ATSDR
Health Consultation

Evaluation of Ethylene Oxide in Outdoor Air
Near the
Sterigenics Sterilization Facility
Cobb County, Georgia

USEPA Facility ID: 110000355963

Public Comment Release

January 20, 2026

Public comment end date: March 6, 2026

U.S. Department of
Health and Human Services
Agency for Toxic Substances
and Disease Registry

Health Consultation: A Note of Explanation

A health consultation is written documentation of analysis and health conclusions from ATSDR or ATSDR's Cooperative Agreement Partners to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. To prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; collection and analysis of additional environmental samples to better characterize exposures; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This health consultation is released for a 45-day public comment period. ATSDR or ATSDR's Cooperative Agreement Partners will address all public comments and revise or append the document as appropriate. The health consultation will then be reissued as a final document. The final document will conclude the public health assessment process for this site, unless additional information is obtained by ATSDR or ATSDR's Cooperative Agreement Partner which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

Please address comments regarding this report to:
Agency for Toxic Substances and Disease Registry Attn: Records Center, 4770 Buford Highway NE, MS S106-5 Atlanta, Georgia 30341

Email comments will also be accepted at: OCHHAPublicComment@cdc.gov

You may contact ATSDR toll free at 1-800-CDC-INFO or 1-800-232-4636

or

visit our home page at: https://www.atsdr.cdc.gov

Health Consultation

Evaluation of Ethylene Oxide in Outdoor Air Near the Sterigenics Sterilization Facility

Cobb County, Georgia

USEPA Facility ID: 110000355963

U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry
Office of Community Hazard Assessment
Atlanta, Georgia, 30333

About ATSDR

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency of the U.S. Department of Health and Human Services (HHS). ATSDR works with other agencies and tribal, state, and local governments to study possible health risks in communities where people could come in contact with dangerous chemicals. For more information about ATSDR, visit the ATSDR website at www.atsdr.cdc.gov/.

Contents

List of Tables

List of Figures

Acronyms and Abbreviations

AAMP Ambient Air Monitoring Program
ADAF Age-dependent adjustment factor
AirToxScreen Air Toxics Screening Assessment
AQS Air Quality System
ATSDR Agency for Toxic Substances and Disease Registry
BH Benjamini-Hochberg
CDC Centers for Disease Control and Prevention
CEMS Continuous emissions monitoring system
CI Confidence interval
CR Cancer risk
CRDS Cavity ring-down spectroscopy
CREG Cancer risk evaluation guide
CTE Central tendency exposure
CV Comparison value
ED Exposure duration
EMEG Environmental media evaluation guide
EPA United States Environmental Protection Agency
EPC Exposure point concentration
EPD Environmental Protection Division
ERG Eastern Research Group, Inc.
EtO Ethylene oxide
GAM Generalized additive model
GC General Coffee
HbEO Hemoglobin adducts of ethylene oxide
HHS Health and Human Services
HMC Hamiltonian Monte Carlo
IARC International Agency for Research on Cancer
inHg Inches of mercury
IQR Interquartile range
IUR Inhalation unit risk
LDAR Leak detection and repair
LY Lifetime years
MDL Method detection limit
NATA National Air Toxics Assessment
NATTS National Air Toxics Trends Sites
NHANES National Health and Nutrition Examination Survey
NIOSH National Institute for Occupational Safety and Health
NTP National Toxicology Program
PTE Permanent total enclosure
PO Propylene oxide
RME Reasonable maximum exposure

RMP	Risk Management Plan
ROS	Regression on order statistics
SD	South DeKalb
SLAMS	State and Local Air Monitoring Stations
TRI	Toxics Release Inventory
UATS	Urban Air Toxics Strategy
UCL	Upper confidence limit
$\mu g/m^3$	Microgram per cubic meter

1. Summary

The Agency for Toxic Substances and Disease Registry (ATSDR) in Atlanta, Georgia, is a federal, nonregulatory, environmental public health agency within the U.S. Department of Health and Human Services (HHS). ATSDR's mission is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent people from coming into contact with harmful toxic substances. This health consultation presents the findings of ATSDR's health evaluation of outdoor ethylene oxide (EtO) air monitoring data measured in Cobb County, Georgia near the Sterigenics sterilization facility.

The Sterigenics facility in Cobb County has used EtO to sterilize consumer products, primarily medical devices, since 1967. In the summer of 2019, ATSDR received four petitions, including a letter from then State Senator Jen Jordan, a letter from several members of the Atlanta City Council, a resolution from the Atlanta City Council, and a letter from the Atlanta Board of Education to evaluate health risks from EtO emissions from the Sterigenics facility. ATSDR agreed to conduct a health consultation if and when the appropriate long-term EtO air sampling information became available to evaluate whether breathing EtO could pose a health hazard to community members.

From September 2019 through October 2022, the Georgia Environmental Protection Division (EPD) measured levels of EtO in outdoor air near Sterigenics at six sampling locations and at two other locations with no known source of EtO in DeKalb County (called the "South DeKalb" sampling location) and in General Coffee State Park in Coffee County (called the "General Coffee" sampling location). EPD conducted additional, less frequent EtO sampling at fewer locations from October 2021 through October 2022. The Sterigenics facility temporarily shut down before EPD began collecting air sampling data in September of 2019. In April 2020, Sterigenics reopened with a new permanent total enclosure (PTE) emissions control system. ATSDR evaluated Georgia EPD's outdoor air sampling data collected to determine whether EtO emissions from Sterigenics could pose a health hazard. ATSDR used EtO air concentrations to estimate EtO exposure and the associated cancer and noncancer risks to residents and off-site workers within 1 mile of Sterigenics. ATSDR compared the outdoor EtO air concentrations measured when Sterigenics was shut down to outdoor EtO air concentrations measured after it re-opened. ATSDR also compared EtO concentrations at sampling locations near Sterigenics compared to background locations and examined whether concentrations were affected by wind direction or wind speed. There are no outdoor EtO air sampling data to inform whether EtO from Sterigenics could have posed a past health hazard before Sterigenics closed to upgrade emissions controls in September 2019.

In 2018, the United States Environmental Protection Agency (EPA) and other agencies started measuring background EtO concentrations in the outdoor air in two longstanding monitoring networks at locations across the United States away from known emissions sources. Since 2020, the EPA has expressed concerns about several uncertainties in measuring low-level background air concentrations of EtO. These uncertainties have prevented EPA from putting an exact number on background EtO air concentrations. One of those uncertainties is positive sampling bias caused by EtO forming in some air monitoring canisters (Yelverton, Hays and Rice 2024;

EPA 2021a). Positive sampling bias is the artificially high measurement and reporting of EtO concentrations in some outdoor air samples. To address positive bias in Georgia EPD EtO air sampling data, ATSDR used a Bayesian generalized additive model (GAM) to estimate the effects of canister type and holding time on EtO concentrations measured at a background sampling location in DeKalb County, Georgia. The GAM was used to adjust the measured Georgia EPD EtO air concentrations near Sterigenics for the effects of canister type, holding time, and seasonal pattern. The GAM reduces bias from the canister effect in EtO concentration measurements and associated cancer risk, but it does not remove all uncertainty from measurements.

To determine whether exposure to EtO concentrations in the outdoor air near Sterigenics could adversely affect public health, ATSDR evaluated the cancer and noncancer risks to residents living within 1 mile of Sterigenics during closure and after re-opening. ATSDR calculates high-end lifetime excess cancer risk estimates from breathing EtO concentrations measured in outdoor air over many years using health protective values. The health protective values and assumptions used to calculate lifetime cancer risks include the 95% upper confidence limit (UCL) of the mean EtO concentrations, EPA's cancer risk value (the inhalation unit risk or IUR), and reasonable maximum exposure (RME) assumptions about how much, how long, and how often someone may breathe the levels of EtO measured near Sterigenics. The calculated lifetime excess cancer risks are designed to be protective of health and likely overestimate the potential cancer risk from breathing EtO. The actual cancer risks from EtO exposure may be lower than the calculated lifetime excess cancer risk estimates.

The lifetime excess cancer risk estimates are tools for making public health conclusions and recommendations. ATSDR considers any lifetime excess cancer risk estimate of more than 1 excess cancer case in 10,000 persons exposed as a potential increased cancer risk and as such requires a recommendation to minimize exposure to protect public health. These estimates do not represent the actual diagnosed cases of cancer in Cobb County, cannot predict an individual's risk of developing cancer, and should be distinguished from the observable, average lifetime risk of cancer from all causes. In the United States, 1 out of every 3 people will develop cancer during their lifetime. The ATSDR calculated lifetime excess cancer risks for residents breathing EtO for many years are estimates of excess cancer risk that may contribute to a small increase in cancer risk in addition to the already existing observed lifetime risk of cancer from all causes.

After evaluating available data ATSDR reached the following conclusions:

Conclusion 1

ATSDR concludes that breathing EtO concentrations in outdoor air near Sterigenics is not expected to cause noncancer health effects. The lifetime excess risk of cancer from breathing EtO for people who live, work, or attend school near Sterigenics is similar to lifetime excess cancer risk from breathing background EtO concentrations in Georgia and other areas of the country with no

known source of EtO emissions. This finding was based on EtO concentrations measured from April 2020 to October 2022.

Basis for Conclusion

- EtO concentrations measured in the outdoor air at sampling locations within about one mile of Sterigenics from April 2020 to October 2022 are similar to background EtO concentrations measured elsewhere in Georgia and in the U.S. with no known source of EtO emissions nearby.
- After adjusting for seasonal variation and positive bias, EtO concentrations measured at sampling locations near Sterigenics after Sterigenics reopened in April 2020 with new emissions controls were not statistically significantly greater than the background EtO concentrations measured at the same locations from September 2019 to April 2020 when Sterigenics was closed.
- Adjusted EtO concentrations in outdoor air near Sterigenics from April 2020 to October 2022 were not statistically significantly greater than outdoor EtO concentrations at Georgia EPD's two background locations (South DeKalb and General Coffee).
- Calculated, high-end, lifetime excess cancer risk estimates were similar at sampling locations near Sterigenics and at the two Georgia background locations. EtO concentrations at background sites while the Sterigenics facility was operating were associated with an estimated 5 additional cases in 10,000 people, while sites near Sterigenics ranged from 4 to 7 estimated additional cases in 10,000 people during the same time period.
- The highest EtO concentrations measured near Sterigenics are well below the ATSDR noncancer health guidelines and significantly below the lowest concentrations that have been reported to result in noncancer health effects in scientific studies of acute (less than 2 weeks), intermediate (2 weeks to 1 year), and chronic (greater than 1 year) exposure to EtO.

