RISK MANAGEMENT STRATEGY FOR ETHYLENE OXIDE

1. ISSUE

Ethylene oxide was placed on the second Priority Substances List (PSL2) in December 1995. This list identified substances that would be given priority for assessment to determine whether they are "toxic" under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). 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.

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). The instrument must be finalized no later than 18 months after it is proposed. 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.

The risk management strategy outlines the objectives, instruments and approaches proposed to reduce the risk to human health associated with ethylene oxide. The strategy covers two priority sectors for the management of ethylene oxide: sterilization applications and chemical industries.

The development of the risk management strategy was coordinated by the Chemicals Control Division with the input of the Sustainable Consumption Division of Environment Canada, and risk managers at Health Canada.

2. BACKGROUND

2.1. Basic Properties

At room temperature and normal atmospheric pressure, ethylene oxide (C_2H_4O) is a colorless, highly reactive and flammable gas. It has a high vapor pressure and high water solubility. It is very reactive in both the liquid and vapor phases.

2.2. Uses

The Ethylene Oxide Assessment Report indicates that, in 1996, 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. Among the remaining 1%, ethylene oxide is utilized in the manufacture of choline chloride, glycol ethers, polyglycols. Ethylene oxide is also used in the sterilization of various heat-sensitive goods. However, ethylene oxide produced in Canada is not used in sterilization applications, as it is not produced to the specific

sterilization grade required. Ethylene oxide used as a sterilization agent is entirely imported into Canada.

An estimated 101 tonnes of ethylene oxide was used in Canada in 2000 as a sterilization agent, either pure or in combination with other gases that are inert. There are three main end-use sectors for ethylene oxide as a sterilization agent in Canada: (i) contract sterilizers; (ii) spice manufacturers; and (iii) healthcare facilities. In the sterilization application to control bacteria in spices and natural seasoning, ethylene oxide is registered as an active ingredient in one pest control product in Canada. Contract sterilizers and spice manufacturers combined represent 88% of annual ethylene oxide consumption as a sterilization agent in Canada.

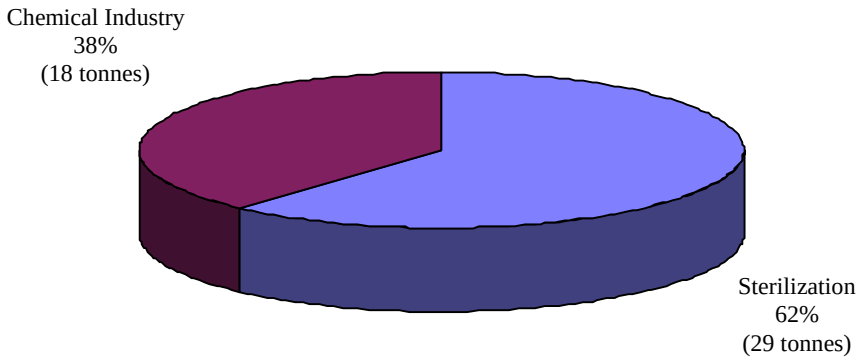
The quantity of ethylene oxide imported or exported represents less than 1% of the Canadian production.

2.3. Releases

There are only two sectors that contribute to point source releases of ethylene oxide in Canada: sterilization and chemical industries (Figure 1). Point source releases from Canadian chemical operations result from the original production of this chemical or when it is used as a process reactant in the manufacture of other substances. On-site releases represent a small portion of total quantities used in this sector and are primarily air emissions originating from fugitive equipment leaks, stack and vent sources and aboveground storage tanks.

Although sterilization is not a major use of ethylene oxide in terms of volumes consumed, it is the most significant source of release to the environment.

