Government of Canada / Gouvernement du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

1,3-Butadiene, 2-Methyl
(Isoprene)

Chemical Abstracts Service Registry Number (CAS RN):
78-79-5

Environment Canada
Health Canada

January 2009

Canada

Table of Contents

This proposed risk management approach document builds on the previously released risk management scope document for isoprene, 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 1,3-butadiene, 2-methyl, Chemical Abstracts Service Registry Number (CAS RN)[1] 78-79-5, referred to throughout this document as "isoprene," 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 where 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 Isoprene

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 isoprene on January 31, 2009, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that isoprene 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 isoprene, for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margins of exposure for non-cancer effects, it is concluded that isoprene be considered as 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 isoprene does not meet the criteria in paragraphs 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 isoprene 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 isoprene in the environment does not result primarily from human activity.

For further information on the final screening assessment report conclusion for isoprene, 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 Ministers proposed to recommend the addition of isoprene 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 isoprene meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, isoprene 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.

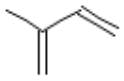
2. BACKGROUND

2.1 Substance Information

Isoprene is part of the chemical grouping organics.

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

Table 1. Identity of Isoprene

Chemical Abstracts Service Registry Number (CAS RN)	78-79-5
Name on Domestic Substances List (DSL)	1,3-butadiene, 2-methyl-
National Chemical Inventories (NCI) names[2]	1,3-butadiene, 2-methyl- (TSCA, ENCS, AICS, SWISS, PICCS, ASIA-PAC, NZIoC) isoprene (EINECS, PICCS) 2-Methyl-1,3-butadiene (ECL) BUTA-1,3-DIENE, 2-METHYL- (PICCS)
Other names	ß-methylbivinyl; 2-methylbutadiene; 3-methyl-1,3-butadiene; isopentadiene
Chemical group (DSL stream)	Organics
Chemical formula	C_5H_8
Chemical structure	
Simplified Molecular Input Line Entry (SMILES)	C(C=C)(C)=C
Molecular mass	68.12 g/mol

[2]National Chemical Inventories (NCI). 2007: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NZloC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (Inventory of Newly Notified Substances and Giftlist 1- List of Toxic 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 of several international and national agencies (IARC 1999, NTP 2004, NTP 1999, European Commission 2004), a critical effect for characterization of risk to human health for isoprene is carcinogenicity. In chronic bioassays, isoprene consistently induced tumours at multiple sites in both mice and rats. This substance was also genotoxic in *in vivo* assays in mice. Thus, in light of these data, a mode of induction for tumours involving direct interaction with genetic material cannot be precluded. Although epidemiological data are inadequate for evaluation, isoprene is a structural analogue of 1,3-butadiene, which has been associated in lymphohematopoietic cancer in exposed workers.

With respect to consderation of critical non-cancer effects in a screening context, comparison of the conservatively selected lowest identified inhalation effect level (11 mg/m^3or 11 000 $\mu g/m^3$) from a subchronic study, with the highest identified concentration of isoprene (30.5 $\mu g/m^3$) reported in indoor air in Canada in 2006 (the principal source of exposure for the general population), results in a margin of exposure of approximately 360. Comparison of this effect level with the highest identified concentration of 9.48 $\mu g/m^3$ reported in ambient air in an urban area in Canada yields a margin of exposure of approximately 1160. While it is recognized that endogenous production and natural sources of isoprene contribute to overall exposure in addition to anthropogenic sources, it is not possible to separate the relative contribution of each of these sources in the scope of a screening level assessment. In addition, data indicate that cigarette smoking results in higher concentrations of isoprene in indoor air; therefore, the margin of exposure may be smaller in the homes of smokers. Thus, in light of the uncertainties in the databases, including those relating to the mode of induction of tumours, it is considered that these margins of exposure may not be adequately protective of human health (Canada 2008a).

