



Proposed reduction of the NPRI reporting threshold for ethylene oxide

Consultation document

October 2024



Executive summary

The National Pollutant Release Inventory (NPRI) is Canada's legislated, publicly accessible inventory of pollutant releases (to air, water, and land), disposals and transfers for recycling. It supports a wide number of environmental initiatives, including pollution prevention and abatement. A Multi-Stakeholder Work Group advises Environment Climate Change Canada (ECCC) on proposed changes to reporting requirements and other issues related to the NPRI. The priority of considering an alternate NPRI reporting threshold for ethylene oxide was identified by both internal experts and environmental non-government representatives on the NPRI multi-stakeholder work group.

Ethylene oxide (CAS 75-21-8) is a colourless and highly reactive gas currently used in Canada primarily as both a chemical intermediate in the production of ethylene glycol and other chemicals, and as a sterilizing agent, mainly for medical equipment that cannot be sterilized by other means. In 2001, Environment Canada and Health Canada found ethylene oxide to be toxic under the *Canadian Environmental Protection Act* based primarily on carcinogenic effects to humans from exposure by inhalation. Since then, new information has shown that ethylene oxide has higher toxicity than previously thought and that current NPRI reporting requirements may not adequately capture relevant point sources of this substance.

Ethylene oxide has been listed on the NPRI since its inception (1993) at the standard 10-tonne manufacture, process or other use threshold and 1% concentration threshold. ECCC is now proposing to lower the reporting threshold to require reporting by any facility that manufactures, processes or otherwise uses ethylene oxide (including in activities related to education/training of students) in amounts of 1 kilograms or more per year, at a concentration of 0.1% by weight or more, starting with the 2025 reporting year. Previously excluded activities related to the education or training of students will now also be required to be included in a facility's mass threshold calculation. This proposed change is lower than the 10kg MPO threshold proposed in early engagement documents on this topic due to new information suggesting that emissions coverage at that threshold would potentially be inadequate. This proposed change will support current risk management tools and inform the public about relevant releases in their communities

The purpose of this consultation document is to obtain input on the proposed change to the ethylene oxide reporting requirements. A Multi-Stakeholder Work Group (MSWG) advises ECCC on proposed changes to reporting requirements and other issues related to the NPRI. We invite the Work Group, other interested or impacted stakeholders and the public to comment on this proposal before December 2, 2024, via email at inrp-npri@ec.gc.ca.

Table of Contents

Executive summary	ii
1. Introduction.....	4
2. Proposed change.....	4
3. Background	6
3.1 Government of Canada action on ethylene oxide	6
3.1.1. Risk Assessment	6
3.1.2. Risk Management	6
3.1.3. Research and monitoring	7
3.1.4. Risk Management Performance Measurement	8
3.1.5. Provincial Risk Management.....	8
3.2. NPRI data for ethylene oxide	9
3.2.1. Releases.....	9
3.2.2. On-site disposals	13
3.2.3. Off-site transfers (for recycling, treatment, or disposal)	14
3.3. Risk assessment and management in the US.	16
4. Rationale	18
4.1. Rationale for deciding if the EtO threshold should be lowered.....	18
4.1.1. Air quality research: unreported sources may be significant.....	19
4.1.2. Ontario facilities authorized to use EtO	19
4.1.3. Evolving toxicity information in the United States	19
4.2. Rationale for selecting the new EtO threshold	20
4.2.1. Alignment and support of ECCC emission reduction guidelines for the sterilization sector..	20
4.2.2. Exposure estimates based on release quantities	21
4.2.3. A concentration threshold of 0.1% by weight is standard for Carcinogenic, Mutagenic and Reproductive toxicants (CMR)	22
4.2.4. Inclusion of activities related to education or training of students (universities, colleges, etc.).	22
.....	22
5. Impact on reporting facilities	22
5.1. Facilities that may now need to report.....	22
5.2. Methods for estimating threshold and release/transfer quantities	23
6. Specific questions to address	25
Appendix A – Facilities with environmental permission to use EtO in Ontario*	26

1. Introduction

The National Pollutant Release Inventory (NPRI) is Canada's legislated, publicly accessible inventory of pollutant releases (to air, water, and land), disposals and transfers for treatment or recycling. It supports a wide number of environmental initiatives, including pollution prevention and abatement. More details on the purpose of the NPRI are described on the [NPRI website](#).

The NPRI is one of a number of information gathering tools available to Environment and Climate Change Canada (ECCC). Keeping in mind the scope of the NPRI, as well as evolving progress and knowledge about pollutants in Canada, there are a variety of potential drivers for changes to the NPRI, including (but not limited to):

- Ensuring that the NPRI substance list and reporting thresholds are appropriate for gathering data on pollutant releases in Canada;
- Ensuring that the NPRI substance list and reporting thresholds, and information collected, meet proponent (and other users) needs. For example:
 - supporting the risk management of substances,
 - supporting the development of other pollutant inventories (such as the Air Pollutant Emissions Inventory), and related international reporting commitments,
 - supporting international initiatives such as the Commission for Environmental Cooperation (CEC) Action Plan to Enhance the Comparability of Pollutant Release and Transfer Registers (PRTRs) in North America, which aims to enhance the comparability of the NPRI with other PRTRs such as the U.S. Toxics Release Inventory, where such alignment would also be in the Canadian interest and appropriate, and
 - adapting to input received from the community of NPRI stakeholders, reporters and data users and other parties;
- Strategic alignment opportunities between the NPRI and other ECCC programs such as the Chemicals Management Plan (CMP) where appropriate; and
- Consideration of substances on Schedule 1 of the Canadian Environmental Protection Act (CEPA), that are released by facilities.

This consultation document aims to obtain input on the proposed change to lower the NPRI reporting threshold for ethylene oxide, as explained in the following sections, starting in the 2025 reporting year.

A Multi-Stakeholder Work Group advises ECCC on proposed changes to reporting requirements and other issues related to the NPRI. We invite the working group, other interested or impacted stakeholders, and the public to comment on this proposal before December 1, 2024 via email at inrp-npri@ec.gc.ca.

ECCC will consider comments received in response to this consultation and will provide a consultation summary once a decision has been made. Final reporting requirements for reporting years 2025, 2026, 2027 will be published in Part I of the *Canada Gazette* in early 2025.

2. Proposed change

Ethylene oxide (EtO) (CAS 75-21-8) is a colourless and highly reactive gas that is used in Canada (and elsewhere) as both a chemical intermediate in the production of ethylene glycol, and as a sterilizing agent, mainly for medical equipment and other heat-sensitive materials that cannot be sterilized by other means.

It has been listed on the NPRI since 1993 as a Part 1A substance. In 2001, Environment Canada and Health Canada undertook a [Priority Substances List \(PSL\) Assessment of ethylene oxide](#) and, with the information available at the time, found it to be toxic under the Canadian Environmental Protection Act and added it to [Schedule 1 of CEPA](#). The main adverse effects identified in the PSL assessment were primarily carcinogenic effects on human health resulting from exposure by inhalation. The Canadian sources identified included the ethylene glycol manufacturing sector and the sterilization sector (including both medical facility sterilization processes and commercial sterilization operations). As elaborations below will show, risk management of EtO was subsequently initiated between 2001-2007 to reduce Canadian emissions from both sources through non-regulatory approaches.

As will also be described below, since the PSL assessment (2001), new information has come to light in both Canada and the United States that shows EtO toxicity is more potent than originally thought and suggests that some relevant ethylene oxide point sources exist in Canada that may not be adequately captured by current NPRI reporting requirements.

It is proposed here to reduce the reporting threshold for EtO by moving it from Part 1A to Part 1B of the NPRI substance list. In Part 1A, reporting of this substance is required if the facility manufactures, processes, or otherwise uses (“MPO”) the substance in a mass greater than the 10 tonne (t) mass threshold (at a concentration by weight of 1%) or more, in a given calendar year. Moving this substance to Part 1B, will allow the mass threshold to be reduced to an alternate threshold which is proposed here to be 1 kilogram (kg) MPO (with 0.1% concentration by weight), starting with the 2025 reporting year. It is also proposed that the conventional mass calculation exclusion of activities related to the education or training of students for EtO reporting be removed. Note that this proposed change is lower than the 10 kg MPO threshold proposed in early engagement documents on this topic due to new information suggesting that emissions coverage at that threshold would potentially be inadequate.

Table 1. Current and Proposed EtO Reporting Requirements Compared

	Current Part 1A Requirements	Proposed Part 1B Requirements
Types of facilities required to report	Contiguous, portable or offshore facilities with 20,000 or more employee hours or undertake specified activities.	Same
Mass threshold	10 t	1 kg
Concentration threshold	1% by weight	0.1% by weight
Threshold type	Based on quantity (mass) manufactured, processed or otherwise used (MPO), excluding quantities related to various activities, including the education or training of students.	Based on quantity (mass) manufactured, processed or otherwise used (MPO), and including activities related to the education or training of students.
Reporting units	Tonnes (t)	Kilograms (kg)

3. Background

3.1 Government of Canada action on ethylene oxide

3.1.1. Risk Assessment

In Canada, the following risk assessment activities have occurred or are ongoing for EtO:

- In 2001, a Priority Substance List assessment on EtO was conducted under the *Canadian Environmental Protection Act*, which concluded EtO is toxic to human health due to potential for exposure by inhalation and carcinogenic effects ([Environment Canada and Health Canada, 2001](#)). It was added to schedule 1 of CEPA and identified two main point sources of concern, including:
 - Chemical manufacture (of ethylene glycol, ethoxylates, ethers, and ethanolamines)
 - Sterilization processes (e.g. commercial and hospital settings, etc.) excluding uses exclusively regulated by PMRA (Pest Management Regulatory Agency) under the PCPA (Pest Control Products Act)

3.1.2. Risk Management

To address the two main point sources of concern, ECCC and Health Canada implemented the following risk management actions:

- **Chemical manufacturing sector:** this sector was managed during 2001-2005 through a [Memorandum of Agreement between the Government of Canada, the Canadian Chemical Producer's Association and the Governments of Ontario and Alberta](#). This was a voluntary agreement that aimed to reduce VOC emissions, including EtO, by 25% from 1997 values by 2002. The CCPA reportedly achieved this target.
- **Sterilization sector:** This sector is managed through the [Guidelines for the reduction of ethylene oxide releases from sterilization applications](#), which focus on facilities that use or purchase EtO as a biocide, in quantities of 10 kg per year or more, for sterilization purposes. They encourage these facilities to vent sterilizer exhaust streams through an emission control system with 99% removal efficiency, to vent aerator exhaust streams through an emissions control system with 95-99% efficiency (or to the point where the exhaust stream is below 1 ppm EtO), to abide by [Canadian Standards Association \(CSA\) standards for EtO sterilizers](#), and to report annually to ECCC on, among other things, annual quantities of EtO released to the atmosphere. These guidelines are voluntary.

