



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF: **AT-18J**

Sandra Hart
Lake County Board Office
18 North County Street – 10th Floor
Waukegan, Illinois 60085-4351

Dear Ms. Hart:

Thank you for your April 15, 2021 letter about ethylene oxide (EtO) emissions from two facilities in Lake County—Medline Industries, a commercial sterilization facility at 1160 Northpoint Road in Waukegan, and Vantage Specialty Chemicals, a chemical production facility at 3938 Porett Drive in Gurnee. Specifically, the Lake County Board requested that the U.S. Environmental Protection Agency conduct a risk assessment of Lake County, Illinois similar to the one that was done for Willowbrook, Illinois. Please know that the Agency shares your concerns, is taking actions to address EtO emissions, and is committed to continuing to provide information to the public through transparent processes.

EPA does not have enough information to conduct a full assessment of risks associated with EtO emissions in Lake County, but we have gathered and reviewed all available data. The results of that review and our analysis are below. Our review is not meant to take the place of the more complete review that we understand the Agency for Toxic Substances and Disease Registry (ATSDR) is conducting.

- I. Background
 - a. EPA Risk Assessment Framework

EtO 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 or other means, such as medical equipment. EPA regulates EtO and other hazardous air pollutants by setting limits on the amount of pollution that sources can emit. Emissions that remain after facilities implement technology-based standards to reduce air toxics emissions are assessed as part of a residual risk review. EPA is required to assess these remaining health and environmental risks. When estimating cancer risk, EPA assumes people are

exposed to the pollutant for 24 hours a day, 365 days a year, for 70 years, to represent a lifetime exposure. The estimated risk is in addition to people's overall risk for getting cancer for other reasons.

In the first step, EPA generally limits the maximum individual risk (MIR) to no higher than 1 in 10 thousand (or 100 in a million). The MIR is based on continuous exposure to the maximum pollutant concentrations for 70 years.

In the second step of the risk assessment framework, EPA establishes an "ample margin of safety." In this step, EPA strives to protect the greatest number of persons possible to an estimated individual excess lifetime cancer risk level of no higher than 1 in a million. EPA considers both population and individual risk, as well as other factors such as technological feasibility, costs and economic impacts of controls, uncertainties, and any other relevant factors.

b. EtO and Cancer Risk

In December 2016, EPA finalized its Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (USEPA, 2016), which addresses the potential carcinogenicity from long-term inhalation exposure to EtO. EPA characterizes EtO as "carcinogenic to humans" by the inhalation route of exposure based on the total weight of evidence, in accordance with the EPA's 2005 Guidelines for Carcinogen Risk Assessment (Cancer Guidelines).¹ The lines of evidence supporting this characterization include: (1) strong, but less than conclusive on its own, epidemiological evidence of lymphohematopoietic cancers and breast cancer in EtO-exposed workers, (2) extensive evidence of carcinogenicity in laboratory animals, including lymphohematopoietic cancers in rats and mice and mammary carcinomas in mice following inhalation exposure, (3) clear evidence that EtO is genotoxic and sufficient weight of evidence to support a mutagenic mode of action for EtO carcinogenicity, and (4) strong evidence that the key precursor events are anticipated to occur in humans and progress to tumors, including evidence of chromosome damage in humans exposed to EtO. Overall, confidence in the hazard characterization of EtO as "carcinogenic to humans" is high.

In addition to EPA, the International Agency for Research on Cancer and the National Toxicology Program also classifies EtO as carcinogenic to humans. Evidence in humans indicates that long-term exposure to EtO by inhalation increases the risk of cancers of the white blood cells, including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia. Studies also show that long-term exposure to EtO increases the risk of breast cancer in females.

EtO is mutagenic (i.e., it can change the DNA in a cell). Children may be more susceptible to the harmful effects of mutagenic substances. Because EtO can damage DNA, cancer risk for a single year of exposure to EtO is greater for children than for adults. As with any air pollutant, potential cancer risk associated with EtO depends on the amount inhaled and the duration of exposure. The greatest risk is for people who have lived near a facility releasing EtO into the air for their entire lifetime. For everyone, including children, risks would decrease with decreased exposure.