Recommendations and Next Steps

ATSDR recommends EPA continue to improve the analytical methods to accurately measure EtO at lower concentrations and identify potential background EtO sources. Research on this topic is currently underway (Yelverton, Hays and Rice 2024; EPA 2024).

Conclusion 2

ATSDR cannot determine whether breathing EtO concentrations near Sterigenics could have harmed people's health before September 2019 when Sterigenics closed to upgrade emissions controls.

Basis for Conclusion	• There are no outdoor EtO air sampling data available prior to Sterigenics temporarily shutting down in September 2019. Sterigenics subsequently re-opened with new emissions controls in April 2020. • Before Sterigenics closed to install new emissions controls, emissions from Sterigenics may have been higher than they are now.

Recommendations and Next Steps	• ATSDR recommends community members keep up to date with routine medical checkups and recommended age-appropriate health screening tests.
	• Clinicians interested in learning more about EtO exposure and health may access ATSDR's online resources on EtO for clinicians at the website links below. Community members who wish to speak to their doctors about their exposure may share the following resources:
	  ○ **ATSDR Clinician Brief: Ethylene Oxide**
	  ○ **ATSDR Clinician Overview: Ethylene Oxide**

For More Information	If you have questions about this document or ATSDR's work on EtO, call our toll-free number at 1-800-CDC-INFO, and ask for information on the Sterigenics EtO health consultation in Cobb County, Georgia.

2. Background

2.1. Statement of Issue and Purpose

Sterigenics is a commercial sterilization facility located in an unincorporated area of Cobb County, Georgia near the cities of Atlanta and Smyrna. Since 1967, the facility has used EtO, a colorless gas with no odor at the levels measured in Cobb County, to sterilize consumer products, primarily medical devices. This health consultation was conducted in response to community petitions and evaluates outdoor EtO air sampling data, primarily data collected by Georgia EPD, from September 2019 through October 2022 to evaluate whether EtO emissions from Sterigenics pose a health risk to the nearby community. The purposes of this health consultation document are:

- To estimate exposure to EtO in outdoor air for people who live and/or work near Sterigenics.
- To estimate lifetime excess cancer risk from EtO exposure and evaluate the possibility of other (noncancer) health effects from EtO exposure.
- To understand background levels of EtO in outdoor air in order to accurately evaluate lifetime cancer risk estimates and distinguish the industrial contribution to EtO concentrations in outdoor air from background EtO concentrations in outdoor air.

From 2020 through 2024, the EPA informed the ATSDR of several issues that prevent EPA from putting an exact number on background EtO concentrations measured using the analytical method TO-15 for analysis of volatile organic compounds including EtO (U.S. EPA 2021a; McClenny and Holdren 1999). These issues include:

1. There is uncertainty in measuring low levels of EtO near the method detection limit (MDL), or lowest concentration of EtO that can be measured in a given laboratory.
2. EtO may form after a sample is collected in some but not all canisters used to sample outdoor air. This issue causes positive sampling bias, meaning air sampling results may be higher than what is truly in the air.
3. Other chemicals, called interferents, may be accidentally measured as EtO in laboratory analysis, causing the amount of EtO measured in some samples to be higher than what is truly in the air.

ATSDR addresses these TO-15 sampling and analytical method issues in this consultation using the following methods:

1. ATSDR uses a health protective statistical approach (95% UCL of the mean) for the EtO concentration and RME assumptions in our calculations of EtO exposure to ensure our conclusions protect public health even when there are measurements of contaminants near or below the MDL.

2. ATSDR conducted an independent analysis to estimate the effect of positive bias on background EtO concentrations in outdoor air that Georgia EPD measured at their South DeKalb air sampling location. This analysis led to an adjustment of measured EtO air concentrations in Cobb County using a Bayesian GAM which allowed for better estimates of EtO concentrations that people may have been breathing in the community.
3. ATSDR explored whether GAM-adjusted EtO air concentrations in Cobb County were likely related to facility emissions or if they were more likely explained by other factors such as uncharacterized background sources or positive bias due to data quality challenges.

2.2. Site Description and Timeline

2.2.1. Sterigenics Facility Overview

Sterigenics is a medical device and consumer product sterilization facility located in an industrial area surrounded by residential neighborhoods in an unincorporated suburb of Atlanta in Cobb County, Georgia (Figure 1). Since 1967, the facility has used EtO, a colorless gas, to sterilize various products including medical devices. The facility also has occasionally used propylene oxide (PO) to sterilize specific products including nutmeats and cosmetics. PO is used so infrequently that Sterigenics did not meet the reporting threshold for PO use (10 pounds) for 20 years from 1996–2016, and the facility has temporarily halted use of PO since September 2019. The use and emissions control of EtO is described here. The emissions controls described are also used for PO when it is used.

Products are placed in a sealed sterilization chamber inside the facility, and EtO is dispensed into the chamber to sterilize the devices. After sterilization, a vacuum pump removes EtO from the sterilization chamber and sends it to air pollution control devices. The sterilization chamber door opens, backvent fans are turned on, and the product is then moved into a sealed aeration room to allow it to off-gas (release left-over EtO) in a controlled environment. Before 2020, the facility captured EtO from the sterilization chamber and sent it to one control device (the ceilcote scrubber) designed to treat air with higher concentrations of EtO, while EtO from the aeration chambers was sent to another set of emissions control devices (a scrubber system and dry beds) to treat air with lower concentrations of EtO. The ceilcote scrubber converts EtO gas into liquid ethylene glycol. This liquid by-product is stored in tanks and either recycled or disposed of off-site. Prior to 2020, any EtO that was not removed by the emissions control system was released into the atmosphere through one of the facility's stacks. The facility's permit required that at least 99% of the EtO be removed from gas that is released through the stacks. EtO may have been released into the environment from Sterigenics in the past through stack emissions or through fugitive emissions. Fugitive emissions are releases that have not been captured, treated, or routed through a stack, such as air that escapes from doorways and vents. Beginning in 2015, the facility started to capture emissions from back vents connected to the aeration and sterilization chambers in order to reduce fugitive emissions.

In late August 2019, Sterigenics began winding down operations and by September 6, 2019 the plant voluntarily shut down to expedite the installation of new emissions controls. The facility

stayed shut for several months due to an investigation initiated by Cobb County related to the facility's Certificate of Occupancy. Starting on April 8, 2020, Sterigenics reopened with a new PTE emissions control system designed to capture air not only from the sterilization and aeration chambers, but from anywhere in the building, including hallways, work areas, storage areas, and shipping areas. This system is designed to prevent fugitive emissions from escaping the building and to remove 99.9% of EtO from the captured air. Sterigenics also now routes air from the ceilcote scrubber through the emissions system designed to treat air with lower concentrations of EtO to further reduce the concentration of EtO before releasing air through the stack. Emissions from the stacks are monitored by a continuous emissions monitoring system (CEMS). The CEMS monitors the amount of EtO being released from Sterigenics's two stacks in real time.

2.2.2. Background on Petitions to Conduct a Health Consultation at Sterigenics

EPA develops health guidelines that are used to estimate theoretical, lifetime excess cancer risk from breathing chemicals like EtO in the air. These health guidelines are updated periodically as new scientific information becomes available. In 2016, EPA updated their IUR for EtO, which provides an estimate of the theoretical risk of cancer from breathing a certain concentration of EtO in the air over a lifetime. Based on the updated IUR, EtO could pose an elevated cancer risk at lower levels than previously believed.

As a result of this change, the EPA's 2014 National Air Toxics Assessment (NATA), published in 2018, identified new areas of the country, including areas near Sterigenics in Cobb County, as having an elevated theoretical cancer risk due to EtO. NATA was an ongoing screening review of air toxics in the United States based on air modeling. It has since been replaced by a similar EPA modeling effort called the Air Toxics Screening Assessment (AirToxScreen for short). Both NATA and AirToxScreen calculate risk from national air modeling of emissions from mobile sources (like cars, trucks, buses, and trains) as well as stationary sources (like factories, refineries, and power plants), yielding cancer and non-cancer health risk estimates for census tracts, counties, and states. They are screening tools for state, local, and tribal air agencies to identify which pollutants, emission sources and places they may wish to study further to better understand any possible risks to public health from air toxics.

According to the 2014 NATA released by EPA in August 2018, the Sterigenics Georgia location was one of 25 facilities with cancer risks in at least one census tract (a geographic area the government uses to take a U.S. population census) that had higher than 100 theoretical cancer cases in 1 million exposed people. EPA uses the number of additional theoretical cancer cases to prioritize industries and facilities that require work to reduce emissions. The 2020 AirToxScreen uses emissions estimates from Sterigenics with their improved emissions controls in place. The 2020 AirToxScreen does not predict that any of the census tracts near Sterigenics have estimated excess cancer risks greater than 100 in 1 million (1 in 10,000).

ATSDR may conduct a health consultation at a site where we receive a petition when appropriate environmental sampling data are available to make public health conclusions. ATSDR received four petitions in the summer of 2019 to evaluate health risks from EtO

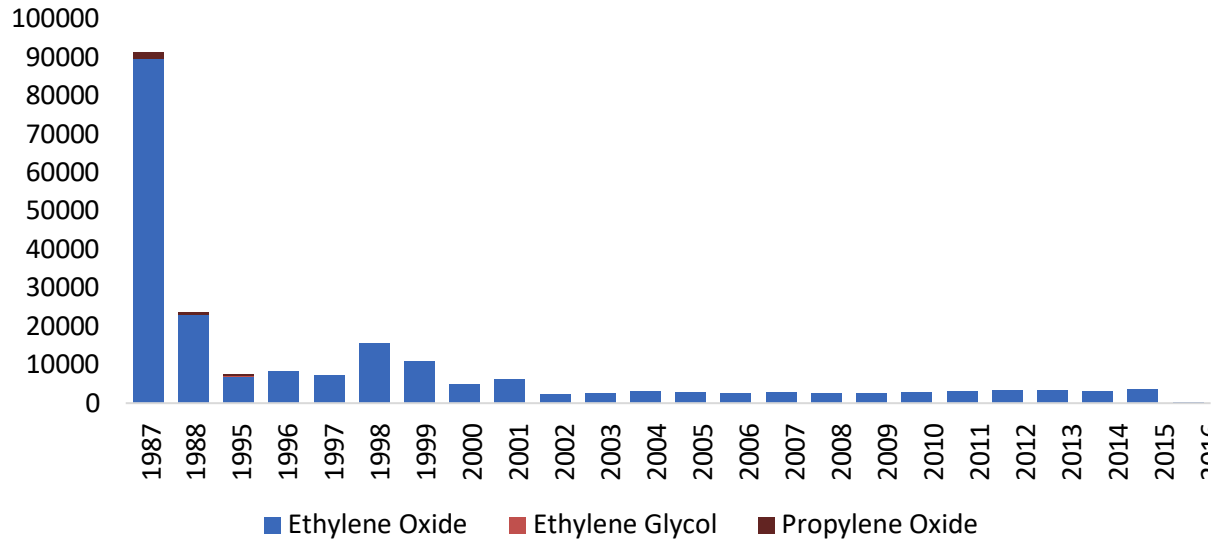
emissions from the Sterigenics facility: one from Georgia State Senator Jen Jordan, two from the Atlanta City Council and one from the Atlanta Board of Education. At the time ATSDR received the first petition, we did not have the appropriate long-term EtO air monitoring data to conduct a health consultation. In order to estimate lifetime excess cancer risk associated with EtO exposure over many years, ATSDR needed to estimate the average concentration of EtO someone living or working near Sterigenics may breathe over many years. The best way to estimate the long-term average EtO concentration in outdoor air is with outdoor EtO air sampling data collected over an extended period of time while the facility was operating. Georgia EPD announced at an August 19, 2019 public meeting that they would conduct air sampling for EtO near Sterigenics, providing ATSDR with data to investigate health risks for people who live and work near Sterigenics. ATSDR therefore committed to conducting a health consultation once the data were available.

