

**BEFORE THE ILLINOIS POLLUTION CONTROL BOARD**

IN THE MATTER OF:	)	
	)	
PROPOSED NEW 35 ILL. ADM. CODE 250	)	R19-
ETHYLENE OXIDE AMBIENT AIR	)	(Rulemaking – Air)
MONITORING	)	

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PROPOSED NEW 35 ILL. ADM. CODE 250 ) R19-  
ETHYLENE OXIDE AMBIENT AIR ) (Rulemaking – Air)  
MONITORING )

**NOTICE**

TO: Don Brown Office of Legal Services  
Clerk Illinois Department of Natural Resources  
Illinois Pollution Control Board One Natural Resources Way  
James R. Thompson Center Springfield, IL 62702-1271  
100 West Randolph Street, Suite 11-500  
Chicago, IL 60601-3218

Division Chief of Environmental Enforcement  
Office of the Attorney General  
100 West Randolph Street, Suite 1200  
Chicago, IL 60601

PLEASE TAKE NOTICE that I have today filed with the Office of the Clerk of the Illinois Pollution Board the RULEMAKING PROPOSAL entitled "PROPOSED NEW 35 ILL. ADM. CODE 250, ETHYLENE OXIDE AMBIENT AIR MONITORING" AND APPEARANCES of the Illinois Environmental Protection Agency, a copy of which is herewith served upon you.

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: /s/ Antonette R. Palumbo  
Antonette R. Palumbo  
Assistant Counsel  
Division of Legal Counsel

DATED: December 17, 2019

1021 N. Grand Ave. East  
P.O. Box 19276  
Springfield, IL 62794-9276  
(217) 782-5544

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MONITORING )

**APPEARANCE**

The undersigned hereby enters her appearance as an attorney on behalf of the Illinois Environmental Protection Agency.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: /s/ Dana Vetterhoffer  
Dana Vetterhoffer  
Deputy General Counsel  
Division of Legal Counsel

DATED: December 17, 2019

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Respectfully submitted,

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: /s/ Antonette R. Palumbo  
Antonette R. Palumbo  
Assistant Counsel  
Division of Legal Counsel

DATED: December 17, 2019

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**ILLINOIS ENVIRONMENTAL PROTECTION AGENCY'S PROPOSAL OF  
REGULATION**

The Illinois Environmental Protection Agency moves that the Illinois Pollution Control Board adopt the attached regulation.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: 

John J. Kim  
Director

DATED: December 17, 2019

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**CONSENT TO RECEIPT OF E-MAIL SERVICE**

I, the undersigned, authorize the service of documents on me by e-mail in lieu of receiving paper documents in the above-captioned proceeding. My e-mail address to receive service is as follows:

dana.vetterhoffer@illinois.gov

Respectfully submitted,

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: /s/ Dana Vetterhoffer  
Dana Vetterhoffer  
Deputy General Counsel  
Division of Legal Counsel

DATED: December 17, 2019

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I, the undersigned, authorize the service of documents on me by e-mail in lieu of receiving paper documents in the above-captioned proceeding. My e-mail address to receive service is as follows:

antonette.palumbo@illinois.gov

Respectfully submitted,

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: /s/ Antonette R. Palumbo  
Antonette R. Palumbo  
Assistant Counsel  
Division of Legal Counsel

DATED: December 17, 2019

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**STATEMENT OF REASONS**

**I. INTRODUCTION**

The Illinois Environmental Protection Agency (“Illinois EPA” or “Agency”) submits this Statement of Reasons to the Illinois Pollution Control Board (“Board”) pursuant to Sections 27 and 28 of the Environmental Protection Act (“Act”) (415 ILCS 5/27 and 28) and 35 Ill. Adm. Code 102.202 in support of the attached proposal of regulation. The proposed rulemaking would create a new section of the Illinois Administrative Code establishing a system to ascertain baseline levels of ethylene oxide (“EtO”) across Illinois. This rulemaking is proposed in order to meet the requirements of Section 9.16(n) (text from P.A. 101-22)<sup>1</sup> of the Environmental Protection Act (“Act”), a new section of the Act signed into law on June 21, 2019.

**II. PURPOSE AND EFFECT**

The purpose and effect of this rule is very specific – to satisfy the mandate of the Illinois legislature and collect monitoring data to supplement the monitoring being conducted by the United States Environmental Protection Agency (“USEPA”) and to further assess ambient levels of EtO in Illinois. The proposed rule sets forth a mechanism to collect air samples to determine background levels of EtO throughout the State.

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<sup>1</sup> Public Acts 101-22 and 101-23 both created a new Section 9.16, and both were published in the Illinois Compiled Statutes with that designation. Therefore, the Sections are distinguished from one another by referring to the appropriate Public Act number after the Section number.

There is no federal ambient air quality standard for EtO or other Hazardous Air Pollutants (“HAPs”) (except for lead, which is also a criteria pollutant), and the purpose of the rule is not to establish a standard for EtO in Illinois. HAPs have historically been regulated through facility-level emissions standards rather than ambient air standards because HAPs are generally emitted in much smaller quantities than criteria pollutants, and the impacts from HAPs tend to be more localized.

Ambient monitoring will provide data regarding EtO in the State and enable a determination of the average baseline background concentrations of EtO in different geographical areas. Data collected by Illinois EPA and USEPA, coupled with any federal action taken to further regulate EtO on a national level, will help inform any appropriate next steps.