Additional risk management actions on EtO sources outside of these two main sectors included:

- **Pesticide use:** EtO use as a fumigant on spices has been regulated since 1971 under the Food and Drugs Regulations and now instead (since 1976) under the Pest Control Products Act. Pesticides currently on the market are re-evaluated on a 15-year cycle. In the most recent re-evaluation decision for EtO (2013), Health Canada (via the PMRA) [re-evaluated the safety of EtO as a spice fumigant, and has allowed continued registration for the sale and use of products containing EtO in Canada](#). Historically, only [Linde Canada Inc.](#) (formerly Praxair) and one other

confidential company have ever [applied to register an EtO pesticide product](#), and currently, Linde Canada Inc. holds the only [EtO pesticide product registration](#), which expires in 2027.

Note: in 2017, [Health Canada removed EtO from its list of permitted food additives with other accepted uses](#) as this permission was duplicative of existing PMRA management described above.

- **Environmental Emergency regulations:** the Environmental Emergency (E2) Regulations initially came into force in [2003](#) and were repealed and replaced in 2019. These regulations aim to reduce the frequency and impacts of accidental releases of hazardous substances from facilities in Canada by requiring high-risk facilities to develop and bring into effect Environmental Emergency Plans when they are equal to or above container system capacity and total quantity threshold. The facility also has requirements to notify ECCC of any environmental emergencies. EtO has been listed in the E2 regulations since 2003 and has an established threshold of 4.5 t equal to or above 10% w/w concentration. To date, two facilities have submitted notifications to ECCC (two of the three Canadian EtO manufacturers), and these are also NPRI reporters. As will be discussed below, the assessment of EtO has been an evolving effort. Given the latest toxicity information (see section **3.3**), revisions to lower the threshold in the E2 regulations is being considered.

3.1.3. Research and monitoring

Several studies on EtO in Canada have taken place in the last decade that suggest EtO continues to be present in the environment, sometimes at exposure levels of concern, and in locations where no EtO is reported to the NPRI.

- A study by Galarneau et al. (2023) entitled [From hotspots to background: High-resolution mapping of ethylene oxide in urban air](#) described mobile measurements taken across Toronto and showed that short-term ethylene EtO near (and attributed to) a Scarborough sterilization facility (Sterigenics) had the potential to exceed [Ontario's 24-hr ambient air guidelines for the protection of human health](#). The average 1-second mixing ratio for all plumes detected downwind of Sterigenics was 0.43 ppb (parts per billion) with a max of 18 ppb. While not directly comparable to the Ontario 24-hour ambient air quality guideline of 0.11 ppb, these measurements suggested that downwind concentrations had the potential to exceed the guideline.
- The same research in Toronto identified other plumes of EtO from unknown sources but spatially co-located with several hospitals and universities, none of which have reported EtO to the NPRI. Galarneau et al. noted that information from Ontario Spills Action Centre includes two accidental EtO releases from nearby hospitals as recently as 2020, corroborating the notion that the plume source may relate to the local hospital sector. Environmental permissions from the Ontario provincial government (discussed below in section 4.2.4) confirm that EtO uses/emissions are authorized for several local healthcare and university facilities.
- An earlier study by Galarneau et al. (2016) entitled [Air toxics in Canada measured by the National Air Pollution Surveillance \(NAPS\) program and their relation to ambient air quality guidelines](#), presented 2009 monitoring data from 7 sites across British Columbia and showed EtO levels were often firmly above the Ontario (ON) 24-hr guideline of 0.11 ppb (used here as a benchmark in the absence of BC or federal guidelines). The highest EtO concentration was observed at Quesnel, B.C., where no facilities reported EtO to the NPRI. It is worth noting that the method detection limit in this study was above the ON guideline, suggesting that even non-detect values in this study may be above the ON guidelines and thus still of concern. However, potential artifacts

associated with canister sampling of EtO also suggest that earlier measurements with this method may be inaccurate, including being biased high. Further investigation with improved sampling methodology would bring clarify these results.

- Canada has no national or federal ambient air quality guidelines for EtO. Three provinces have such guidelines – Alberta, Ontario and Quebec – with Quebec’s guideline being the strictest (see table below). Note that the current Alberta guideline is based on Ontario’s old guideline and has not been revised in light of current toxicity information.

Table 2. Summary of Ethylene Oxide Air Quality Guidelines (occupational exposures not included)

Jurisdiction	Last updated	Ambient Guideline – Annual	Ambient Guideline – 24hr	Chronic Exposure Concentration for 1 in 1,000,000 Cancer Risk	1-hr exposure, acute effects
Canada	N/A	N/A	N/A	N/A	N/A
Quebec	2011	0.0005 ug/m ³ (0.28 parts per trillion, ppt)	N/A	N/A	
Ontario	2020	0.04 ug/m ³ (22 ppt)	0.2 ug/m ³ (110 ppt)	N/A	
Alberta	2017 (adopted from Ontario 1999)	N/A	N/A	N/A	15 ug/m ³ (8.3 ppt)
US	2016	N/A	N/A	0.0002 ug/m ³ (0.11 ppt)	

3.1.4. Risk Management Performance Measurement

To measure the effectiveness of the Government of Canada’s risk management actions in place for ethylene oxide, a [performance measurement evaluation process is currently underway for EtO](#).

3.1.5. Provincial Risk Management

In addition to federal action on EtO, the provinces have also implemented risk management, including environmental permissions and occupation health and safety standards for using and emitting this substance. More information can be found on the respective provincial websites such as:

- Ontario’s [Designates Substances regulations](#), [Air pollution – Local air quality regulations](#), and associated [environmental permissions](#).
- Alberta’s [Occupational Health and Safety rules and requirements](#), *Environmental Protection and Enhancement Act* [approvals and registrations regulations](#) for [designated activities](#), [Ambient Air Monitoring Directive](#) and associated [CEMS Code](#).
- Quebec’s [Clear Air regulations](#)
- B.C.’s [occupation health and safety guidelines](#), as well as similar standards across other provinces.

3.2. NPRI data for ethylene oxide

Ethylene oxide has been listed on the NPRI since its inception (1993) at the standard 10 t manufacture, process or other use threshold and 1% concentration threshold. The NPRI has received reports every year (1993-2023¹). Over this time, 28 facilities reported on EtO to the NPRI. The following paragraphs provide a breakdown of the NPRI data.

3.2.1. Releases

- 17 facilities have reported over the last 30 years, totalling ~420 t of releases to air (assuming the likely scenario that reports of releases to 'sum of all media' were, in fact, to air).
- Releases over the last 30 years were dominated by the chemical manufacturing sector. Overall releases have declined sharply (**Fig. 1**), with a notable drop after 2006, mostly attributable to decreased emissions from the chemicals manufacturing sector and potentially related to federal attention on this substance in both Canada and the US at that time (see above), as well as [increases in overseas EtO manufacturing](#).
- More recently, over the last ten years, releases totalled <25 t from nine facilities, and annual emissions peaked in 2018 at 3 t/year, down to <2 t/ year in 2023 (**Fig. 2**). The main contributing sector remained the chemicals manufacturing sector (four facilities), with the sterilization sector (four facilities) playing a lesser but substantial role up to 2022 whereafter its contributions were less. The hazardous waste management sector contributed releases to a lesser degree still.
- The Sterigenics Scarborough facility discussed above in the study by Galarneau (2023) reported annual releases above their provincial environmental permission in all years but 2022 (when it closed) (See **Fig. 3**). By contrast, the new Sterigenics Mississauga (which opened in 2022) reported annual releases that, when scaled to grams/second, equate to rates below their provincial environmental permission (see section 4.1.2 and Appendix A for more details).

¹ Note that NPRI data for 2023 was preliminary and subject to correction following annual quality control activities.