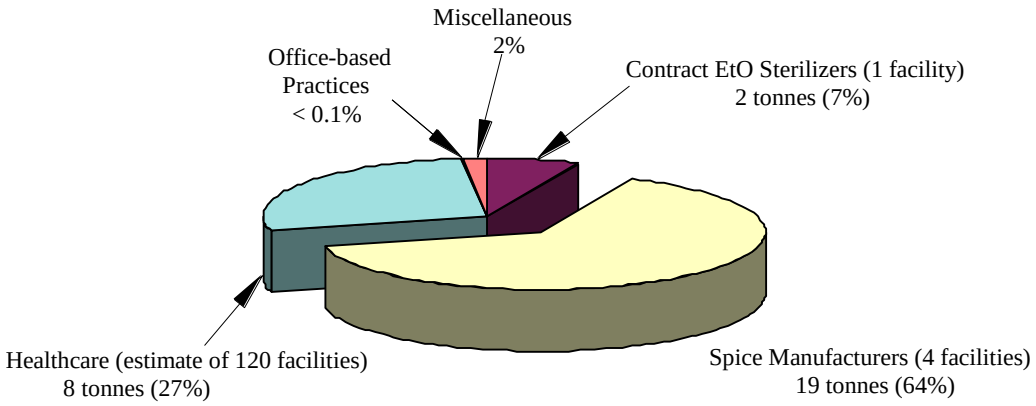
Figure 1: Air Releases by Sectors in Canada (year 2000)



Source of data: Technical and Socio-economic Background Study on EtO in Sterilization Applications and NPRI

Within the three main end-use sectors that perform sterilization in Canada, there are 1 contract sterilizer, 4 spice manufacturers and an estimated 120 healthcare facilities (Figure 2). It is estimated that 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.

Figure 2 : Summary of Estimated Ethylene Oxide Emissions to Air In Sterilization Applications (year 2000)



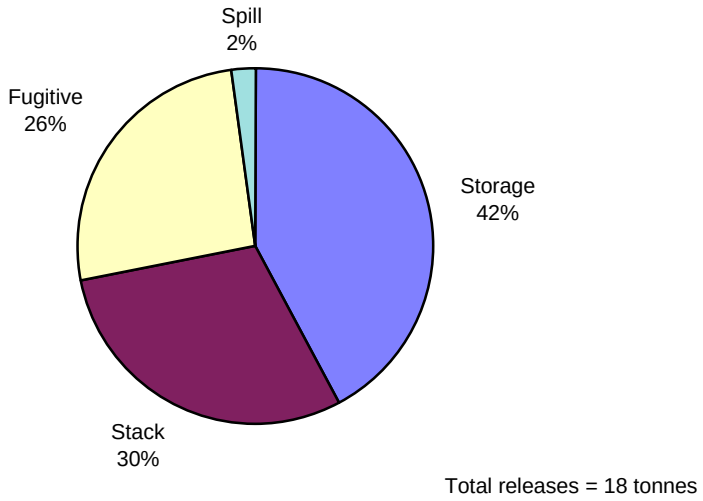
Source of data: Technical and Socio-economic Background Study on EtO in Sterilization Applications

According to the National Pollutant Release Inventory (NPRI)[1], 18 tonnes of ethylene oxide were released from the chemical industry in the year 2000. This represents an 83% reduction in ethylene oxide emissions from this sector between 1993 and 1998. Reductions in emissions 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 also occurred during this period. Releases between 1998 and 2000 remained constant at 18 tonnes (Figure 3).

Anthropogenic sources also include the diffuse release (non-point sources) of ethylene oxide from the use of surfactants and other chemicals, but these releases are estimated to be negligible. Similarly, production of ethylene oxide from natural sources is expected to be negligible.

[1] The NPRI emissions are the same as those reported by the Canadian Chemical Producers' Association in their 2000 Emissions Inventory Report 9.

Figure 3: Chemical Industries Releases of Ethylene Oxide by Type - NPRI 2000



3. CONCERNS (WHY WE NEED ACTION ON ETHYLENE OXIDE)

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.