2.2.3. Sterigenics Emissions History

Sterigenics reported their estimated EtO emissions to EPA's Toxics Release Inventory (TRI) from 1987–2015. TRI is an EPA database in which industries self-report an estimate of their emissions of certain chemicals. Reporting requirements or a company's interpretation of their reporting requirements can change over time, potentially leading to reporting gaps. Emissions from Sterigenics were not reported in the years 2017 through 2021. There are several limitations to the estimates of EtO emissions reported to TRI. ATSDR does not use TRI emissions data to evaluate potential health hazards from exposure to chemicals released from a facility.

Based on the emissions reported to TRI, EtO emissions may have been greater in the past (Figure 1). Propylene oxide emissions were reported for a few years and represented a fraction of overall emissions (Figure 1). A single emission of 10 pounds of gaseous ethylene glycol was reported in 1995.

Figure 1. Emissions (in pounds) reported to the Toxic Release Inventory (TRI) by Sterigenics 1987-2016



In addition to TRI, Sterigenics has reported three events resulting in EtO leaks greater than 0.1 pounds that may have temporarily increased outdoor EtO air concentrations for the surrounding community, including one explosion that resulted in an employee injury (Table 1). Air sampling data are not available to evaluate the outdoor EtO air concentrations during these leaks.

Table 1. EtO releases of greater than 0.1 pounds reported by Sterigenics since January 2018

Release Date	Estimated Release Pounds	Reported Cause of Release
April 2, 2018	2.6	Defects in the anti-cavitation pipe (cracks in the threading). This took place over about 12 minutes.
July 10, 2018	1	Leak into chamber resulting in internal explosion and employee injury.
July 31, 2019	5.6	Leaking drum after drum change. This took place over about 1 hour.

Georgia EPD required that Sterigenics include a leak detection and repair (LDAR) program plan designed to prevent leaks in the future as part of their new permit application. Sterigenics sent the LDAR program plan to Georgia EPD in March 2022 (Sterigenics 2022).

2.2.4. Air Modeling at Sterigenics Based on New Emissions Controls

Both Sterigenics and EPA conducted air modeling using information on EtO emissions points and emissions rates of the emissions control system installed in April 2020. Both air models estimated the maximum EtO concentration in the air near where people live. These modeled EtO concentrations represent only how much EtO Sterigenics would be expected to add to the air. They do not include a consideration of background EtO concentrations.

Sterigenics was required to conduct air modeling as part of their air quality permit application. Georgia EPD reviewed Sterigenics' s air model. The modeled maximum annual ambient air concentration was 0.005 micrograms per cubic meter ($\mu g/m^3$), a concentration that is below MDLs, or the lowest amounts of EtO that can be reliably measured using the analytical method Georgia EPD used to measure EtO [GA EPD 2020].

In August 2022, EPA released information about modeled EtO emissions from nearly 100 sterilizers across the United States as part of their process for updating the rules that govern the emissions of EtO from commercial sterilizers. Cobb County, Georgia did not have a cancer risk exceeding 1 estimated additional cancer case in 10,000 people exposed to EtO based on the modeled EtO emissions from Sterigenics.

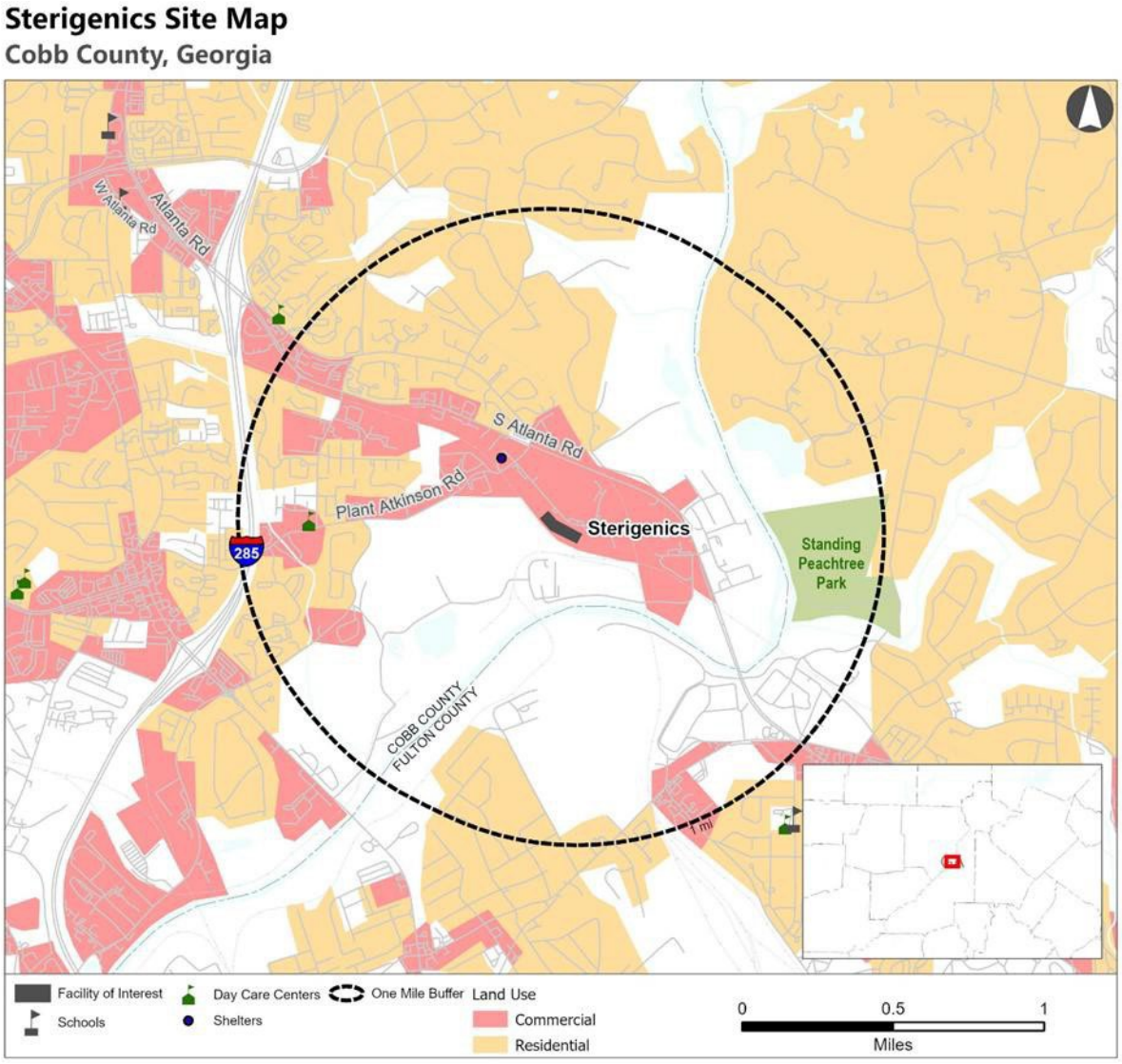
While air modeling can provide important supporting information, ATSDR uses measured concentrations in the environment, when available, as the basis of our public health decisions. In this health consultation, Georgia EPD's EtO air sampling data served as the basis of ATSDR's public health conclusions.

3. Community Description and Concerns

Sterigenics is located within an unincorporated suburban area of Cobb County near Atlanta. Approximately 5000 people live within one mile of the facility. There are shelters for men, women and children, and an early childhood education facility within one mile of Sterigenics. There are several schools and daycare facilities between one and three miles from Sterigenics. The area immediately surrounding the facility (the closest quarter mile) is industrial rather than residential, but there are several neighborhoods located within one mile (Figure 2).

EPA hosted a public meeting on August 19, 2019 at the Cobb Civic Center concerning the 2014 NATA and EtO emissions from Sterigenics in Georgia. ATSDR presented on the health effects associated with breathing EtO and our health consultation process at that meeting. ATSDR hosted a series of virtual public availability sessions in September 2021 to hear from groups of concerned community members living or working near Sterigenics. Through these two forums and correspondence with individual community members, we heard a number of concerns including concern that EtO could be causing cancer or other health effects, as well as concern about specific daycares, schools, parks, and a shelter near Sterigenics. Specific concerns are addressed in a Q&A format in Appendix A: Community Questions and Answers.

Figure 2. Map of community surrounding Sterigenics



4. Sampling Data

For this health consultation, ATSDR reviewed three outdoor EtO air sampling datasets collected near Sterigenics while the facility was closed from September 2019 through the beginning of April 2020 and after it had re-opened in April 2020 with new emissions controls. ATSDR also evaluated two background outdoor EtO air sampling datasets: one from Georgia EPD at two locations in Georgia and another from EPA and state, tribal, and local agencies at locations across the country. All five datasets collected 24-hour outdoor air samples that represent the average EtO air concentration during a 24-hour period.

1. Georgia EPD conducted 24-hour outdoor air sampling measuring EtO concentrations every 6 days at four air sampling locations (S1–S4) within one mile of Sterigenics from September 2019 through September 2021. There was less frequent sampling or non-continuous sampling at additional locations for a total of 7 air sampling locations (Figure 3). This sampling was analyzed at the Eastern Research Group Inc. (ERG) laboratory.