4. CURRENT USES AND INDUSTRIAL SECTORS

The substance isoprene is primarily used as a monomer in the production of rubber, particularly polyisoprene (*cis*-1,4-polyisoprene), butyl rubber (isobutene-isoprene copolymer) and thermoplastic, elastomeric co-block polymers (e.g., styrene-isoprene-styrene, or SIS, rubber) (Environment Canada 2007, Shell 2008). Polyisoprene is used mostly in the production of vehicle tires and in the manufacture of a wide variety of products including medical equipment, toys, shoe soles, elastic films and threads for textiles and golf balls, adhesives and paints and coatings. Butyl rubber is typically used in the manufacture of inner tubes while styrene-isoprene-styrene rubber is used in pressure-sensitive adhesives (Environment Canada 2007, IARC 1999, OECD 2005). Isoprene may also be used in the formulation of viscosity improvers and in the production of agrochemicals, pharmaceuticals and other chemicals (Shell 2008).

Responses to a section 71 notice indicate that in 2006, the total quantity of isoprene manufactured in Canada exceeded 10 000 000 kg and the total quantity imported ranged from 1 000 000 to 10 000 000 kg. More than 10 000 000 kg were exported during the same calendar year, however. Sectors identified in the section 71 responses include chemical manufacturing, rubber, and petroleum. Specific uses in Canada include as an intermediate for the manufacture of

butyl rubber; and as an incidentally produced substance present in products such as fuel (Environment Canada 2007). Isoprene is found in food packaging materials at concentrations of less than 1%. Butyl rubber is used in can end compounds, coatings for plastic films, sealing compound for crown corks used for beer bottles and seam end tops used in packaging in accordance with good manufacturing practice (GMP) where any contact with food is expected to be incidental (as per email from Health Products and Food Branch, dated 15 February 2008, unreferenced).

Isoprene is also released in tobacco smoke (Canada 2008a). Cosmetic products formulated with polyisoprene and other isoprene copolymers are available in Canada but no information on the amount of unreacted isoprene in these products is available (as per email from Cosmetic Products Branch, dated 9 June 2008, unreferenced).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

The National Pollutant Release Inventory (NPRI) reports that industrial emissions of isoprene have decreased from 54 900 kg in the year 2000 to 14 500 kg in 2006. The emissions from 2006 were almost exclusively from one company, as reported both by NPRI and in the responses to the section 71 notice (NPRI 2007, Environment Canada 2007). The substance isoprene is also released to the environment via endogenous production in the human body (Gelmont et al. 1981, Hartmann 1994, Tallman 1996) and biogenic production by plants (Chang et al. 1996, Guenther et al. 1994, Geron et al. 2001, Sharkey and Yeh 2001), as well as in vehicular exhaust (Borbon et al. 2001, Reimann et al. 2000). The natural releases are greater than industrial releases of isoprene (Canada 2008a).

5.2 Exposure Sources

The draft screening assessment report indicates that indoor air is the main source of environmental exposure to isoprene for all age groups of the general population in Canada. Sources of isoprene in indoor air include tobacco smoke, endogenous production, and possibly consumer products containing isoprene-derived polymers, such as polyisoprene rubber (Canada 2008a). Isoprene is one of the primary hydrocarbons in sidestream cigarette smoke, at 90–3194 μg/cigarette (as per email from Health Canada Tobacco Control Directorate, 29 July 2008, unreferenced), and indoor air concentrations have been found to be four times higher in smoking homes than in non-smoking homes (Heavner et al. 1996). Consumer products are likely to be only a minor source of isoprene in indoor air, as a study by the Organisation for Economic Co-operation and Development (OECD) detected no residual isoprene in 17 of 19 samples of polyisoprene rubber, and trace amounts (0.02–0.04 ppm) in the remaining two samples (OECD 2005). A number of reports have identified isoprene produced endogenously in the human body as a contributor to indoor air levels (Gelmont et al. 1981, Hartmann 1994, Tallman 1996).

Ambient air is the second-largest source of exposure of the general population to isoprene. Biogenic production of isoprene by plants (Chang et al. 1996, Guenther et al. 1994, Geron et al.