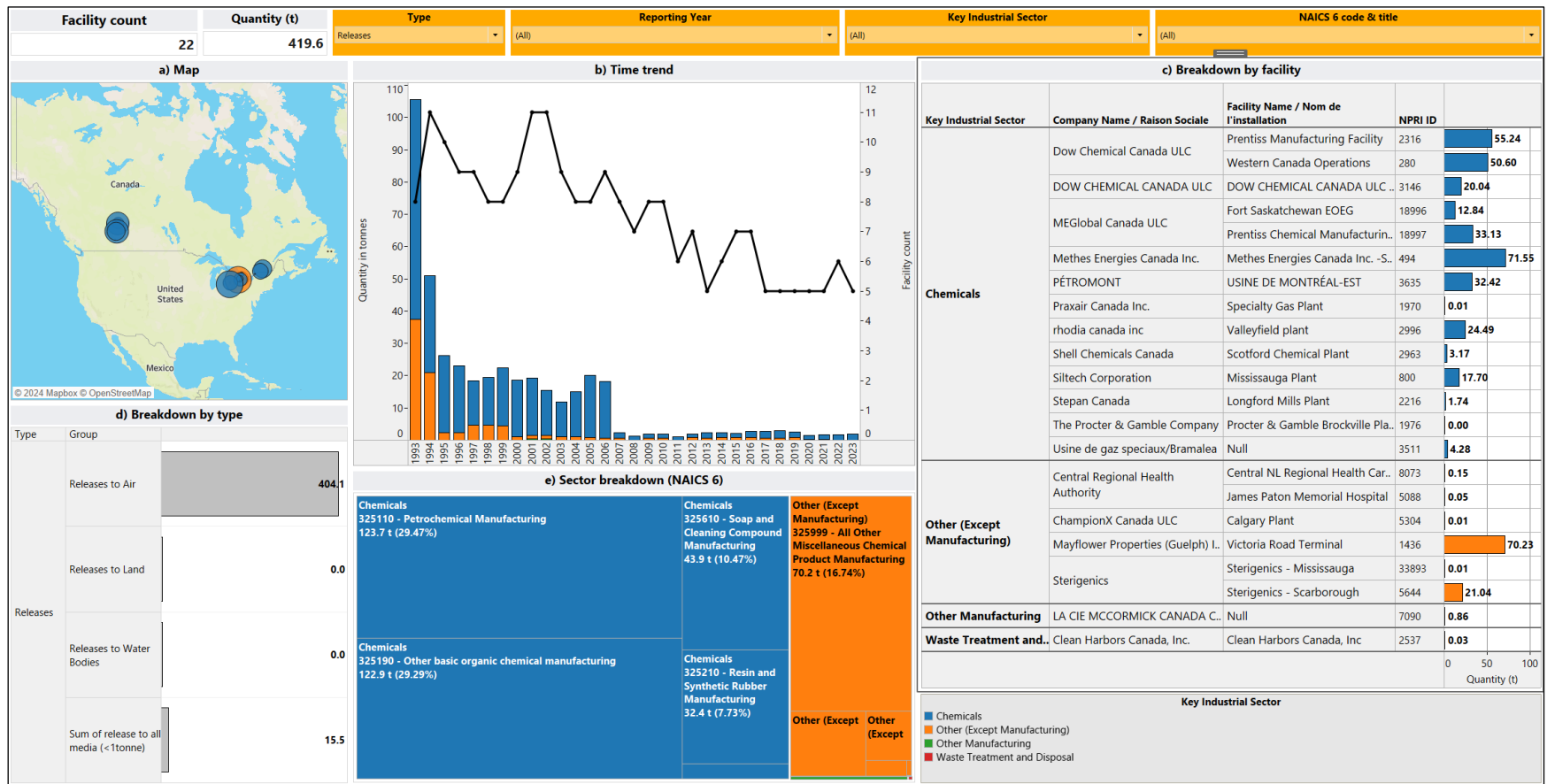


Figure 1: EtO release data from the NPRI over 1993-2023, colour-coded by key industrial sector. Note that the 2023 data are [preliminary](#).



Figure 2: EtO release data from the NPRI over 2013-2023 colour-coded by key industrial sector. Note that the 2023 data are [preliminary](#).

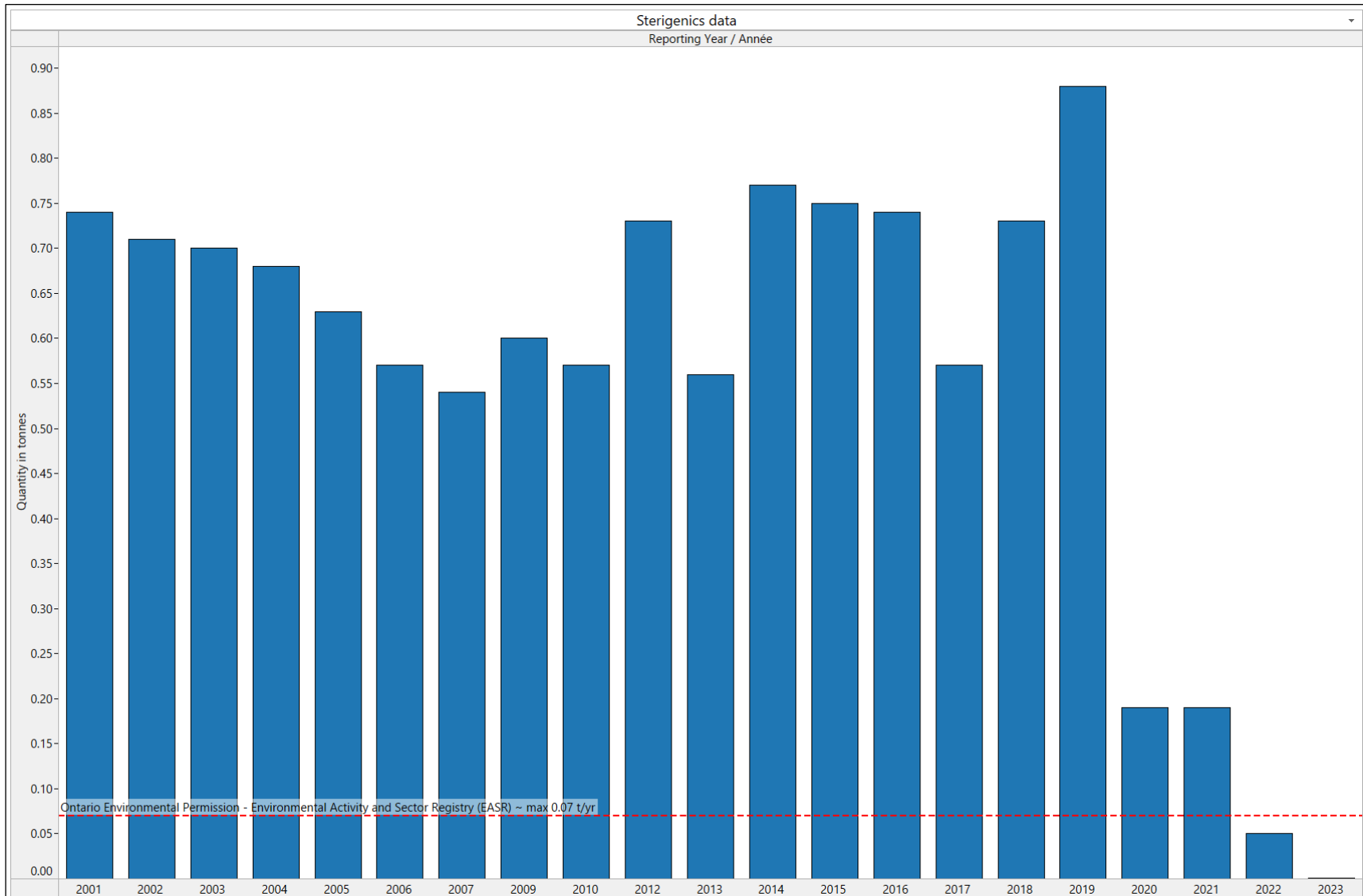


Figure 3: Sterigenics Scarborough NPRI data (releases to air and sum of all media), overlaid with the facility’s [provincially authorized emission rate](#) (scaled from grams/second emission rate reported in the facility’s [Environmental Activity and Sector Registration \(EASR\)](#) to tonnes/year by assuming a maximum operation schedule of 24 hours/day, 365 days/year). Note that the 2023 data are [preliminary](#).

3.2.2. On-site disposals

Over the last 30 years, four facilities have reported ~39 t of on-site disposals of EtO, mainly to landfills (Fig. 4). The main contributors were two facilities from the hazardous waste management sector, who reported only in the last decade, and yielding no discernable quantity trend. These varying disposals are reportedly due to the variable composition and volumes of incoming waste to these facilities.

