, odour), and the ambient air quality criteria value is 1200 µg/m³ (24 hr, health) (MOE 2005).

6.2 Existing International Risk Management

- DEGME has been added to Annex I of Directive 76/769/EEC (EC 1976b). The amendment (Decision 1348/2008/EC) sets a maximum concentration of 0.1% DEGME in consumer paints, paint strippers, cleaning agents, self-shining emulsions or floor sealants, effective June 27, 2010 (European Parliament and Council 2008).
- In the European Union, DEGME is banned in cosmetics, according to Directive 76/768/EEC (EC 1976a)
- The Netherlands has established maximum permissible limits of 87 mg/L for total intake of DEGME in food and water, and 7 mg/L in drinking water alone (Bodar 2008).
- DEGME is listed as an inert ingredient in non-food-use pesticides under the U.S. *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA) (US EPA 2008a).

- DEGME is also listed on the United States *Toxic Substances Control Act* (TSCA) Inventory (US EPA 2008b).
- As a volatile organic compound (VOC), DEGME may be subject to the US EPA National Volatile Organic Compound Emission Standards for Consumer and Commercial Products under the *Clean Air Act* (CAA) (US EPA 1998); the Ozone Transport Commission Model Rule (OTC 2006 a,b); and the California Air Resources Board regulations prescribing VOC content limits for antiperspirants, deodorants and consumer products (ARB 2008).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information on alternatives was submitted by industry through section 71 responses or questionnaires. However, other information provided by the paints and coatings industry indicates that substitutes for DEGME in paint strippers/removers are available, as DEGME is not extensively used for this purpose. 2-Butoxyethanol (CAS RN 111-76-2) is a substitute for DEGME in paints and coatings; however this substance has been declared toxic to human health (CEPA 1999, 64(c)) and is listed on Schedule 1 (List of Toxic Substances) of the Canadian Environmental Protection Act (Canada 1999). 2-Butoxyethanol is controlled in consumer products with indoor use through the *2-Butoxyethanol Regulations* (Canada 2006a) as well as through the Environmental Performance Agreement with the Canadian Paint and Coatings Association and Participating Paint and Coatings Companies Respecting 2-Butoxyethanol (Canada 2007b). The Canadian Paint and Coatings Association provided mixed views on whether or not other possible substitutes for DEGME are available in paints and coatings. According to European Commission Decision 1348/2008/EC (European Parliament and Council 2008), consumer products including paints, paint stripper, cleaning agents, self-shining emulsions and floor sealants will not be permitted to contain more than 0.1% DEGME as of June 27, 2007. Furthermore, European Commission documents (EC 2007; European Economic and Social Committee 2008) indicate that DEGME is at this time only rarely used in the aforementioned consumer products in the European Union. Clearly it is therefore possible to either reduce DEGME levels or find a substitute for DEGME in these consumer products.

In the context of jet fuel additives, 2-Methoxyethanol (2-ME, CAS RN 110-49-6) was previously used as a jet fuel de-icer; however it has been concluded toxic according to paragraph 64(c) of CEPA 1999 and is on Schedule 1 of CEPA 1999 and on Schedule 2 of the *Prohibition of Certain Toxic Substances Regulations, 2003* (Canada 2005). DEGME is listed as an alternative to 2-ME in the Regulatory Impact Analysis Statement for the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (2-Methoxyethanol, Pentachlorobenzene and Tetrachlorobenzene)* (Canada 2006b) specifically for the following uses: fuel additives / decontamination agents, chemical intermediates and industrial processing agents / analytical solvents.

7.2 Alternative Technologies and/or Techniques

No information on alternative technologies was submitted by industry.

7.3 Socio-economic Considerations

Socio-economic factors will be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

Socio-economic considerations for DEGME include:

- Based on responses to a 2007 section 71 notice, there are no manufacturers of DEGME in Canada; however, 1 000 000 to 10 000 000 kg of DEGME were imported into Canada in 2006 (Environment Canada 2008).
- The industry sectors to which importers, formulators and users of the substance belong may include but are not limited to: Toilet Preparation Manufacturing (NAICS 325620) and Paint and Coating Manufacturing (NAICS 325510) (Environment Canada 2008).
- DEGME is used in some hairsprays, skin creams and cleansers that are included in the Toilet Preparation Manufacturing industry (NAICS 325620). The revenue of this industry was \$1.8 billion in 2006, with 285 establishments employing approximately 5700 employees (Statistics Canada 2008).
- Canadian annual exports for Toilet Preparation Manufacturing products increased from \$504 million in 1997 to \$1.3 billion in 2007. During the same period, Canadian annual imports rose from \$948 million to \$1.8 billion (Industry Canada 2008).
- The revenue of the Paints and Coating Manufacturing Industry (NAICS 325510) was approximately \$2 billion in 2006 with 273 establishments employing approximately 6,100 employees (Statistics Canada 2008)..
- Canadian annual exports for Paint and Coating Manufacturing products increased from \$302 million in 1997 to \$454 million in 2007. During the same period, Canadian annual imports rose from \$705 million to \$956 million (Industry Canada 2008).

