THE HEARTLAND INSTITUTE

ARTHUR B. ROBINSON CENTER ON CLIMATE & ENVIRONMENTAL POLICY

OCT 2020 POLICY BRIEF

# Managing Ethylene Oxide:
## An Air Quality Professional's Perspective

**By Rich Trzupek**

## Summary

**The Myth:** Ethylene oxide is a uniquely hazardous manmade compound. It is commonly found at dangerous concentrations in the air, near commercial and industrial facilities that use it, and it is virtually unregulated.

**Realty:** Ethylene oxide is produced at petrochemical facilities, but is also regularly found in natural, biological systems, such as the human body. It is also commonly found in ambient air throughout industrial, residential, and rural areas. It is one of hundreds of potentially hazardous chemicals that is meticulously regulated by a variety of federal, state, and local agencies, which enforce regulations that are carefully designed to protect human health and the environment.

### The Exposure Question

In a world filled with thousands upon thousands of chemicals, natural and manmade, defining "safe" exposure levels to any one of them is an incredibly complex exercise. The risk associated with exposure depends on the state of a person's health, other exposures and risk factors, the frequency of exposure, genetic predispositions, and many other factors.

One of the more valuable ways of looking at exposure is to compare how exposure to a particular compound near manmade sources differs from natural background exposure in areas far removed from a manmade source. People are generally comfortable accepting the idea that natural background concentrations of air, water, and soil contaminants can serve as a baseline when examining risks associated with exposure. If 10 parts per billion of a compound can be regularly found in the air in remote locations, far away from potential industrial sources, there is no reason to suspect that a similar exposure of 10 parts per billion near an industrial source should be cause for concern.

When examined from this perspective, monitoring efforts in the public and private sectors tell a compelling story about ethylene oxide (EtO). Numerous studies have examined ethylene-oxide concentrations in the ambient air near industrial facilities that use the chemical, such as sterilization operations and petrochemical plants utilizing it as a precursor. These concentrations have been compared to ethylene-oxide concentrations in the ambient air at locations far removed from facilities handling ethylene oxide, and what researchers have found is that there is no meaningful statistical difference between the datasets. The air near a plant handling ethylene oxide is about as likely to contain a slightly higher concentration of the compound compared to Remote Area A as it is to contain a slightly lower concentration of the compound near Remote Area B.

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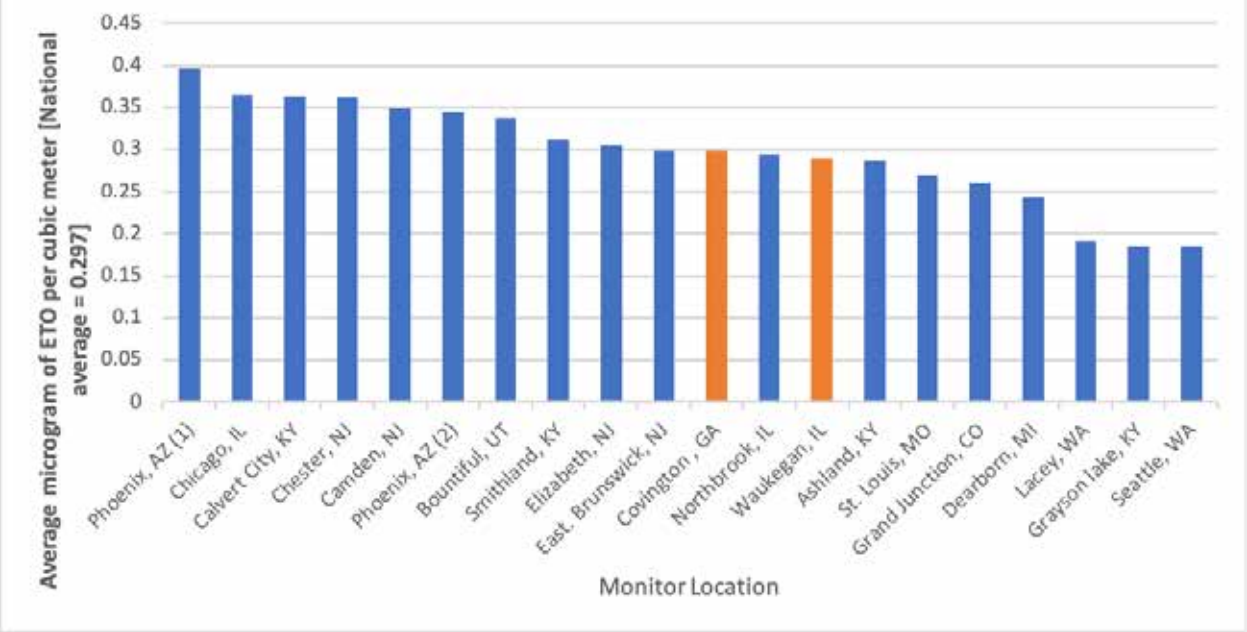
### Sample Air Monitoring Results from Two Sites with Facilities that Use Ethylene Oxide for Sterilizing Medical Equipment