4. EXPOSURE SOURCES

Most ethylene oxide is released to the atmosphere and little transfer to water or soil is expected. Ethylene oxide is expected to undergo numerous fate processes in water, including evaporation, hydrolysis, and aerobic and anaerobic biodegradation. Evaporation from water appears to be a significant removal process. Because of its high vapour pressure, a spill of ethylene oxide to soil will result in most volatilizing to the atmosphere, with only a small fraction infiltrating the soil.

The potential for adverse effects is greatest for humans exposed to contaminated air. Therefore, the risk management strategy focuses on airborne exposure.

5. CONSIDERATIONS

5.1. Existing Canadian Legislation, Regulations and Guidelines

5.1.1. General

The Ontario Ministry of the Environment (MOE) has developed air quality standards for priority contaminants, which include ethylene oxide. The MOE uses a combination of Point of Impingement (POI) guidelines and regulated POI standards in reviewing Certificates of Approval (C of As). Under the Ontario *Environmental Protection Act* (EPA), it is required to obtain C of As for the construction, alteration or extension of any plant structure, equipment, mechanism or thing that emits a contaminant to the environment. Alteration of a process or rate of production also requires approval. Contract sterilizers, spice manufacturers and healthcare facilities located in Ontario are subject to the requirements of the Ontario EPA.

POI standards are listed in Regulation 346 and can be used directly as enforcement tools. POI guidelines are derived based on the same considerations as standards. They are used by the MOE in reviewing applications for C of As and to approve new and modified emission sources. Once incorporated into a legal instrument such as a C of A, POI guidelines are legally binding. However, unlike POI standards in Regulation 346, they do not automatically apply to existing sources at the time the guidelines are approved. The half-hour POI guideline for ethylene oxide is 15 µg/m^3.

The province of Alberta has established Ambient Air Quality Guidelines, which for ethylene oxide is 15 µg/m^3 (30-min avg.). These guidelines are used in a number of ways, including establishing approval conditions for regulated industrial facilities. Once incorporated into an approval, they become legally binding. Proposed industrial projects that could cause an adverse effect on the environment must apply for an approval. The *Environmental Protection and Enhancement Act* provides that approvals may be issued for specified periods. Generally the maximum term is 10 years, however shorter term can be set. The Act also provides that an amendment can be made to the approval to deal with an adverse effect that was not reasonably foreseeable when the approval was first issued.

In Quebec ambient air quality criteria were recently developed. These criteria were developed with the objective of providing protection against adverse health effects, nuisance and effects on the ecosystems. An air concentration under the level of the criteria is assumed to present no health risk to the population. These criteria are used in a number of ways, including monitoring of ambient air quality and as approval conditions for industrial facilities. The ambient air quality criteria for ethylene oxide is 0.01 µg/ m^3 (annual avg.).

The other Canadian provinces and territories either do not have air quality guidelines for ethylene oxide specifically, or have not established any air quality criteria/guidelines at all.

As a general proposed action related to the management of hazardous chemicals in Canada, Environment Canada is developing a regulation under section 200 of CEPA 1999, namely the *Environmental Emergency Regulations* (E2 Regulations). These proposed regulations targets all facilities that store or manage chemicals listed in the regulation at or above specified threshold quantities. A threshold of 4.5 tonnes has been established in these regulations for ethylene oxide. If both the total amount of ethylene oxide on site at any time and the single largest container exceed this threshold quantity, the owner or operator must comply with the requirements of these regulations. Once the E2 Regulations are in force, which is expected by spring 2003, every company that

meets the criteria for ethylene oxide will be required to file information with Environment Canada. Notices identifying the amount of this substance stored and/or processed by the facility, its single largest container, the company's location, and indicating that an environmental emergency plan has been prepared and implemented, will have to be filed within specified time periods.

5.1.2. Sterilization

CFCs were widely used as an inert gas mixed with ethylene oxide in sterilization applications. Canada published regulations banning the importation of CFCs effective January 1st 1996, in compliance with the Montreal Protocol on Substances that Deplete the Ozone Layer. Most provinces have established control measures on uses. This has resulted in significant changes to sterilization practices: use of pure ethylene oxide, conversion to gas plasma and use of central facilities.

