Government of Canada / Gouvernement du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Oxirane, (chloromethyl)-
(Epichlorohydrin)

Chemical Abstracts Service Registry Number (CAS RN):
106-89-8

Environment Canada
Health Canada

January 2009

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for epichlorohydrin, 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 oxirane, (Chloromethyl)- , Chemical Abstracts Service Registry Number (CAS NR)[1] 106-89-8, referred to throughout this document by "epichlorohydrin," was included in Batch 2 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 Epichlorohydrin

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 epichlorohydrin on January 31, 2009, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that epichlorohydrin 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.

On the basis of the carcinogenicity of epichlorohydrin, for which there may be a probability of harm at any level of exposure, it is concluded that epichlorohydrin is a substance that 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. It is therefore concluded that epichlorohydrin does not meet the criteria in paragraph 64(a) and 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 epichlorohydrin does meet the criteria for persistence and does not meet the criteria for bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations* (Canada 2000) made under CEPA 1999. The presence of epichlorohydrin in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for epichlorohydrin, refer to the final screening assessment report, available at www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_2_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 Minister proposed to recommend the addition of epichlorohydrin 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 epichlorohydrin meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, epichlorohydrin 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.

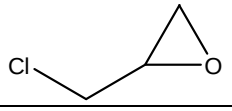
2. BACKGROUND

2.1 Substance Information

Epichlorohydrin is part of the chemical grouping discrete organics and the chemical sub-grouping halogenated alkyl epoxides.

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

Table 1. Substance Identity for Epichlorohydrin

Chemical Abstracts Service Registry Number (CAS RN)	106-89-8
Name on Domestic Substances List (DSL)	Oxirane, (chloromethyl)-
Inventory names[2]	Oxirane, (chloromethyl)- (TSCA, DSL, AICS, SWISS, PICCS, ASIA-PAC, NZIoC); 1-chloro-2,3-epoxypropane (EINECS, ECL); epichlorohydrin (ENCS, ECL); copolymer of oxirane, (chloromethyl)-(PICCS); propane, 1-chloro-2,3-epoxy (PICCS)
Other names	(±)-Epichlorohydrin; (chloromethyl)ethylene oxide; (chloromethyl)oxirane; (*RS*)-epichlorhydrin; α-epichlorohydrin; γ-chloropropylene oxide; 1,2-epoxy-3-chloropropane; 2,3-epoxypropyl chloride; 2-(chloromethyl)oxirane; 2-chloropropylene oxide; 3-chloro-1,2-epoxypropane; 3-chloro-1,2-propylene oxide; 3-chloropropene-1,2-oxide; 3-chloropropylene oxide; chloropropylene oxide; glycerol epichlorohydrin; glycidyl chloride; J 006; NSC 6747; oxirane, 2-(chloromethyl)-; UN 2023; UN 2023 (DOT)
Chemical group (DSL stream)	Discrete organics
Major chemical class or use	Epoxides
Major chemical sub-class	Halogenated alkyl epoxides
Chemical formula	C_3H_5ClO
Chemical structure	
Simplified Molecular Input Line Entry System (SMILES)	O(C1CCl)C1
Molecular mass	92.52 g/mol

[2] National Chemical Inventories (NCI). 2007: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Combined Inventories from the Asia-Pacific Region); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (SWISS Giftliste 1 and Inventory of Notified New Substances); and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Based principally on the weight-of-evidence assessments or classifications of several national and international agencies (US EPA 1994, IARC 1999, NTP 2005, ESIS 2007), the critical effect for human health risk characterization is carcinogenicity. Epichlorohydrin was genotoxic in a wide range of *in vitro* and *in vivo* experimental systems, as well as in investigations of occupationally exposed humans. Therefore, a mode of action for carcinogenicity involving direct interaction with genetic material cannot be precluded.

Based on its possible uses, oral exposure to epichlorohydrin via food/drinking water may occur at low levels for the general population of Canada. Contributions from ambient air and soil are expected to be negligible due to the lack of manufacture in and/or import of this substance into Canada. As exposure from environmental media was not quantified, margins of exposure for chronic non-cancer effects could not be calculated. Margins between any exposures from environmental media and the chronic oral critical effect level of 2 mg/kg-bw per day, however, are expected to be large.