2. Georgia EPD conducted less frequent sampling at fewer locations near Sterigenics (S2, S6 and S7) from October 2021 to October 2022. These samples were analyzed at Georgia EPD's internal laboratory.

3. Georgia EPD also conducted 24-hour outdoor air sampling for EtO at background sampling locations in South DeKalb and General Coffee State Park in South Georgia to capture urban and rural background concentrations of EtO, respectively. EtO concentrations were measured every 6 days in South DeKalb and every 12 days at General Coffee. As with sampling near Sterigenics, analysis of EtO samples collected at background locations was transferred from the ERG laboratory to the Georgia EPD laboratory in October 2021.

4. Several local governments including Cobb County, the City of Smyrna, Fulton County, and the City of Atlanta hired a private firm (GHD) to conduct daily 24-hour air sampling for EtO from September 4th–September 7th, 2019 (while Sterigenics was winding down operations) and again from July 7th–July 16th, 2020 (after Sterigenics reopened with new emissions controls) at 20 sampling locations. Many samples were flagged during the second round of data collection due to interference from isobutane. Air sampling locations associated with this dataset are displayed in Figure B1 in Appendix B: Descriptive Statistics of EtO Air Sampling Data in Georgia Reviewed by ATSDR.

5. The EPA Air Quality System (AQS) database is a repository of air pollution data from thousands of air monitoring sites run by EPA, state, local, and tribal agencies. AQS includes 50 air sampling locations across the United States that reported EtO concentrations measured from 2018 to 2021. Appendix G: Background Levels of EtO Throughout the U.S. summarizes AQS background EtO air concentrations across the nation to put the EtO concentration data collected in Georgia into context.

To evaluate the potential adverse health effects from EtO in outdoor air, ATSDR calculates an exposure point concentration (EPC), which is a health protective estimate of the average EtO concentration someone might breathe over many years to evaluate health risks from long-term

(chronic) breathing of EtO. The most reliable estimates of that long-term average concentration are calculated using outdoor air sampling data measured over multiple seasons for a long period of time. Georgia EPD's EtO air sampling data collected over three years was used for assessing the possibility of health effects that might occur from inhaling EtO over a long period of time (1 year or more). GHD measured EtO concentrations over a much shorter time period at 20 locations for 5 days in September 2019 and 9 days in July 2020, so that dataset was not used for evaluating long-term trends and health effects that may occur from long-term (chronic) exposure. Concentrations from GHD's sampling data were considered in screening for health effects that may occur from intermediate or short-term exposure.

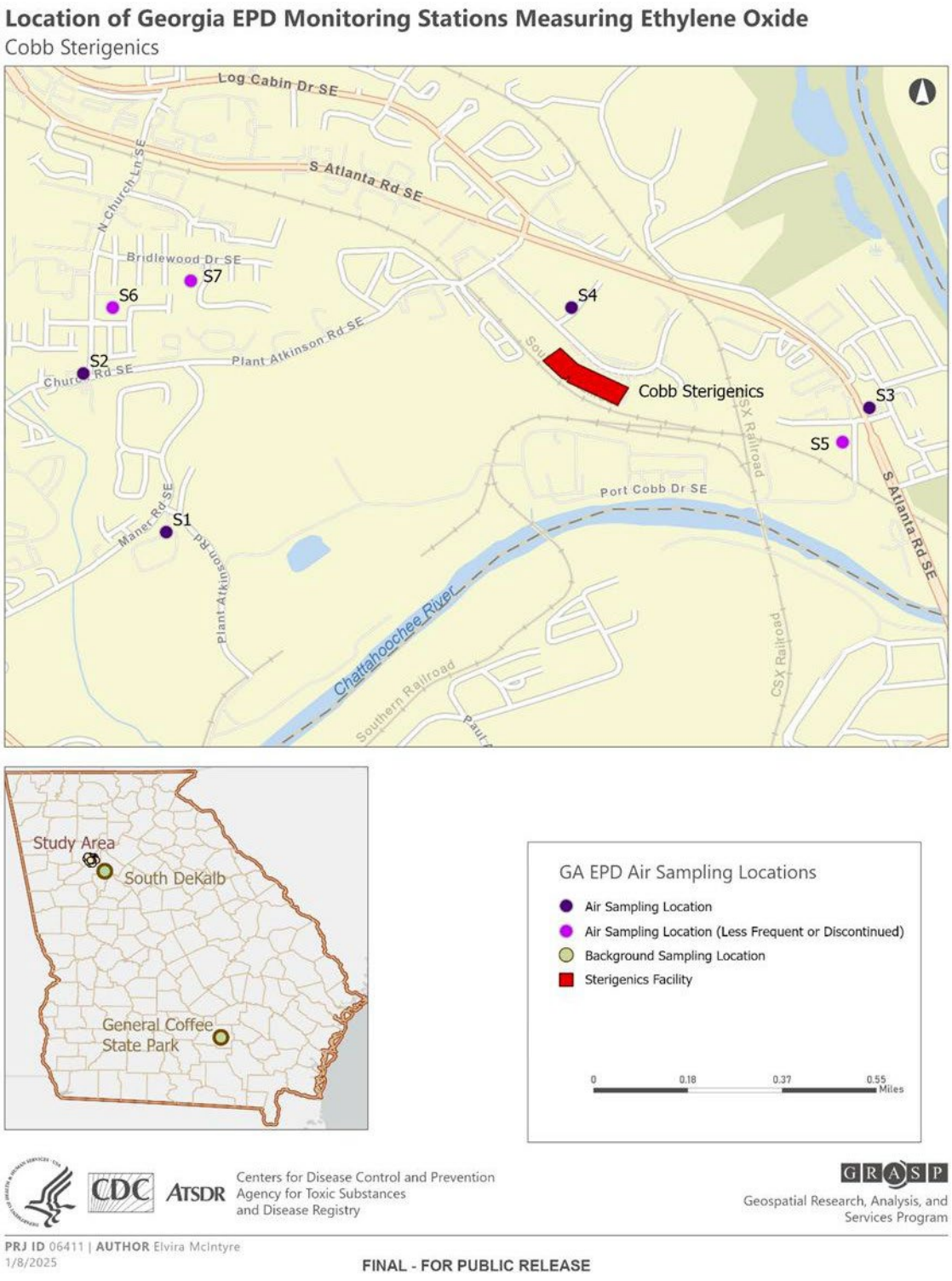
Table 2. Characteristics of EtO air sampling data used in the health evaluation in this consultation

Investigation	Number of Sample Locations	Number of Samples per Location
Total Georgia EPD sampling near Sterigenics (September 2019 – October 2022)	4 continuously operating, 7 total	96–114*
Georgia EPD when Sterigenics closed, analysis at ERG laboratory (September 2019 – March 2020)	4*	17–24
Georgia EPD when Sterigenics re-opened, analysis at ERG laboratory (April 2020 – September 2021)	6	49–67 (more frequently sampled) 8–13 (upwind locations)
Georgia EPD after Sterigenics was re-opened, analysis at Georgia EPD laboratory (October 2021 – October 2022)	3	34 (more frequently sampled) 9–11 (upwind locations)
Georgia EPD background sampling (September 2019– October 2022)	2	59–222
GHD sampling data total	20	14
GHD, Sterigenics closed (September 2019)	20	5
GHD, Sterigenics after re-opened (July 2020)	20	5

*These numbers exclude sampling locations that were not continuously operating during the time period and therefore did not have a sufficient number of samples to calculate an exposure point concentration (EPC).

The top map of Figure 3 shows the locations of Georgia EPD's air sampling near Sterigenics. All seven air sampling locations are located within about one mile of the facility. The map of Georgia shows the locations of Georgia EPD's background EtO air sampling. One background air sampling location was at EPD's NATTS (National Air Toxics Trends Site) in south DeKalb, and the other was in General Coffee State Park in South Georgia.

Figure 3. Location of Georgia EPD sampling locations measuring EtO near Sterigenics and at background locations



Georgia EPD was awarded a Community Scale Air Toxics grant from EPA to explore cavity ring down spectroscopy (CRDS) as an experimental technology for measuring background levels of EtO. The CRDS sampled hourly EtO concentrations from April 2021 through December 2021. Georgia EPD experienced challenges with instrument drift, which resulted in negative EtO concentrations early in the sample period. With adjustments from the manufacturer, Georgia EPD found drift was within the specifications outlined in their Quality Assurance Project Plan (QAPP) by the end of the sampling period.

Hourly EtO concentrations from the CRDS were consistently lower than 24-hour passive canister sampling at South DeKalb conducted during the same time period (EPD 2021). The primary purpose of ATSDR's analysis of background EtO concentrations at South DeKalb is to adjust near-site sampling to better estimate levels of exposure and to identify the potential industrial contribution to total exposure. The data Georgia EPD collected using the CRDS are not analyzed in this consultation because they are not directly comparable to the passive 24-hour canister sampling that was conducted near the facilities. A summary of EtO concentrations measured by the CRDS instrument is reported in Georgia EPD's October 2021 Ethylene Oxide Monitoring Report, Figure 70, and all data are reported in the appendix of that report (EPD 2023).

5. EtO Sampling Challenges

5.1. Controlling for Positive Bias and Seasonal Variation

In May 2021, EPA released two memorandums summarizing findings of positive sampling bias in EtO air concentrations (artificially high EtO concentrations) measured in some canisters using EPA Method TO-15 to sample and analyze EtO air concentrations at air quality sampling locations and near some facilities across the United States (EPA 2021b, EPA 2021c). Some canisters form EtO, likely as the result of a reaction between humidified air and the canister lining. This effect can make measured EtO concentrations higher than what is truly in the air ("positive sampling bias"). EPA is still investigating this finding and has implemented additional quality assurance procedures in the updated EPA Method TO-15a for sampling and measuring volatile organic compounds (EPA 2018; Yelverton, Hays and Rice 2024).

To address the positive sampling bias in EtO air concentrations, ATSDR used a Bayesian GAM analysis to adjust EtO concentrations measured by Georgia EPD. The GAM was fit to EtO air concentrations measured at the South Dekalb background sampling locations. General Coffee sampling data were not used for the purpose of development of the GAM because they were collected in a different way (using a device to pump air into a canister rather than a canister under vacuum collecting air passively) than most of the sampling in Cobb County (EPD 2021). Canister lining type and holding time (the amount of time between when a sample was collected and when it was analyzed) were both related to EtO concentrations. Samples collected in electropolished-lined canisters with longer holding times tended to have the highest EtO concentrations, likely due to positive sampling bias from EtO formation and growth in the canister. ATSDR also observed that EtO concentrations tended to be lower in the winter and higher in the summer in Georgia and at other locations measuring EtO across the country.