The *Pest Control Products Act* (PCPA) requires that all pest control products used or imported into Canada be registered unless expressly exempted by regulation from this requirement. The Pest Management Regulatory Agency (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 use of ethylene oxide to sterilize spices and herbs is a pest control application and subject to the requirements of the PCPA. Currently, registration conditions allow the use of ethylene oxide for this purpose. Ethylene oxide can only be used according to the directions of the label. The current label requires that "[e]thylene oxide be removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device". The registration of this product expires on December 31, 2003. Ethylene oxide is consequently under re-evaluation by the PMRA and should a decision to renew the registration be taken, it will be an opportunity to upgrade the directions on the product label.

5.1.3. Chemical Industry

Between 1993 and 1995, under the CCME NOx/VOC Management Plan, guidelines and codes of practice were developed for controlling emissions of smog volatile organic compounds (VOCs) from chemical and petroleum refinery operations. Ethylene oxide is considered a smog VOC. These performance standards address fugitive equipment leaks, stack/point sources and releases from aboveground storage tanks. The current codes and guidelines do not address VOCs from a 'toxics' perspective.

A Memorandum of Understanding (MOU) was signed in 2001 between the Canadian Chemical Producers' Association (CCPA), Environment Canada, Industry Canada and the Provinces of Alberta and Ontario. This MOU identifies, as a priority, reviewing CCPA progress in reducing emissions to air of CEPA toxic substances. It also contains a VOC Annex outlining reduction goals and timelines to address VOC releases from CCPA member companies. The MOU Annex references the use of the existing (or amended) CCME Codes and Guidelines as benchmarks for determining appropriate practices for VOC emission reductions.

5.2. United States Legislation

5.2.1. General

Under the United States Environmental Protection Agency's (EPA) Risk Management Planning (RMP) [Rule s112r of the Clean Air Act Amendments, 1990], ethylene oxide is listed as a toxic substance with a threshold quantity of 10,000 lbs. Those facilities covered by the RMP rule must develop and implement a risk management program and maintain documentation of the program at the site. The program includes an analysis of the potential off-site consequences of an accidental release, a 5-year accident history, a release prevention program and an emergency response program.

5.2.2. Sterilization

Under the provisions of the 1990 Clean Air Act Amendments (CAA), the EPA has promulgated national emission standards (NESHAP) for ethylene oxide commercial sterilization and fumigation operations. Sources affected by the final standards include medical equipment suppliers, pharmaceuticals, other health related industries, spice manufacturers, large libraries, large museums and archives and contract sterilizers.

Consistent with the CAA, the EPA has elected to regulate both major (i.e., sources that emit or have the potential to emit 10 tons per year or more of any hazardous air pollutant (HAP) or 25 tons per year or more of any combination of HAPs) and area sources (i.e., any source that is not a major source). Existing and new major sources have to control emissions to the level achievable by the maximum achievable technology (MACT); existing and new area sources need to control emissions using generally available control technology (GACT). The regulation specifies emissions standards as shown in Table 1 below.

Table 1. U.S. EPA NESHAP Emissions Reductions and Limits for Ethylene Oxide

Source size, yearly EO usage	Emissions standards for each source type		
	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent
< 1 ton	No control required; minimal recordkeeping requirements apply		
≥ 1 ton and < 10 tons	99% emission reduction	No control	No control
≥ 10 tons	99% emission reduction	1 ppmv maximum outlet concentration --OR-- 99% emission reduction	No control

The original regulation contained reduction standards for the chamber exhaust vent. However, the EPA has since eliminated the requirement to control chamber exhaust emissions due to explosions that were attributed to the control of ethylene oxide using catalytic oxidation technology. It is therefore no longer required to control emissions from the chamber exhaust vent.

Although the regulations apply to virtually all commercial sterilization and fumigation sources that use ethylene oxide as a sterilant, it specifically exempts the following types of sources:

- beehive fumigators
- research and laboratory facilities
- medical facilities such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is providing medical services to humans or animals.

