

# ENGO REPORT ON ETHYLENE OXIDE (EO)

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## Responding to Environment Canada Consultations on Ethylene Oxide in Sterilization Applications

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### Preface

Ethylene Oxide (EO) is a substance that has been declared “toxic” under section 64(c), of the Canadian Environmental Protection Act (CEPA 1999)<sup>1</sup>. It is a non-threshold human carcinogen that is manufactured and in use in Canada. In accordance with requirements of CEPA 1999, a strategy must be developed to manage the risk associated with EO.

The two sectors that are the primary sources of releases of Ethylene Oxide in Canada are the Chemical Industry and Sterilization Applications. Multi-stakeholder consultations were held in June 2003 to discuss the proposed risk management of Ethylene Oxide specifically with respect to the Healthcare Sector in Canada and to obtain feedback from the various stakeholders<sup>2</sup>.

This report is intended to inform the Canadian environmental community of the proposed risk management strategy on and to provide recommendations from Environmental Non-Governmental Organizations (ENGOS) to Environment Canada on its proposed risk management objectives and management instruments and implementation as well as other related issues arising from the consultations. While two sectors were identified as primary sources of releases of EO, the report focuses on the consultation material and hence the Healthcare Sector.

To provide context to the reader, the report includes background information on CEPA 1999 relevant to Ethylene Oxide; information on the use and release of ethylene oxide; and a description of Environment Canada’s proposed risk management strategy.

### **A. Ethylene Oxide and the Canadian Environmental Protection Act, 1999**

Ethylene Oxide (EO) was added to the Priority Substance List (PSL) of the Canadian Environmental Protection Act (CEPA) in 1995<sup>3</sup>. In accordance with requirements under the *Canadian Environmental Protection Act, 1999* (CEPA 99), Federal Ministers of Health and Environment are required to assess substances on the Priority Substances List (PSL) and determine whether they are toxic or capable of becoming toxic as defined in Section 64 in CEPA

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<sup>1</sup> Section 64 CEPA 99 defines a substance to be toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health.

<sup>2</sup> There were two multi-stakeholder meetings, June 17 in Ottawa and June 19 in Vancouver.

<sup>3</sup> The PSL identifies substances that may be harmful to the environment or constitute a danger to human health.

99. Substances assessed as "toxic" may be placed on Schedule 1 of CEPA (List of Toxic Substances) and considered for possible risk management measures.

The Priority Substances List Assessment Report for Ethylene Oxide concluded that the substance constitutes a danger to human life or health, but does not have harmful effects on the environment. On April 13, 2002, a summary of the Assessment Report was published in Part I of the *Canada Gazette* along with a statement under Subsection 77(6) recommending that ethylene oxide be added to the List of Toxic Substances (Schedule 1) of CEPA 1999.

The PSL2 Assessment Report has concluded that, based on studies on animals, cancer is the main impact of ethylene oxide on human health. Furthermore, ethylene oxide is believed to be a substance for which there is no threshold below which this effect may not occur and therefore there is considered to be some probability of harm at any level of exposure. The Assessment Report for ethylene oxide recommends that options to reduce exposure be investigated, particularly in the vicinity of point sources. Since ethylene oxide is neither persistent nor bioaccumulative, it is considered a Track 2 substance under the Toxic Substances Management Policy and therefore requires life cycle management.

Under section 91(1) of CEPA 1999, the Minister of Environment must propose a regulation or instrument respecting preventive or control actions to manage ethylene oxide within 24 months of publication of the statement under Subsection 77(6). Potential risk management instruments include guidelines or code of practice; regulations; pollution prevention plans (P2 plans); or environmental performance agreements. The instrument must be finalized no later than 18 months after it is proposed.

The risk management strategy proposed for the management of ethylene oxide outlines the objectives, instruments and approaches to reduce the risk to human health associated with ethylene oxide. Since the potential for adverse effects is greatest for humans exposed to contaminated air, the risk management strategy focuses on airborne exposure. Two priority sectors are covered by the proposed strategy, namely, sterilization applications and chemical industries.