ATSDR's Bayesian GAM controlled for the effects of canister lining type, holding time, and season in measured EtO concentrations. Controlling for season makes EtO concentrations measured at different times of year more comparable to one another. GAM-adjusted EtO concentrations are ATSDR's best estimate of what EtO concentrations might have been had air samples been collected only in canisters less prone to positive bias and without seasonal variation. The GAM is discussed in greater detail in Appendix H: Bayesian Generalized Additive Model (GAM). Measured (unadjusted) concentrations compared to GAM-adjusted concentrations are available in Appendix B.

5.2. Imprecision in Low Concentrations

Based on Georgia EPD's analysis of samples collected at the same time and location, low-level EtO concentrations, meaning less than five times of the MDL or less than 0.26 µg/m^3 in EPD's sampling, are imprecise. EPA stated in 2021 that they have less confidence in low-level EtO concentrations near the MDL because of the greater uncertainty in the measurement (EPA 2021c). To address this uncertainty in low-level EtO concentrations, ATSDR uses a 95% upper confidence level (95% UCL) of the mean to estimate the EPC, or amount of EtO someone might breathe over many years. Greater variability in low EtO concentrations will make the EPC (95% UCL) higher, which ensures ATSDR's conclusions are health protective. That means our estimates of EPCs and resulting lifetime excess cancer risk for low levels of EtO are likely to be higher than they would be if it were possible to measure low level EtO concentrations with more precision.

5.3. Accounting for Background EtO Concentrations

EtO is present in ambient air across the United States even away from known sources of EtO such as factories or sterilizers. Appendix G: Background Levels of EtO Throughout the U.S. summarizes the EPA AQS EtO air concentrations measured at 50 sampling locations across the U.S. away from known sources since 2018. When adjusting for the factors described in section 5.1 Controlling for Positive Bias and Seasonal Variation, the median background EtO air concentrations ranged from 0.2 to 0.3 µg/m^3 at the two background locations in Georgia. Adjusted median background EtO concentrations ranged from 0.04 to 0.08 µg/m^3 when facilities were closed in two communities in Illinois where ATSDR has completed EtO health assessments. The excess cancer risks in Illinois associated with adjusted EPCs at background locations calculated using ATSDR's assumptions for residents ranged from 2 to 4 in 10,000 people exposed. In Georgia, the median adjusted EtO concentrations at South DeKalb and General Coffee ranged from 0.07 to 0.11 µg/m^3 and excess cancer risks from 4 to 5 in 10,000.

Because the objective of our health assessments is to determine potential health risks posed by inhalation exposures in a community and to make health-protective recommendations, it is important to compare EtO related to an industrial source to "background" EtO. ATSDR made comparisons between background and near-source EtO concentrations as well as concentrations when the facility was closed compared to when it re-opened to understand whether the facility was adding to background EtO (see section 6.1 and Appendix C: Statistical Tests and Plots Supporting Exposure Pathway Analysis with Adjusted Data) for more

information. The influences of positive bias and imprecision in measuring low levels of EtO introduce uncertainty about background concentrations of EtO in the United States.

5.4. Other Sampling Challenges

Georgia EPD's Ambient Air Monitoring Program (AAMP) report in November 2023 summarizes the results of their EtO sampling in Georgia from August 2019–October 2021 including air sampling conducted at Sterigenics, General Coffee, South DeKalb, and two other medical sterilizers in Georgia. At the time Georgia EPD began their EtO sampling, neither EPA nor most states had substantial experience in conducting air sampling for EtO, and they encountered a number of challenges in measuring EtO using EPA's Method TO-15. The impact of some of these sampling challenges on ATSDR's assessment is discussed here briefly.

1. **Pressure challenges:** All of the canisters used at air sampling locations near Sterigenics and some of the canisters used at the South DeKalb air sampling site draw in air through the canister being under vacuum. Some of the canisters were collected from the field at ambient pressure (0 inches of mercury [inHg]). That means that the canister may not have been drawing in air for the entire 24-hour collection period. ATSDR chose to invalidate samples that were collected at ambient pressure, similar to EPA's requirements for National Air Toxics Trends Sites. Georgia EPD presented data both with these samples included and with these samples invalidated in their final report and did not find any meaningful differences between the two datasets. ATSDR did not find differences in concentrations collected in canisters collected from the field at ambient pressure compared to canisters collected still under vacuum.
2. **Siting air monitors**: Georgia EPD intended to locate air monitors in the primary upwind, primary downwind, secondary upwind, and secondary downwind locations from Sterigenics. However, permissions to access areas near the facility were limited which restricted where the monitors could be sited. In addition, one air sampling location (S5) had to be discontinued due to safety concerns for the site operators. In spite of the challenges Georgia EPD faced in siting, Georgia EPD's air sampling locations were appropriate for estimating exposure for the nearest residents.

For more information on sampling methods and challenges, see Georgia EPD's Ethylene Oxide Monitoring Report on their EtO homepage: https://epd.georgia.gov/ethylene-oxide-information (GA EPD 2023).

6. Scientific Evaluations

6.1. Exposure Pathway Analysis

6.1.1. Overview of Potential Exposure Pathways

As the first step in analyzing whether a contaminant could pose a public health hazard, ATSDR considers whether and how a contaminant at a site might go from being released into the

environment to entering someone's body (exposure). This analysis is called exposure pathway analysis. Exposure pathway analysis considers potential sources of contaminants, how those contaminants might move through the environment, where people might come in contact with those contaminants, how contaminants enter someone's body (exposure), and who might be at risk of exposure. These factors are considered for past, present, and possible future exposures (ATSDR 2022a).

People may breathe in EtO that originates from a known source such as Sterigenics or background levels of EtO without a known source. Prior to September 2019, EtO emissions from Sterigenics may have been released from the stack or from fugitive emissions, such as air that escapes from doorways and vents.

Since outdoor EtO air sampling data were not collected before Sterigenics shut down in September 2019 to install a new PTE emissions control system to capture fugitive emissions, ATSDR did not evaluate potential past EtO exposures prior to 2019 or make a health conclusion about EtO emissions from Sterigenics in the past. Without air sampling, ATSDR does not know the concentration someone may have breathed in the past or how far EtO spread from the facility. We used EtO air sampling that took place when the facility was operating (April 2020–October 2022) to evaluate present and potential future exposures.

Residents may also have occasionally breathed in air containing propylene oxide (PO) in the past prior to 2019. Sterigenics intermittently used PO to sterilize specific products and still has the capability to use PO. PO was not evaluated in this consultation. It was not included in air sampling because it is only used occasionally, air modeling from NATA and AirToxScreen does not predict PO poses a health risk, and it is controlled by the same emissions control systems used for EtO.

Ethylene glycol, a liquid at room temperature and the main component of antifreeze, is produced and collected as a by-product of Sterigenics's emissions control system used to remove EtO from air. The liquid ethylene glycol is stored in sealed tanks, which are transported off site for disposal or use in other products. There have not been any spills of liquid ethylene glycol reported from the Sterigenics facility. Because Sterigenics is not known to have released ethylene glycol and there is no environmental sampling data available to evaluate, ethylene glycol from Sterigenics was not evaluated in this health consultation.

6.1.2. Analysis of Georgia EPD EtO Concentrations September 2019–October 2022

ATSDR investigated whether Sterigenics emissions influenced outdoor EtO air concentrations at Georgia EPD's air sampling locations near Sterigenics after it reopened with new emissions controls in April 2020. ATSDR's analysis of outdoor EtO air sampling data did not find evidence that Sterigenics is measurably adding to background EtO concentrations near where people work and live. The lines of evidence we explored to reach this conclusion are summarized below with more detailed statistical information in Appendix C. The analysis described in this section was performed on GAM-adjusted EtO concentrations. As described in section 5.1 and in more detail in Appendix H, Georgia EPD's EtO concentrations were adjusted using a GAM to account for canister type, holding time, sampler type, and seasonal variation.

ATSDR also analyzed unadjusted EtO concentrations. Those analyses also did not indicate Sterigenics influenced EtO concentrations after re-opening in April 2020 (Appendix D: Statistical Tests and Plots of Exposure Pathway Analysis with Raw (Unadjusted Data)).

Based on EPA's EtO air sampling at background locations in the United States not near known sources of EtO, median unadjusted concentrations of EtO measured at background locations range from 0.1–0.3 μg/m^3 (Appendix G, Table G1). Median unadjusted EtO concentrations (0.1–0.4 μg/m^3) measured in Cobb County, including levels near Sterigenics and at EPD's two Georgia background locations, are within the range of medians measured nationally at EPA's Air Quality Sites away from known sources (Appendix B, Table B1, Appendix G, Table G1).