With respect to consumer product exposure, comparison of the critical non-cancer inhalation effect level in subchronically exposed experimental animals (i.e., 2 mg/m^3) with the conservative range of upper-bounding estimates of airborne concentration during use of consumer products containing epichlorohydrin (i.e., 0.000945 mg/m^3 to 0.0372 mg/m^3) results in margins of exposure of 54 to 2116. Given the infrequent use patterns for these consumer products, comparison to short-term inhalation studies would be the most appropriate; however, these studies are not available. As well, since it is likely that the majority of uses will result in exposures below the lower end of the range presented (i.e., 0.000945 mg/m^3), the margin of exposure would likely be closer to the high end of the range (i.e., 2116). The margins of exposure for non-cancer effects are likely sufficiently large to adequately account for uncertainties in the database (Canada 2008).

4. CURRENT USES AND INDUSTRIAL SECTORS

Epichlorohydrin is used as an intermediate in the production of a wide variety of substances. It is mainly used in the production of epoxy resins, although section 71 responses indicate that these resins are likely imported into Canada rather than manufactured in Canada (Environment Canada 2007). Epoxy resins are used in protective coatings including those used for lining food and beverage containers (Solvay 2007). They are also used in structural applications such as circuit board laminates, semiconductor encapsulants, and structural composites; tooling, molding and casting; flooring, adhesives, paints and other coatings. Other uses of epichlorohydrin include phenoxy resins, used to make thermoplastic polymers (Pham and Marks 2004); synthetic glycerol, used to make personal care products, drugs, food products and beverages; and polyamide-epichlorohydrin resins used in Canada to make retention aids and wet-strength resins for use in paper in food contact applications (Health Canada, Food Packaging and Incidental Additives Sections, Health Products and Food Branch, pers. comm., 2008 Feb 27, unreferenced).

Epichlorohydrin is used for manufacturing anion-exchange resins and flocculants used in treating drinking water and wastewater (Solvay 2002). In Canada there are no registered pesticides that contain epichlorohydrin as an active ingredient or formulant (PMRA 2007). Information submitted to Health Canada indicates that polymers manufactured with epichlorohydrin may be used in the production of some cosmetic products, including hair dyes, lipsticks, eye and face makeup, and nail lacquers (Health Canada, Cosmetics Division, Healthy Environments and Consumer Safety Branch, pers. comm., 2008 March 27 and 2008 April 11, unreferenced). It has been reported as a precursor in the manufacture of medical devices, but the Medical Devices Bureau of Health Canada has not currently identified a specified licensed medical device with which it is manufactured (Health Canada, Medical Devices Bureau, Health Products and Food Branch, pers. comm., 2007 Nov 02, unreferenced). Epichlorohydrin can also be used as a starch-modifying agent. It is listed as a food additive under Division 16 of Canada's *Food and Drug Regulations* which allow it to be used as a starch-modifying agent according to good manufacturing practices (Table XIII) (Canada 1985). However, based on industrial data provided to Health Canada by industry in the late 1970s, it is unlikely that epichlorohydrin is used today by North American starch manufacturers, and if it were used as a starch-modifying agent, residual levels of epichlorohydrin in the modified starch would be negligible (Health Canada, Chemical Hazards Assessment Division, Health Products and Food Branch, pers. comm., 2007 Nov 01, unreferenced). Recent editions of the Food Chemicals Codex (Institute of Medicine 1996, 2000) no longer list epichlorohydrin for use as a starch-modifying agent, and the internationally recognized Joint WHO/FAO Expert Committee on Food Additives does not include epichlorohydrin in its most recent food-grade specification for modified starches (JECFA 2001). Direct use of epichlorohydrin by consumers is not expected.

Responses to a section 71 notice indicate that epichlorohydrin was not manufactured or imported by any company in Canada above the 100-kg reporting threshold (Environment Canada 2007). Epichlorohydrin is likely being imported in small quantities below the reporting threshold as a residual monomer in products containing epoxy resins or other resins made using epichlorohydrin.