The Agency has determined that a six-month monitoring period in which samples are collected every 12 days is appropriate to meet the requirements of Section 9.16(n) (text from P.A. 101-22), particularly since USEPA’s increased monitoring will provide a broader picture of ambient EtO levels. As this proposed rule is limited in scope to this six-month monitoring period, the Agency further proposes that the rule sunset after 24 months, which provides adequate time for the Agency to set up and conduct the monitoring.

### **III. BACKGROUND**

#### **Ethylene Oxide**

EtO is a flammable gas that is used in two ways: 1) it can be combined with other chemicals, resulting in a wide array of consumer products, including detergents, solvents, plastics, antifreeze, textiles, and adhesives; and 2) it is used as a sterilizing agent for medical equipment and a fumigating agent for food products. UNITED STATES ENVTL. PROTECTION AGENCY, BACKGROUND INFO. ON ETHYLENE OXIDE (Nov. 22, 2019), <https://www.epa.gov/>

hazardous-air-pollutants-ethylene-oxide/background-information-ethylene-oxide#what. EtO is also an unintended byproduct of certain processes, including combustion. *Id.* Sources of EtO emissions include plants, microbes, human exhalation, cigarette smoke, automobile exhaust, and industrial sources, like commercial sterilizers and chemical facilities. *Id.*

Regulation of Ethylene Oxide

EtO is one of 187 HAPs regulated under Section 112 of the Clean Air Act, all of which have been identified as presenting a potential threat of adverse human health effects, such as cancer, reproductive effects, or birth defects. 42 U.S.C. § 7412. As noted above, in contrast to criteria pollutants, such as ozone and particulate matter, USEPA does not promulgate maximum ambient air concentrations for HAPs. Instead, USEPA regulates HAPs by “establishing emission standards for each category or subcategory of major sources and area sources of hazardous air pollutants listed” in Section 112. 42 U.S.C. § 7412(d). These emission standards are known as the National Emission Standards for Hazardous Air Pollutants (“NESHAPs”) and are determined based on assessment of the degree of emissions reduction achievable and also a complex assessment of the health risks associated with HAP emissions. USEPA is required to reevaluate each NESHAP at least every eight years taking into account developments in practices, processes, and control technologies, which is called a technology review. If such standards are found lacking, USEPA is required to amend them as necessary. 42 U.S.C. § 7412(d)(6).

There are four NESHAPs pertinent to the use of EtO by sources in Illinois: 1) Ethylene Oxide Emissions Standards for Sterilization Facilities (40 CFR Part 63, Subpart O); 2) National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing (40 CFR Part 63, Subpart FFFF); 3) National Emission Standards for Hazardous Air Pollutant Emissions for Polyether Polyols Production (40 CFR Part 63, Subpart PPP); and 4)

National Emission Standards for Hospital Ethylene Oxide Sterilizers (40 CFR Part 63, Subpart WWWW).

The NESHAP covering sterilization facilities was promulgated in 1994, and the current standard requires commercial sterilizers using one ton or more of EtO to reduce EtO emissions from a sterilization chamber vent by at least 99 percent. 40 CFR § 63.362. In 2006, USEPA determined that no additional control requirements were warranted for commercial sterilizers. *Ethylene Oxide Emissions Standards for Sterilization Facilities*, 67 Fed. Reg. 17,712 (Apr. 7, 2006). USEPA published an information collection request on September 26, 2019, which seeks to collect “notifications, performance test reports and periodic reports, as well as maint[enance] records of continuous parameter monitoring data, any malfunctions, and equipment inspections.” *Info. Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Commercial Ethylene Oxide Sterilizers and Fumigation Operations (Renewal)*, 84 Fed. Reg. 50825, 50826 (Sept. 26, 2019).

On December 12, 2019, USEPA published an Advance Notice of Proposed Rulemaking (“ANPRM”) to solicit information and request comment on potential control measures for reducing EtO from commercial sterilization facilities. *Nat’l Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*, 84 Fed. Reg. 67889, 67889 (Dec. 12, 2019). The ANPRM does not impose any requirements on these sources, but instead seeks information regarding the capture and control of fugitive emissions, the control of chamber exhaust vent emissions, and new types of control devices and process equipment, amongst other topics. *Id.* at 67894. USEPA is accepting comments through February 10, 2020. *Id.* at 67890.

The miscellaneous chemical manufacturing standard was first promulgated in 2003 and was amended in 2006 to clarify the applicability of the regulations, provide additional avenues for compliance, and streamline recordkeeping and reporting requirements. *Nat'l Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing*, 71 Fed. Reg. 40,316, 40,317 (July 14, 2016). Miscellaneous organic chemical manufacturers that are major sources of HAPs must comply with Subpart FFFF, which sets forth emission limits and work practice standards for continuous process vents, batch process vents, storage tanks, transfer racks, equipment leaks, and wastewater streams and liquid streams in open systems within the source. *See* 40 CFR Part 63, Subpart FFFF, Tables 1 – 7. Under a court order to complete a review of Subpart FFFF by March 2020, USEPA announced its proposed amendments to this NESHAP on November 6, 2019. According to USEPA, the amendments will “provide clarifications, corrections, and improved compliance and will reduce emissions of HAPs from the source category by 116 tons per year, which includes reductions in EtO emissions of approximately 10 tons per year.” UNITED STATES ENVTL. PROTECTION AGENCY, PROPOSED AMENDMENTS TO AIR TOXICS STANDARDS FOR MISCELLANEOUS ORGANIC CHEMICAL MFG.: FACT SHEET 1 (Nov. 6, 2019). The reductions will come from stricter requirements for storage tanks, process vents, and equipment leaks. *Id.* at 2. Upon publication in the *Federal Register*, there will be a 45-day comment period.