## **B. Ethylene Oxide**

### **i) Applications**

**Chemical:** Ethylene Oxide is primarily used for production of ethylene glycol (95%) and in the manufacture of surfactants (4%). Among the remaining 1%, ethylene oxide is utilized in the manufacture of choline chloride, glycol ethers, and polyglycols<sup>4</sup>.

**Sterilization:** Ethylene oxide is used in the sterilization of various heat-sensitive goods. An estimated 101 tonnes of ethylene oxide was used in Canada in 2000 as a sterilization agent<sup>5</sup>, either pure or in combination with other gases that are inert. The three main end-use sectors are: (i) (1) contract sterilizer; (ii) (4) spice manufacturers; and (iii) healthcare facilities (at least 60 have

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<sup>4</sup> According to the 1996 Ethylene Oxide Assessment Report which indicates that approximately 95% (595 000 tonnes) of the Canadian production of ethylene oxide was used for production of ethylene glycol and an estimated 4% (26 000 tonnes) was used in the manufacture of surfactants.

<sup>5</sup> The quantity of ethylene oxide imported or exported represents less than 1% of the Canadian production.

been identified). The ethylene oxide produced in Canada is not of the specific grade required for sterilization. Consequently, ethylene oxide for use as a sterilization agent is entirely imported into Canada.

Note: Ethylene oxide mixed with CFCs as an inert gas was widely used in sterilization applications. As of 1996, upon Canada banning the importation of CFCs<sup>6</sup>, most provinces have established control measures on uses resulting in significant changes to sterilization practices: use of pure ethylene oxide, conversion to gas plasma and use of central facilities.

**Pest Control:** Ethylene oxide is registered as an active ingredient in one pest control product in Canada in the sterilization application to control bacteria in spices and natural seasoning. The use of ethylene oxide to sterilize spices and herbs is subject to the requirements of the *Pest Control Products Act* (PCPA). Currently, registration conditions allow the use of ethylene oxide for this purpose according to the directions of the label<sup>7</sup>.

Contract sterilizers and spice manufacturers combined represent 88% of annual ethylene oxide consumption as a sterilization agent in Canada.

## ii) Releases of Ethylene Oxide

Most ethylene oxide is released to the atmosphere with little transfer to water or soil. While sterilization may not represent a major use of ethylene oxide in terms of volume consumed, it is the most significant source of release to the environment. In 2000, releases from sterilization applications were 29 tonnes (as compared to releases of 18 tonnes from the Chemical Industry)<sup>8</sup>.

Approximately 71% of the 101 tonnes of ethylene oxide used annually as a sterilant in Canada are destroyed by some facilities through the use of a destruction technology; the remaining 29% are released to air. Of the estimated 28 tonnes released from sterilization operations, spice manufacturers contribute the largest amount - 19 tonnes (64%), healthcare facilities- 8 tonnes (27%), and the one contract sterilizer – 2 tonnes (7%)<sup>9</sup>.

The diffuse release (i.e., from non-point sources) of ethylene oxide from the use of surfactants and other chemicals are estimated to be negligible. Similarly, production of ethylene oxide from natural sources is expected to be negligible.

## C. Alternatives and Control Technologies in Sterilization Applications

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<sup>6</sup> Regulations to ban the importation of CFCs became effective January 1<sup>st</sup> 1996, in compliance with the Montreal Protocol on Substances that Deplete the Ozone Layer.

<sup>7</sup> The PMRA administers the PCPA and has the mandate to protect human health and the environment by minimizing the risks associated with pest control products. The current label requires that "[e]thylene oxide be removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device".

<sup>8</sup> National Pollutant Release Inventory (NPRI) for 2000.

<sup>9</sup> Miscellaneous use is about 2%, office-based practices are considered to be < 0.1%. These estimates are from "Technical and Socio-Economic Background Study for Ethylene Oxide in Sterilization Applications by Cheminfo Services Inc." and based on interviews conducted by Cheminfo with a sample of healthcare facilities and equipment manufacturers/ethylene oxide suppliers.