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

The National Pollutant Release Inventory (NPRI) reported no emissions of epichlorohydrin for the year 2006. The last year in which epichlorohydrin emissions were reported was 2003, and the quantities were extremely small (2 kg) (NPRI 2007). No releases of epichlorohydrin were reported in response to the recent section 71 notice or the Challenge Questionnaire (Canada 2007a, Environment Canada 2007). Therefore, industrial releases of epichlorohydrin are not expected to be significant. Epichlorohydrin may be used for the treatment of drinking water and wastewater in Canada. Although no measured data are available on the release, if any, of this substance to water, not more than 2 ppb of epichlorohydrin are expected to be present in treated drinking water, according to current voluntary National Sanitation Foundation (NSF) International standards (NSF International 2005).

5.2 Exposure Sources

In Canada, since epichlorohydrin is present only as a residual, environmental and consumer product exposures are expected to be low to negligible. No measured concentrations of epichlorohydrin in environmental media, food or water in Canada are available. Responses to the section 71 notice and NPRI reports indicate that industrial emissions are negligible (Environment Canada 2007, NPRI 2007). Exposure to epichlorohydrin in food is possible given the use of this substance in a variety of food contact applications, including papers treated with polyamide-epichlorohydrin resins and cans lined with epoxy resin coatings. Based on data submitted to Health Canada, the residual levels of epichlorohydrin in wet-strength resins are up to 0.0775 ppm, which results in an estimated daily intake ranging from 2 to 7.4 ng/kg-bw per day for the general population of Canada. Reported residual levels of epichlorohydrin in retention aids are predicted to result in significantly lower exposures. Although it is likely that polymers manufactured using epichlorohydrin are used for drinking water treatment in Canada, there were no measured values of residual levels of epichlorohydrin identified in water. Epichlorohydrin may be found in a variety of epoxy adhesives, coatings and putties as a residual monomer in epoxy resins. However, only trace quantities of epichlorohydrin monomer are likely to be present in the resins. Therefore, in spite of its high vapour pressure, emissions of epichlorohydrin to either indoor or ambient air are expected to be negligible. Residual epichlorohydrin in polymers used to manufacture various types of cosmetics may also lead to exposure via the inhalation and dermal routes. The residual concentrations in these products are unknown and therefore exposure from this source cannot be quantified, however, it is expected to be low (Canada 2008).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Epichlorohydrin is subject to
- the *Environmental Emergency Regulations* under CEPA 1999 (Canada 2003);
- the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* under CEPA 1999 (Canada 2005);
- 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);
- 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 *Regulations for the Prevention of Pollution from Ships and for Dangerous Chemicals* (Canada 2007b);
- reporting under the National Pollutant Release Inventory (NPRI 2007); and
- Division 16 (Food Additives) of the *Food and Drug Regulations* (Canada 1985).

As epichlorohydrin-containing polymers can be used in drinking water treatment, Canada currently has voluntary health-based standards for additives that limit the amount of epichlorohydrin residual that can be present in the finished drinking water (National Sanitation Foundation Standard 60/61) (NSF International 2005).

6.2 Existing International Risk Management

- European Commission Directive 2004/93/EC amending European Commission Directive 76/768 prohibits the use of epichlorohydrin in cosmetics (European Commission 2004);
- European Commission Directive 2007/54/EC amending European Commission Directive 76/768 prohibits certain hair dyes made with epichlorohydrin; in particular, HC Blue No. 5 and HC Blue No. 4 (European Commission 2007);
- The U.S. *National Primary Drinking Water Regulations* require a concentration of free epichlorohydrin of less than 2 ppb (US EPA 2008);
- The member countries of the United Kingdom have set maximum concentrations for epichlorohydrin in drinking water at 0.10 µg/L (0.10 ppb) (OPSI 2003a, b, 2007a-c);
- The World Health Organization (WHO) provisional guideline value for epichlorohydrin in drinking water is 0.4 µg/L (0.4 ppb) (WHO 2004).
- The *Plastic Materials and Articles in Contact with Food Regulations 1998* state a maximum concentration of 1 mg/kg for epichlorohydrin in plastics in contact with food (OPSI 1998);
- Epichlorohydrin is also on the US Food and Drug Administration's List of "Indirect" Additives Used in Food Contact Substances (under 21 CFR), specifically as a component of coatings, a component of paper and paperboard, a basic component of single and repeated use food contact surfaces, and as a component of articles intended for repeated use (US FDA 2007).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information on potential substitutes for epichlorohydrin was brought forward in the voluntary Challenge Questionnaire submissions.