2001, Sharkey and Yeh 2001), industrial stack emissions by the rubber manufacturing sector (Environment Canada 2007, NPRI 2007), and emission in automobile exhaust (Borbon et al. 2001, Reimann et al. 2000) are the main contributors to ambient air levels.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Isoprene is subject to
- the *Tobacco Reporting Regulations* (Canada 2000)
- the *Environmental Emergency Regulations* under CEPA 1999 (Canada 2003a)
- the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* under CEPA 1999 (Canada 2005a)
- the *Consumer Chemicals and Containers Regulations, 2001* established under the *Hazardous Products Act*, which require 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*, which require 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 2007)

Other regulations relevant to isoprene are those concerning vehicle exhaust emissions: the *On-Road Vehicle and Engine Emission Regulations* (Canada 2003b), the *Off-Road Compression-Ignition Engine Emission Regulations* (Canada 2005b), and the *Off-Road Small Spark-Ignition Engine Emission Regulations* (Canada 2003c) (all under CEPA 1999). These regulations target volatile organic compounds (VOCs) as a group and are likely to reduce isoprene emissions as they reduce those of other VOCs.

6.2 Existing International Risk Management

- Isoprene is on California's list of Known Carcinogens and Reproductive Chemicals, under California Proposition 65: the *Safe Drinking Water and Toxic Enforcement Act* (State of California EPA 2008);
- Isoprene is on the Food and Drug Administration's List of "Indirect" Additives Used in Food Contact Substances (under 21 CFR; US FDA 2007);
- Isoprene is on the Inventory of Chemicals in Commerce under the U.S. *Toxic Substances Control* Act (US EPA 2008);
- Isoprene is also a reportable substance under the U.S. *Comprehensive Environmental Response, Compensation, and Liability Act* (also known as Superfund) (US EPA 2001);
- Isoprene is subject to the U.K.'s *Dangerous Substances and Preparations (Safety) Regulations 2006* (OPSI 2006), where it is listed as a dangerous substance because of its classification as a Category 2 carcinogen;

- According to European Commission Directive 76/768/EEC, isoprene is on the "List of Substances which must not form part of the composition of cosmetic products" (European Commission 1976);
- European Commission Directive, 2002/72/EC, lists isoprene as a substance permitted to be in plastics in contact with food, but only with a maximum residual concentration in the finished product of 1 mg/kg, and a specific migration limit in food below detection (i.e., below 0.02 mg/kg) (European Commission 2002).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

Isoprene is required for the manufacturing of polyisoprene rubber, butyl rubber, halobutyl rubbers (chlorobutyl and bromobutyl) and styrene-isoprene-styrene rubber, and may be present at residual concentrations in all of these (Lanxess 2007). However, other types of rubber can be manufactured without the use of isoprene. These include acrylic rubber, butadiene rubber, chlorinated polyethylene, chlorosulphonated polyethylene, epichlorohydrin rubber, ethylene acrylic rubber, ethylene propylene rubber, fluoroelastomers, hydrogenated nitrile rubber, nitrile rubber, perfluoro elastomers, polychloroprene, polynorbornene rubber, polysulphide rubber, polyurethane rubber, silicone (and fluorosilicone) rubber, styrene butadiene rubber and tetrafluoroethylene/propylene (MERL 2008). One of the keys properties of butyl rubber, however, is its impermeability to air, which allows the manufacture of tubeless tires; other types of rubber do not necessarily share this characteristic.

It is also important to note that 1,3-butadiene (CAS RN 106-99-0), used in manufacturing butadiene rubber and styrene butadiene rubber, and potentially present as a residual in these rubbers (Leber 2001), has been assessed under CEPA 1999 and declared toxic under paragraphs 64(b) and 64(c). It is listed on Schedule 1 of CEPA 1999. Acrylonitrile (CAS RN 107-31-3), used in manufacturing acrylic, nitrile and hydrogenated nitrile rubber (Industrial Rubber Goods 2008), has been assessed under CEPA 1999 and declared toxic under paragraph 64(c). It is also listed on Schedule 1 of CEPA 1999. Epichlorohydrin (CAS RN 106-89-8), used in manufacturing epichlorohydrin rubber (Canada 2008b, Dow 2008), has been concluded toxic under paragraph 64(c) of CEPA 1999. Siloxanes D4 (CAS RN 556-67-2) and D5 (CAS RN 541-02-6) are used in the manufacture of silicone rubber (Canada 2008c), and are concluded toxic under paragraph 64(a) of CEPA 1999.