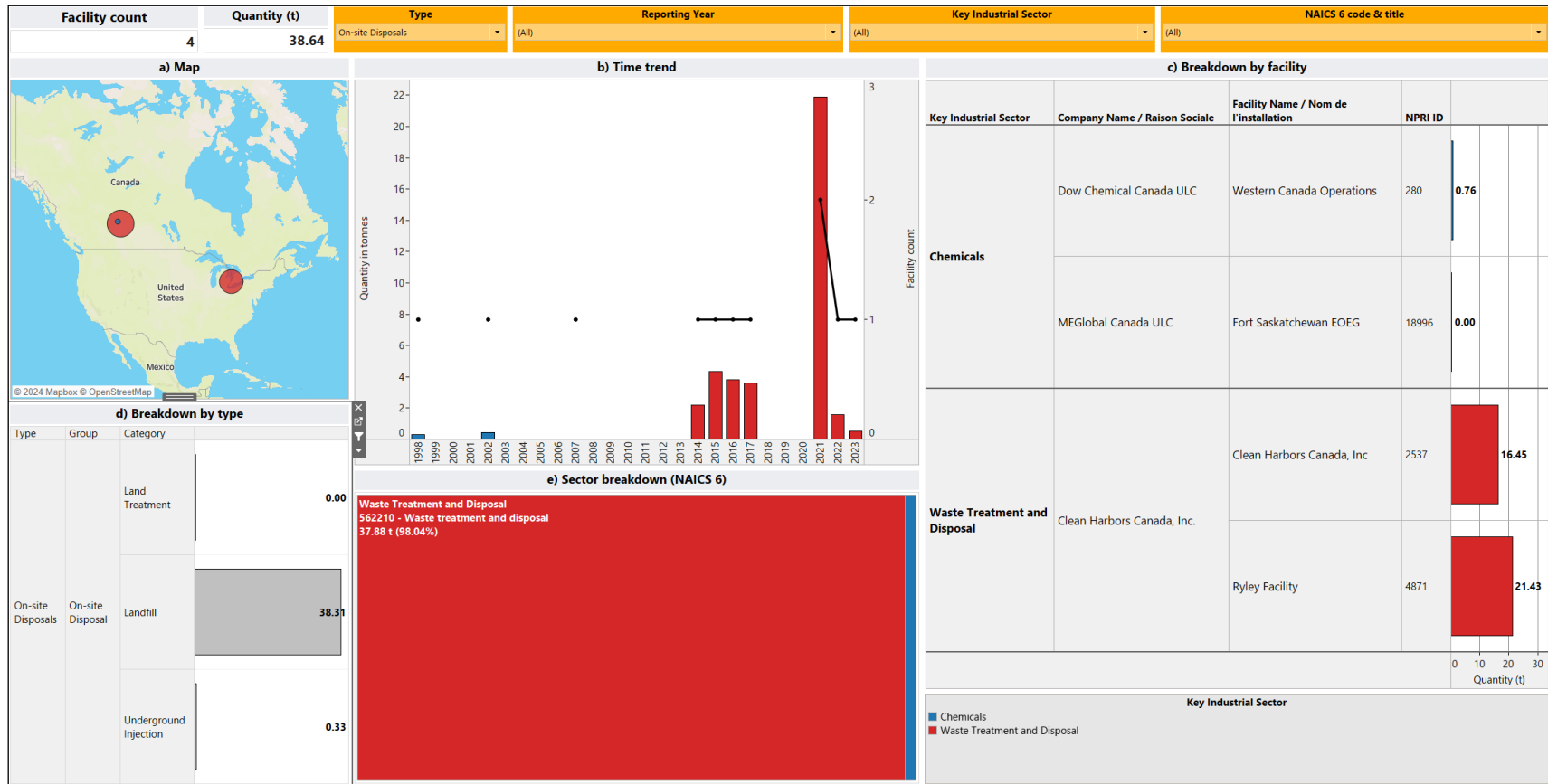


Figure 4: EtO on-site disposal data from the NPRI over 1993-2023, colour-coded by key industrial sector. Note that the 2023 data are [preliminary](#).

3.2.3. Off-site transfers (for recycling, treatment, or disposal)

By quantity, off-site transfers of EtO for recycling, treatment, or disposal make up the largest proportion of NPRI data. Over 1993-2023, 10 facilities reported almost ~560 t of EtO transferred to off-site destinations for either disposal, recycling, or treatment. Most of this total came in the last ten years of reporting, from only four facilities in the hazardous waste management sector (**Fig. 5**). These facilities transferred EtO to other waste management facilities (sometimes within their own company, as was often the case for Clean Harbors transfers) (**Fig. 6**).

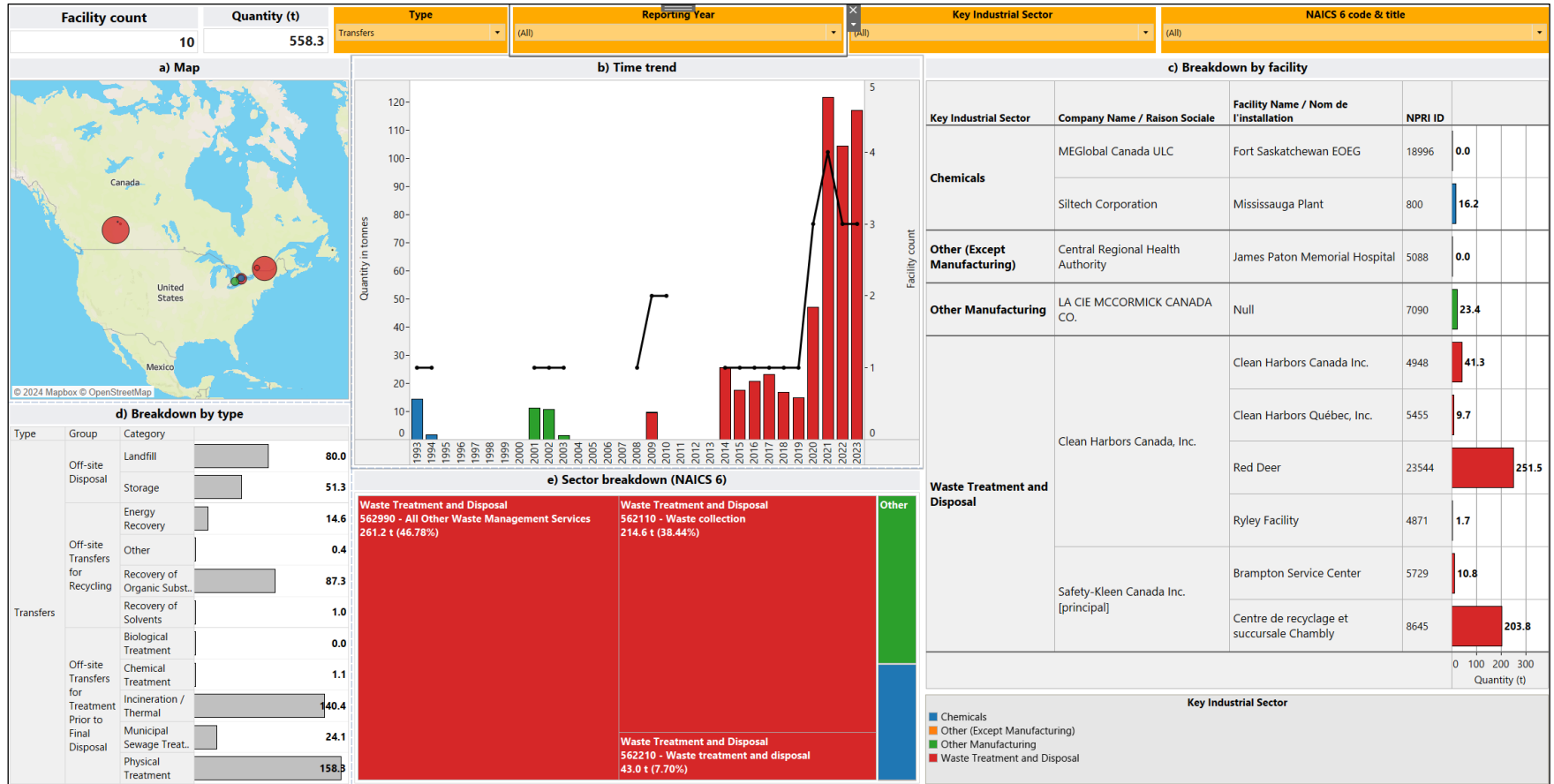


Figure 5: EtO off-site transfers for recycling, treatment or disposal from the NPRI over 1993-2023, colour-coded by key industrial sector. Note that the 2023 data are [preliminary](#).

Off-site disposals (78 t) stayed within Canada, and mainly went to landfill, reportedly as a result of contaminated material, production residues, pollution abatement residues, etc. Off-site recycling (63 t) went mainly to one Canadian site (ReNue Recycling Ltd.) for recovery organic solvents. Off-site transfers for treatment by incineration (111 t) went mainly to incineration facilities owned by Clean Harbors in both Canada and the US. Off-site transfers for treatment by physical treatment (144 t) went mainly to hazardous waste management facilities within Canada.