7.2 Alternative Technologies and/or Techniques

Epichlorohydrin consumption for the production of drinking water treatment chemicals is projected to be relatively modest over the next few years because of cost-effective competing technologies (SRI Consulting 2007). EpiDMA (epichlorohydrin/dimethylamine polymer) polyelectrolyte has been identified as the major epichlorhydrin-containing chemical used in water treatment in Canada. Polyelectrolytic coagulants/flocculants such as epiDMA are generally used in combination with a hydrolyzing metal salt coagulant (e.g., Alum) or alone as filter aids to improve treatment efficiency (AWWA 1999). Other cationic polyelectrolytes including chitosan and pDADMAC (poly(diallyldimethyl ammonium chloride)) exist and may potentially serve as alternatives to epiDMA. However, pDADMAC also has the issue of residual DMA (dimethylamine), the precursor to NDMA (N-nitrosodimethylamine), which is already on

the List of Toxic Substances (Schedule 1) of CEPA 1999. Improved treatment efficiency may also come about by replacing granular filtration unit processes with new membrane technologies that may require minimal to no pre-treatment with coagulants/flocculants or filter aids. However, there are still many technical (e.g., fouling and integrity testing) and economic challenges associated with the use of membrane technologies for drinking water treatment that have prevented them from becoming mainstream yet.

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*.

Epichlorohydrin is used as an intermediate in the production of a wide variety of substances, and is mainly used in the production of epoxy resins. Epichlorohydrin was not manufactured or imported by any company in amounts greater than 100 kg in Canada in 2006.

If the proposed risk management approach on future uses is adopted, the socio-economic impacts may not have a large immediate effect on the costs to Canadian industry. Further analysis on importers of products containing epichloroydrin will need to be assessed.

An economic analysis will be conducted as part of any regulation or instrument developed for epichlorohydrin. This analysis will identify economic factors as they relate to its use in Canada, wherever data are available, and may include employment, and regional dispersion of industries that import products containing this substance. The benefits of pursuing instruments, regulations, and/or tools will be identified wherever possible, 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 epichlorohydrin is to minimize exposure to epichlorohydrin and hence risk to human health associated with this substance to the extent practicable.

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 risk management objective for epichlorohydrin is to prevent increases in exposure to the substance.

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 regulation and instrument 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 epichlorohydrin will be a requirement for notification of the federal government regarding any proposed future uses.

9.1.1 Future Uses

It is proposed to create a provision whereby any proposed future uses of epichlorohydrin would be subject to federal government notification.

9.1.2 Epichlorohydrin in Food Packaging

Information provided to Heath Canada by industry on migration tests has indicated that only negligible amounts of epichlorohydrin would potentially be found in food and this is not considered to represent a safety concern. To ensure that the potential for migration of

[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."

epichlorohydrin into food is negligible, all future submissions for the use of epichlorohydrin in epoxy linings will be scrutinized to ensure that residual levels in the finished packaging material are as low as possible.

9.1.3 Epichlorohydrin as a Food Additive

Heath Canada will investigate delisting epichlorohydrin from the food additives table, Division 16 (Food Additives) of the *Food and Drug Regulations* (Canada 1985).