Options to control ethylene oxide emissions from sterilization operations are either: (i) destruction technology or (ii) substitute sterilization processes. The three destruction technologies that can reduce ethylene oxide emissions from sterilizers are catalytic oxidizers, acid-water scrubbers and thermal oxidizers. Acid-water scrubbers and catalytic oxidizers can reduce emissions from the sterilizer vent and aeration vent by 99%+. The only remaining untreated vent, the chamber exhaust vent, represents less than 1% of all emissions from sterilization processes.

**a) Contract Sterilizer:** The two main contract sterilization technologies utilized in North America today are ethylene oxide and gamma radiation. Ethylene oxide sterilization was the dominant technology until the 1980s, when the widespread usage of gamma sterilization began. Gamma radiation grew in popularity due to the availability of radiation-compatible plastics for products and packaging materials. However, the growth has slowed because many of the manufacturers that could easily convert to gamma-compatible products have already done so.

**b) Healthcare facilities:** Several sterilization methods other than the use of EO are available for the re-use of medical devices<sup>10</sup>. EO is typically the last resort used in healthcare facilities to sterilize products due to its disadvantages (flammability, toxicity, cost, etc.). It appears that none of the alternative sterilization processes may be capable of totally replacing ethylene oxide as a sterilization agent with a broad spectrum of applicability in the medical device industry. The new technologies appear to be product-dependent, occupying niche areas such as endoscopy, dental practice or specific industry applications and potentially limiting the number of products in healthcare facilities currently sterilized with ethylene oxide that could be sterilized using non-ethylene oxide alternatives.

**c) Spice Manufacturers:** Alternative chemicals for spice fumigation are available but at this stage, are not currently expected to be used to any great extent, purportedly due to their ineffectiveness or the prohibitive capital expenditure required to install the technology. Spice manufacturers could forward some of their products to the major gamma sterilization facilities in Canada. Gamma radiation is not a viable option on certain spices due to product damage.

#### **D. Proposed Risk Management Objectives and Instruments**

In formulating appropriate risk management instruments and levels of reduction, existing regulations and guidelines as well as other factors are highly relevant. For example with respect to Ethylene Oxide:

- United States standards and regulations exist for the chemical industry and well as commercial sterilization, with the intent to develop regulations for hospitals by 2004.
- Ontario and Alberta have developed air quality guidelines which are only legally binding when incorporated into establishing approvals (i.e. operating permits). However, the application of these guidelines is related to the specific permitting requirements of these provinces and, in that sense, limited.<sup>11</sup>. Quebec has set the ambient air quality criteria for

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<sup>10</sup> For example, steam, vapour phase hydrogen peroxide, gas plasma (hydrogen peroxide), peracetic acid, glutaraldehyde, and ozone.

<sup>11</sup> The Ontario Ministry of Environment uses Point of Impingement (POI) guidelines and regulated POI standards in reviewing CofAs. Under the Ontario Environmental Protection Act, CofAs are required for the construction, alteration or extension of any plant structure, equipment or mechanism that emits a contaminant to the environment. They do not apply to existing sources, only to new or modified facilities. The half-hour POI guideline is 151 g/m<sup>3</sup>. The ambient air

EO at 0.01 g/m<sup>3</sup> (annual average)<sup>12</sup>. **No other Canadian jurisdiction has any criteria/guidelines or regulations with respect to EO.**

- The present availability of control equipment to reduce emissions of EO
- Existence of alternatives to EO sterilization

The following objectives have been proposed by Environment Canada for both the chemical Industry and the Sterilization Sectors:

**Environmental objective:** Reduce exposure of the general population to the greatest extent possible and hence reduce ambient concentrations of ethylene oxide to the lowest practical level.

**Risk Management Objectives (RMO):** to reduce air emissions of ethylene oxide to lowest achievable levels by the application of BATEA - Best Available Techniques Economically Achievable. This objective is in accordance with Environment Canada's objective for Track 2 substances - "minimizing the releases through implementing best technologies and practices for pollution prevention and reduction"<sup>13</sup>.