The NESHAP for polyether polyols production was promulgated in 1999 and is applicable to producers of polyether polyols and polyether mono-ols. *Nat'l Emission Standards for Hazardous Air Pollutants for Polyether Polyols Prod.*, 64 Fed. Reg. 29,420, 29,420 (June 1, 1999). Manufacturing polyether polyols results in HAPs emissions, including EtO. *Id.* Under the NESHAP, emissions of EtO from process vents must be controlled by either an aggregate

reduction in emissions; maintenance of an outlet concentration; or maintenance of an emission factor. 40 CFR § 63.1426(b), (c). Existing polyether polyol production sources also have the option to reduce emissions from each process vent using a flare. *Id.* at (b)(2)(i). This NESHAP was not amended by USEPA after the most recent residual risk and technology review performed in 2012 under Sections 112(d)(6) and 112(f)(2) of the Clean Air Act. *Nat'l Emission Standards for Hazardous Air Pollutant Emissions: Group IV Polymers and Resins; Pesticide Active Ingredient Prod.; and Polyether Polyols Prod.*, 79 Fed. Reg. 17340, 17341 (March 27, 2014).

Promulgated in 2007, the NESHAP for hospital sterilizers is applicable to sterilization facilities at a hospital that is an area source of HAPs. 40 CFR § 63.10381. This provision sets forth a best practice standard that requires sterilizers to “sterilize full loads of items having a common aeration time, except under medically necessary circumstances.” *Id.* at 63.10390. USEPA has not performed a technology review of this NESHAP under Section 112(d)(6) of the Clean Air Act.

#### Events Preceding Current Rulemaking

In 2016, USEPA’s Integrated Risk Information System (“IRIS”) program released an “Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide” (“IRIS Report”) that changed EtO’s hazard characterization from “probably carcinogenic” to “carcinogenic to humans” and increased EtO’s lifetime inhalation cancer unit risk estimate significantly, indicating that the concentration of ethylene oxide associated with a one-in-a-million cancer risk for a lifetime of continuous exposure is 0.0002 micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ). UNITED STATES ENVTL. PROTECTION AGENCY, EVALUATION OF THE INHALATION CARCINOGENICITY OF ETHYLENE OXIDE, EXEC.SUMMARY IN SUPPORT OF SUMMARY INFO. ON THE INTEGRATED RISK INFO. SYS. 1-2 (Dec. 2016).

USEPA also released its most recent National Air Toxics Assessment (“NATA”) report, based on 2014 data, in August 2018, which incorporated its updated risk value for EtO. UNITED STATES ENVTL. PROTECTION AGENCY, FREQUENT QUESTIONS: HEALTH INFO. ABOUT ETHYLENE OXIDE (Dec. 4, 2019), <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-health-information-about-ethylene-oxide#carcinogen>. NATA is “a screening tool, intended to help EPA and state, local and tribal air agencies determine if areas, pollutants or types of pollution sources need to be examined further to better understand risks to public health.” UNITED STATES ENVTL. PROTECTION AGENCY, 2014 NAT’L AIR TOXICS ASSESSMENT: FACT SHEET (2018). Based largely on the updated risk value, the NATA results showed that long-term exposure to EtO could lead to elevated cancer risks. *Id.* Such elevated cancer risk equates to “a potential cancer risk of greater than 100 in 1 million at a census tract.... A risk level of 100 in 1 million refers to the likelihood that 100 in 1 million (1 in 10,000) people would develop cancer if they breathe air containing the same amount of the same air toxic for 70 years.” *Id.*

In response to the NATA report, USEPA announced a two-pronged approach to addressing EtO emissions. The first prong is to review the federal EtO regulations, particularly 40 CFR Part 63 Subparts O and FFFF, and revise such regulations if necessary. UNITED STATES ENVTL PROTECTION AGENCY, ETHYLENE OXIDE UPDATES (Nov. 22, 2019), <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-updates>.

The second prong is to conduct more air monitoring to determine background concentrations of EtO. USEPA has air toxics monitoring networks, including the National Air Toxics Trend Stations (“NATTS”) and Urban Air Toxics Monitoring Program (“UATMP”). USEPA developed the NATTS Network to provide long-term monitoring of HAPs. The

purposes of the NATTS are “assessing trends and emission reduction program effectiveness, assessing and verifying air quality models, and as direct input to source-receptor models.”

UNITED STATES ENVTL. PROTECTION AGENCY, AIR TOXICS – NAT’L AIR TOXICS TRENDS STATIONS (Sept. 12, 2019), <https://www3.epa.gov/ttnamti1/natts.html>. The NATTS Network consists of 27 sites across the country. The goal of the UATMP is “to characterize the composition and magnitude of air toxics pollution through ambient air monitoring.” UNITED STATES ENVTL. PROTECTION AGENCY, 2013 NAT’L MONITORING PROGRAMS ANNUAL REPORT (UATMP, NATTS, CSATAM) 1-1 (2015). There is a NATTS monitoring site in Northbrook and a UATMP site in Schiller Park.