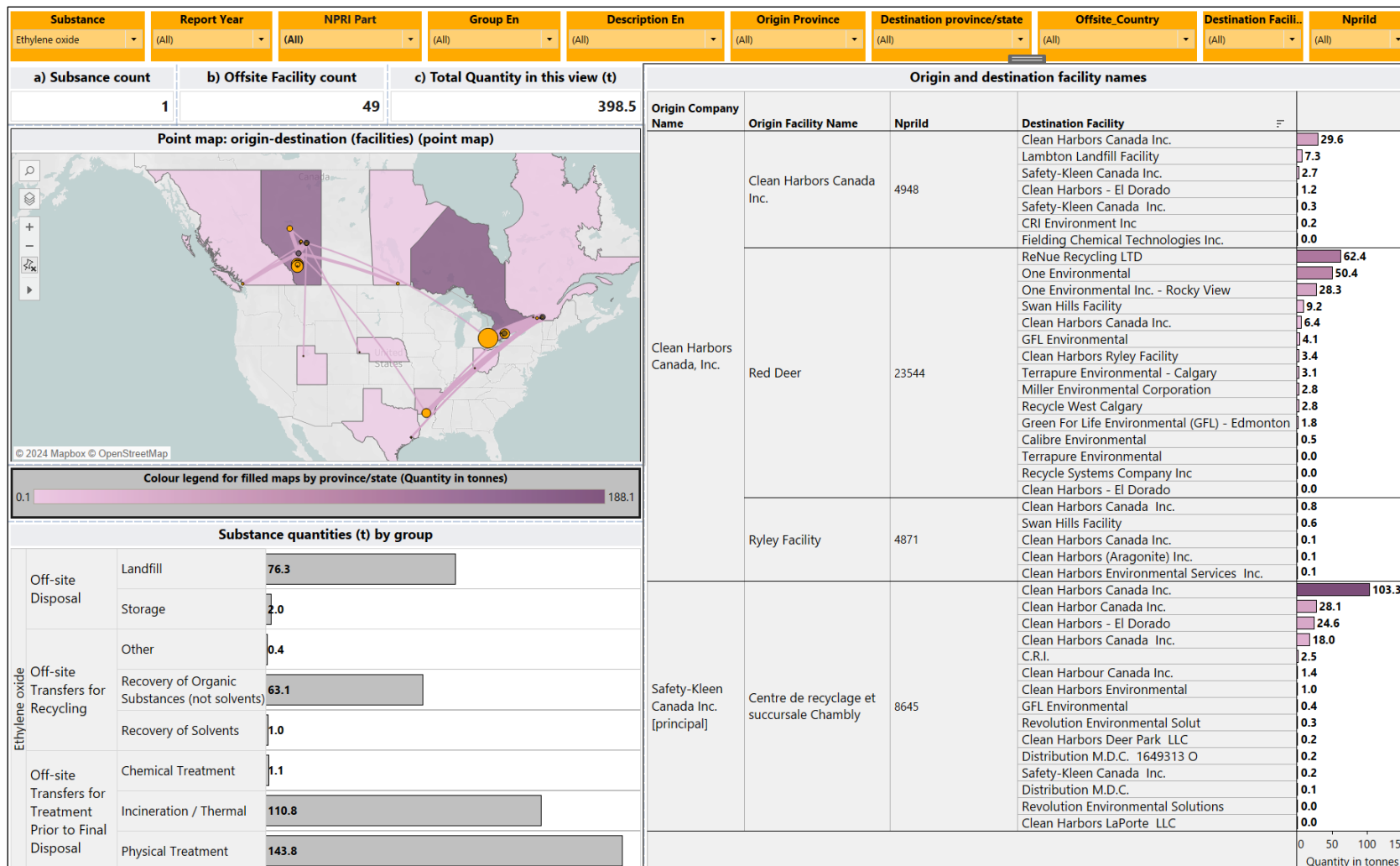


Figure 6: Summary of offsite transfers from origin to destination EtO off-site transfers for recycling, treatment or disposal from the NPRI over 2013-2022, colour-coded by key industrial sector.

Aside from incineration, the treatment and disposal data reported to the NPRI may require further investigation, compliance promotion, and/or data quality control. A literature scan suggests that unused EtO in the chemical manufacturing or sterilization sector is generally destroyed on-site by pollution abatement technologies (e.g. catalytic oxidizer) or vented/leaked to the atmosphere. Disposal of EtO remaining in pollution abatement residues being generated at these facilities may be sent to disposal by incineration and as discussed below in **section 3.3.**, this pattern of disposal is reflected in US EtO disposal (See **Fig. 7**). However, this flow of EtO to disposal is not evident from current NPRI reporting, where if this were the case, we would expect chemical manufacturing or sterilization sector facilities to be reporting off-site transfers (for disposal/incineration, treatment, etc.) from their facilities to hazardous waste management facilities. But this is not the case. Why NPRI contains high values of EtO going to off-site landfill or solvent recovery and where these quantities are coming from upstream of the hazardous waste management sector (who do not appear to generate EtO waste themselves) is unknown and requires further investigation (beyond scope of this consultation).

3.3. Risk assessment and management in the US.

In the US, the health assessment of EtO has been an evolving effort since 1985, when the first EPA health assessment report was published. Since then, new toxicity information has come to light, enabling the EPA's Integrated Risk Information System (IRIS) assessment program to publish a formal [toxicity assessment \(2016\)](#) showing that EtO is 30 times more toxic than previously thought. Moreover, analytical techniques have advanced, lowering detection limits and enabling reliable detection of EtO in air at levels near the revised EPA threshold of concern for continuous exposure ([0.0002 ug/m³, or 0.11ppt](#)). These advances have led to research and monitoring [studies](#) showing that certain population exposures near chemical producers and commercial sterilizers that emit EtO are at levels linked to increased cancer risk. Combined, these advances have prompted new risk management on EtO, which include:

- **Chemical manufacturing sector:** In Spring 2024, the EPA announced a set of final air toxics rules under the Clean Air Act intended to reduce emissions of toxic air pollution from chemical plants that make synthetic organic chemicals (including EtO) and polymers and resins, including neoprene. These are the [Hazardous Organic National Emission Standards for Hazardous Air Pollutants \(NESHAP\), often called the "HON"](#) and are expected to cut nearly 54 tons of EtO emissions per year once fully implemented (over 2 years). Implementation of the emissions reductions relies on improving the efficiency of pollution control systems (i.e., flares, heat exchange systems, process vents, and storage vessels), removal of exemptions from these requirements for certain cases (i.e. startup, shutdown, malfunction), and fenceline air emissions monitoring with requirements to act if these measurements exceed specified "action levels" (currently set to 0.2 ug/m³ (or 0.1 parts per billion, ppb) for EtO, which is equal to [Ontario's 24-hr ambient air quality guideline](#)).
- **Sterilization sector:** In Spring 2024, EPA announced [Final Amendments to Strengthen Air Toxics Standards for Ethylene Oxide Commercial Sterilizers | US EPA](#), that focus on emissions reductions through pollution control devices, and EtO continuous emissions monitoring (and quarterly reporting of emissions that will be published) at commercial sterilization facilities, under the National Emissions Standards for Hazardous Air Pollutants (NESHAP). 88 facilities are expected to be impacted.
- **US Toxics Release Inventory (TRI):** EtO has been listed on the US TRI at a reporting threshold of 10,000lbs (~4.5 metric t) of manufacture, process or otherwise use (MPO), since 1987. However, the TRI generally applies only to certain industrial sectors, meaning that facilities that use TRI-listed

substances that fall outside these sectors are not required to report. Up until recently, this was the case for the commercial sterilization sector. In 2021, the TRI took action to address this gap by specifically [requiring reporting from 29 contract sterilization facilities if they met TRI reporting thresholds](#). These facilities had not previously reported to TRI and were expected to use the highest amounts of EtO in the contract sterilization sector (likely above the 10,000 pounds per year “otherwise used” part of the TRI reporting threshold for EtO). All 29 facilities reported in 2022, totalling 9166 lbs. (~4.1 metric tonnes) of releases, which equates to 7% of total EtO release data for 2022 (the remainder comes mainly from the chemical manufacturing sector, similar to Canada). 2023 data suggested a similar increasing trend (see **Fig. 6**). Substantially increased reporting of EtO going to on-site waste management by treatment was also unveiled in recent years, largely attributable to the chemical manufacturing sector (see **Fig. 7**). This is in contrast to the Canadian situation where far more disposals are reported as going to off-site waste management. It is unclear how much additional EtO reporting would result from the sterilization sector if the MPO threshold were lower than the current 4.5 metric t MPO threshold.

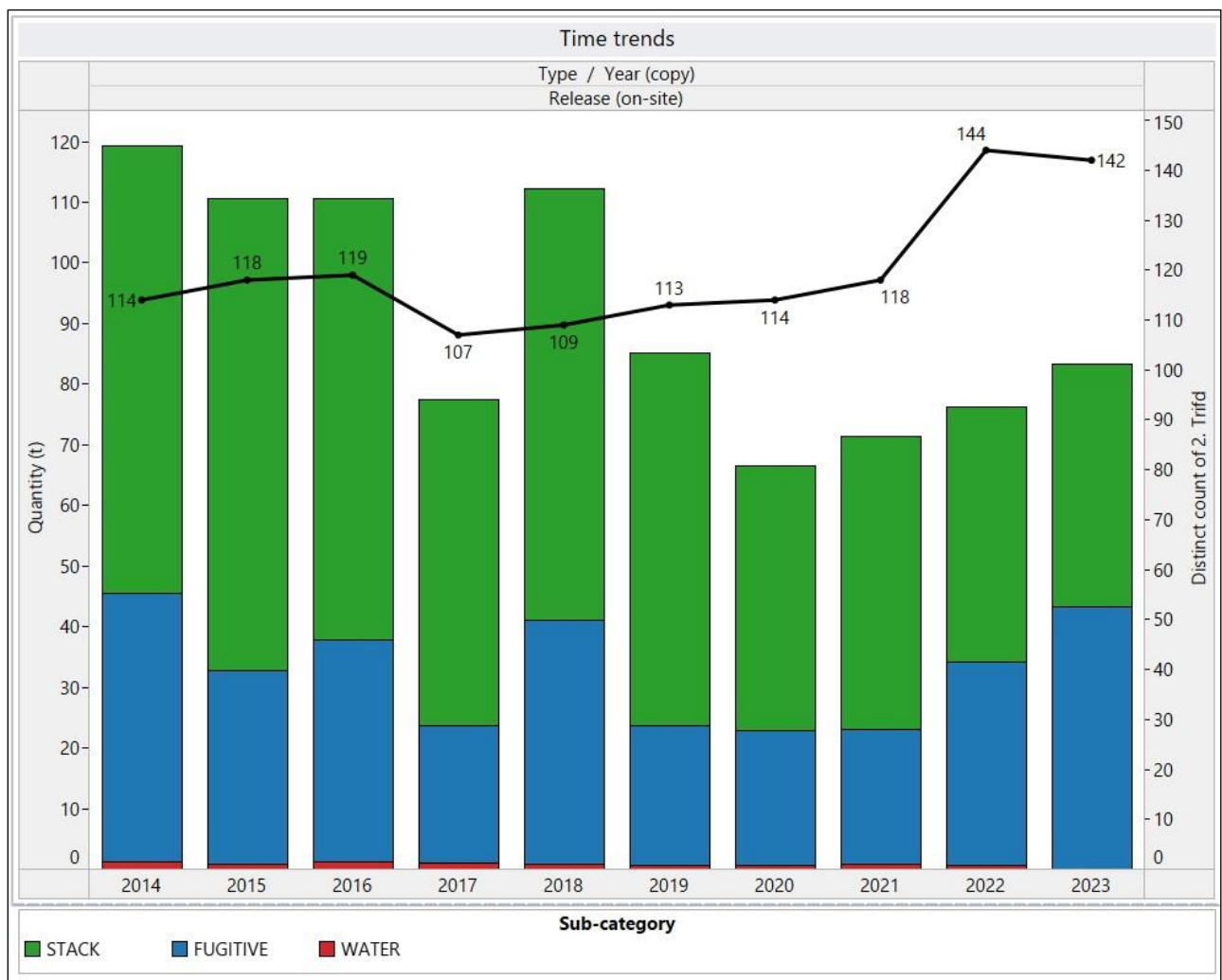


Figure 7: The time trend of air (stack and fugitive emissions) & water releases of ethylene oxide reported to the US TRI over 2013-2023. Note that the 2023 data are [preliminary](#).