7.2 Alternative Technologies and/or Techniques

There are no known data or studies on alternative technologies to produce butyl rubber. In the polymerization process, roughly 60% of the isoprene feedstock is converted in the reaction. The unreacted isoprene is recovered through a stripping operation. No process alternatives are known. However this does not exclude possible efficiency improvements to the equipment.

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*.

Isoprene is used primarily as a monomer in the production of rubber, including the production of butyl rubber. Isoprene was manufactured in Canada in amounts exceeding 10 000 000 kg in 2006, and the quantity imported ranged from 1 000 000 to 10 000 000 kg in 2006.

Total industrial emissions of isoprene decreased by almost 75% between 2000 and 2006, and in 2006 emissions were almost exclusively from one manufacturer involved in the production of butyl rubber (NPRI 2007). The manufacturer is located in Sarnia, Ontario, the only location of butyl rubber production in Canada. Comments submitted during the 60-day public comment period state that the company employs over 600 people in Sarnia and the surrounding area.

An analysis of benefits and costs will be conducted as part of the regulation or instrument development for isoprene. This analysis will identify economic factors as they relate to the use of isoprene in Canada, including employment, and regional dispersion of industries that use isoprene in the manufacturing process. The benefits of pursuing regulatory 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 isoprene is to minimize exposure to

isoprene and hence the 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 is to reduce exposure to isoprene from industrial emissions to the extent practicable.

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 isoprene is action under CEPA to ensure the application of best available technology economically achievable (BATEA) in industrial sectors, particularly the rubber manufacturing sector.

9.1.1 Isoprene Emissions from the Rubber Manufacturing Sector

There is only one company in Canada that imports pure isoprene to use in a rubber application (Environment Canada 2007).

Based on the NPRI reports of the last 5 years (NPRI 2007) and on reports from the section 71 notice (Environment Canada 2007), this facility releases the large majority of all industrial isoprene emissions and has already reduced its emissions by 75% over the last 5 years.

To minimize human exposure in the vicinity of a facility using isoprene as a feedstock, the risk management objective within the rubber manufacturing sector will be to control and/or reduce isoprene air stack releases by the application of the best available technology economically achievable (BATEA) Ensuring BATEA application will help minimize isoprene emissions and give a framework for isoprene monitoring and reporting to inform decision making.

[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."

9.1.2 Isoprene in Tobacco Smoke

Health Canada has been monitoring tobacco smoke of cigarettes sold in Canada for over 30 years. Tobacco smoke is a combination of poisonous gases, liquids and breathable particles that are harmful to health. It contains over 4000 chemicals, including at least 50 that cause, initiate or promote cancer. Isoprene is one of these carcinogenic chemicals found in the cigarette smoke (Smith et al. 2003).

The emissions data on cigarettes sold in Canada in 2004 show that the level of isoprene found in Canadian cigarette smoke under ISO standards on smoking conditions in mainstream smoke is 30–397 µg/cigarette and 395–864 µg/cigarette under modified smoking conditions. For the same year, the level of isoprene found in sidestream smoke is 90–3194 µg/cigarette (Industrial Reports 2004).

Given the broad range of activities included in Canada's comprehensive tobacco control strategy, no new risk management initiatives are planned at this time as a direct result of the designation of isoprene as "toxic."

9.1.3 Isoprene in Consumer Products

Consumer products made with isoprene-based rubber are not expected to be an important source of exposure to isoprene, as a study by the Organisation for Economic Co-operation and Development (OECD) detected no residual isoprene in 17 of 19 samples of polyisoprene rubber, and trace amounts (0.02–0.04 ppm) in the remaining two samples (OECD 2005). Therefore consumer products will not be targeted for risk management.

9.1.4 Isoprene in Paints and Coatings

Industry has confirmed that there is no use of isoprene in paints and coatings within Canada. Therefore, no risk management regulations, instruments or tools will be developed for this sector.

9.1.5 Isoprene in Medical Devices

Health Canada's Medical Devices Bureau has no concerns about the safety of butyl rubber other than the known issue of potential sensitization in susceptible subpopulations. It is otherwise a biocompatible and biologically safe material which is used in a variety of medical devices.