Starting in October 1, 2018, USEPA directed the NATTS and UATMP labs to analyze EtO concentrations. UNITED STATES ENVTL. PROTECTION AGENCY, HAZARDOUS AIR POLLUTANTS: ETHYLENE OXIDE, ETHYLENE OXIDE - UPDATES (Dec. 12, 2019), <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-updates>. The goal of the increased monitoring by these sites is to gain an understanding of the distribution of EtO in areas that do not have significant sources of EtO and determine any variability in ambient levels of EtO. *Id.* USEPA has acknowledged that there are challenges to this monitoring, including the sensitivity of the only viable method for analyzing ambient EtO and the lack of knowledge about what other sources could be contributing to ambient levels. *Id.*

#### State Legislation

The Illinois General Assembly passed Senate Bill 1852 during the 2019 spring legislative session, which was signed into law as Public Act 101-0022, effective on June 21, 2019. The legislation amends the Act by adding Section 9.16, setting forth more stringent capture and control requirements for commercial sterilizers. Commercial sterilizers are also required by this

legislation to conduct ambient air monitoring at least quarterly near the property boundaries of the facility and at community locations with the highest modeled impact.

Pertinent to this rulemaking, Section 9.16(n) provides as a separate requirement that “[t]he Agency shall conduct air testing to determine the ambient levels of ethylene oxide throughout the State. The Agency shall, within 180 days after the effective date of this amendatory Act of the 101<sup>st</sup> General Assembly, submit rules for ambient air testing of ethylene oxide to the Board.” 415 ILCS 5/9.16(n), P.A. 101-22. Thus, the General Assembly has directed the Agency to undertake steps similar to those of USEPA and conduct ambient monitoring to determine background concentrations of EtO.

#### **IV. GEOGRAPHIC REGIONS AFFECTED**

This proposed rule requires ambient air monitoring of EtO statewide, with monitors located in Northbrook, Schiller Park, Nilwood, Alton, and Bondville. These sites were chosen in order to fulfill the General Assembly’s mandate of conducting testing throughout the State. The sites represent urban and rural locations in Illinois. ILLINOIS ENVTL. PROTECTION AGENCY, TECHNICAL SUPPORT DOCUMENT FOR PROPOSED NEW 35 IAC PART 250: ETHYLENE OXIDE AMBIENT AIR MONITORING, AQPSTR 19-06, 6 (Dec. 2019).

No sources are affected by this proposed rule, as the regulations simply set forth the Illinois EPA’s ambient air monitoring plan to assess background EtO levels in the State.

#### **V. TECHNICAL FEASIBILITY AND ECONOMIC REASONABLENESS**

The Illinois EPA’s analysis, explained in the *Technical Support Document*, demonstrates the technical feasibility and economic reasonableness of this proposed rulemaking.

**VI. SYNOPSIS OF TESTIMONY**

The Illinois EPA anticipates calling David Bloomberg, Manager, Air Quality Planning Section (“AQPS”), Bureau of Air, Illinois EPA, and Rory Davis, Environmental Protection Engineer, AQPS, Bureau of Air, Illinois EPA, as witnesses at hearing to testify regarding the proposed rule. Written testimony will be submitted prior to hearing in accordance with the Board’s procedural rules. Mr. Bloomberg and Mr. Davis will be available for questions.

**VII. PUBLIC OUTREACH**

The Agency provided an opportunity for review of the proposed rule to environmental and industry groups. The Agency received limited comments and, in response, added some information to the Technical Support Document. Additionally, the Board’s rulemaking process will provide interested parties with ample opportunity to provide feedback on this proposed rule.

**IX. CONCLUSION**

For the reasons stated above, the Illinois EPA hereby submits this regulatory proposal and requests the Board to adopt these rules for the State of Illinois.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: /s/ Antonette R. Palumbo  
Antonette R. Palumbo  
Assistant Counsel  
Division of Legal Counsel

DATED: December 17, 2019

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**TITLE 35: ENVIRONMENTAL PROTECTION**  
**SUBTITLE B: AIR POLLUTION**  
**CHAPTER I: POLLUTION CONTROL BOARD**  
**SUBCHAPTER M: MONITORING REQUIREMENTS**

**PART 250**  
**ETHYLENE OXIDE AMBIENT AIR MONITORING**

**Section**

250.100	Purpose
250.105	Monitoring Locations
250.110	Ethylene Oxide Ambient Air Monitoring Requirements
250.115	Monitoring Results
250.120	Sunset Provisions

AUTHORITY: Implementing Section 9.16, P.A. 101-22, and authorized by Sections 27 and 28 of the Environmental Protection Act [415 ILCS 5/9.16, P.A. 101-22; 27; and 28].

SOURCE: Adopted and codified at \_\_\_\_\_, effective \_\_\_\_\_.

**Section 250.100      Purpose**

The purpose of this Part is to set forth the manner in which the Agency shall conduct ambient air monitoring of ethylene oxide in accordance with the requirements in Section 9.16 (text from P.A. 101-22) of the Environmental Protection Act (415 ILCS 5/9.16, P.A. 101-22).

(Source: Added at \_\_\_\_\_, effective \_\_\_\_\_)

**Section 250.105      Monitoring Locations**

The Agency shall monitor levels of ethylene oxide in the ambient air in or around the following locations in Illinois in accordance with the requirements set forth in Section 250.110:

- a) Northbrook;
- b) Schiller Park;
- c) Nilwood;
- d) Alton; and
- e) Bondville.