9.1.4 Epichlorohydrin in Drinking Water Treatment

Oral exposure to epichlorohydrin through drinking water is expected to be well within acceptable limits. NSF/ANSI standards 60 and 61 apply to water treatment chemicals, including coagulation/flocculation aids and indirect additive materials including epoxy and ion exchange resins used in water treatment. Although the standards are voluntary in Canada, a Health Canada survey conducted in 2006 on the provincial/territorial adoption of these standards across Canada found that almost all provinces and territories in Canada had adopted these standards into their provincial water regulations and/or water treatment permitting process. Due to the widespread adoption of these standards and protocols in Canada, it would be highly unlikely that products that are not certified or that do not meet these standards would be easily available for use in water treatment in Canada.

9.1.5 Epichlorohydrin in Cosmetics

It is proposed that epichlorohydrin and the two hair dyes that use epichlorohydrin in their manufacture, that is HC Blue No. 5 (CAS RN 68478-64-8; CAS RN 158571-58-5) and HC Blue No. 4 (CAS RN 158571-57-4), be recommended for addition to the Cosmetic Ingredient Hotlist as prohibited for use in cosmetics products.

9.1.6 Epichlorohydrin in Adhesives

No adhesives have been identified in Canada that contain epichlorohydrin and that are intended for consumer use. Therefore, consumer exposure to this substance from adhesives is expected to be negligible.

9.1.7 Epichlorohydrin in Coatings

Epichlorohydrin is used as a monomer in the production of industrial products and is not used in consumer products. There is minimal use in Canada. Therefore, the risk of exposure to consumers is assumed to be negligible.

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 January 2011, as per the timelines legislated in CEPA 1999.

Releases of epichlorohydrin will continue to be monitored under the National Pollutant Release Inventory.

10. CONSULTATION APPROACH

The risk management scope for epichlorohydrin, which summarized the proposed risk management under consideration at that time, was published on May 17, 2008, and is available at www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=236&par_actn=s1. 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 January 31, 2009, and a 60-day public comment period.

The primary stakeholders include

- manufacturers and producers of food packaging, food, cosmetics and personal care products, epoxy resins, adhesives, coatings and glycol ethers in general;
- drinking water treatment related stakeholders such as the National Sanitation Foundation; and
- Health Canada and Environment Canada, provincial environment ministries and municipalities.

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach	January 31, 2009 to ,April 1, 2009
Response to comments on the risk management approach	At time of publication of proposed instrument
Consultation on the draft instrument	Spring-Summer 2009
Publication of the proposed instrument	No later than January 2011
Formal public comment period on the proposed instrument	No later than Spring 2011
Publication of the final instrument	No later than July 2012

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or to provide other information that would help to inform decision making. Please submit comments prior to April 1 2009, since the Government of Canada will be moving forward with the risk management of epichlorohydrin 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:

Existing Substances 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

AWWA. 1999. Water Quality and Treatment : A handbook of community water supplies. 5th Ed. McGraw-Hill, Inc Canada, 1999. *Canadian Environmental Protection Act, 1999 = Loi Canadienne sur la Protection de l'Environnement, 1999*. Statutes of Canada = Statuts du Canada. Ottawa: Queen's Printer. Ch. 33. Available at Canada Gazette (Part III) 22(3):chapter 33 http://canadagazette.gc.ca/partIII/1999/g3-02203.pdf.

Canada. 1985. *Food and Drugs Act*, R.S.C. 1985, c. F-27.

Canada. 1988. *Hazardous Products Act: Controlled Products Regulations (Ingredient Disclosure List)*, S.O.R./88-66, December 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. 2000. *Canadian Environmental Protection Act, 1999: Persistence and Bioaccumulation Regulations,* P.C. 2000-348, 23 March, 2000, SOR/2000-107. Canada Gazette. Part II, vol. 134, no. 7, p. 607−612. Ottawa: Queen's Printer. Available from: http://canadagazette.gc.ca/partII/2000/20000329/pdf/g2-13407.pdf

Canada. 2001. *Hazardous Products Act: Consumer Chemicals and Containers Regulations*, P.C. 2001-1343, 1 August 2001, SOR/2001-269. Canada Gazette Part II, vol., 135 no. 17, p. 1552-1628. Ottawa: Queen's Printer. Available from: http://canadagazette.gc.ca/partII/2001/20010815/pdf/g2-13517.pdf