To address the disproportionate impacts of air toxics hazards in urban areas from the cumulative effect of many, varied sources of emissions, EPA is supplementing the existing regulatory program with the Integrated Urban Air Toxics Strategy. Under this strategy, EPA intends to develop regulations by the year 2004 for hospital sterilizers.

5.2.3. Chemical Industry

The EPA has developed national emission standards and regulations for the release of HAPs from fugitive, stack and storage sources for major stationary sources. Ethylene oxide is included on the U.S. HAPs list. Standards include MACT for the Synthetic Organic Chemical Manufacturing Industry (SOCMI). Some of these requirements are more stringent than those incorporated into the current CCME codes and guidelines for smog VOCs.

5.3. Alternatives and Control Technologies in Sterilization Applications

Options to control ethylene oxide emissions from sterilization operations can be classified either as: (i) destruction technology, or (ii) substitute sterilization processes. There are three destruction technologies that can reduce ethylene oxide emissions from sterilizers, namely 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%+ and therefore allow achieving the risk management objective. The only remaining untreated vent, the chamber exhaust vent, represents less than 1% of all emissions from sterilization processes.

5.3.1. Contract Sterilizer

Contract sterilization facilities only offer sterilization services and are not involved in the manufacture of any goods. There are two main contract sterilization technologies that are utilized in North America today, namely 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. There is still a trend among medical device manufacturers to fabricate products with polymers that are more conducive to gamma radiation. However, there are currently no new polymers that are available for use by medical device manufacturers to further improve the market share for gamma radiation.

5.3.2. Healthcare facilities

In healthcare facilities, there are several other sterilization methods available for the re-use of medical devices: steam, vapour phase hydrogen peroxide, gas plasma (hydrogen peroxide), peracetic acid, glutaraldehyde, ozone. Ethylene oxide is typically the last resort used in healthcare facilities to sterilize products due to its disadvantages (flammability, toxicity, cost, etc.). In general, it appears that none of the ethylene oxide alternative sterilization processes will 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 instead appear to be product-dependent, occupying niche areas of use such as endoscopy, dental practice or specific industry applications. Therefore, the number of products currently sterilized with ethylene oxide that could be sterilized using non-ethylene oxide alternatives in healthcare facilities is limited.

5.3.3. Spice Manufacturers

Alternative chemicals for spice fumigation are available but are not expected to be used to any large extent, either because of their effectiveness 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. However, gamma radiation is not a viable option on certain spices due to product damage and therefore only certain spices would be able to be sterilized with this technology.

6. PROPOSED ENVIRONMENTAL OBJECTIVE

The environmental objective describes a condition of the environment that is desirable to achieve, taking human health concerns and environmental issues into account. It is a long term objective that serves as a benchmark to determine when the issue has been addressed.

The focus of the human health assessment on ethylene oxide is airborne exposure. Based upon studies conducted in animals, cancer is considered the critical endpoint for effects of ethylene oxide on human health. In inhalation studies, ethylene oxide has induced a wide range of tumors with a strong likelihood that the mode of action involves direct interaction with genetic material.

For carcinogenic effects likely mediated through direct interaction with genetic material, it is considered that there is some probability of harm to human health at any level of exposure. As a result, continuing efforts should be made to reduce exposure of the general population to the greatest extent possible. However, it is recognized that incremental risks associated with exposure to low levels of such substances may be sufficiently small so as to be essentially negligible compared with other risks encountered in society.

As a basis against which to evaluate the comparative impact of various proposed risk management measures, a measure of carcinogenic potency is presented here, and guidance provided for interpretation in the context of relative risks associated with a range of airborne levels in the general environment. Health Canada does not deem any of these values as "acceptable" from a societal viewpoint, but rather as indicated above, encourages reduction to the extent possible of exposure of the general public to

compounds which are carcinogenic with likely mode of action involving direct interaction with genetic material.