¹ U.S. Environmental Protection Agency. 2005b. Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F. <https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment>.

The concentration of EtO associated with a 100-in-a-million cancer risk is 0.02 micrograms per cubic meter of air ($\mu\text{g}/\text{m}^3$) for a lifetime of continuous exposure. In other words, if a person were to continuously breathe air with an average concentration of 0.02 $\mu\text{g}/\text{m}^3$ of EtO over a lifetime, he or she would theoretically have an additional 100-in-a million increased chance of developing cancer as a direct result of breathing air containing EtO. This risk would be in addition to any cancer risk borne by a person not exposed to EtO in the air. According to the National Institutes of Health (NIH), “Approximately 39.5% of men and women will be diagnosed with cancer at some point during their lifetime (based on 2015–2017 data),” which corresponds to a risk of 395,000-in-a-million. There are many risk-factors related to the likelihood that any one individual will develop cancer, including diet, exercise, demographics, smoking status and genetics.

The table below provides EtO concentrations at specified risk levels.

Estimated cancer risk	Concentration of lifetime of continuous exposure
1-in-a-million cancer risk	0.0002 $\mu\text{g}/\text{m}^3$
10-in-a-million cancer risk	0.002 $\mu\text{g}/\text{m}^3$
100-in-a-million cancer risk	0.02 $\mu\text{g}/\text{m}^3$

c. Background Concentrations of EtO

The term “background EtO” refers to EtO in the outdoor air that is not clearly linked to a particular industrial facility, such as a chemical plant or commercial sterilizer. EPA does not yet know the sources of this background EtO. Beginning in late 2018, a number of state and local air agencies have monitored for EtO at locations in two longstanding monitoring networks: the National Air Toxics Trends Stations and Urban Air Toxics Monitoring Program sites. These networks, which are not focused on specific industrial sources, are designed to help track progress in reducing air toxics across the country. They include monitoring locations in both urban and rural areas. EPA, state, and local agencies have also monitored near facilities.

EPA has more confidence in the results of EtO monitoring results immediately downwind of facilities in comparison with areas not impacted by sources. Confidence in any results assumes that all quality assurance quality control procedures are followed. The potential measurement differences related to the method are small, so they would not have much impact on facility-focused monitoring results which have largely been significantly above the detection limit. However, when it comes to quantifying concentrations of background EtO, while we are confident that there is background EtO in the air, we are less confident in the exact amounts. There are several reasons for this uncertainty, including that some results of the background monitoring have shown EtO at levels as low as 0.06 to 0.08 $\mu\text{g}/\text{m}^3$ – which is the approximate detection limit at EPA’s national contract lab. When EtO levels in the air are near these limits, EPA is less confident in the accuracy of these values.

EPA scientists are working to improve the current test method, which is known as “TO-15A.” A test method is a set of approved scientific techniques for measuring the presence of a single

pollutant or a suite of pollutants. TO-15A is commonly used to measure air toxics, including EtO. Air samples are collected in a canister over a set time period, then sent to a laboratory for analysis. EPA is working to improve this method and to develop new technologies and test methods that would allow us to measure EtO at lower levels than is currently possible, and in near-real time. EPA also is working to improve our understanding of how EtO interacts with other pollutants in the atmosphere and to determine how EtO moves in the environment. This work will take time, but ultimately, it will help EPA identify the sources of background EtO.²

Annual summaries of air toxics data, including EtO, are available at

<https://www.epa.gov/outdoor-air-quality-data/monitor-values-report-hazardous-air-pollutants>.

