Government of Canada / Gouvernement du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Ethanol, 2-methoxy-, acetate
(2-Methoxyethanol acetate, 2-MEA)

Chemical Abstracts Service Registry Number (CAS RN):
110-49-6

Environment Canada
Health Canada

March 2009

Canada

Table of Contents

1. ISSUE **3**

1.1 CATEGORIZATION AND THE CHALLENGE TO INDUSTRY AND OTHER INTERESTED STAKEHOLDERS 3
1.2 FINAL SCREENING ASSESSMENT REPORT CONCLUSION FOR 2-MEA 4
1.3 PROPOSED MEASURE 4

2. BACKGROUND **5**

2.1 SUBSTANCE INFORMATION 5

3. WHY WE NEED ACTION **6**

3.1 CHARACTERIZATION OF RISK 6

4. CURRENT USES AND INDUSTRIAL SECTORS **6**

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES **7**

5.1 RELEASES TO THE ENVIRONMENT 7
5.2 EXPOSURE SOURCES 7

6. OVERVIEW OF EXISTING ACTIONS **8**

6.1 EXISTING CANADIAN RISK MANAGEMENT 8
6.2 EXISTING INTERNATIONAL RISK MANAGEMENT 8

7. CONSIDERATIONS **8**

7.1 ALTERNATIVE CHEMICALS OR SUBSTITUTES 8
7.2 ALTERNATIVE TECHNOLOGIES AND/OR TECHNIQUES 8
7.3 SOCIO-ECONOMIC CONSIDERATIONS 8
7.4 CHILDREN'S EXPOSURE 9

8. PROPOSED OBJECTIVES **9**

8.1 ENVIRONMENTAL OR HUMAN HEALTH OBJECTIVE 9
8.2 RISK MANAGEMENT OBJECTIVE 9

9. PROPOSED RISK MANAGEMENT **10**

9.1 PROPOSED RISK MANAGEMENT INSTRUMENT 10
9.2 IMPLEMENTATION PLAN 10

10. CONSULTATION APPROACH **11**

11. NEXT STEPS / PROPOSED TIMELINE **11**

12. REFERENCES **12**

This proposed risk management approach document builds on the previously released risk management scope document for 2-MEA, 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-methoxy-, acetate, Chemical Abstracts Service Registry Number (CAS RN)[1] 110-49-6, referred to throughout this document by "2-MEA," 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 2-MEA

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 2-MEA on March 7, 2009, under paragraphs 68(b) and 68(c) of CEPA 1999. The final screening assessment report concluded that 2-MEA is entering or 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.

Based principally on the non-distinguishable intrinsic hazard potential between 2-Methoxyethanol (CAS RN 109-86-4) (2-ME), which is already listed on Schedule 1 of CEPA 1999, and 2-MEA on a wide range of health effects, including reproductive and developmental endpoints for which there may be a probability of harm at any level of exposure, it is proposed that the conclusion on 2-ME under paragraph 64(c) of CEPA 1999 should be expanded and applied to its acetate moiety, 2-MEA. Therefore, it is proposed that 2-MEA meets the criterion in paragraph 64(c) of CEPA 1999.

Based on the information presented in this draft screening assessment, it is proposed that 2-MEA 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.

It is therefore proposed that 2-MEA does not meet the definition of “toxic” as set out in paragraphs 64(a) or 64(b) of CEPA 1999.

The final screening assessment report also proposes that 2-MEA 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. 2-MEA in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for 2-MEA, 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 68 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 2-MEA 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 2-MEA meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, 2-MEA 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.

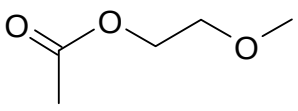
2. BACKGROUND

2.1 Substance Information

2-MEA is part of the chemical grouping discrete organics and the chemical sub grouping esters.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure, and the molecular mass for 2-MEA.

Table 1. Substance identity of 2-MEA

Chemical Abstracts Service Registry Number (CAS RN)	110-49-6
DSL Name	Ethanol, 2-methoxy-, acetate
National Chemical Inventories (NCI) names[2]	Ethanol, 2-methoxy-, 1-acetate (TSCA); 2-methoxyethyl acetate (EINECS)
Other names	Acetate, 2-methoxyethyl; Ethyl glycol, monomethyl ether acetate; ß-Methoxyethyl acetate; 1-Acetoxy-2-methoxyethane; 2-Methoxyethanol acetate; Acetic acid, 2-methoxyethyl ester; Acetyl methyl cellosolve; Ethylene glycol acetate monomethyl ether; Ethylene glycol methyl ether acetate; Ethylene glycol monomethyl ether acetate; Glycol monomethyl ether acetate; Methyl Cellosolve acetate; Methyl glycol acetate
Chemical group (DSL stream)	Organics
Chemical sub-group	Esters
Chemical formula	$C_5H_{10}O_3$
Chemical structure	
SMILES	O=C(OCCOC)C
Molecular mass	118.13 g/mol