### Risk Management Instruments

#### Sterilization Sector – Healthcare facilities and contract sterilizers:

Environment Canada has proposed the use of voluntary instruments, that is, guidelines requiring a 99% reduction from uncontrolled emissions levels from the sterilizer vent and aeration vent. The rationale for this choice was that:

- Guidelines allow for industry and government to respond faster to the environmental concerns and minimize incompatibilities with actions that may already be underway to control releases of ethylene oxide through controls imposed at the provincial level;
- If designed according to CEPA requirements, guidelines fulfill CEPA 1999 sections 91 and 92 requirements, unlike environmental performance agreements;
- Facilities that already meet the objective will not be required to take any further actions with guidelines, as can possibly be the case with other instruments, such as P2 plans; and
- Costs to government of developing guidelines are expected to be lower than costs of developing regulations;
- Since the only contract sterilizer and an estimated 50% of healthcare facilities already have control technology in place allowing them to meet the risk management objective, it is not warranted for Environment Canada to incur high regulatory development costs; and
- While not regulation, they may form the basis for laws and regulations

The 99% reductions target (abatement objective) would result in reduction of air emissions from this sector to less than 1 tonne per year and is comparable to what is currently in place in the

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guideline in Alberta is 15 g/m<sup>3</sup> (30-minutes).

<sup>12</sup> An air concentration under the criteria level is assumed to present no risk to the population.

<sup>13</sup> The RMO adheres to the Toxic Substances Management Policy in that it considers 1) existing available instruments, 2) technical and socio-economic factors, and 3) efficiency and economy in choosing and developing management strategies for toxic substances.

United States. Current destruction technologies have capabilities of greater than 99 percent removal efficiency of ethylene oxide<sup>14</sup>.

These guidelines would apply to any facility that uses bulk sterilization and meets the annual proposed threshold of use - 25 kg or more EO per year with the exclusion of facilities that only sterilize for pest control- spice sterilization. The abatement objective is to be met by summer-fall of 2005 (that is, within one year of publication of the final instrument in the *Canada Gazette*). Facilities have one year (2006) with which to “comply” with the guideline.

A monitoring scheme will be used to determine the effectiveness of the guidelines in reducing releases of ethylene oxide. If guidelines are determined not to have met the risk management or environmental objectives, subsequent action such as regulations will be considered.

**Contract Sterilizer:** Guidelines or an environmental performance agreement (EPA) are the voluntary instruments being considered for this industry. This instrument could also capture any new facility. The rationale for a voluntary instrument is that the one facility meets or exceeds all the criteria for reporting to the NPRI and hence the contract sterilizer must report its emissions to the program; and the contract sterilizer is currently subjected to the Point of Impingement (POI) guideline for ethylene oxide via its certificate of approval<sup>15</sup>.

**Spice Manufacturers:** Health Canada’s Pest Management Regulatory Agency (PMRA) is responsible for the risk management of air emissions from the spice manufacturers. Registration of EO expires December 2003 and is under re-evaluation. Should a decision to renew the registration be taken, it will be an opportunity to upgrade the directions on the product label to minimize risks from its use.

**Chemical Industry:** Environment Canada proposes to meet the proposed risk management objective by addressing releases of ethylene oxide through the Memorandum of Understanding (MOU) between government departments and the Canadian Chemical Producers’ Association (CCPA) (See Appendix 1).

**E. Summary of Proposed Implementation Plan - Timelines**

Item	Specific Actions for ethylene oxide management	Goal/Target
<b>Sterilization Application</b>		
1	Completion of qualitative screening study	Nov. 2002
2	Begin stakeholders meetings	June 2003
3	Draft chosen instrument	Oct. 2003
4	Consultation on draft instrument	Nov. 2003
5	Publish proposed instrument in Part I of the <i>Canada Gazette</i>	April 2004
6	Publish instrument in Part I of the <i>Canada Gazette</i>	Oct. 2005
<b>Chemical Industry</b>		

<sup>14</sup> The Technical and Socio-Economic Background Study for ethylene oxide in Sterilization applications proposed destruction technologies to reflect the BATEA.