Extensive monitoring data from multiple sites show that ethylene-oxide concentrations in the air do not correlate to the location of sterilization facilities that use ethylene oxide. Based on readings reported in March 2020 by the U.S. Environmental Protection Agency (EPA), which were taken from 18 sites across nine states that include a wide range of demographic and climate characteristics, EPA found the average presence of EtO in ambient air ranged from 0.2 to 0.4 micrograms of EtO per cubic meter of air (µg/m3).[1]

In Figure 1 on page 3, EPA's National Air Toxics Trends Station program and local monitoring data show average levels of ethylene oxide in various locations nationwide. As the graph reveals, in two locations in which ethylene oxide is used in the sterilization of medical equipment—Covington, Georgia and Waukegan, Illinois—EtO ambient air levels are within the normal range as determined by EPA's nationwide study. Indeed, EtO levels at those two locations are lower than small towns in Kentucky, New Jersey, and even Bountiful, Utah, a bedroom community of Salt Lake City.

Furthermore, Figure 1 shows the average level of EtO in Covington, Georgia's ambient air is 0.298 µg/m, according to the combined results of data collected from November 2019

**Figure 1: Average Ethylene-Oxide Levels at Sterilization Facilities vs. National Averages**




This graph shows the average ethylene-oxide levels at sterilization facilities compared to the national average. *Sources*: U.S. Environmental Protection Agency Air Quality System,[7] Lake County Health Department and Community Health Center,[8] and Georgia Environmental Protection Division.[9]

through March 2020 by the Georgia Environmental Protection Division[2] and a third-party environmental consulting firm engaged by Becton Dickinson, the company that operates the sterilization plant in Covington.

Compared to the recently announced results by the Georgia Chemistry Council,[3] the data from Covington are lower than all other locations measured by the council, including a rural site in the Pine Mountain area that averaged 0.38 μg/m$^3$. The council also found that the overall average in the Atlanta area is 1.14 μg/m$^3$.

Air monitoring results taken near a facility in Waukegan, Illinois—conducted by the Lake County Health Department from April 4, 2020, to May 2, 2020—found an average of only 0.29 μg/m$^3$, less than that of remote test sites in Lake County.[4]

The air monitoring results confirm the effectiveness of the different facilities' EtO emissions controls. The best available emissions control technology eliminates 99.999 percent of EtO emissions from the sterilization process.

**Figure 2: Who Regulates Exposure Risks?**

| *Organization or Program* | *Purpose* |
|---|---|
| National Emissions Standards for Hazardous Air Pollutants | Controls hazardous air pollutants |
| Occupational Safety and Health Administration | Ensures workplace safety |
| Resource Conservation and Recovery Act | Requires safe, responsible disposal |
| Toxic Release Inventory | Tracks releases to the environment |
| Emergency Planning and Community Right-to-Know Act | Coordinates emergency response, if needed |
| Toxic Substances Control Act | Evaluates toxic risks of compounds |
| Department of Transportation, Department of Homeland Security | Ensures safe transport of substances |
| Spill Prevention, Control and Countermeasures, Stormwater Pollution Prevention Planning | Prevents, manages releases to water |

## Who Is Minding the Store?

The United States is one of the most effective nations in the world at ensuring potentially harmful compounds, natural and manmade alike, are handled safely. Although the spotlight typically shifts to the EPA when considering air quality issues, there are number of other programs and agencies that factor into the equation as well. (See Figure 2.)