[2] National Chemical Inventories (NCI). 2007: EINECS (European Inventory of Existing Chemical Substances); and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

3. WHY WE NEED ACTION

3.1 Characterization of Risk

As there is no distinguishable variation with respect to the profile of toxic effects between 2-ME and 2-MEA, the two chemicals are considered to have similar intrinsic hazard potential and, in light of the more limited database for the acetate, it is considered appropriate to incorporate information on the toxicity of 2-ME in the characterization of risk to human health for 2-MEA. The health effects associated with exposure to 2-ME and 2-MEA are primarily developmental and reproductive toxicity (including severe and irreversible teratogenic effects), with effects being observed at very low doses, often the lowest dose tested in a study. Although analyses of the mode(s) of induction of these effects is beyond the scope of this screening assessment under the Challenge, based on the observation of effects in experimental animals at low exposure levels (in some studies at the lowest doses or concentrations tested) and the genotoxicity profile of 2-MEA, 2-ME and subsequent metabolites (particularly, genetic effects induced in germ cells), it cannot be precluded at this time that interaction with genetic material, for which there may be a probability of harm at any level of exposure, may play a role. In addition, other effects such as those on hematological, immunological and nervous systems, were also observed in experimental animals, as well as in humans exposed to 2-ME or 2-MEA along with other substances in the occupational environment.

In light of rapid conversion of 2-MEA to 2-ME and the common profile of induced critical effects, although exposure to 2-MEA in Canada is expected to be very low, it is considered appropriate to extrapolate the conclusion reached in the PSL assessment for 2-ME (i.e., that, “on the basis principally of its high health hazard potential, 2-methoxyethanol is considered to constitute a danger in Canada to human life or health”) to 2-MEA. (Canada 2008).

4. CURRENT USES AND INDUSTRIAL SECTORS

Based on a survey conducted under section 71 of CEPA 1999, 2-MEA was not manufactured in Canada in the 2006 calendar year. 2-MEA was imported in quantities less than 100 kg/year and was used below the 1000 kg/year threshold (whether alone, in a mixture, in a product or manufactured item). No submission was reported under section 71 of CEPA 1999 to indicate that 2-MEA would be present in consumer products in Canada. Considering that 2-MEA is used neither in the United States nor the European Union, it is likely not present in Canadian consumer products.

Historically, 2-MEA was used most commonly as an industrial solvent. Applications included glues and adhesives used for bonding floor coverings and waterproof surfaces fitted to household fixtures. It has also been used as a solvent for surface coatings such as paints, coatings, varnishes, lacquers for paper and leather, and for acetate adhesives. It had a wide application as a solvent in nitrocellulose, cellulose acetate, gums, resins, waxes, and oils and as a solvent component in textile printing and photographic film as well as in nail polish and dry-cleaning treatments.

There is some evidence that 2-MEA can be used in cosmetics as a solvent and viscosity decreasing agent. No current cosmetic use of 2-MEA has been notified in Canada, while its corresponding alcohol, 2-ME, is currently listed on the Health Canada List of Prohibited and Restricted Cosmetic Ingredient Hotlist in Canada. However, 2-MEA as well as 2-ME are both prohibited in cosmetics in the European Union.

2-MEA is not currently used in food packaging in Canada. However, it is used as a component in the formulation of a cleaner applied on food contact surfaces which are subsequently rinsed with potable water, and as a cleaner on non-food contact surfaces under well-ventilated conditions in food processing plants. (Canada 2008).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

According to data submitted in CEPA 1999 section 71 responses, no significant releases of 2-MEA were identified in the 2006 calendar year. In addition, no manufacture or import of 2-MEA was reported above the reporting threshold of 100 kg (although smaller quantities were reported to be imported). Environment Canada's National Pollutant Release Inventory (NPRI) data from 1994 to 2006 also indicated no reported releases of 2-MEA. Therefore, total industrial releases of 2-MEA to the environment are expected to be negligible (Canada 2008).

5.2 Exposure Sources

No measured concentrations of 2-MEA in Canadian environmental media were identified. According to the National Pollutant Release Inventory (NPRI), there has not been any significant release of 2-MEA in Canada reported since 1994 (Environment Canada 2007). In addition, 2-MEA is not manufactured in Canada and is only imported in very small quantities according to the section 71 submission. Therefore, this substance is not expected to be present in the environment in significant concentrations.

Based on its physical and chemical properties, and since it was not reported to have been released in Canada in significant amounts (Canada 2007), 2-MEA is not expected to be present in any significant concentrations in air, water, soil or sediment. It is also not expected to be present in food.