(Source: Added at \_\_\_\_\_, effective \_\_\_\_\_)

**Section 250.110 Ethylene Oxide Ambient Air Monitoring Requirements**

- a) The Agency shall conduct ambient air monitoring for ethylene oxide in or around each location specified in Section 250.105 for a period of six consecutive calendar months. During that time frame, the Agency shall collect a sample every 12 days. Each sample shall be collected over a period of approximately 24 hours.
- b) The six-month monitoring period shall commence no later than one year after the effective date of this Part.
- c) The Agency shall comply with all applicable USEPA guidelines for ambient air monitoring.

(Source: Added at \_\_\_\_\_, effective \_\_\_\_\_)

**Section 250.115 Monitoring Results**

The Agency shall make the ambient air monitoring results publicly available on the Agency's website within 30 days of receipt of each set of quality assured data.

(Source: Added at \_\_\_\_\_, effective \_\_\_\_\_)

**Section 250.120 Sunset Provisions**

The provisions of this Part shall no longer apply 24 months after the effective date of this Part.

(Source: Added at \_\_\_\_\_, effective \_\_\_\_\_)

**TECHNICAL SUPPORT DOCUMENT**

**for**

**PROPOSED NEW 35 IAC PART 250:  
ETHYLENE OXIDE AMBIENT AIR MONITORING**

**AQPSTR 19-06**

**December 2019**

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY  
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**List of Acronyms and Abbreviations**

Act	Illinois Environmental Protection Act
Agency	Illinois Environmental Protection Agency
Board	Illinois Pollution Control Board
Illinois EPA	Illinois Environmental Protection Agency
GC/MC	Gas Chromatography/Mass Spectrometry
USEPA	United States Environmental Protection Agency
$\mu\text{g}/\text{m}^3$	micrograms per cubic meter

## **1.0 Executive Summary**

On June 21, 2019, a new section of the Environmental Protection Act (“Act”), Section 9.16(n) (text from P.A. 101-22), was signed into law requiring the Illinois Environmental Protection Agency (“Illinois EPA” or “Agency”) to “conduct air testing to determine the ambient levels of ethylene oxide throughout the State.” The section also required the Agency to submit rules for this testing to the Illinois Pollution Control Board (“Board”) within 180 days of the amendment’s effective date. The Agency has submitted proposed amendments to Title 35 of the Illinois Administrative Code, adding a new Part 250: Air Monitoring of Ethylene Oxide.

The purpose of this document is to provide the Board and the public with technical support regarding the proposed regulation, including monitor siting and test methods, and a discussion of the technical feasibility and economic reasonableness of the proposed amendments.

In brief, the proposed amendments at 35 Ill. Adm. Code Part 250 address the requirements of the Act regarding ethylene oxide monitoring by the Illinois EPA, and their implementation is both technically feasible and economically reasonable.

## **2.0 Introduction**

Ethylene oxide is a chemical used as a sterilizing agent for medical equipment and a fumigating agent for food products, as well as being an intermediate chemical in the manufacture of ethylene glycol. It is listed by the United States Environmental Protection Agency (“USEPA”) as a hazardous air pollutant. Sources of ethylene oxide emissions to the air include chemical operations and sterilization operations, release from fumigated materials, cigarette smoke, automobile exhaust, plants, microbes, human exhalation, and other combustion processes.<sup>1</sup>

In regard to regulating hazardous air pollutants, USEPA has explained that it “has typically not attempted to address estimated cancer risks caused by emissions from an individual facility if the risks to the most exposed person [are] below 1 in a million, or in some cases, if they are below 100 in a million.” Per USEPA, the concentration of ethylene oxide associated with a one-in-a-million cancer risk for a lifetime of continuous exposure is 0.0002 micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ). In other words, USEPA has estimated that an individual continuously breathing air containing ethylene oxide concentrations of 0.0002  $\mu\text{g}/\text{m}^3$  in the air, over an entire lifetime, would have less than a one-in-a-million increased chance of developing cancer as a result. USEPA similarly estimates concentrations of 0.02  $\mu\text{g}/\text{m}^3$  would result in not greater than a 100-in-a-million increased chance.<sup>1</sup>

## **3.0 Proposed Rule**

The Act requires the Agency to conduct air testing to determine ambient levels of ethylene oxide throughout the State, and to submit rules for such ambient air testing of ethylene oxide to the Board within 180 days of the effective date of the amendment of the Act, which was June 21,

2019. To this end, the proposed new Part 250 requires the Agency to conduct air monitoring to determine the ambient levels of ethylene oxide in Illinois by collecting air samples. Five monitoring locations in Illinois have been selected. The sampling locations would be in Northbrook, Schiller Park, Alton, Nilwood, and Bondville. Sampling would be conducted every 12 days for the period of six months and consist of a 24-hour sample for each monitoring day. Samples collected from all sites would be analyzed to determine ethylene oxide concentrations, and the Agency will make test results publicly available within 30 days of receipt of a quality assured data set. The Agency has also included a provision to sunset the proposed rule 24 months after its effective date.

### 3.1 Monitor Sites in Illinois

The Illinois monitoring sites in the proposed rule are currently in use by the Agency for the purposes of ambient air monitoring and are adequate to provide the Agency and the public with information about ambient levels of ethylene oxide throughout the State.