The site allows selection of the year and geographic area of interest. Detailed monitoring data are available in EPA's Air Quality System (AQS), a technical website that houses outdoor air quality data collected by EPA, state, local, and tribal air pollution control agencies across the country. To log in to AQS, register for a free account to get access. Anyone planning to use the data should consult with the air agency (such as the state regulatory agency) that provided it and consider data quality "flags" attached to individual measurements.

d. Medline and Vantage Contribution to Risk, Prior to Recent Control Enhancements

In August 2018, EPA released the results of its latest National Air Toxics Assessment (NATA), based on modeling of 2014 emissions of hazardous air pollutants, and using the updated cancer risk estimate for EtO. NATA is the Agency's nationwide air toxics screening tool, designed to help EPA and state, local and tribal air agencies identify areas, pollutants, or types of sources for further examination.

The 2014 NATA estimated that EtO significantly contributed to potential elevated cancer risks in some census tracts across the U.S. (less than 1 percent of the total number of tracts). Census tracts near Medline in Waukegan were among the areas of elevated cancer risk (i.e., higher than 100-in-a million). While areas in Gurnee near Vantage were not estimated to have high risk from EtO concentrations in NATA, EPA subsequently discovered that emissions from Vantage were not analyzed in NATA due to an error.

As a consequence of the NATA model-predicted concentrations identifying the Waukegan and Gurnee areas as having elevated risk, the Lake County Health Department (LCHD) conducted EtO sampling in 2019 and 2020 to establish real-world measurements in the local area of the county near the facilities. LCHD conducted three phases of monitoring, from June through early July of 2019 (Phase 1), from October 2019 through January 2020 (Phase 2), and from April through early May 2020 (Phase 3). Phase 1 and 2 were conducted prior to the full implementation of controls at the facilities, and Phase 3 after implementation was complete. Sampling was conducted on a 24-hour basis, generally on a 1-in-3 day schedule. In total, 606

² U.S. Environmental Protection Agency. EPA's Work to Understand Background Levels of Ethylene Oxide. https://www.epa.gov/sites/production/files/2020-09/documents/background_eto_monitoring.september_2020.pdf

samples were taken on 54 days as part of LCHD three-phase sampling program. In addition, Medline and Vantage independently performed monitoring and collected 58 samples during the Phase 1.³

While EPA has not conducted a statistical evaluation of the Phase 1 and Phase 2 monitoring data, due to uncertainties created by a significant number of non-detects, we believe that the available validated results indicate that, prior to the installation of additional controls, both Medline and Vantage contributed to 24-hour concentrations at some sampling locations that 1) were above background levels; and 2) would result in a cancer risk above 100 in a million beyond the fence line of these facilities (if these concentrations persisted continuously for 70 years). In some instances, it is clear that monitors, especially closer to the sites, are impacted from emissions from the sites, but the statistical analysis is ongoing to create a cohesive assessment of intermittent data (the small number of samples in Phases 1 complicate this evaluation).

II. Evidence of Current Impact of Medline and Vantage on Cancer Risk

While the evidence suggests that past emissions of EtO-associated cancer risks were elevated near Medline and Vantage, significant emissions reductions required under the 2019 Illinois Public Acts 101-0022 and 101-0023 have reduced this risk. This section summarizes evidence regarding the extent of the risk that remains after these reductions.

a. Emissions Reductions

At Medline, reductions were achieved through enhanced controls on stack emissions, as well as by elimination of “fugitive” emissions through a permanent total enclosure that directs air from all parts of the building where EtO is used or where sterilized equipment is stored to control devices. Fugitive emissions are emissions that escape from a facility without first being routed to a control device. Medline’s estimated stack emissions were 2,863 pounds of EtO in 2017. Medline’s May 2019 air permit requires the facility to limit total emissions to 150 pounds of EtO per year, a 95% decrease from 2017 stack emissions. Fugitive releases were not quantified in the past, but the new controls are designed to capture all fugitive releases in the building and are expected to eliminate fugitive emissions.