<sup>15</sup> To meet this POI of 15µg/m<sup>3</sup>, the facility must meet the proposed risk management objective and use pollution control equipment.

1	Preliminary consultation with Industry, Provinces, NGO's, CCPA	Winter 2003
2	Initiate implementation through CCPA MOU	Spring 2003
3	Monitor progress of implementation	2003-2005

## **F. Workshop Feedback (Ottawa, June 17, 2003, Vancouver, June 19, 2003)**

### **Comments and Recommendations**

Participants (other than federal government representatives) included industry representatives from healthcare facilities, the sterilization industry and one ENGO at the Ottawa consultation. Most provinces were not represented at the consultation. There was no one from the spice manufacturing industry. In B.C., in addition to the healthcare, industrial and government sectors, there were representatives from CSA and the Centre for Disease Control. There were two ENGO representatives, one with a focus on labour health safety and one on ecological issues.

Similar concerns were shared amongst all participants on Environment Canada's background work and proposed strategy and instrument for managing ethylene oxide. Following is a summary of comments and recommendations on various aspects of the consultation.

### **Risk Management Objective and Instrument – Healthcare Sector**

Many participants recommended that for a risk management strategy to be effective, it needs to be robust, stringent and encourage the shift to alternative technologies and practices for sterilization. Considering that EO is a no-threshold human carcinogen, participants did not see the point of using a voluntary instrument, such as guidelines or environmental performance agreements (EPAs). There would be no incentive on facilities that needed to install abatement equipment to expend funds for technology needed to achieve the 99% abatement unless facilities were mandated to do so. Compliance with voluntary measures is not enforceable. Furthermore, the strategy does not speak to the need to consider pollution prevention at source or to encourage a shift to alternate technologies which are in the market and available. Therefore, participants were clearly in favour of regulatory measures or a ban with a firm deadline within the next 4-5 years or so and definitely not in favour of the proposed guidelines.

The Risk Management Strategy fails to address the importance of worker exposure and occupational health concerns. While occupational health is not under the purview per se of Environment Canada, certainly, it is those who come in contact with EO at the workplace who are at greatest risk. Therefore, any strategy should serve to protect the workers to the ultimate.

Other countries (e.g., Australia) have banned the use of EO for sterilization or have regulations in place. Canada should be doing the same.

The 99% "abatement" target in air releases is an end-of-pipe target and does not address or encourage pollution prevention at source. This would have been more favourable as well as an overall approach to reducing and eliminating the use of EO. In selecting the 99% target it is not clear what baseline was used – 99% of what? Is the reduction target specific to each facility or region?

The Risk Management Objective and guidelines proposal apply to any facility that performs bulk sterilization with EO and meets the annual threshold of use of 25 kg. In light of the non-threshold nature of EO, participants felt that the threshold use should be much lower, in the order of 10 kg, and in fact, some (including the ENGO) expressed the need for a zero threshold in use of EO. In

fact, if the 25 kg. threshold were used in BC then the only facility required to report would be Vancouver General Hospital. All other facilities would not be captured under this threshold. The consensus reached in the BC session was to have no threshold and include all facilities, thus capturing small privately run surgical facilities, which are often housed in office buildings and medical clinics. Apparently some of the latter facilities pose a greater risk to the public and employees than the large hospitals with expert knowledge of sterilization techniques and alternatives.

Furthermore, facilities that only sterilize for pest control (spices) are excluded (as it is assumed that registration of pesticide use will address this matter). It is unsure how Health Canada will proceed in this regard. Therefore, it seems unwise to exclude a major emitter of EO. If the product is no longer going to be registered, than its use is moot, but that assumption may not be realized.