The monitoring locations were selected to provide ethylene oxide concentration data from a diverse cross section of locations in Illinois. Monitoring locations would sample densely populated urban areas in Illinois (Chicago and Metro-East St. Louis areas), as well as rural areas (Nilwood and Bondville). The monitoring locations are also spread out geographically consistent with the Section 9.16(n) (text from P.A. 101-22) requirement to “determine the ambient levels of ethylene oxide throughout the State.”

Table 1 contains information regarding each proposed monitoring site’s distance from a known emission source of ethylene oxide, as well as from major highways.

**Table 1. Monitoring Site Geographical Information**

<b>Monitor Location</b>	<b>Distance from Nearest Permitted Ethylene Oxide Emitting Source</b>	<b>Distance from Major Highways</b>
Alton	Anderson Hospital – 15.1 miles Southeast	State Rte. 3 – 1.4 miles Southeast; Interstate 270 - 8.7 miles South
Bondville	Tate & Lyle – 32.2 miles Southwest	Interstate 57 – 3.7 miles East
Nilwood	Memorial Medical Center – 29.6 miles North-Northeast	Interstate 55 – 8.9 miles East
Northbrook	Highland Park Hospital – 3.5 miles North	State Rte. 68 – 0.14 miles South; Interstate 94 – 0.4 miles North
Schiller Park	Sun Chemical – 4.65 miles South-Southwest	Interstate 294 – 0.05 miles East; O’Hare Airport – 0.3 miles Northwest

The use of sites currently being utilized for air monitoring ensures efficient and proper sampling by the Agency. Additionally, such locations have already undergone review to ensure they meet siting requirements. Figure 1 is a map of the proposed monitoring locations.

**Figure 1. Ethylene Oxide Monitoring Locations**



### **3.2 Ambient Air Sampling**

Under the proposed rule, air samples would be collected every 12 days for a period of six months. This sampling frequency ensures that samples would be taken on different days of the week, and that at least two samples would be taken on each day of the week during the sampling period. The six-month duration of sampling would result in approximately 15 samples taken at each monitoring location.

### **3.3 Test Method**

The test method that would be used to analyze the air monitoring samples collected pursuant to the proposed regulation is USEPA Method TO-15, Determination of Volatile Organic Compounds (VOCs) in Air Collected in Specially-Prepared Canisters and Analyzed by Gas Chromatography/ Mass Spectrometry (GC/MS).<sup>2</sup>

Method TO-15 begins with collecting atmospheric samples into a specially-prepared stainless steel canister using a sampling train that regulates the rate and duration of the sampling. The sampled air is then taken to a laboratory for analysis. To analyze the sample, a known volume is directed from the canister, purged of water content, and concentrated. This concentrated sample is then released onto a gas chromatographic column for separation and analyzed by mass spectrometry to determine concentrations of compounds that exist in the sample. Test results for ethylene oxide are typically reported in units of micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ) of sampled air.

According to USEPA, Method TO-15 is currently the only viable method for testing air samples for ethylene oxide concentrations. USEPA acknowledges that the method has sensitivity challenges relative to the most recent risk assessments discussed above in Section 2.0 of this document. This is because the method detection limit (“MDL”) for ethylene oxide using Method TO-15 is in the range of  $0.06 - 0.08 \mu\text{g}/\text{m}^3$ , meaning concentrations of ethylene oxide lower than those levels will not be detected, whereas USEPA’s risk assessment refers to concentrations between  $0.0002 - 0.02 \mu\text{g}/\text{m}^3$ . Additionally, the science for accurately measuring ethylene oxide levels in ambient air is currently still developing. Results from Method TO-15 have an uncertainty of approximately 30% in the measurement of VOCs in general.<sup>3</sup> This means that a given analyzed sample measurement could be as much as 30% higher or lower than the actual value. As such, a single monitored result that seems to be higher or lower may simply fall within that uncertainty range.<sup>3</sup>

### **4.0 Technical Feasibility and Economic Reasonableness**

The proposed rule is both technically feasible and economically reasonable. The sampling and analysis necessary to meet the requirements of Section 9.16(n) of the Act can be achieved using the afore described methods developed and established by the USEPA. The rule as proposed can be implemented without economic burden to any entity in the State except for the Illinois EPA,

and the Agency considers the costs associated with the monitoring requirements as proposed to be reasonable to meet the requirements set forth in the Act.

## 5.0 References

1. United States Environmental Protection Agency. Ethylene Oxide (fact sheet). <https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf>
2. U.S. Environmental Protection Agency. 1999. "Air Method, Toxic Organics-15 (TO-15): Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air, Second Edition: Determination of Volatile Organic Compounds (VOCs) in Air Collected in Specially-Prepared Canisters and Analyzed by Gas Chromatography/Mass Spectrometry (GC/MS)." EPA 625/R-96/010b.
3. Lewis Weinstock, United States Environmental Protection Agency, Update on Ethylene Oxide Monitoring Activities (Oct. 3, 2019). (Attachment A).