Canada. 2003. *Canadian Environmental Protection Act: Environmental Emergency Regulations*, P.C. 2003-1293, 20 August 2003, SOR/2003-307. Canada Gazette Part II, vol. 137, no. 19, p. 2394-2420. Ottawa: Queen's Printer. Available from: http://canadagazette.gc.ca/partII/2003/20030910/pdf/g2-13719.pdf

Canada. 2005. *Canadian Environmental Protection Act, 1999: Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations*, P.C. 2005-930, 17 May 2005, SOR/2005-149. Canada Gazette. Part II, vol. 139, no. 11, p. 1197-1304. Ottawa: Queen's Printer. Available from: http://canadagazette.gc.ca/partII/2005/20050601/pdf/g2-13911.pdf

[Canada], Dept. of the Environment. 2007a. Challenge Questionnaire [voluntary data submitted by industry]. Gatineau (QC): Environment Canada, Existing Substances Division. Available upon request from: Existing Substances Division, Environment Canada, Ottawa, K1A 0H3.

Canada. 2007b. Canada Shipping Act: Regulations for the Prevention of Pollution from Ships and for Dangerous Chemicals, P.C. 2007-699, 3 May 2007, SOR/2007-86. Canada Gazette Part II, vol. 141, no. 10, p. 705-768. Ottawa: Queen's Printer. Available from: http://canadagazette.gc.ca/partII/2007/20070516/pdf/g2-14110.pdf

Canada. 2008. Screening assessment for the Challenge – (chloromethyl)-oxirane (epichlorohydrin), Chemical Abstracts Service Registry Number 106-89-8.

Environment Canada. 2007. Data for Batch 2 substances collected under the Canadian Envrionmental Protection Act, 1999, Section 71: *Notice with respect to certain Batch 2 Challenge substances*. Data prepared by: Environment Canada, Existing Substances Program.

[ESIS] European Chemical Substances Information System. 2007 [database on the Internet]. Version 4.60. Available from: http://.jrc.it/esisecb/esis.

European Commission. 2004. Commission Directive 2004/93/EC of 21 September 2004 amending Council Directive 76/768/EEC for the purpose of adapting its Annexes II and III to technical progress. Official Journal of the European Union L 300/13-41.

European Commission. 2007. Commission Directive 2007/54/EC of 29 August 2007 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Anexes II and III thereto to technical progress. Official Journal of the European Union L 226/21-27.

[IARC] International Agency for Research on Cancer. Working Group on the Evaluation of Carcinogenic Risks to Humans. 1999. Re-evaluation of some organic chemicals, hydrazine and hydrogen peroxide. IARC Monogr Eval Carcinog Risks Hum. 1999:71 Pt 2:603-628.

Institute of Medicine. 1996. Food Chemicals Codex. Fourth Edition. [place unknown]: National Academy Press. 882p.

Institute of Medicine. 2000. Food Chemicals Codex. Second Supplement to the Fourth Edition. [place unknown]: National Academy Press. 100p.

[JECFA] Joint FAO/WHO Expert Committee on Food Additives. 2001. Modified Starches. Prepared at the 57th JECFA meeting in Rome, June 2001. Published in FAO JECFA Monographs 1, Combined Compendium of Food Additive Specifications, Volume 2, Food and Agriculture Organization of the United Nations, Rome, 2005. [cited 2008 January 10]. Available from: http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-287.pdf

[NCI] National Chemical Inventories [database on CD]. 2007. Columbus (Ohio): Thomas Technology Solutions Inc. American Chemical Society. Available from: http://www.cas.org/products/cd/nci/index.html

[NPRI] National Pollutant Release Inventory [database on the Internet]. 2007. Gatineau (QC): Environment Canada. [cited December 2007]. Available from: http://www.ec.gc.ca/pdb/querysite/query_e.cfm

NSF International. 2005. NSF/ANSI Standard 60/61: Drinking Water Treatment Additives – health effects/Drinking Water System Components -- health effects. Ann Arbor, MI.