#### **Information gaps:**

- Inventories of users and emitters need to be improved. It was questionable as to whether Environment Canada (and the consultants) had adequately identified the number of healthcare facilities and other users (e.g. offices, etc) of EO in sterilization.
- Small facilities may be larger emitters of EO than facilities with up-to-date equipment and destruction facilities. With the present provincial governments leaning toward privatization and the use of a variety of private clinical and surgical services, it is necessary to capture these facilities. The private clinics may take the most convenient sterilization method (EO) and not have the best expertise to operate these devices.
- Does cost and benefit analysis take into account cost avoidance by switching to alternate sterilization techniques?
- The only provinces with some measure of action on EO are Ontario, Alberta and Quebec and these are variable in terms of emission limits and their very nature, that is, they function primarily as guidelines or regulatory limits. Thus, it is not possible to compare the numerical values, and issues related to compliance, permitting provisions and enforcement. (For example, the Quebec air quality criteria are not legally enforceable.)
- More information is needed about action on EO in other countries – such as regulatory measures, control technology and use of alternatives for sterilization.
- How many healthcare facilities are aware of the issues related to EO and Environment Canada's risk management proposal? How informed are workers who are most likely exposed to EO, in particular, workers in small privately run facilities?
- The Assessment Report indicates that EO is a highly reactive chemical. What is the nature of that reactivity? What other unstable products may be formed under varying atmospheric conditions?
- What is the basis for estimates of EO emissions? Are the emissions based on specifications described by the manufacturer of the equipment being used by any facility? Some measurement/testing and verification process must be in place to ascertain actual emissions.
- The role of the Canadian Standards Association (CSA) with regards to sterilization equipment is not clear. (According to the health professionals who attended the BC session the CSA has a significant role in this matter.) Environment Canada (CEPA) needs to have discussions with the CSA and any other standards-setting organization in all affected industries.
- What other industries may be using EO and are not being addressed?

**Use of EO by spice manufacturers:** This is a major issue which was not adequately dealt with – it was deferred to Health Canada as an issue regarding registration of use of product but there was insufficient information (other than total use and emissions) on this usage. There is a question of EO as residue in food. How informed are spice manufacturers about EO? What safe alternates are available?

**Communication and Awareness:** This is an issue on three fronts, firstly, the need to communicate with the appropriate individuals in hospitals and spice manufacturers that use EO; secondly, the need to raise public awareness on the toxicity, application and prevalence of EO; and thirdly, to communicate to manufacturers of surgical instruments and devices of the issues associated with sterilization and/or disposal of the equipment they design and manufacture.

**Chemical Industry:** Even though the risk management objective and subsequent monitoring and reporting apply to the chemical industry, since the consultation was focussed on the healthcare sector) it is impossible to comment on any aspect of the risk management as applied to this sector.

#### **Monitoring and Reporting - Compliance**

Environment Canada has indicated that it will be developing a monitoring program to assess the effectiveness of the proposed instruments and risk management objective in reducing atmospheric emissions of ethylene oxide from both the chemical industry and sterilization sectors.

Possible elements include ambient air monitoring of ethylene oxide and/or certificates from manufacturers of pollution abatement equipment. Options for reporting are the National Pollutant Release Inventory (NPRI) data; reports requested under the guidelines; and routine surveys.

These elements are vague at this stage and difficult to comment on without more details. Crucial elements of monitoring include reliability and authenticity to ascertain trends and compliance with the “objective”. It is unclear as to whether the monitoring is mandatory for all facilities for whom the objective is applicable, who funds the monitoring, what is the required monitoring frequency and the acceptable quality of equipment used – level of detection and so on? Are the results verified by third party?

As to reporting out, it is unclear what the nature of requested reports or surveys will be or their frequency and whether these reports are confidential or in the public domain. While NPRI is a mandatory publicly-available inventory, reliance on reporting releases of ethylene oxide to NPRI at the present 10 tonne threshold is insufficient – it is simply too large by magnitudes. Also, it will not capture facilities with fewer than 10 employees (20 000 yearly hours).