At Vantage, reductions were achieved through installation of enhanced controls on the single EtO emissions stack, as well as reduction of fugitive emissions through upgraded equipment and an enhanced leak detection and repair (LDAR) program. Vantage’s estimated emissions were 1,547 pounds of EtO in 2017—737 pounds from controlled stack emissions and 811 pounds from fugitive sources. Vantage’s December 2019 permit limits current emissions to 110 pounds of EtO per year, of which no more than 60 pounds from fugitive sources, which is a 93% decrease from estimated emissions in 2017.

b. Estimate of Remaining Risk Based on Modeling

To determine the remaining risk after the emissions reductions required by the facilities’ permits, Illinois EPA required the facilities to submit modeling based on emissions at the maximum

³ Monitoring results at <https://www.lakecountyil.gov/4188/EtO-Monitoring-Results>.

permitted level. This modeling was used to predict the maximum concentration, the maximum off-site concentration, and the maximum residential concentration on a five-year average basis, and to conservatively equate each concentration to an estimated lifetime cancer risk. For residential areas, risk was calculated based on the assumption that a resident would be present continually for 70 years, including during childhood. For non-residential areas, risk was calculated based on the assumption that exposure would be to adults, for 8.5 hours per day, 250 days per year for 25 years. The model predicted concentrations and risks represent the incremental contribution of emissions from each facility to risk, and do not incorporate background concentrations of EtO.

For Medline, the maximum predicted modeled concentration occurred on Medline property, and equated to a risk to workers of 3.7 in a million. The maximum five-year average off-property concentration was in an area that is not zoned for residential development and equated to a risk to workers of 3.3 in a million. The maximum five-year average concentration at a residence equated to a risk of 22.1 in a million.⁴ This modeling assumed a 60-foot stack height (i.e., the height of the existing stack); modeling indicated that maximum risk and area-wide risk would be reduced further with an 85-foot stack, which Medline would be required to have under its permit if local zoning would allow it.

For Vantage, maximum permitted emissions were modeled under two different scenarios, one with the existing stack height of 64 feet, the other with a stack height of 113 feet, which Vantage would be required to have under its permit if local zoning would allow it. For the 64-foot scenario, the maximum five-year average modeled concentration was located on Vantage property and equated to a risk to workers of 62 in a million. The maximum five-year average off-property concentration equated to a risk to workers of 36 in a million. The maximum five-year average concentration in a residential area equated to risk of 70 in a million. Increasing the stack to 113 feet would reduce the maximum residential risk to 64 in a million.⁵

The terrain in the area surrounding both facilities is generally flat. Thus, the underlying scientific principles of atmospheric dispersion indicate impacts and risk will decrease with distance from the Medline and Vantage facilities. Therefore, modeling indicates that neither Medline nor Vantage would contribute more than 100-in-a-million to cancer risk to any resident or worker if their emissions were at maximum permitted levels. The 100-in-a-million cancer risk level is considered the upper limit of what EPA generally considers to be acceptable risk for the most exposed person. Quantifying risk levels help the Agency identify what facilities and areas may need more detailed assessments, including emissions testing and more refined modeling.

⁴ Illinois Environmental Protection Agency. Memo from Steven King to File, Construction Permit No. 19020013. March 27, 2020. https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Documents/MEMO_IEPA%20Review_Medline%20EtO%20Follow-up%20Modeling.pdf

⁵ Illinois Environmental Protection Agency. Memo from Steven King to File, Construction Permit No. 19100015. December 17, 2019. https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Documents/MEMO_IEPA%20Review_Air%20Quality_Impact%20Analysis_Vantage_097035AAQ_Permit%20App19100015_FINAL%20Dec%2017%202019.pdf

These estimated cancer risks are theoretical and are not based on actual cancer cases in these communities. Medline and Vantage must emit less EtO than what would cause a cancer risk of 100 in a million. Their new permits demonstrate that if they emitted EtO up to the permit limit, they would emit EtO that would result in less than a risk of 100 in a million for communities nearby (estimated maximum residential risk was 22 in a million at Medline and 70 in a million at Vantage). These theoretical risks are in addition to the U.S. background cancer risk for Americans of 395,000 in 1 million people.