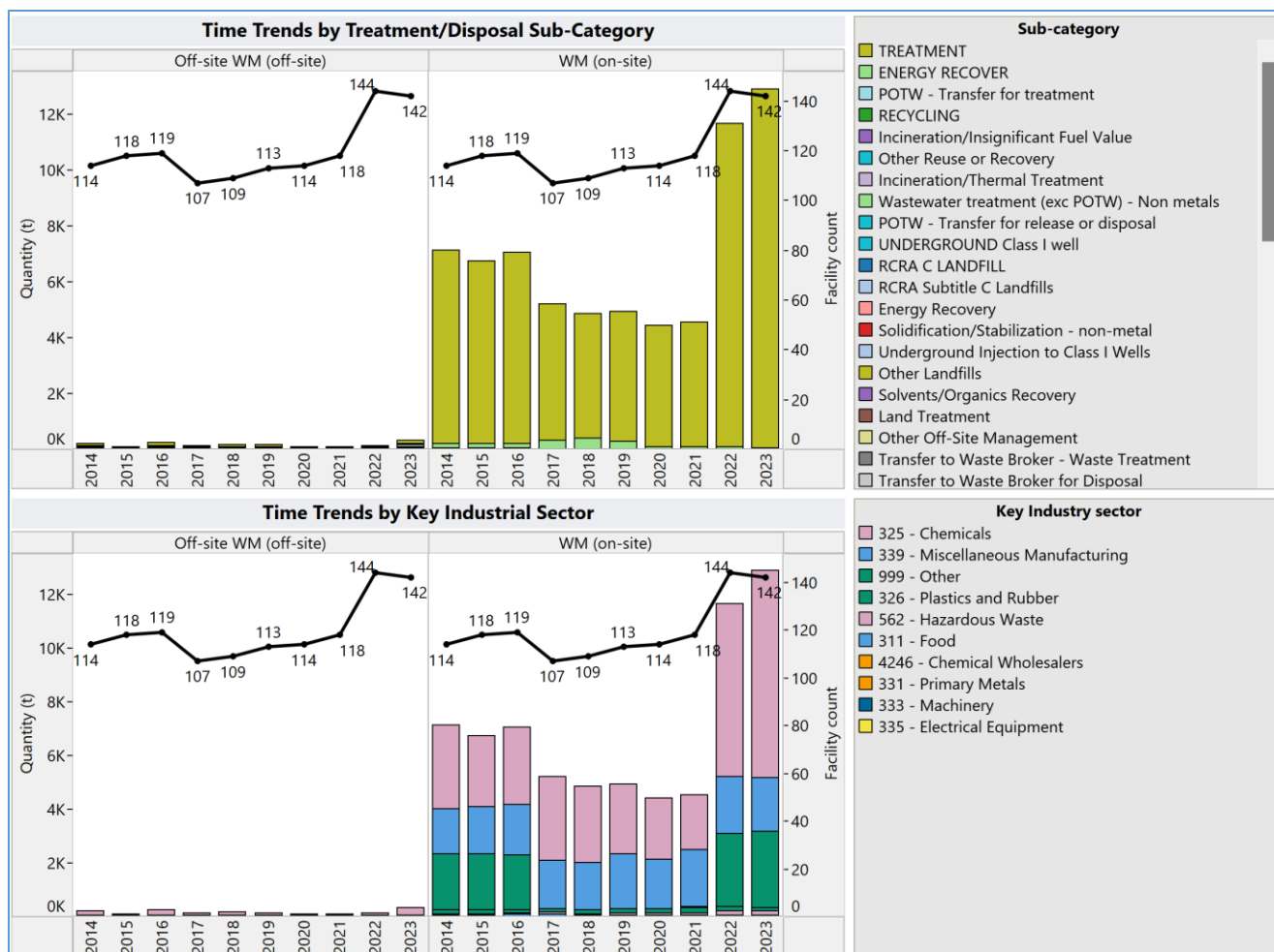


Figure 8: The time trend of on- & off-site disposals of ethylene oxide reported to the US TRI over 2013-2023. Note that the 2023 data are [preliminary](#)

4. Rationale

4.1. Rationale for deciding if the EtO threshold should be lowered

Proposals to make changes to the NPRI are evaluated according to the [Process for proposing and considering changes to NPRI](#), which includes an evaluation of four decision factors as well as additional considerations such as value versus cost, the capability of facilities to provide the required information, coverage and comprehensiveness and other data gathering planned. While EtO has already met the decision factors for addition to the NPRI, and is currently listed in Part 1A at the standard 10 t MPO threshold, new research, monitoring and policy evaluation efforts in Canada suggest that there are reporting gaps in the release data for EtO from smaller-scale handlers of EtO (i.e. those below the 10 t MPO threshold) that is preventing the NPRI from meeting its program objectives, which are:

- To improve public understanding

- To identify priorities for action
- To encourage voluntary action to reduce releases
- To allow tracking of progress in reducing releases (including successful reductions)
- To support targeted regulatory initiatives
- To support development of other pollutant release inventories, such as the Air Pollutant Emissions Inventory, and related international reporting obligations, where appropriate.

The following paragraphs describe these reporting gaps.

4.1.1. Air quality research: unreported sources may be significant.

As noted above, the Toronto-based air quality study by Galarneau et al. (2023) observed a significant short-term EtO plume from an unidentified source around the University of Toronto St. Georges campus. The plume location was near several hospitals, none of which have reported EtO to the NPRI, but which likely use EtO, as suggested by other lines of evidence such as the Ontario Spills Action Centre, Ontario environmental permissions granted to these facilities (i.e. the University Health Network) and an unpublished voluntary survey by ECCO to the sterilization sector (2020). Moreover, the same study suggested that the commercial sterilization facility, Sterigenics – Scarborough, reported releases as low as ~0.2 t in recent years (2020-21) of EtO per year, which still may cause exposure levels of concern in local ambient air. This implies that other facilities that handle (manufacture, process or otherwise use) far less than 10 t of EtO but do emit this substance may potentially be causing or contributing to exposures of concern. Also, earlier monitoring in British Columbia (B.C.) identified EtO air quality hot spots where no NPRI facilities reported EtO and suggested current reporting requirements do not cover sources of concern in this region. The NPRI threshold change proposed here would aim to capture these missing facilities and release data, and thus enable the NPRI to better meet the objectives of improving public understanding of pollutants in their communities, identify priorities for action and encourage voluntary action to reduce releases.

4.1.2. Ontario facilities authorized to use EtO

Information derived (post early-engagement) from Ontario's provincial [environmental permissions](#) program indicates that of the 21 facilities that hold active [Environmental Activity and Sector Registrations](#) (EASRs) for EtO, only two of these have reported to the NPRI, and all are located in Southern Ontario. See Appendix A. While information on the EtO quantities these facilities manufacture, process or otherwise use is lacking, the NPRI threshold change proposed here would aim to capture most/all of these that emit EtO but do not meet the current 10 t MPO threshold, and thus enable the NPRI to better meet the objectives of improving public understanding of pollutants in their communities, identify priorities for action and encourage voluntary action to reduce releases.

4.1.3. Evolving toxicity information in the United States

As noted above, the understanding of EtO toxicity has and continues to evolve in recent years. One of these advancements is the [2016 toxicity assessment published by the US EPA](#), which found EtO toxicity to be about 30x higher than previously thought, indicating that the cancer risk in excess of 1-in-a-million occurs at a chronic exposure rate of 0.0002 mg/m³ (0.11 ppt), which is roughly two orders of magnitude lower than the current Ontario annual ambient air guideline of 22 ppt. This suggests that air concentration data in Canada that was previously found to be within the Ontario ambient guidelines (annual) could now be considered above the EPA-determined threshold for increased cancer risk. This new understanding

of EtO toxicity further supports the point that even small EtO releases may be of concern and supports the drive to lower the NPRI reporting threshold to ensure these small quantities are tracked.

4.2. Rationale for selecting the new EtO threshold

NPRI uses thresholds to determine which facilities are required to report based on the principle that the reporting requirements should not pose an unreasonable burden on facilities that have to report, and that small facilities may not have the technical expertise to report quality data. Thresholds have been reduced or removed over the years in cases where there is information to demonstrate them to be barriers to comprehensive reporting, for example:

- There is no mass threshold for reporting of dioxins, furans and hexachlorobenzene, instead facilities must report if they engage in specified activities (e.g., incineration), since these substances are toxic even in extremely low quantities
- There is no concentration threshold for reporting of criteria air contaminants, since these substances are released in very low concentrations
- The employee threshold does not apply to specified activities where releases from facilities with few employees are known to be significant (e.g., wastewater treatment facilities and incinerators)

The information presented in the sections above explain initial justifications for lowering the EtO threshold, and the following paragraphs further explain the rationale for proposing that the new threshold be set at 1 kg MPO with a 0.1% concentration by weight, and includes activities related to education/training of students.

Note that ECCC does not currently have enough evidence to justify reducing or removing the employee threshold for EtO reporting and is therefore proposing that the current employee threshold (20,000 hours or more, or 10 full-time employee equivalents) will apply.