**Attachment A: Update on Ethylene Oxide Monitoring Activities (A Presentation of Lewis Weinstock, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency)**

## Update on Ethylene Oxide Monitoring Activities

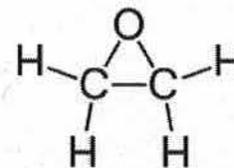
Lewis Weinstock – EPA/OAQPS  
NACAA Air Toxics and Monitoring Committees  
October 3, 2019



2

### Quick EtO Introduction

- The National Air Toxics Assessment released in 2018 indicated that ethylene oxide significantly contributes to elevated risks of cancer in some census tracts across the country – i.e., about 20 areas have risks greater than 100-in-a-million (map on next slide).
- In response, EPA has taken a two-pronged approach to address ethylene oxide emissions, including reviewing Clean Air Act regulations for industrial facilities that emit ethylene oxide and getting additional information to determine whether more immediate emission reduction steps are possible in the higher risk areas.
- Ambient air monitoring has been conducted in a few areas with a significant industrial source of ethylene oxide emissions (Willowbrook, IL; Grand Rapids, MI; and Lakewood, CO). In each of these areas, elevated levels of ethylene oxide were recorded at monitoring sites on days when they were downwind of the industrial facility of interest.
  - Lower, yet measurable levels of ethylene oxide were recorded at monitoring sites on days when they were upwind or on days when the industrial facility of interest was not operating.



Ethylene oxide is a flammable, colorless gas used to make a range of products, including antifreeze, textiles, plastics, detergents and adhesives. EtO also is used to sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment. The Clean Air Act lists EtO as a Hazardous Air Pollutant. U.S. EPA recently updated its risk value for ethylene oxide and is working with industry, and state, local and tribal air agencies to address this chemical



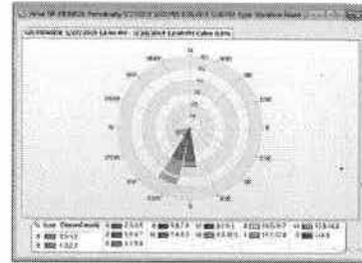


### Recent Ambient Monitoring Projects for EtO – Grand Rapids, MI

[https://www.michigan.gov/egle/0,9429,7-135-3310\\_70314\\_89277--,00.html](https://www.michigan.gov/egle/0,9429,7-135-3310_70314_89277--,00.html)

Two 1-day duration studies  
(Phase I and II)  
November 2018 & March 2019

#### Phase II Results



- The highest concentration of ethylene oxide ( $2.08 \mu\text{g}/\text{m}^3$ ) was measured at a parking lot directly across the street from Viant, Location #2. Given the wind direction, out of the south-southwest/south at speeds of 0-10 mph on the sampling day, the discharge from the air vent at Viant was in direct line with this sample location.
- The Phase II sampling results appear to support a background level of around  $0.18 \mu\text{g}/\text{m}^3$  in the Grand Rapids area. This suggested background level can be seen at both Locations #10 and #11.



### Recent Ambient Monitoring Projects for EtO – Lakewood, CO

<https://www.colorado.gov/pacific/cdphe/ethylene-oxide>

Two 7-day duration studies  
August & October 2018



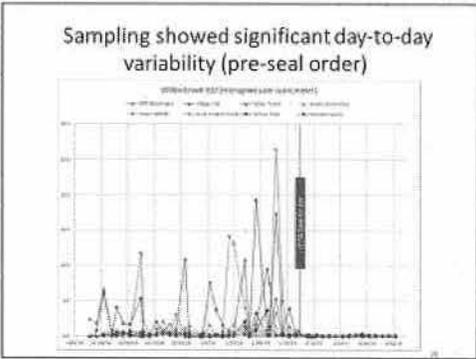
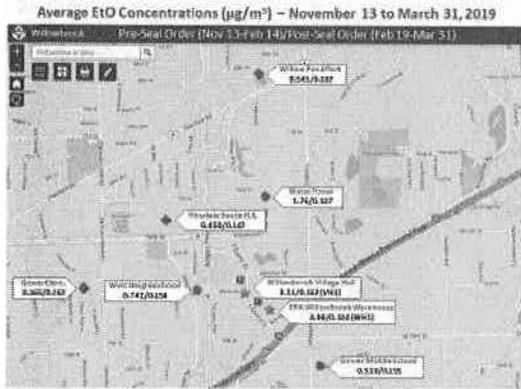
- For the pre-control monitoring, site #3 on the east side of the Terumo BCT facility had the highest pre-control average concentration over the 7 days of sampling at  $3.092 \mu\text{g}/\text{m}^3$ , followed closely by Site #2 on the west side at  $2.996 \mu\text{g}/\text{m}^3$ .
- For the post-control monitoring, Site #3 also had the highest post-control average concentration over the 7 days of sampling at  $0.993 \mu\text{g}/\text{m}^3$ , followed by Site #2 at  $0.774 \mu\text{g}/\text{m}^3$ .
- Mean background levels were approximately  $0.253 \mu\text{g}/\text{m}^3$ .



Recent Ambient Monitoring Projects for EtO – Willowbrook, IL

<https://www.epa.gov/il/sterigenics-willowbrook-facility>

4 1/2 Month study -  
November 13, 2018 –  
March 31, 2019

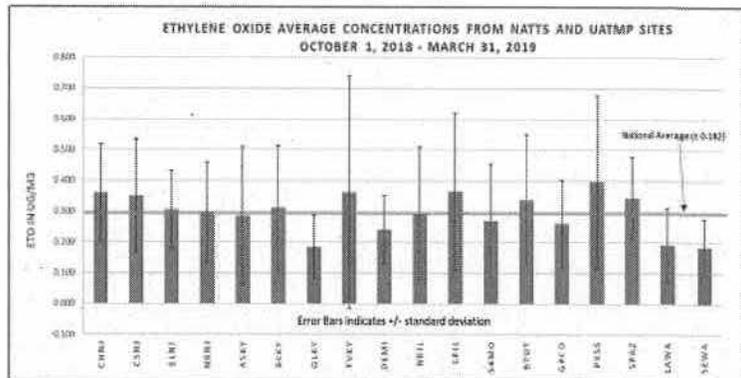


- EPA conducted 24-hour sampling at eight sites near a commercial sterilization facility (Sterigenics). Site averages when the facility was operating (32 sample days) ranged from 0.37 to 3.96 µg/m3. Highest 24-hour averages exceeded 10 µg/m3 on several occasions.
- The 6-week average background concentration after the facility was sealed by the IEPA was 0.15 µg/m3.