Medline has firm EtO emissions limits, in pounds per year and pounds per month, in its permit, along with measurement, monitoring and reporting requirements that assure that Illinois EPA would be aware of any violation of these emissions limits. The permit requires a continuous emissions monitoring system (CEMS) at the stack and measurement of parameters that assure maintenance of the permanent total enclosure. A CEMS measures the stack concentration of EtO and flow rate in the exhaust stream and ensures proper operation of the facility's controls. The data is recorded continuously and compiled quarterly in reports to Illinois EPA. Medline's quarterly emissions reports indicate that its actual emissions have been well below permitted levels starting in at least March of 2020. Total emissions for 12-month period ending in June of 2021 were less than 60 pounds of EtO, compared with the permitted level of 150 pounds of EtO per year. The highest reported monthly emissions, 8.7 pounds, occurred in July of 2020, compared with the permitted maximum monthly emissions of 15 pounds of EtO.

Similarly, Vantage has firm EtO emissions limits, in pounds per year, in its permit, along with measurement, monitoring and reporting requirements that assure that Illinois EPA would be aware of any violation of these emissions limits. This permit also requires a CEMS at the stack. For fugitive emissions, the situation is different than at Medline, because it is not feasible to construct a permanent total enclosure at a chemical plant such as Vantage. However, Vantage is required to conduct enhanced LDAR monitoring and calculate its fugitive emissions using EPA guidance. Vantage's quarterly emissions reports indicate that its actual emissions were well below permitted levels starting in January of 2020. Total emissions for 2020 were 62.44 pounds of EtO, compared with the permitted level of 110 pounds. In the first half of 2021, Vantage reported 11.54 pounds of EtO emissions.⁶

Because of the quality of the emissions data, EPA considers the modeling results to be the best available information about EtO risks created by Medline and Vantage in the period after controls were required. While there is ambient air monitoring data available, for the reasons discussed below, we have limited ability to draw conclusions about facility impacts from that data.

Some members of the community have expressed concerns about reliance on modeling of facility emissions to determine risks created by the facilities. In particular, they have expressed that the modeling relies on self-reported emissions that could be falsified. Enforcement of the Clean Air Act relies on self-reporting by facilities. This approach is utilized at both the federal

⁶ Quarterly reports for both Medline and Vantage can be found at <https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Pages/default.aspx>

and the state level because it is considered impractical and excessively resource-intensive to utilize government agents for collection of the data required to determine compliance at the thousands of facilities subject to environmental regulation. We rely on accurate reporting by facilities, and create significant penalties, including criminal sanctions, for companies and individuals who falsify records required to assess compliance. EPA believes that this system is effective, particularly in cases where continuous emissions monitoring is required and therefore the potential for manipulating results is limited.

Moreover, in the case of Medline and Vantage's requirements for control, monitoring, and reporting of ethylene oxide emissions, both Illinois and the federal government have enforcement authority. Under the Clean Air Act, false statements or concealment of relevant facts in documentation required under state or federal clean air requirements, as well as tampering with monitoring devices, are offenses punishable by up to two years in prison, on a first offense, and four years on subsequent offenses, in addition to criminal and civil fines. See 42 USC § 7413(c)(2).

c. Monitoring Data

EPA has high confidence in the results of EtO monitoring results immediately downwind of uncontrolled sources of EtO emissions, where results have generally been well above the level of EtO that the current monitoring method can detect. However, quantifying low concentrations at or near detection limits is more problematic. Specifically, as stated in Section I.c. above, when EtO concentrations in the air are near background concentrations or close to where current monitoring methods and instrumentation can detect, EPA is less confident in the accuracy of these values. EPA has provided additional information about EtO monitoring issues on its website.⁷

Components of canisters used to collect air samples, such as the materials used to line the inside of the canister and how the canisters are cleaned, can bias monitoring results as well. Even though the impact of these issues on measurements is expected to be relatively small, it can affect our understanding of EtO levels, especially at lower concentrations. EPA work is ongoing to better understand and address these issues, as well as improve the monitoring methods.