Therefore, the environmental objective is to reduce ambient concentrations of ethylene oxide to the lowest practical level.

In developing risk management options based upon the environmental objective, additional guidance is provided in the assessment report. In assessing the health risk of Existing Substances under CEPA 1999, tumorigenic potencies for carcinogens acting through direct interaction with genetic material are estimated in the range of the experimental data in animal species or epidemiological studies. Specification of low dose risks in absolute terms of predicted incidence or numbers of excess deaths per unit of the population is not considered justified, due to the numerous uncertainties inherent in extrapolating over many orders of magnitude particularly from experimental studies in animals without a clear understanding of mode of action. Therefore, for studies in experimental animals, potency is expressed as the concentration or dose which induces a 5% increase in the incidence of tumors (Tumorigenic Concentration or Dose 05, TC_{05} or TD_{05}).

For ethylene oxide, the Tumorigenic $Concentration_{05}$ is 2.2 mg/m^3. As examples against which to evaluate the comparative impact of various proposed risk management measures, values based on division of the TC_{05} by a margin of (5,000 to 50,000) afford similar protection to that associated with the range for low dose risk estimates generally considered by various agencies to be "essentially negligible" (i.e., 10^{-5} to 10^{-6}). For ethylene oxide, these values equate to 0.44 and 0.044 $\mu g/m^3$.

7. PROPOSED RISK MANAGEMENT OBJECTIVES

The risk management objective is to reduce air emissions of ethylene oxide to lowest achievable levels through the application of BATEA - Best Available Techniques Economically Achievable in order to reduce the health risks associated with ethylene oxide.

This risk management approach 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". It 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.

7.1. Sterilization

The Technical and Socio-Economic Background Study for ethylene oxide in Sterilization applications proposed destruction technologies to reflect the BATEA. Current destruction technologies have an ethylene oxide removal efficiency greater than 99 percent. It is therefore proposed that the risk management objective for the sterilization sector consists of a 99% reduction from uncontrolled emissions level from the sterilizer vent and aeration vent. This is comparable to what is currently in place in the United States for sterilization operations. With this target, air emissions from this sector could come down to less than 1 tonne per year.

7.2. 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. It is proposed that this would be accomplished through the implementation of performance standards comparable to what is currently in place in other jurisdictions, primarily the United States, for similar industrial operations.

8. PROPOSED RISK MANAGEMENT INSTRUMENT/TOOLS TO BE DEVELOPED

8.1. Sterilization

The sterilization sector is the most significant source of release and it is expected that one of the instruments (if more than one) developed for this sector will fulfill the requirements of s.91 of CEPA 1999. The instrument will be proposed prior to April 2004 to comply with the CEPA 1999 timeline.

A qualitative assessment of relevant risk management instruments identified the following most promising instruments for the contract sterilizer and healthcare facilities:

- guidelines or code of practice
- regulations
- pollution prevention plans (P2 plans)
- environmental performance agreement.

8.1.1. Healthcare Facilities

Guidelines are being proposed as the risk management instrument for healthcare facilities. Guidelines are proposed for the following reasons:

* Guidelines allow the industry and government to respond faster to the environmental concerns as they are less time consuming and less expensive to develop than regulations.
* Guidelines minimize incompatibilities with actions that may already be underway to control releases of ethylene oxide through controls imposed at the provincial level.
* 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.
* 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.
* Guidelines, if designed according to CEPA requirements, fulfill CEPA 1999 sections 91 and 92 requirements, unlike environmental performance agreements.

Compliance promotion will be key to the success of the guidelines requirements. A compliance promotion plan will be drafted. The monitoring scheme discussed in section 8.3 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.

8.1.2. Contract Sterilizer

For the contract sterilizer, the following instruments are being considered: guidelines or an environmental performance agreement (EPA). Given that the same risk management objective (RMO) is being proposed for healthcare facilities and the contract sterilizer, the similarity in control technologies used in these facilities, it would be practical to use the same instrument for these two sectors. A further advantage of using guidelines for the contract sterilization sector is that this instrument could also capture any new facility.