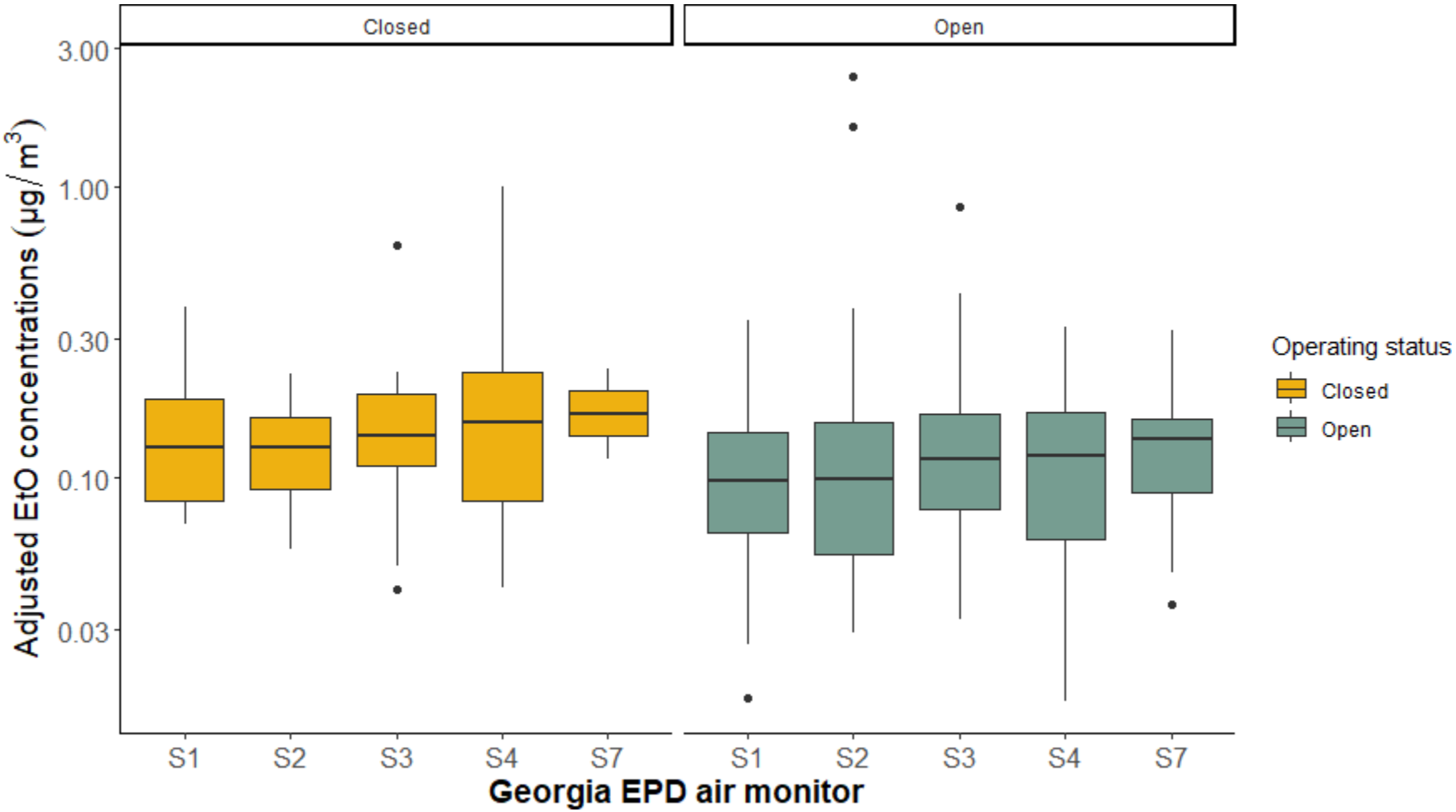
The mean GAM-adjusted background EtO concentrations measured at air sampling locations near Sterigenics when the facility was closed (ranging from 0.11–0.21 μg/m^3) and at South DeKalb (0.13 μg/m^3) are somewhat higher than GAM-adjusted background EtO concentrations measured at other EtO-emitting sites where ATSDR has performed similar analyses in Lake County, Illinois, Cook County, Illinois, and Willowbrook, Illinois. Adjusted background concentrations in Illinois ranged from 0.07–0.17 μg/m^3 when nearby facilities were closed and at background locations (ATSDR 2023a; ATSDR 2024). These differences may be due to differences in measurement methods, canisters, climate, or adjustment methods.

ATSDR compared adjusted EtO concentrations at sampling locations near Sterigenics when the facility was closed (September 2019–April 2020) to after the facility re-opened (April 2020–October 2022). ATSDR performed statistical tests to calculate the probability that the difference in Georgia EPD GAM-adjusted EtO concentrations measured at sampling locations near Sterigenics while Sterigenics was closed compared to after it re-opened could be observed if there were no difference other than random fluctuations in concentrations. GAM-adjusted EtO concentrations measured when Sterigenics was closed were similar to and not statistically significantly greater than GAM-adjusted EtO concentrations after the facility re-opened in April 2020 (Figure 4, Appendix C). Adjusted EtO concentrations measured at locations near Sterigenics after April 2020 were also similar to and not significantly different than concentrations measured at the South DeKalb background location during the same time period (Figure 5, Appendix C).

Air modeling associated with the 2022 Sterigenics air emissions permit predicted that the maximum annual contribution of the facility to EtO concentrations near where people live (0.005 μg/m^3) would be about one tenth of background concentrations (GA EPD 2020). If the modeled concentrations are accurate, facility-related EtO concentrations would be too low to be measurably different from background concentrations.

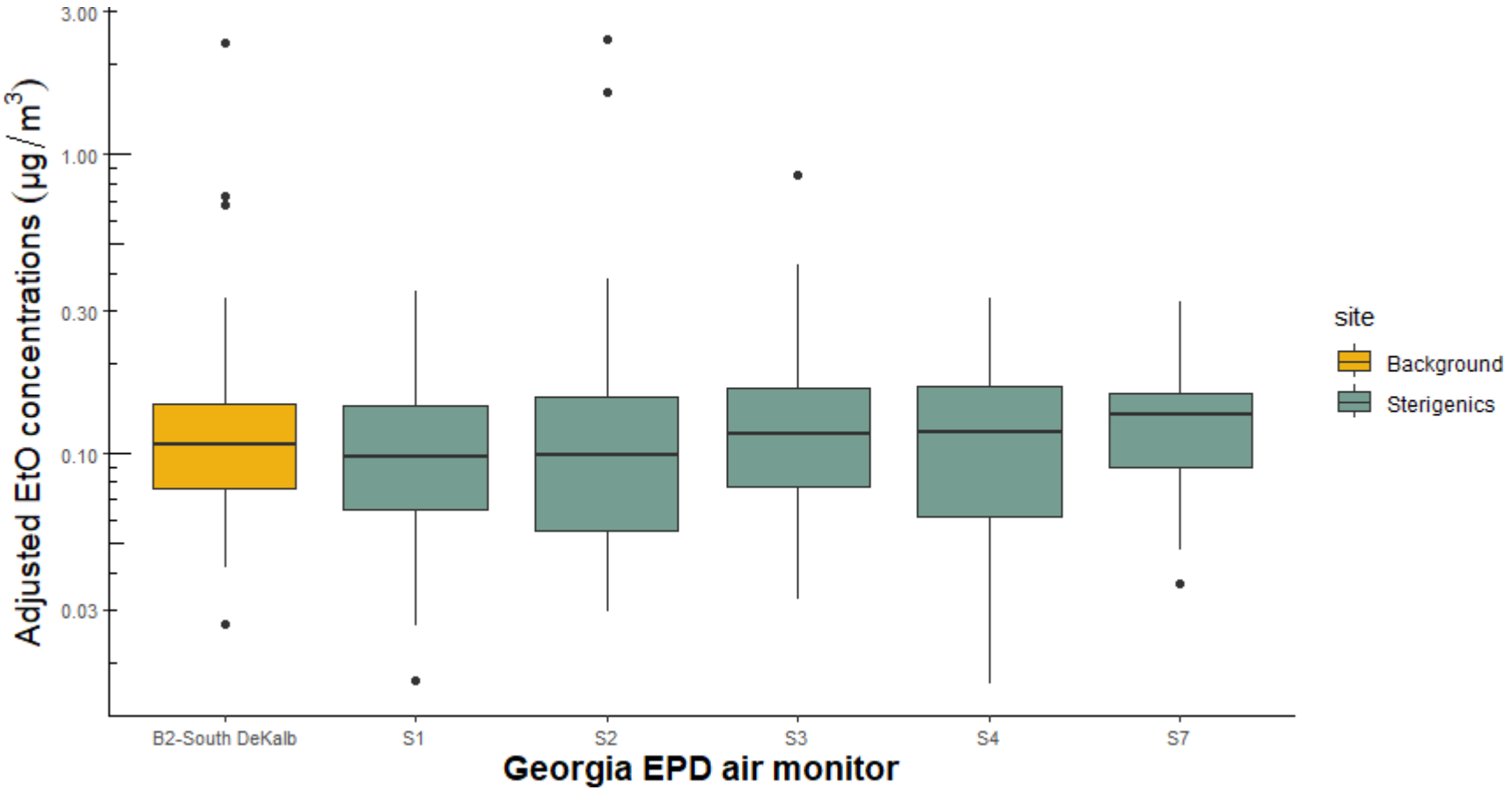
In addition to statistical testing, ATSDR visualized the relationship between EtO concentrations, wind direction, and wind speed using polar plots. We created polar plots both for when the facility was closed and after it re-opened. The polar plots did not provide a clear indication that Sterigenics is contributing to EtO concentrations above background (Appendix C).

Figure 4. Boxplot of GAM-adjusted EtO concentrations measured when Sterigenics was closed (September 2019–March 2020, in yellow) compared to GAM-adjusted EtO concentrations measured after Sterigenics re-opened (April 2020–October 2022, in green).



See Appendix I: Explanation of a Boxplot for more information about boxplots

Figure 5. Boxplot of EtO GAM-adjusted EtO concentrations at the South DeKalb background sampling location (in yellow) and locations near Sterigenics (in green) after the facility re-opened (April 2020–October 2022).



See Appendix I: Explanation of a Boxplot for more information about boxplots

6.2. Screening Analysis

ATSDR screened chemicals for further evaluation by comparing EtO concentrations at each sampling location against ATSDR health-based comparison values (CVs). ATSDR inhalation CVs are health-protective air concentrations for a given duration of exposure to the contaminant that are not expected to cause harmful health effects. CVs may be developed for acute (less than 2 weeks), intermediate (2 weeks up to 1 year), or chronic (1 year or more) exposure durations.

Exposures to chemical concentrations detected below ATSDR's CVs are not expected to cause harmful health effects in people. Therefore, concentrations below CVs are not evaluated further. Contaminant concentrations that exceed CVs do not indicate that a health risk is likely but rather that the pollutant should be evaluated further to determine the potential public health impact.

The ATSDR CV for chronic exposure to EtO is the ATSDR cancer risk evaluation guide (CREG), which is based on EPA's IUR for EtO (ATSDR 2022a). ATSDR CREGs are estimated contaminant concentrations that are expected to result in no more than 1 excess cancer in 1 million persons exposed during their lifetime. The CREG for EtO considers early-life susceptibility to EtO and applies weighting factors known as age-dependent adjustment factors (ADAFs), as EtO has been designated as a mutagen (a chemical that causes genetic mutations). ATSDR's CREG for EtO is 0.00021 $\mu g/m^3$.

The ATSDR acute and intermediate CVs for EtO are based on ATSDR's acute and intermediate minimal risk levels (MRLs). An inhalation MRL is an estimate of the contaminant concentration that someone can breathe over a specific duration that is not expected to cause noncancer health effects. ATSDR's acute MRL is 720 $\mu g/m^3$, and the intermediate MRL is 130 $\mu g/m^3$ (ATSDR 2022b).