9.1.6 Isoprene in Cosmetics and Personal Care Products

Although currently there is no expected exposure to isoprene (monomer) from the use of cosmetics, uncertainty exists with regard to its residual levels in copolymers/polymers. It is recommended to add isoprene to the Cosmetic Ingredient Hotlist to prohibit it from being deliberately used in cosmetics sold on the Canadian market.

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 isoprene will continue to be monitored under the National Pollutant Release Inventory.

10. CONSULTATION APPROACH

The risk management scope for isoprene, 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 of rubber and rubber products and the tobacco industry
- Ontario Ministry of the Environment; Health Canada; Environment Canada

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 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 isoprene 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

Borbon A, Fontaine H, Veillerot M, Locoge N, Galloo JC, Guillermo R. 2001. An investigation into the traffic-related fraction of isoprene at an urban location. Atmos. Environ. 35 : 3749-3760.

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. *Tobacco Act: Tobacco Reporting Regulations*, SOR-2000/273, P.C. 2000-1040, Ottawa, June 2000.

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. 2003a. *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. 2003b. *Canadian Environmental Protection Act: On-Road Vehicle and Engine Emission Regulations*, SOR/2003-2, P.C. 2002-2164, Ottawa, December 12, 2002.

Canada. 2003c. *Canadian Environmental Protection Act: Off-Road Small Spark Ignition Engine Emission Regulations*, SOR/2003-355, P.C. 2003-1774, Ottawa, November 6, 2003.

Canada. 2005a. *Canadian Environmental Protection Act: 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. 2005b. *Canadian Environmental Protection Act: Off-Road Compression Ignition Engine Emission Regulations*, SOR/2005-32, P.C. 2005-138, Ottawa, February 8, 2005.

Canada. 2007. *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. 2008a. Screening assessment for the Challenge – 2-methyl, 1,3-butadiene (isoprene), Chemical Abstract Service Registry Number 78-79-5.

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

Canada 2008c. Screening assessment for the Challenge – Siloxanes (octamethyl-cyclotetrasiloxane, D4, decamethyl-cyclopentasiloxane, D5), Chemical Abstract Service Registry Numbers 556-67-2, 541-02-6 and 540-97-6.

Canada. 2008d. Screening assessment for the Challenge – Siloxanes (octamethyl-cyclotetrasiloxane, D4, decamethyl-cyclopentasiloxane, D5), Chemical Abstract Service Registry Numbers 556-67-2, 541-02-6 and 540-97-6.

Chang ME, Hartely DE, Cardelino C, Chang W-L. 1996. Inverse modeling of biogenic isoprene emissions. Geophys. Res. Lett. 23(21): 3007-3010.

Dow 2008. Product safety assessment: Epichlorohydrin. Dow Chemical Company. Available from: http://www.dow.com/productsafety/finder/epi.htm

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.

European Commission, 1976. Commission Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. Official Journal of the European Union L 262 p. 169.

European Commission. 1976. Commission Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. Official Journal of the European Union L 262 p. 169.

European Commission. 2002. Commission Directive 2002/72/EEC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs. Official Journal of the European Union L 220/18.

European Commission. 2004. *Isoprene (stabilized).* Commission Directive 2004/73/EC of 29 April 2004. Annex 1B. Official Journal of the European Union 16.6.2004. L216:27. European Commission. 29th ATP. Available from: http://ecb.jrc.it/documents/Classification-Labelling/DIRECTIVE_67-548-EEC/ATPS_OF_DIRECTIVE_67-548-EEC/29th_ATP.pdf

Gelmont D, Stein RA, Mead JF. 1981 Isoprene – The Main Hydrocarbon in Human Breath Biochem Biophys Res Commun 99(4):1456-1650.

Geron C, Harley P, Guenther A. 2001. Isoprene emission capacity for US tree species. Atmos. Environ. 35: 3341-3352.

Guenther A, Zimmerman P, Wildermuth M. 1994. Natural volatile organic compound emission rate estimates for U.S. woodland landscapes. Atmos. Environ. 28(6): 1197-1210.

Hartmann M. 1994. Pharmakokinetik und endogene production von isoprene beim menschen. GSF Report 21/94. [cited in BG Chemie 2000].

Heavner DL, Morgan WT, Ogden MW. 1996. Determination of volatile organic compounds and respirable suspended particulate matter in New Jersey and Pennsylvania homes and workplaces. Environ Int 22(2): 159-183.