EPA regulates 187 "hazardous air pollutants" (HAP) through a program that started in 1990 under the George H.W. Bush administration.[5] EPA evaluates the risks associated with each HAP, the best means of controlling each HAP across multiple industries, the importance of industries that use HAPs, and conducts a cost-benefit analysis associated with regulatory compliance.

> "Like thousands of other compounds used around the world, ethylene oxide is enormously useful when safely used, and potentially harmful when misused."

The development of the resulting rules is a long and painstaking process. Anyone can submit public comments prior to rules being issued, and EPA must, by law, respond to every comment.[6] If someone is dissatisfied with a particular rule, he or she can appeal EPA's decision in courts.

Like thousands of other compounds used around the world, ethylene oxide is enormously useful when safely used,

and potentially harmful when misused. The same can be said of virtually any substance, from gasoline to table salt, from natural gas to nutritional supplements.

Ethylene oxide has been, and is, extensively regulated. The rules that EPA first put into place to establish ethylene-oxide sterilization procedures were carefully designed and extremely stringent. And as strict as federal standards are, many states have promulgated their own air toxics programs to supplement, not supersede, the federal rules. As a result of these regulations, ethylene-oxide emissions remain incredibly low—far lower than a number of other potentially harmful HAPs, in fact—and the ambient air concentrations analyzed over the fence line at the facilities referenced in this paper are a testament to the high degree of effectiveness of facilities' control systems.

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## Notes

[1] U.S. Environmental Protection Agency, "Hazardous Air Pollutants: Ethylene Oxide," epa.gov, last updated September 30, 2020, accessed October 14, 2020, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-updates; data summary available at U.S. Environmental Protection Agency, "Ethylene Oxide Ambient Concentrations at National Air Toxics Trends Stations and Urban Air Toxics Monitoring Program stations," epa.gov, https://www.epa.gov/sites/production/files/2019-11/documents/data_summary_stations.pdf

[2] Georgia Environmental Protection Division, "Covington Monitoring Results," epd.georgia.gov, accessed October 14, 2020, https://epd.georgia.gov/covington-monitoring-results

[3] American Chemistry Council, "ACC Assists Georgia with Important Ethylene Oxide Research," americanchemistry.com, April 10, 2020, https://blog.americanchemistry.com/2020/04/acc-assists-georgia-with-important-ethylene-oxide-research

[4] Lake County Health Department and Community Health Center, "EtO Monitoring Results," lakecountyil.gov, updated June 16, 2020, https://www.lakecountyil.gov/4188/EtO-Monitoring-Results

[5] U.S. Environmental Protection Agency, "National Emission Standards for Hazardous Air Pollutants (NESHAP)," epa.gov, accessed October 2020, https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9

[6] U.S. Environmental Protection Agency, "Developing Clean Air Programs Through Dialogue," epa.gov, accessed October 2020, https://www.epa.gov/clean-air-act-overview/developing-clean-air-programs-through-dialogue

[7] U.S. Environmental Protection Agency, "Air Data: Air Quality Data Collected at Outdoor Monitors Across the US," epa.gov, accessed October 14, 2020, https://www.epa.gov/outdoor-air-quality-data

[8] Lake County Health Department and Community Health Center, *supra* note 4.

[9] American Chemistry Council, *supra* note 3.

## About the Author

**Rich J. Trzupek** is a chemist who has been employed as an environmental consultant to industry for more than 35 years. He specializes in air quality issues and has worked for several Fortune 500 companies. Trzupek has also participated in the development of environmental legislation and regulation, and he continues to represent industrial concerns as an air quality consultant. Trzupek currently serves as a policy advisor to The Heartland Institute

Trzupek's commentaries have appeared in a variety of regional and national publications, including the *Chicago Tribune*, *Crain's Chicago Business*, and Reuters. He blogs at the-Pipeline.org, and he is the author of *Regulators Gone Wild: How the EPA Is Ruining American Industry* (Encounter Books, 2011).

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