Next EPA Steps in Investigating the Distribution of EtO data Across the U.S.

- EPA has worked with the national air toxics contract lab to analyze EtO concentrations at a subset of the NATTS and UATMP sites for the 4thQ 2018 – 1stQ 2019 period
- Outreach calls have been completed with the affected states and the data are in final QA review prior to AQS posting
- The average concentration for this data set is 0.297 µg/m3
  - Equivalent to a long-term cancer risk of 1500 in 10<sup>6</sup>
- There is a statistical difference (lower) between a grouping of [GLKY, LAWA, SEWA] and the other sites



## Goals of the NATTS EtO enhancement

- Improve understanding of the national distribution of this compound in areas away from major EtO sources in different parts of the country
- Provide national or regional context for the results of case by case modeling results on individual facilities
- Support analysis of community-led ambient monitoring programs
- Increase and improve national air toxics analytical capacity for EtO
  - Analysis currently limited to a few commercial labs and Region 4/Athens
- Training programs with all the NATTS labs began on August 28
  - <https://www3.epa.gov/ttn/amtic/airtox.html>

## NATTS Sites & Years Established



## Summary – Current Measurement Challenges with EtO

### What do we know

- Method for characterizing EtO in the ambient air is adequate although the sensitivity needs to be improved
- Elevated levels of EtO have been measured near known industrial sources
- Ambient data collected from 18 monitoring sites located away from known sources has shown lower but measurable levels of EtO

### What don't we know

- How do the ambient levels of EtO vary nationally and seasonally across the country
- What are the sources of the EtO being measured away from known sources
- How long does EtO persist in the atmosphere; what is its involvement in atmospheric chemistry and transport
- What are the best methods for measuring EtO in real-time and/or in source streams
- What are the next steps if the presence of EtO is confirmed to be ubiquitous?

### Sampling of Public Reactions to Local Issues

**CALL TO ACTION**

**EIO Research and Response**

**THE TRUTH ABOUT ETHYLENE OXIDE**

**GAL CHARNLEY, Ph.D.**

EPA raises concern about elevated cancer risk for people living around B. Braun plant near Allentown

**Air testing for ethylene oxide in Waukegan, Gurnee shows highest results in residential area near Medline**

**AJC**  
Allentown, Northampton, Lehigh, Berks, York, Lancaster, Schuylkill, Chester, Delaware, and Philadelphia Counties

**Fear, doubt linger over toxic emissions, as regulatory battle rages**

**SHUT IT DOWN**



# Questions?



**CERTIFICATE OF SERVICE**

I, the undersigned, an attorney, state that I have served the attached RULEMAKING PROPOSAL entitled "PROPOSED NEW 35 ILL. ADM. CODE 250, ETHYLENE OXIDE AMBIENT AIR MONITORING" AND APPEARANCES upon the person to whom it is directed, by placing a copy in an envelope addressed to:

Office of Legal Services  
Illinois Department of Natural Resources  
One Natural Resources Way  
Springfield, IL 62702-1271

and mailing it by first-class mail from Springfield, Illinois, with sufficient postage affixed.

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: /s/ Antonette R. Palumbo  
Antonette R. Palumbo  
Assistant Counsel  
Division of Legal Counsel

DATED: December 17, 2019

1021 N. Grand Ave. East  
P.O. Box 19276  
Springfield, IL 62794-9276  
(217) 782-5544

**CERTIFICATE OF E-MAIL SERVICE**

I, the undersigned, on affirmation, state the following:

That I have served the attached RULEMAKING PROPOSAL entitled "PROPOSED NEW 35 ILL. ADM. CODE 250, ETHYLENE OXIDE AMBIENT AIR MONITORING" AND APPEARANCES by e-mail upon:

Illinois Pollution Control Board  
Don Brown, Clerk  
James R. Thompson Center  
100 West Randolph St., Suite 11-500  
Chicago, IL 60601  
[Don.brown@illinois.gov](mailto:Don.brown@illinois.gov)

Division Chief of Environmental Enforcement  
Office of the Attorney General  
100 West Randolph St., Suite 1200  
Chicago, IL 60601  
[enviro@atg.state.il.us](mailto:enviro@atg.state.il.us)

That my e-mail address is [antonette.palumbo@illinois.gov](mailto:antonette.palumbo@illinois.gov).

That the number of pages in this e-mail transmission is 36.

That the e-mail transmission took place before 5:00 p.m. on the date of December 17, 2019.

ILLINOIS ENVIRONMENTAL  
PROTECTION AGENCY

By: /s/ Antonette R. Palumbo  
Antonette R. Palumbo  
Assistant Counsel  
Division of Legal Counsel

DATED: December 17, 2019

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