[NTP] National Toxicology Program (US). 2005. 11th Report on carcinogens. Substance profile: epichlorohydrin. Research Triangle Park (NC): National Toxicology Program. Available from: http://www.iso.org/en/prods-services/iso3166ma/02iso-3166-code-lists/index.html

[OPSI] Office of Public Sector Information. 1998. Statutory instrument no.1376. Plastic Materials and Articles in Contact with Food Regulations. Available at: http://www.opsi.gov.uk/si/si1998/98137603.htm

[OPSI] Office of Public Sector Information. 2003a. Statutory instrument no.139. The Natural Mineral Water, Spring Water, and Bottled Water (Scotland) Regulations, 2003. Available at: http://www.opsi.gov.uk/legislation/scotland/ssi2003/ssi_20030139_en.pdf

[OPSI] Office of Public Sector Information. 2003b. Statutory instrument no.182. The Natural Mineral Water, Spring Water, and Bottled Water (Northern Ireland) Regulations, 2003. Available at: http://www.opsi.gov.uk/sr/sr2003/nisr_20030182_en.pdf

[OPSI] Office of Public Sector Information. 2007a. Statutory instrument no. 147. The Water Supply (Water Quality) Regulations (Northern Ireland). Available at: http://www.opsi.gov.uk/sr/sr2007/nisr_20070147_en_8

[OPSI] Office of Public Sector Information. 2007b. Statutory instrument no. 3165. The Natural Mineral Water, Spring Water, and Bottled Water (Wales) Regulations, 2007. Available at: http://www.opsi.gov.uk/legislation/wales/wsi2007/wsi_20073165_en_5

[OPSI] Office of Public Sector Information. 2007c. Statutory instrument no. 2785. The Natural Mineral Water, Spring Water, and Bottled Water (England) Regulations, 2007. Available at: http://www.opsi.gov.uk/si/si2007/uksi_20072785_en_5

Pham HQ, Marks MJ. 2004. Epoxy resins. Kirk-Othmer Encyclopedia of Chemical Technology, online version. Available from: http://www.mrw.interscience.wiley.com/emrw/9780471238966/search/firstpage

[PMRA] Pest Management Regulatory Agency. 2007. PMRA Product Label Database [database on the internet]. [cited 21 December 2007]. Available from: http://pr-rp.pmra-arla.gc.ca/portal/page?_pageid=34,17551&_dad=portal&_schema=PORTAL.

Solvay. 2002. Applications of Epichlorohydrin [Internet]. Brussels (BE): Solvay Chemicals; [cited 2007 Dec 05]. Available from: http://www.solvaychlorinatedorganics.com/docroot/chlo_org/static_files/attachments/applications_epichlorohydrin.pdf

Solvay. 2007. Epichlorohydrin [Internet]. [place unknown]: Solvay Chemicals US; [updated 2007 Dec 07; cited 2007 Dec 21]. Available from: http://www.solvaychemicals.us/services/resourcelibrary/epichlorohydrin/0,,36378-2-0,00.htm

SRI Consulting (by E.O.C.Greiner, T. Kälin and I.K. Nak). December 2007. CEH Product Review: Epichlorohydrin. Chemical Economics Handbook—SRI Consulting.

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

[US EPA] United States Environmental Protection Agency. 1994. Epichlorohydrin (CASRN 106-89-8). Washington (DC): US Environmental Protection Agency, Integrated Risk Information System (IRIS). Available at: http://www.epa.gov/iris/subst/0050.htm

[US EPA] United States Environmental Protection Agency. 2008. National Primary Drinking Water Regulations: List of Contaminants and their Maximum Contaminant Levels (MCLs). Available at: http://www.epa.gov/safewater/contaminants/index.html#inorganic

[US FDA] United States Food and Drug Administration. 2007. The list of indirect additives used in food contact substances. Available at: http://www.cfsan.fda.gov/~dms/opa-indt.html

[WHO] World Health Organization. 2004. Guidelines for drinking-water quality. 3rd ed. Vol. 1: recommendations. World Health Organization, Geneva. http://whqlibdoc.who.int/publications/2004/9241546387.pdf.