7.4. Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, it is proposed that no risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Environmental or Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed human health objective for DEGME is to reduce exposure of the general population to DEGME to levels that are adequately protective of human health.

8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). The proposed risk management objective for DEGME is to ensure that the concentrations of DEGME in cosmetics and consumer products do not exceed levels that are adequately protective of human health.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Regulations, Instrument(s) and/or Tool(s)

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*,³ and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management regulations, instrument(s) and/or tool(s) were selected using a consistent approach, and took into consideration the information that has been received through the Challenge and other information available at the time.

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management being considered for DEGME is adding DEGME to the Cosmetic Ingredient Hotlist and investigating whether action under the *Hazardous Products Act* is required with regard to consumer products.

9.1.1 Cosmetics

The screening assessment indicates that the margins for dermal exposure to cosmetics may not be adequately protective of human health. Therefore, the government will take action to manage DEGME in cosmetic products, in accordance with section 16 of the *Food and Drugs Act*, which states that no person shall sell a cosmetic product that has in it any substance that may injure the health of the user when the cosmetic is used according to its customary method. The

³ Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

government proposes to achieve this goal through addition of DEGME to the Health Canada Cosmetic Ingredient Hotlist, which is an administrative tool to help cosmetic manufacturers satisfy the provisions of section 16. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations of the Food and Drugs Act*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

9.1.2 Consumer Products

The screening assessment indicates that the margins for dermal exposure to a number of consumer products may not be adequately protective of human health. These products include paint, paint remover, sealant/caulking, floor cleaner, floor sealer and floor polish. Health Canada will investigate whether action under the *Hazardous Products Act* is required with regard to these products. The initial step will involve further characterization of the exposure potential to reduce the uncertainty in the exposure estimates.

9.1.3 Jet Fuel Additive

DEGME is used as a jet fuel additive—in particular as a de-icing agent. As it is consumed in combustion reactions in jet engines (according to a questionnaire submitted by Air Canada Jazz –Environment Canada 2008), and as any release of remaining DEGME would be highly dispersive, this is not a significant source of human exposure. Risk management of DEGME in jet fuel is therefore not required.

9.1.4 Pest Control Products

DEGME is used as a formulant in pest control products. Responses to a section 71 notice (Environment Canada 2008) indicate that pest control products containing DEGME are used predominantly in the pulp and paper industry and that concentrations of DEGME in the final paper products are very low. Full personal protective equipment including use of a respirator, is required for persons handling these pest control products. DEGME is also used as a formulant in four antifouling paint products. Concentrations of DEGME in these products are less than 0.02%. The registration of the only pest control product containing DEGME which has food applications has been discontinued. Therefore, based on the required use of personal protective equipment for pulp and paper applications and the low concentrations of DEGME for other uses, human exposure to DEGME from pest control products is expected to be minimized.

9.1.5 Food Packaging

DEGME may be used as a solvent in the manufacture of inks and can end coatings used in food contact applications; however, the potential daily intake resulting from this use is considered to be negligible as the coating is cured, evaporating the solvent from the surface. It has also been used in cleaners used in the food industry; however, the surfaces that come into direct contact with food must be thoroughly rinsed with potable water, and non-food contact surfaces (e.g. floors) must be cleaned under well-ventilated conditions. Thus population exposure from this use is also expected to be negligible. To ensure that residual levels in food packaging applications remain low, data will be requested on residual levels of DEGME for new food packaging submissions with direct food contact.

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to this substance will be published in the *Canada Gazette*, Part I, no later than March 2011, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope for DEGME, which summarized the proposed risk management under consideration at that time, was published on August 23, 2008, and is available at www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_3_e.html#release2. Industry and other interested stakeholders were invited to submit comments on the risk management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Consultation for the risk management approach will involve publication on March 7, 2009, and a 60-day public comment period.

The primary stakeholders include

- the cosmetics, paints and coatings, cleaning products, and do-it-yourself home products industries
- non-governmental organizations
- Health Canada and Environment Canada

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach	March 7, 2009, to May 6, 2009
Response to comments on the risk management approach	At time of publication of proposed instrument
Consultation on the draft instrument	Summer-Fall 2009
Publication of the proposed instrument	No later than March 2011
Formal public comment period on the proposed instrument	No later than spring 2011
Publication of the final instrument	No later than September 2012

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to May 6, 2009, since the Government of Canada will be moving forward with the risk management of DEGME after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister of the Environment under CEPA 1999 may submit with the information a request that it be treated as confidential. During the development of regulations, instrument(s) and/or tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
Gatineau QC K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 1-800-410-4314 / 819-953-4936
Email: Existing.Substances.Existantes@ec.gc.ca

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