4.2.1. Alignment and support of ECCC emission reduction guidelines for the sterilization sector

The [2007 Guidelines for the reduction of ethylene oxide releases from sterilization applications](#) encourage voluntary reporting of NPRI-like information on EtO releases by sterilization facilities if they handle (e.g. manufacture, process or otherwise use) EtO in quantities greater than 10kg (if they do not already report to the NPRI). Note that the Guidelines' 10kg reporting threshold was set before the more recent understanding of elevated EtO toxicity (see section 3.3). The reporting provisions of the guidelines comprise information on facility name, address, contact information, the quantity of ethylene oxide released to the atmosphere, among other production and use metrics. However, actual reporting is voluntary, and ECCC has received no reports related to these guidelines since 2018. Also, a 2022 voluntary survey was conducted by ECCC (Products Division, Industrial Sectors and Chemicals Directorate, Environmental Protection Branch), targeting hundreds of hospitals and sterilizers to update knowledge on EtO use in this sector (who, how much used, how much released, etc.). Only 21 stakeholders responded, with mainly incomplete information meaning the status of who uses and releases EtO in the sterilization sector remains unclear. The NPRI reporting threshold change proposed here would align mandatory NPRI reporting at a level that would meet (and appropriately exceed, given the current EtO toxicity knowledge) the Sterilization sector Guidelines, enabling more effective tracking of releases, reductions, and a better understanding of regulatory effectiveness.

4.2.2. Exposure estimates based on release quantities

In the absence of comprehensive monitoring studies to determine the potential exposure scenarios caused by variations in EtO emissions, a model-based estimation approach was taken here. [The Risk Assessment Identification and Ranking \(RAIDAR\)](#) model combines mechanistic mass balance environmental fate and food web bioaccumulation models to quantify chemical transport from diffuse sources in a steady-state evaluative environment of 100,000km² (roughly the size of the [island of Newfoundland](#), or [Southern Ontario](#)) to representative ecological receptors and humans (e.g. worms, fish, birds, mammals at various trophic levels, etc.). RAIDAR is a screening-level tool to help prioritize substances for more in-depth exposure and risk assessment and comes with [several limitations](#). Nonetheless, it is useful here to give a sense of the potential exposures from a range of EtO emissions and can help understand what NPRI threshold could be appropriate. Here, a range of EtO annual releases (1 – 1000 kg) were simulated using RAIDAR to estimate the resulting potential ambient exposure levels if these releases occurred in a diffuse manner in an environment the size of Southern Ontario. **Table 3** below shows the outcomes and compares the estimated exposure concentrations with the US EPA's elevated cancer risk threshold of 0.11 ppt and with Ontario's annual ambient air guideline of 22 ppt.

Table 3: Exposure estimates for EtO annual release quantities between 1-1000 kg, simulated using RAIDAR.

EtO annual air release quantity (in kg, steady/diffuse emission)	RAIDAR Ambient, steady state air exposure concentration ng/m ³	RAIDAR exposure in mg/m ³	RAIDAR exposure in ppt	Above EPA 0.11 ppt chronic exposure guideline?	Above Ontario 22 ppt annual ambient guideline?
1	1.08E-04	1.08E-07	0.06	No	No
5	5.41E-04	5.41E-07	0.30	Yes	No
10	1.08E-03	1.08E-06	0.60	Yes	No
50	5.41E-03	5.41E-06	3.00	Yes	No
100	1.08E-02	1.08E-05	6.00	Yes	No
1000	1.08E-01	1.08E-04	59.96	Yes	Yes

The results indicate that if total quantities as low as 5 kg were released (either from a single facility or spread among several) within an area the size of southern Ontario, the ambient exposure could exceed the US EPA's human health guideline. While emissions are not always equal to the quantity a facility manufactures, processes, or otherwise uses, they can be in circumstances where EtO is used and vented to the atmosphere with no emission control. Given that risk management in Canada for this substance currently relies on non-regulatory guidelines, and there is at least one example of multiple facilities authorized to use EtO co-located in a region the size of southern Ontario (see Appendix A), such an emission scenario is conceivable. This example demonstrates that even a low quantity of EtO manufacture, process or other use (<5 kg) could result in releases relevant to NPRI audiences. The NPRI reporting threshold change proposed here would enable more comprehensive tracking of releases, better inform Canadians about pollutant releases in their communities and better inform related regulatory initiatives.

4.2.3. A concentration threshold of 0.1% by weight is standard for Carcinogenic, Mutagenic and Reproductive toxicants (CMR)

A concentration threshold of 0.1% by weight is proposed to align with the requirements for disclosing CMRs on Safety Data Sheets (SDSs) as per the [Hazardous Products Regulations](#), which many facilities use to calculate and report quantities of NPRI substances. Information on EtO use in the sterilization sector suggests that it is used in concentrations well above this 0.1% level, and thus this is not expected to cause a reporting barrier.

Note that various low mass thresholds, combined with 0.1% by weight concentration thresholds, have been previously established for multiple part 1B substances - see [NPRI Notice for 2022 – 2024](#) (Sch. 3, Table 1).

4.2.4. Inclusion of activities related to education or training of students (universities, colleges, etc.).

According to current NPRI reporting requirements, in calculating the mass reporting thresholds, facilities can exclude the quantity of a substance that is manufactured, processed or otherwise used in a number of activities, including in the education or training of students. However, in the case of EtO, this exclusion may be a barrier to satisfactory coverage of relevant releases since information derived from Ontario's provincial [environmental permissions](#) program indicates that of the 21 facilities holding active [Environmental Activity and Sector Registrations](#) (EASRs), permitting them to use/emit EtO, 48% (10) are in the education sector (i.e. universities, colleges and schools). All are in southern Ontario, with a potential cumulative annual release of >6500 kg in this region (see Appendix A). Using RAIDAR to estimate exposures based on release quantities (see above, section 4.2.2), these cumulative emissions would potentially cause regional ambient exposures above both the Ontario and US human health guidelines (see **Table 3**), highlighting the relevance of considering these facilities within the NPRI.

Given the substantial proportion of facilities in the education sector and the potential magnitude of their EtO emissions, it is proposed to include these facilities in NPRI reporting of EtO to meet NPRI objectives of both informing the Canadian public about emissions in their communities and enabling more effective tracking of releases and reductions and related regulatory initiatives.

5. Impact on reporting facilities

5.1. Facilities that may now need to report

The proposed requirements to report on EtO to the NPRI at a lower MPO threshold will potentially impact additional facilities in the sterilization sector or those who conduct sterilization activities beyond those that currently report (including hospitals, veterinary clinics, commercial sterilizers and educational institutions). Other sectors, including those that are identified in the 2001 PSL assessment report (spice manufacturers/distributors, manufacturing (chemicals, soaps, plastic, other)), may also be impacted. However, it is unclear how many facilities will be impacted. For example:

- Chemical manufacturing sector: three known EtO users in the ethylene glycol manufacturing sector – all currently report.
- Sterilization sector: ECCC currently counts [~900+ hospitals across Canada](#), some of whom may use EtO, though it is unclear how many actually do. Over time, NPRI has received reports from only two hospitals, and it is unclear if this low count was due to the high MPO threshold, or because EtO was not used by other facilities. Regarding veterinary clinics, it is unclear how many may qualify for reporting.
- As discussed above (section 4.2.4) in Ontario, 21 facilities currently hold [Environmental Activity and Sector Registrations](#) (EASRs) for EtO under the Ontario Environmental Protection Act. Using estimates of potential annual releases (calculated by scaling the emission rate cited in their EASR (in grams/second) to a maximum annual value in tonnes/year), of the 21 Ontario facilities,
 - None met the previous EtO reporting threshold of 10 t
 - 19 (90%) could potentially meet the new 1 kg MPO threshold to report. Of these,
 - 7 are related to healthcare sterilization activities
 - 1 is related to packaging and labelling services
 - 11 are in the post-secondary education sector – most of which may also span the healthcare sterilization sector as well.
- Facilities associated with EtO as a pesticide/fumigant: It is unknown how many facilities use EtO as a fumigant, however, the only current [EtO pesticide product registration is for Linde Canada](#), which is expected to report.

Due to a lack of quantitative data for EtO using facilities beyond Ontario, ECCC cannot offer a precise number of new or existing NPRI facilities that would be required to report for EtO.

5.2. Methods for estimating threshold and release/transfer quantities

NPRI reporting is based on information that the owner or operator of a facility has or can be reasonably expected to have access to. Facilities select their method for reporting to NPRI from a list of allowable methods:

- Continuous emission monitoring systems
- Predictive emission monitoring
- Source testing
- Remote quantification
- Mass balance
- Site-specific emission factor
- Published emission factor
- Speciation profile
- Engineering estimates