[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. Isoprene. IARC Monogr Eval Carcinog Risks Hum. 71(3): 1015-25.

Industrial Rubber Goods. 2008. B2B Trading Zone of Industrial Rubber Goods. Available at: http://www.industrialrubbergoods.com/acrylic-rubber.html.

Industry Reports. 2004. TRR 14(11). December 2004. Health Canada, *Tobacco Reporting Regulations*, SOR-2000/273, P.C. 2000-1040, Ottawa, June 2000.

Lanxess. 2007. Lanxess Butyl Rubber Tech Center EMEA Available at http://techcenter.lanxess.com/bur/emea/en/products/description/3/index.jsp?docId=4014&pid=3.

Leber AP. 2001. Human exposure to monomers resulting from consumer contact with polymers. *Chemico-Biological Interactions* 135-136: 215-220.

MERL Ltd. 2008. MERL complete engineering solutions: Rubber selection – A guide to outlining properties. Available at http://www.merl-ltd.co.uk/2003_materials/rubber12.shtml.

[NCI] National Chemical Inventories [database]. 2007. Issue 1. Columbus (Ohio): American Chemical Society, Chemical Abstracts Service. [cited 2007 Oct]. Available at: http://www.cas.org/products/cd/nci/require.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

[NTP] National Toxicology Program (US). 1999. NTP report on carcinogens background document for isoprene [Internet]. Research Triangle Park (NC): U.S. Department of Health and Human Services, National Toxicology Program. [cited 10 January 2008]. Available at: http://ntp.niehs.nih.gov/files/Isoprene.pdf

[NTP] National Toxicology Program (US). 2004. Substance profiles: isoprene CAS No. 78-79-5 [Internet]. Research Triangle Park (NC): U.S. Department of Health and Human Services, National Toxicology Program [page last updated 26 Aug 2005; cited 3 April 2007]. Available at: http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s099isop.pdf.

[OECD] Organisation for Economic Co-operation and Development. 2005. Isoprene CAS No. 78-79-5 [Internet]. United Nations Environment Program (UNEP) Publications. [Cited 21 March 2007] Available at: http://www.chem.unep.ch/irptc/sids/OECDSIDS/78795.pdf.

[OPSI] Office of Public Sector Information. 2006. Statutory instrument no. 2916. The Dangerous Substances and Preparations (Safety) Regulations 2006. Available at: http://www.opsi.gov.uk/si/si2006/20062916.htm

Reimann, S., Calanca, P. and Hofer, P. 2000. The anthropogenic fraction contribution to isoprene concetrations in a rural atmosphere. Atmos. Environ. 34: 109-115.

Sharkey TD, Yeh S. 2001. Isoprene emission from plants. Annu. Rev. Plant. Physiol. Plant. Mol. Biol. 52: 407-436.

[Shell] Shell Chemical Company. 2008 Product Overview [Internet]. Shell Chemical Company [Cited 2008, Jan] Available at: http://www.shellchemicals.com/isoprene/1,1098,1503,00.html

Smith CJ, Perfetti TA, Garg R, Hansch C. 2003. IARC Carcinogens reported in Cigarette Mainstream smoke and their calculated log P values. *Food Chem. Toxicol*., *41* (6), 807-817.

State of California Environmental Protection Agency. 2008. Safe Drinking Water and Toxic Enforcement Act of 1986: Chemicals Known to the State to Cause Cancer or Reproductive Toxicity. Available from: http://www.oehha.ca.gov/prop65/prop65_list/files/P65single080108.pdf.

Taalman R. 1996. Isoprene: background and issues. Toxicology 113: 242 – 246.

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. 2001. Office of Solid Waste and Emergency Response. *LIST OF LISTS: Consolidated List of Chemicals Subject to the Emergency Planning and Community Right-To-Know Act (EPCRA) and Section 112(r) of the Clean Air Act: CERCLA Hazardous Substances*.http://www.epa.gov/ceppo/pubs/title3.pdf.

[US EPA] United States Environmental Protection agency. 2008. What is the TSCA Chemical Substances Inventory? Available at: http://www.epa.gov/oppt/newchems/pubs/invntory.htm.

[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