ATSDR compared EtO concentrations over the appropriate duration of exposure to each CV. The maximum 24-hour concentration at each air sampling location was compared to the acute and intermediate CVs (ATSDR 2022a). ATSDR used both GHD and EPD sampling data to compare against intermediate and acute MRLs. The maximum EtO concentrations did not exceed the acute and intermediate CVs at any of the sampling locations (Table 3). Therefore, acute and intermediate exposure to EtO concentrations do not pose a public health hazard and were not evaluated further.

Table 3. Maximum EtO concentrations measured at Georgia EPD's and GHD's air sampling locations. No maximum concentrations exceeded ATSDR's intermediate or acute MRLs.

Air Sampling Location	Data Source	Maximum EtO Concentration (μg/m³)	ATSDR Intermediate MRL (μg/m³)	ATSDR Acute MRL (μg/m³)
S1	EPD	2.0	130	720
S2	EPD	6.5	130	720
S3	EPD	2.5	130	720
S4	EPD	1.6	130	720
S5	EPD	2.0	130	720
S6	EPD	1.4	130	720
S7	EPD	1.5	130	720
Smyrna 1	GHD*	2.4	130	720
Smyrna 2	GHD	2.4	130	720
Smyrna 3	GHD	2.1	130	720
Smyrna 4	GHD	2.6	130	720
Smyrna 5	GHD	3.2	130	720
Smyrna School 1	GHD	2.6	130	720
Cobb 1	GHD	3.4	130	720
Cobb 2	GHD	5.7	130	720
Cobb 3	GHD	3.5	130	720
Cobb 4	GHD	7.9	130	720
Atlanta 1	GHD	7.1	130	720
Atlanta 2	GHD	4.3	130	720
Atlanta 3	GHD	5.7	130	720
Atlanta 4	GHD	4.7	130	720
Atlanta 5	GHD	2.0	130	720
Atlanta 6	GHD	4.1	130	720
Atlanta 7	GHD	3.0	130	720
Atlanta 8	GHD	2.4	130	720
Atlanta 9	GHD	3.8	130	720
Atlanta 10	GHD	2.4	130	720

*Data from GHD does not include samples that were invalidated due to isobutane interference. The concentrations in these invalidated samples were below ATSDR's MRLs, so the decision to treat these samples as invalid did not change the conclusion that intermediate- and short-term non-cancer health effects are not a concern for people who live or work near Sterigenics.

For chronic EtO exposure, ATSDR compared the 95% UCL of the mean EtO concentrations (95% UCL) at each EPD sampling location against the ATSDR CREG for EtO. GHD sampling was not

compared to the CREG because the sampling took place over a much shorter time period than Georgia EPD sampling, and in most cases, there were too few valid samples per sampling location to calculate an EPC. The CREG was exceeded at all sampling locations. Therefore, additional health evaluation of the potential health risks associated with chronic exposure to EtO in the air near Sterigenics follows below.

Table 4. Exposure Point Concentration (EPC) for each air sampling location after Sterigenics reopened (April 2020–October 2022) based on Georgia EPD's air sampling data. Every EPC exceeded ATSDR's CREG.

Air Sampling Location	GAM-Adjusted EPC in µg/m^3, Sterigenics (After Reopening)	Cancer Risk Evaluation Guideline (CREG), µg/m^3
S1	0.123	0.00021
S2	0.216	0.00021
S3	0.174	0.00021
S4	0.145	0.00021
S7	0.163	0.00021
South DeKalb	0.157	0.00021
General Coffee	0.165	0.00021

EPC = exposure point concentration; µg/m^3 = micrograms per cubic meter; CREG = cancer risk evaluation guide

6.3. Health Evaluation

6.3.1. Noncancer Health Effects Evaluation

To evaluate long-term (chronic) inhalation exposure to EtO in the air near Sterigenics, ATSDR calculated an EPC, which is an estimate of the average EtO concentration someone may breathe over many years at each air sampling location. The EPCs were calculated using the GAM-adjusted EtO air concentrations Georgia EPD collected at each of the five air sampling locations near Sterigenics after Sterigenics reopened on April 8, 2020 and at EPD's two background locations during the same time period. The EPC is a health protective concentration calculated using the 95% UCL of the mean. The highest EPC for EtO at any air sampling location that measured long-term EtO concentrations was 0.29 µg/m^3. Based on non-cancer health effects observed in animal studies and case studies of workers with chronic inhalation exposure to very high EtO concentrations, ATSDR concludes that the EtO concentrations measured near Sterigenics and at background locations in Georgia do not pose a current concern for non-cancer health effects for people living, working, or attending a school nearby.

There was no evidence in Georgia EPD's air sampling data that Sterigenics was measurably contributing to nearby EtO concentrations during this time based on statistical testing and visualizations described in the section 6.1 Exposure Pathway Analysis.

Four chronic studies of animals inhaling very high EtO concentrations observed adverse effects in several body systems between 10 and 21 ppm (18,000 and 37,800 µg/m^3) EtO. Limitations in these animal studies prevented ATSDR from deriving a chronic inhalation MRL for EtO.

Some of the effects observed in these chronic animal studies are supported by intermediate duration animal studies reported in the toxicological profile (ATSDR 2022b). An intermediate study of rodents exposed to slightly lower EtO concentrations than in the chronic database (6.9 ppm or about 12,000 μg/m^3) observed reduced body weight gain and survival in the offspring of pregnant rodents. No adverse health effects were observed at a duration-adjusted concentration of 3,800 μg/m^3 in the same study. The very high EtO concentration rodents exhibiting adverse effects were exposed to in these animal studies was 40,000 times higher than the highest long-term average EtO concentration of 0.29 μg/m^3 at any of the EPD air sampling locations near Sterigenics.

Case studies of workers exposed to EtO for various durations reported neuropathy (weakness, numbness, and pain in the extremities), impaired hand-eye coordination, cognitive dysfunction (deficits in normal thought function), memory loss, headache, and hand numbness. These case studies were not used to derive a chronic MRL for EtO because they do not have adequate exposure-response data and were considered insufficient to establish a causal relationship between chronic EtO exposure and neurological effects in humans. These studies did not have reliable estimates of worker EtO exposure levels, but the provided estimated EtO exposures were at least several thousand times higher than the highest long-term average EtO concentration of 0.29 μg/m^3 at any of the Georgia EPD air sampling locations near Sterigenics.

Limited research looked at pregnant women who were exposed to EtO in the workplace. Limitations in these studies preclude drawing conclusions about whether EtO can cause miscarriage or other harmful effects related to pregnancy.

6.3.2. Cancer Risk Evaluation

Various agencies have classified EtO as a human carcinogen (substance that can cause cancer) by the inhalation route of exposure, including the National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences, EPA, and the International Agency for Research on Cancer (IARC) (NTP 2021; EPA 2016a; IARC 2012). The classification of EtO as a carcinogen by these three agencies is based on the following evidence:

1. carcinogenicity in workers breathing EtO (summarized below),
2. carcinogenicity in experimental animal studies, and
3. EtO causes changes to DNA and other precursor events in humans that might be expected to lead to cancer (NTP 2021; EPA 2016a; IARC 2012).

In December 2016, EPA finalized the “Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide” report that provides scientific support and rationale for the hazard and dose-response assessment pertaining to the carcinogenicity from chronic inhalation exposure to EtO (EPA 2016a). EPA used epidemiological studies based on a National Institute for Occupational Safety and Health (NIOSH) cohort of workers exposed to EtO to develop the IUR for inhalation exposure to EtO (Steenland et al. 2004; Steenland et al. 2003). This occupational study is a high-quality large size cohort design with males and females, adequate follow-up, absence of known

confounding exposures, and individual worker exposure estimates from a high-quality exposure assessment (EPA 2016a). Workers were exposed to a measured geometric mean EtO concentration of 4,000 μg/m^3 and a modeled geometric mean of 2,100 μg/m^3 (Hornung, et al. 1994).

Steenland et al. (2004) evaluated cancer mortality in the entire NIOSH cohort of 18,235 men and women workers employed at 14 commercial sterilization facilities. There were no statistically significant increases in mortality in the overall cohort from any cancer compared to the general U.S. population. Workers with the highest cumulative exposures and longest latency (time between EtO exposure and observed mortality) had statistically significant excess mortality for lymphoid cancers (non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) as a group in males and female breast cancer. The standardized mortality ratio (SMR) for non-Hodgkin lymphoma was statistically significantly elevated in the highest cumulative exposure group of males compared to the U.S. population, but there were not statistically significant elevations for myeloma or lymphocytic leukemia individually (Steenland, Stayner, and Deddens 2004).

Steenland et al. (2003) studied female breast cancer incidence in a subset of the original NIOSH cohort described above; this cohort included 7,576 women who were employed at one of the 14 sterilization facilities for at least one year. The authors concluded the data suggest that EtO exposure is associated with breast cancer, but the causal interpretation is weakened due to some inconsistences in exposure-response trends, possible biases due to lack of response from study participants, and incomplete cancer ascertainment (Steenland et al. 2003).

Mikoczy et al. (2011) studied mortality and incidence from breast and lymphohematopoietic cancers in 2,171 male and female Swedish workers in sterilizing facilities over 34 years (1972–2006). The study indicated there was a positive-response relationship for breast cancer with increased rate ratios for the upper two quartiles of cumulative exposure (Mikoczy et al. 2011).

The low-level outdoor air EtO concentrations measured in Cobb County are over a thousand times lower than EtO concentrations that workers were exposed to in the worker studies described above. However, these occupational epidemiologic studies represent health effects that occurred in people exposed to high levels of EtO at work over a long period of time. There have not been studies evaluating the health effects from community exposures to low-level EtO concentrations, which would include sensitive populations such as developing babies (in utero) and young children. Worker studies provide the best available information about the risk of cancer due to EtO exposure.

6.3.2.1. Lifetime Excess Cancer Risk Calculations

ATSDR calculated upper bound population-based estimates of lifetime excess cancer risk at each sampling location using the EPC (95% UCL of GAM-adjusted EtO concentrations), an RME scenario, and EPA's IUR to guide public health decisions. ATSDR calculates a theoretical, lifetime excess cancer risk for different groups of people in the community surrounding Sterigenics (for instance workers, residents, and school-age students). In Table 5, ATSDR presents upper bound lifetime excess cancer risks using an RME exposure scenario for residents. The calculated lifetime excess cancer risk estimates are designed to be protective of health, as they use

reasonable upper bound exposure estimates and are likely an overestimate of the potential cancer risk. The actual cancer risks from EtO exposure may be lower than the calculated lifetime excess cancer risk estimates.