LCHD conducted ambient EtO sampling (see Section I.d. above) primarily before the completion of control installation at Medline and Vantage. Only the most recent phase of the sampling, Phase 3, which was conducted in April of 2020, occurred after the December 2019 deadlines for compliance with Public Acts 101-0022 and 101-0033. As requested by LCHD, EPA provided technical assistance in reviewing lab and field reports for Phase 3, and after reviewing canister pressure, EPA recommended the invalidation of nine samples in a letter dated October 6, 2020, with a tenth invalid sample noted in a subsequent email. After excluding invalid samples, we have a limited dataset for comparison—seven to ten samples at each of twelve sites, five near

⁷ <https://www.epa.gov/sites/production/files/2021-05/documents/eto-technical-webinar-041521-w-qandas.pdf>
<https://www.epa.gov/sites/production/files/2021-05/documents/eto-canister-background-memo-05072021.pdf>
<https://www.epa.gov/sites/production/files/2021-05/documents/technical-note-on-eto-canister-effect-052521.pdf>

Medline, five near Vantage, and two remote sites. Given the limited sample size, and the methodological and analytical uncertainties surrounding the collection and measurement of EtO, especially at lower concentrations, any conclusions drawn from these data are tentative and should be interpreted with caution. EPA believes that modeling results provide better evidence for the impacts of Medline and Vantage than these monitoring results do.

While analysis of the monitoring data is limited due to sample size and uncertainties, we did evaluate whether sites near the facilities had higher sampled EtO concentrations compared to sites farther away from the facilities during Phase 3. The analysis showed that there was more variance within each location than between locations. It could not be established that the average concentrations during Phase 3 were higher at any site in comparison with any of the other sites. We did not, however, evaluate whether EtO concentrations were higher downwind on specific days. ATSDR is expected to conduct additional analysis of the data, including a comparison of upwind and downwind values, which may reveal more than this initial evaluation.

We will defer to ATSDR's evaluation of the change in sampled EtO concentrations between Phase 1, prior to installation of required controls, Phase 2, when control installation was occurring, and Phase 3, after installation of controls. However, a preliminary evaluation indicates that concentrations declined in successive phases, particularly at the sites closest to the facilities.

III. Conclusions

Thank you again for your request for information about EtO emissions from two facilities in Lake County. To summarize:

- EPA seeks to protect the public from excess cancer risk caused by air pollution, seeking to limit maximum individual risk from facility emissions to no more than 100 in a million.
- EPA has concluded that EtO is carcinogenic to humans by the inhalation route of exposure.
- EtO may be present in the atmosphere even in areas far from known emissions sources, but these low "background" concentrations are difficult to quantify with current monitoring methods.
- Modeling and monitoring information indicate that EtO emissions from Medline and Vantage may have resulted in excess cancer risk to nearby residents prior to installation of controls.
- As a result of controls required by the State of Illinois, EtO emissions at Medline and Vantage have decreased significantly.
- Modeling indicates that as Medline and Vantage comply with their state EtO emissions limitation requirements, their incremental impact on cancer risk is less than 100 in a million to the public.
- Over the last year, both facilities have been emitting less EtO than allowed under their respective permits. If either facility were to violate its emissions limits in the future, these violations would be detected via continuous emissions monitoring. All available

information shows a significant decline in EtO emissions following the implementation of control requirements at the two facilities.

- ATSDR is currently reviewing the potential health implications of emissions from these facilities in Lake County. Their assessment includes a spatial, temporal, and statistical evaluation of the data.

EPA will continue to coordinate closely with state and local agencies, along with ATSDR, as we continue to work to address EtO and protect public health across the United States. If you have questions, please contact Alexis Cain of my staff at (312) 886-7018 or cain.alexis@epa.gov.

Sincerely,

John Mooney
Director
Air and Radiation Division