No submission was reported under section 71 of CEPA 1999 to indicate that 2-MEA would be present in consumer products in Canada (Canada 2007). Considering that 2-MEA is used neither in the U.S. nor the European Union, it is likely not present in many Canadian consumer products. Based on its historical uses, possible routes of exposure to 2-MEA from consumer products may be inhalation of indoor air, although in light of available information on current uses, exposures are not expected to be significant (Canada 2008).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

2-MEA is subject to

- the C*ontrolled Products Regulations* established under the *Hazardous Products Act* (Canada 1988). These regulations require that 2-MEA be disclosed on the Material Safety Data Sheet that must accompany workplace chemicals, when it is present at a concentration of 0.1% or greater as specified on the Ingredient Disclosure List
- reporting under the National Pollutant Release Inventory (NPRI)

6.2 Existing International Risk Management

In the United States, United States Environmental Protection Agency (US EPA):

- under the *Clean Air Act* (CAA), section 111 – new source performance standards (NSPS) list; section 112(b) – National Emission Standard for Hazardous Air Pollutants (NESHAP)
- Air Contaminants (Occupational and Safety Health Act) list
- *Toxic Substances Control Act* (TSCA) section 5(a)(2) – Significant new use rule (SNUR); 8(b) Chemical Inventory
- Known Carcinogens and Reproductive Toxicants (California Proposition 65): developmental, male

In the European Union, the use of 2-MEA in consumer products is prohibited.

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

Propylene glycol methyl ether acetate (PGMEA) CAS RN 108-65-6 was reported as a substitute for 2-MEA (EGMEA) in the production of commercial photoresist for the semiconductor industry (IC Knowledge 2008). It is important to note that this substitute has not undergone an assessment to determine whether it meets the criteria under section 64 of CEPA 1999.

7.2 Alternative Technologies and/or Techniques

No information is available on alternative technologies and/or techniques.

7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also 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*.

An analysis of benefits and costs will be conducted as part of the regulation or instrument development for 2-MEA. This analysis will identify economic factors as they relate to the use of 2-MEA in Canada, including employment, and regional dispersion of industries that use 2-MEA in the manufacturing process. The benefits of pursuing regulations, instruments and/or tools will be identified, with a valuation of benefits conducted where possible.

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 2-MEA is to minimize, to the extent practicable, exposure to 2-MEA, and hence minimize the risk to human health associated with this substance.

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, instruments(s) and/or tool(s). As the current exposures of Canadians to 2-MEA were considered to be negligible under the current use conditions, the risk management objective is to reduce or eliminate the very small amount currently in use in Canada, and to limit any future uses.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instrument

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 instrument was 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 2-MEA includes a provision whereby any future potential changes in the use-pattern for 2-MEA do not substantially increase the potential for exposure of the general Canadian population and would require that the federal government be notified.

In addition, the Government of Canada will initiate a discussion with the importers and users to investigate possibilities for reducing or eliminating the use of 2-MEA in Canada.

The government will also take action to manage 2-MEA 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 government will achieve this goal through addition of 2-MEA 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.

9.2 Implementation Plan

The proposed risk management approach developed under CEPA 1999 will be published in the *Canada Gazette*, Part I, no later than March 2011. Releases of 2-MEA will continue to be monitored under the National Pollutant Release Inventory. Other monitoring will be considered to assess the performance of the risk management instrument and to determine whether further action needs to be taken with respect to 2-MEA.

[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."

10. CONSULTATION APPROACH

The risk management scope for 2-MEA, 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. 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

- importers and users of 2-MEA
- 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 2-MEA 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

12. REFERENCES

Canada. 1988. *Hazardous Products Act: Controlled Products Regulations*, Ingredient Disclosure List. SOR/88-74, P.C. 1987-2719, Ottawa, December 31 1987.

Canada. 1999. *Canadian Environmental Protection Act, 1999*. S.C., 1999., ch. 33. Canada Gazette. Part III. Vol. 22, no. 3. Available from: http://canadagazette.gc.ca/partIII/1999/g3-02203.pdf

Canada. 2007b. Department of the Environment, Department of Health. *Canadian Environmental Protection Act, 1999*: *Notice with respect to certain substances on the Domestic Substances List (DSL).* Ottawa: Public Works and Government Services Canada. Canada Gazette, Part I, 141(33):2375-2596. Available from: www.ec.gc.ca/Ceparegistry/documents/notices/g1-14133_n2.pdf

Canada. 2008. Department of the Environment, Department of Health. Screening Assessment for the Challenge – 2-MEA, Chemical Abstracts Service Registry Number 110-49-6.

Environment Canada. 2007. National Pollutant Release Inventory [NPRI]. Gatineau (QC): [cited January 2008]. Available from: www.ec.gc.ca/pdb/querysite/query_e.cfm

IC Knowledge. 2008. Chapter on Photolithography, page 16 www.icknowledge.com/misc_technology/PhotoChapter.pdf

[NCI] National Chemical Inventories. 2007. National Chemical Inventories database. American Chemical Society, Chemical Abstract Service, accessed on November 2007.

Treasury Board of Canada Secretariat. 2007. Cabinet directive on streamlining regulation, section 4.4 [Internet]. Available from: www.regulation.gc.ca/directive/directive01-eng.asp