A volontary instrument is considered appropriate for the contract sterilizer for the following reasons:

- since the facility meets or exceeds all the criteria for reporting to the NPRI, the contract sterilizer must report its emissions to the program. The NPRI is a nation-wide, publicly-accessible inventory of pollutants released to the environment. The NPRI program is delivered by Environment Canada under the authority of CEPA 1999. The requirements to submit an annual report to Environment Canada on the releases and transfers of NPRI substances are published in the *Canada Gazette*, Part I. It is therefore possible to monitor the trend in its emissions;
- the contract sterilizer is currently subjected to the Point of Impingement (POI) guideline for ethylene oxide via its certificate of approval. To meet this POI of 15µg/m^3, the facility must meet the proposed risk management objective and use pollution control equipment.

8.1.3. Spice Manufacturers

Health Canada's Pest Management Regulatory Agency (PMRA) will be responsible for the risk management of air emissions from the spice manufacturers'. PMRA has the mandate to protect human health and the environment by minimizing the risks associated with pest control products. PMRA has the appropriate tools/authority under the PCPA to effectively manage the risks of the ethylene oxide emissions from spice manufacturers. Depending on the outcome of the re-evaluation for ethylene oxide, additional control measures will be considered to minimize risks from its use.

8.2. Chemical Industry

To meet the proposed risk management objective for the chemical industry it is proposed to address releases of ethylene oxide through the CCPA MOU. The framework to address toxic substances exists in the MOU. This MOU is an Environmental Performance Agreement involving commitment by member companies to address chemical substances of concern, including a priority towards CEPA toxics, and 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. Since 1993, and even though industrial production capacity increased, voluntary initiatives by this industry have resulted in an 83% reduction of releases of ethylene oxide in the chemical industry. Performance by voluntary initiatives from this sector under the previous MOU has been demonstrated.

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.

8.3. Monitoring

A monitoring program will be developed to assess the effectiveness of the proposed instruments and of the risk management objective in reducing the atmospheric emissions of ethylene oxide from both sectors. The following three elements will be considered:

1. the National Pollutant Release Inventory (NPRI) data;
2. reports that could be requested under the proposed instrument;
3. monitoring at facilities that perform sterilization to determine the concentration of ethylene oxide in ambient air.

9. OUTLINE OF IMPLEMENTATION PLAN

9.1. Sterilization

The objective is to publish the proposed guidelines for healthcare facilities by April 13, 2004 to meet Environment Canada’s legal obligations under section 91.

Compliance promotion will be important to the success of the guidelines requirements. Some targeted users may have incomplete knowledge and understanding of environmental legislation, especially federal legislation. A compliance promotion plan will be drafted in collaboration with Regional offices.

9.2. Chemical Industry

Use of the CCPA MOU as the mechanism to address ethylene oxide would 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.

10. PROPOSED CONSULTATION APPROACH

The risk management strategy for ethylene oxide will be posted on Environment Canada's Green Lane for comments.

10.1. Sterilization

Stakeholders will include contract sterilizers that use ethylene oxide, ethylene oxide sterilization associations, healthcare facilities, healthcare facilities associations, medical device manufacturers, provincial governments and environmental non-government organizations.

Environment Canada will seek advice and comments on the proposed risk management objectives and risk management instruments.

10.2. Chemical Industry

In addition to posting on the Green Lane, the proposed risk management strategy will be mailed to targeted stakeholders including the CCPA, individual chemical manufacturers, the CCPA MOU Environmental Protection Steering Group, provincial authorities and the Canadian Environmental Network (CEN).

11. NEXT STEPS / TIMELINE

Item	Specific Actions for ethylene oxide management	Goal/Target	Status
Chemical Industry			
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	
Sterilization Application			
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 *Canada Gazette*	April 2004	
6	Publish instrument in Part I of the *Canada Gazette*	Oct. 2005	