## ENGO Recommendations

- Regulatory action on a **national basis** on the use of ethylene oxide for sterilization is the appropriate risk management instrument for all users sectors, that is, healthcare facilities, contract sterilizers, manufacturing of spices and any other users identified at **any amounts of EO** (i.e. greater than zero threshold user) with compliance date of 2006. Preferred regulation would be a ban on the use of EO. **ENGOS do not support the voluntary approach to “manage” EO through the development of guidelines.**
- The NPRI reporting threshold for releases of EO must be addressed. In that ethylene oxide is a non-threshold carcinogen, ENGOS recommend reporting releases of EO at any amount (that is, zero threshold) for all users of EO.
- More information is needed about existing safe alternates for sterilization for all present end-users and future trend in the use of such alternatives.
- Environment and Health Canada should prepare a public awareness and risk communication strategy for ethylene oxide to accompany the risk management strategy.
- Environment Canada should conduct a nation-wide survey of all potential facilities that use EO for sterilization to improve the EO data base, (including all privately run surgical and dental clinics or facilities or offices), determine the present use of alternates and update facilities on risk management of EO.
- Both Health Canada and Environment Canada must send a consistent and strong message as to the use of EO as a sterilant. Therefore, it is recommended that Health Canada (the PMRA branch specifically) not re-register EO as a spice fumigant upon its expiry in December 2003. It is essential that government departments work in a co-ordinated fashion in addressing toxic substances such as EO.
- Environment Canada needs to develop a detailed and consistent mandatory monitoring and reporting protocol to be universally applied for the sterilization sector (all end-users).
- Compliance and implementation plans need to be developed for both sectors (sterilization and chemical).
- Full stakeholder consultation with both sterilization and chemical sectors is advised to monitor progress on implementation and a review of the chosen instrument.
- Consideration must also be given to industries, other than the ones highlighted in the consultation, which require highly sterilized environments and may be using EO.

## Appendix 1: Chemical Industry:

The risk management objective for the Chemical Sector is to reduce emissions of ethylene oxide to lowest achievable levels by the application of best available techniques economically achievable. Environment Canada proposes to meet the proposed risk management objective for the chemical industry by addressing releases of ethylene oxide via a Memorandum of Understanding (MOU) with the Canadian Chemical Producers' Association (CCPA) and Environment Canada, Industry Canada and the Provinces of Alberta and Ontario. This MOU (signed in 2001) is an Environmental Performance Agreement involving commitment by member companies to address chemical substances of concern, including a priority towards CEPA toxics. The MOU contains an Annex that specifically addresses smog VOCs, including ethylene oxide. All chemical industry facilities reporting releases of ethylene oxide to NPRI are members of CCPA.<sup>16</sup>

To provide guidance with respect to best available techniques economically achievable, it is proposed that the existing CCME codes/guidelines for fugitive, storage and stack sources be reviewed and recommendations developed for appropriate performance standards for toxic volatile organic substances. It is expected that such standards would be comparable to what is currently in place in other jurisdictions, primarily the United States, for similar industrial operations.

Use of the CCPA MOU as the mechanism to address ethylene oxide include identification of CCPA member facilities releasing ethylene oxide and reporting of actions being considered by these companies to prevent and minimize such releases. Progress by CCPA members for emission reductions would be monitored and reviewed in multi-stakeholder steering group meetings which have been established to manage the MOU. CCPA member companies will continue to report emissions to NPRI allowing progress to also be monitored in a broad public manner.

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<sup>16</sup> Performance by voluntary initiatives from this sector under a previous MOU has been demonstrated. Releases from this industry were 29 tonnes in the year 2000<sup>16</sup>, an 83% reduction in ethylene oxide emissions from this sector between 1993 and 1998. Reductions resulted from a combination of facility closures and improvements (installation of pollution control equipment, process and storage improvements, leak detection and repair program). However additional industrial capacity for the manufacture and use of ethylene oxide occurred during this period. Releases between 1998 and 2000 remained constant at 18 tonnes.