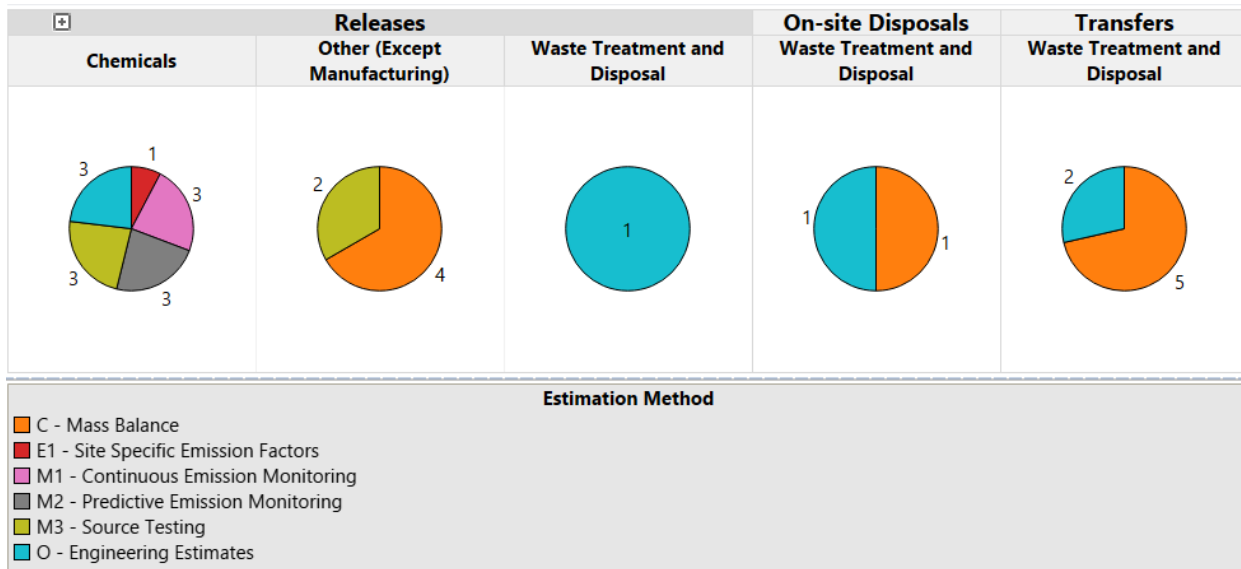


Figure 9: Frequency of various EtO estimation methods used by facilities to report to the NPRI between 2013-2023. Pie angles and labels refer to the # of facilities that used that estimation method. Note that the 2023 data are [preliminary](#).

Figure 9 shows that facilities have used a range of methods, including monitoring, emissions factors, and mass balance calculations to estimate/measure EtO releases. By contrast, facilities have only used mass balance or engineering estimates for EtO transfers and disposals. Published emission factors, remote quantification, or speciation profiles are not currently used. Based on the range of methods available to current reporters, ECCC has concluded that new reporting facilities will be able to estimate MPO and release/transfer quantities of EtO to report to the NPRI. Since methods are continuously being developed, with particularly rapid advances in emissions monitoring techniques and equipment for regulated sectors in the US (e.g., chemical manufacturing and commercial sterilization), facilities' ability to report could also improve over time. Summary information for some example estimation methods is provided below.

- Continuous Emissions Monitoring Systems (CEMS) and services for EtO for in-stack, fenceline or ambient air quality applications are commercially available by several vendors. These are now required for US Sterilization facilities that use EtO in amounts greater than 100 lbs. (~45 kg), and meet the EPA's 2023 performance specification and test procedures for EtO CEMS [performance standard-19](#) or other relevant test methods ([OTM- 47 Measurement of Ethylene Oxide Emissions from Stationary Sources by Cavity-Ring-Down Spectroscopy](#)). For example:

Table 4: Examples of EtO monitoring/estimation approaches

Method/System name	Application (s)	Detection limits
Ethylene Oxide Monitoring Systems Picaro,	Continuous emissions monitoring, fugitive/leak detection, fenceline monitoring	0.2- 0.25 ppb (depending on application)
Ethylene Oxide - Montrose Environmental (montrose-env.com)	Continuous emissions monitoring, fugitive/leak detection, fenceline monitoring	10 ppt – 5ppb (depending on application)

Ethylene Oxide Monitoring Services (cleanair.com)	Continuous emissions monitoring, indoor testing, fugitive/leak detection, fence line monitoring, mobile measurement	250 ppt
EMS-10™ Continuous Emissions Monitoring System (thermofisher.com)	Continuous emissions monitoring	<1 ppb
Ethylene Oxide Testing Down to 0.040 ppbv SGS Galson	Ambient air quality	0.040
Aerodyne Tunable Infrared Laser Differential Absorption Spectroscopy (TILDAS)-CS or TIDAS FD	Fence line/ambient air quality	<10 ppt- 75 ppt (depending on application)

- Additional details on ethylene oxide emissions measurement can be found at: [Ethylene Oxide Emissions Guidance \(itrcweb.org\)](http://itrcweb.org).
- Published emission factors exist, for example, the [US EPA's WebFIRE database of emission factors](#) includes eight emission factors for releases to air from chemical manufacturing processes.
- Facilities can also use mass balance methods to estimate EtO quantities. As a carcinogen, EtO should be disclosed on Safety Data Sheets (see section 4.2.3) and this information can be used for mass balance calculations.

6. Specific questions to address

In addition to seeking general comments on the proposal to lower the NPRI MPO threshold from 10 t (1% concentration by weight) to 1 kg (0.1% concentration by weight), ECCC is seeking information on specific aspects of this proposal, including:

- Whether the employee threshold (10 FTE) will be a barrier to comprehensive reporting coverage. ECCC does not currently have enough information on EtO using facilities nor the number of employees at these facilities to justify removing this part of the reporting requirement and is seeking any concrete evidence to either support or modify the proposal in this regard.
- Given that facilities in the education sector (i.e. Universities and colleges) make up a substantial proportion of the EtO-authorized facilities in Ontario (and potentially in other provinces as well), we are proposing to remove the mass threshold calculation exemption for quantities of EtO used in activities related to education or training of students. We are seeking information from stakeholders that will help with this decision.
- Are there facilities in Canada beyond the chemical manufacturing, clinical or commercial sterilization, and education sectors that may be impacted?
- Emission monitoring technology for sterilization sector facilities appears accessible/implementable (if not already done so) – are there any other barriers to implementation that should be considered?

Appendix A – Facilities with environmental permission to use EtO in Ontario*

PERMIT IDENTIFIER	Facility name	Address	TOTAL FACILITY EMISSION RATE grams/ second	Emission rate in kg/year*
R-010-2113898675	BLUEWATER HEALTH	89 NORMAN ST, SARNIA, ON, N7T 6S3	0.000075	2.3652
R-010-1112304361	J.H. MCNAIRN LIMITED	125 CONSUMERS DR, WHITBY, ON, L1N 1C4	0.0000479	1.5105744
R-010-7112036031	MACKENZIE HEALTH	3150 MAJOR MACKENZIE DR W, VAUGHAN, ON, L6A 1S1	0.005549	174.993264
R-010-1114268794	ST. JOSEPH'S HEALTH CARE, LONDON	268 Grosvenor ST, London, ON, N6A 4V2	0.00005987	1.88806032
R-010-7112309513	STERIGENICS EO CANADA, INC.	400 AMBASSADOR DR, MISSISSAUGA, ON, L5T 2J3	0.0063	198.6768
R-010-1111575589	TRILLIUM HEALTH PARTNERS	100 QUEENSWAY W, MISSISSAUGA, ON, L5B 1B8	0.0006508	20.5236288
R-010-8112602442	TRILLIUM HEALTH PARTNERS	2200 EGLINTON AVE W, MISSISSAUGA, ON, L5M 2N1	0.0007018	22.1319648
R-010-9112167179	TRILLIUM HEALTH PARTNERS	150 SHERWAY DR, ETOBICOKE, ON, M9C 1A5	0.002682	84.579552
R-010-1114285477	FANSHAWE COLLEGE OF APPLIED ARTS & TECHNOLOGY (bldgs A, D, E, F, L)	1001 Fanshawe College BOUL, London, ON, N5Y 5R6	0.0002797	8.8206192
R-010-1114286517	FANSHAWE COLLEGE OF APPLIED ARTS & TECHNOLOGY (bldgs B & T)	1001 Fanshawe College BLVD, London, ON, N5Y 5R6	0.06186	1,950.81696
R-010-7113391408	THE CONESTOGA COLLEGE INSTITUTE OF TECHNOLOGY AND ADVANCED LEARNING	299 Doon Valley DR, Kitchener, ON, N2G 4M4	0.003757	118.480752
R-010-2111522364	TORONTO METROPOLITAN UNIVERSITY	288 Church ST, TORONTO, ON, M5B 1Z5	0.001155	36.42408
R-010-2111542065	TORONTO METROPOLITAN UNIVERSITY	44 Gerrard ST E, TORONTO, ON, M5B 1G3	0.01277	402.71472
R-010-7112917875	TORONTO METROPOLITAN UNIVERSITY	350 VICTORIA ST, TORONTO, ON, M5B 2K3	0.0004122	12.9991392
R-010-9111880824	TORONTO METROPOLITAN UNIVERSITY	245 Church ST, Toronto, ON, M5B 2K3	0.002596	81.867456
R-010-9113623401	UNIVERSITY HEALTH NETWORK / RÉSEAU UNIVERSITAIRE DE SANTÉ	399 Bathurst ST, Toronto, ON, M5T 2S8	0.002778	87.607008
R-010-1114548475	UNIVERSITY OF GUELPH	88 McGilvray RD, Guelph, ON, N1G 2W1	0.000382	12.046752
R-010-2113337247	UNIVERSITY OF OTTAWA / UNIVERSITÉ D'OTTAWA	136 JEAN-JACQUES-LUSSIER, OTTAWA, ON, K1N 6N5	0.001327	41.848272
R-010-4114472178	UNIVERSITY OF WATERLOO	137 GLASGOW ST, KITCHENER, ON, N2G 4X8	0.12	3,784.32
R-010-3112106205	STERIGENICS EO CANADA, INC.	781 Pharmacy AVE, Scarborough, ON, M1L 3K2	0.00227	71.58672

Note: Grey indicates the facility is now closed, and pink indicates it is associated with the education sector.

*See https://www.ioapplications.lrc.gov.on.ca/Access_Environment/index.html?viewer=Access_Environment.AE&locale=en-CA

**a maximum potential emission calculated here by scaling from grams/second emission rate reported in the facility's [Environmental Activity and Sector Registration \(EASR\)](#) to kg/year by assuming a maximum operation schedule of 24 hours/day, 365 days/year.