ATSDR uses calculated estimates of lifetime excess cancer risk as a tool for making recommendations to reduce exposure and protect public health. ATSDR considers any lifetime excess cancer risk estimate greater than 1 excess cancer case in 10,000 persons exposed as an elevated cancer risk, requiring a recommendation to protect public health. Lifetime excess cancer risks greater than 1 in 10,000 do not necessarily mean any given individual will develop cancer due to exposure.

In the United States, 1 out of every 3 people will develop cancer during their lifetime (American Cancer Society 2025). The lifetime risk of developing cancer from all risk factors during a lifetime is based on the incidence of cancer cases diagnosed and reported to state cancer registries across the United States. In contrast, the lifetime excess cancer risks ATSDR presents below are calculated values not based on actual cases of cancer. They represent high-end estimates of potential cancer risk from EtO exposure over a lifetime.

For the purposes of estimating a lifetime excess cancer risk from chronic exposure to EtO concentrations, ATSDR used RME assumptions about how long, how often, and how much EtO residents and off-site workers may breathe. ATSDR's RME scenario is a continuous residential exposure duration of 24 hours a day for 33 years over a lifetime of 78 years. ATSDR calculates lifetime excess cancer risks based on 33 years of exposure using ADAFs. ADAFs are used to weight risk for exposure of the youngest age ranges (infants and children) to mutagenic compounds like EtO. Mutagens are pollutants that can cause changes in the DNA of the exposed individual which can result in cancer. Pollutants that cause cancer from a mutagenic mode of action may result in a higher risk of cancer for children exposed in early life than for adults. ATSDR calculates lifetime excess cancer risks for residents assuming someone may start breathing EtO beginning at birth. This ensures our estimates lead us to make health-protective conclusions for children living near Sterigenics. In Table 5 below, ATSDR presents the RME scenario for people who live near those air sampling locations because that is the most health-protective scenario. In Appendix F, ATSDR calculates lifetime excess cancer risks for specific scenarios that were the focus of community concern, such as children who may attend school or daycare nearby.

To estimate the long-term (chronic) average EtO air concentration people are exposed to from breathing EtO over their lifetime, ATSDR calculated EPCs using the 95% UCL of GAM-adjusted EtO concentrations at each sampling location during each operation time period. A 95% UCL is a conservative estimate of the average EtO concentration in the air that someone might breathe over many years. The 95% UCL provides reasonable confidence that the true average EtO concentration is not underestimated.

The upper bound assumptions in the EPC, RME, and IUR allow ATSDR to account for uncertainty in measurements by using protective, reasonable upper bound EtO exposure estimates to calculate lifetime excess cancer risk estimates as the basis for determining whether harmful

health effects are possible. The true lifetime excess cancer risk estimate may be less than what ATSDR calculated.

Table 5 presents GAM-adjusted EtO concentrations, EPCs, and cancer risks for sampling locations with samples measured near Sterigenics after the facility was re-opened (April 2020–October 2022). The GAM-adjusted EtO exposure point concentrations were between 0.12 to 0.22 µg/m^3, corresponding to a lifetime RME cancer risk between 4 and 7 excess cases of cancer in 10,000 people (Table 5). The comparable lifetime cancer risk associated with EtO concentrations that were measured when Sterigenics was closed (September 2019–April 2020) were between 5 and 9 in 10,000. The comparable reasonable maximum excess cancer risk at both the South DeKalb background air sampling location and at General Coffee based on air sampling while Sterigenics was open was 5 in 10,000. As previously mentioned, and presented in Figure 4 and Figure 5, EtO concentrations were not statistically significantly greater when Sterigenics was re-opened compared to when it was closed nor were they greater than background locations.

ATSDR also presents, in the tables below, lifetime excess cancer risks calculated using central tendency exposure (CTE) estimates, which use average estimates of how long someone may breathe EtO, how often someone may breathe EtO, and how much EtO someone might breathe over their lifetime. The CTE scenario assumes exposure to EtO for the average person who lives nearby occurs as an adult, assumes exposure lasts for 12 years, which is the average time someone in the U.S. lives in one place, and assumes people are breathing the average (mean) EtO concentration rather than the 95% UCL. CTE lifetime excess cancer risks ranged from 0.5 to 1 in 10,000 (Table 5).

Table 5. Calculated GAM-adjusted mean and EPC EtO concentrations and theoretical lifetime excess cancer risks at each air sampling location based on Georgia EPD air sampling data collected near Sterigenics under current open conditions (April 8, 2020–October 31, 2022) and under closed conditions (September 6, 2019–April 7, 2020)

Air Sampling Location	Distance from Sterigenics (miles)	Sterigenics Operating Status	GAM-Adjusted Mean µg/m^3	CTE Lifetime Cancer Risk for Adult Residents (in 10,000)	GAM-Adjusted EPC µg/m^3	RME Lifetime Cancer Risk for Residents (in 10,000)
S1	0.70	Open	0.107	0.5	0.123	4
S2	0.75	Open	0.157	0.7	0.216	7
S3	0.39	Open	0.148	0.7	0.174	5
S4*	0.08	Open	0.127	0.6	0.145	4
S7	0.60	Open	0.140	0.7	0.163	5
South DeKalb[§]	14	Open	0.136	0.6	0.157	5
General Coffee	200	Open	0.106	0.5	0.165	5
S1	0.70	Closed	0.152	0.7	0.191	6
S2	0.75	Closed	0.133	0.6	0.162	5
S3	0.39	Closed	0.160	0.7	0.204	6
S4*	0.08	Closed	0.208	1	0.286	9
S7	0.60	Closed	0.177	0.8	0.238	7
South DeKalb[§]	14	Closed	0.129	0.6	0.147	5
General Coffee	200	Closed	0.106	0.5	0.134	4

*This monitor is in a commercial area, but since there is no monitor to represent the neighborhood to the north of the neighborhood, ATSDR conservatively applied a residential scenario because this is the exposure scenario with the highest cancer risk. The community also expressed health concerns about a nearby homeless shelter and daycare. More information on those scenarios is presented in Appendix F.

[§]General Coffee is not included in these calculations because General Coffee canisters were all pressurized and near-site sampling was conducted in passive canisters. See Appendix B, which presents summary statistics for all sampling locations.

6.4. Summary of Limitations and Uncertainties

Whenever possible, ATSDR accounts for limitations by using protective, reasonable upper bound exposure estimates as the basis for determining whether harmful health effects are possible. The calculated lifetime excess cancer risk estimates are designed to be protective of health and are likely an overestimate of the potential cancer risk from EtO exposure. Limitations and uncertainties of ATSDR's health consultation include:

1. This analysis has limitations that cause some uncertainty in ATSDR's estimates of lifetime excess cancer risk associated with EtO exposure near or at background concentrations of EtO. There are several factors that contribute to this uncertainty:

a. EPA's current air sampling and laboratory methods (Method TO-15A) to analyze EtO in outdoor air can only report EtO concentrations that are about 200 times higher than ATSDR's comparison value for cancer, which is based on a risk of 1 additional cancer case among a population of 1 million exposed individuals.

b. Outdoor EtO air concentrations as low as 0.03 $\mu g/m^3$, which is lower than background EtO concentrations in Cobb County, would represent a lifetime excess cancer risk for residents greater than 1 additional cancer case in 10,000 people exposed, which is considered an elevated lifetime cancer risk.

c. The MDL is defined as "the minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results" (EPA 2016b). There is generally a higher degree of confidence in quantifying the concentration of any chemical when it is measured well above the MDL, compared to measuring a concentration that is near the MDL. Adjusted median EtO concentrations measured at the background sampling locations and at the various community sampling locations near the Sterigenics facility are only two or three times the MDL, which is below the level at which Georgia EPD stated that measured concentrations are more imprecise. This introduces variability and some uncertainty into the EtO concentrations. This variability is random and is not specific to EtO. ATSDR typically accounts for variability in environmental data by using a 95% UCL to estimate an EPC, regardless of whether the contaminant concentrations measured are near the MDL. Greater variability in concentrations results in a higher 95% UCL to account for greater uncertainty, ensuring our conclusions are still health protective.

d. Other chemicals may be mistakenly measured as EtO, which can artificially inflate EtO concentrations measured in outdoor air. ATSDR investigated several lines of evidence to explore whether other potential sources, including sources of other chemicals, may be contributing to EtO concentrations. ATSDR did not observe evidence that Sterigenics was contributing to EtO concentrations at nearby sampling locations after the facility re-opened with additional emissions controls in April 2020.

2. The positive bias in EtO air measurement due to the canister effect and holding time (i.e., EtO growth inside a canister) resulted in uncertainty about the accuracy of the EtO measurements reported by the laboratory. In addition, seasonal patterns introduced variation in concentrations that could affect estimates of long-term exposure. To address this issue, ATSDR used a Bayesian GAM to adjust EtO concentrations, effectively removing the influence of canister lining type, sampler type, holding time, and seasonal patterns. The Bayesian GAM provides better estimates of cancer risk by minimizing the impact of positive bias, but it does not remove all uncertainty resulting from positive sampling bias nor does it remedy other types of sampling error.

3. We cannot fully evaluate historical trends or chronic exposures in the community to quantify past lifetime excess cancer risks before new emissions controls were in place due to lack of air sampling during that time period.

4. An information data gap exists in the scientific toxicologic literature on how human exposure to lower EtO concentrations affects development of adverse health outcomes, especially in utero and in young children. Young children may be particularly susceptible to adverse health effects from chronic EtO exposure. ATSDR uses EPA's ADAFs to calculate lifetime excess cancer risk that accounts for potential greater cancer risk for children exposed to mutagenic compounds.

6.5. Medical Questions and Concerns

Community members and local officials have inquired about medical monitoring (biological testing) for EtO exposure. While there are medical tests that can indicate exposure to EtO, these tests cannot determine the source of exposure or if an existing or future health problem may be related to EtO exposure. ATSDR does not recommend EtO exposure-related blood testing for community settings.

ATSDR recommends that community members who are concerned about EtO exposures or have health-related questions talk with their doctor. Important additional steps in maintaining health and detecting problems early include keeping up to date with routine medical checkups and age-appropriate health screening tests (e.g., breast cancer screening recommended by the U.S. Preventive Services Taskforce) (United States Preventative Services Taskforce 2024) and being evaluated by their doctor between checkups if unusual symptoms or concerns arise. Clinicians interested in learning more about EtO exposure and health may also access ATSDR resources on EtO for clinicians through our website at the links below. Community members who wish to speak to their doctors about their exposure may share the following resources:

- ATSDR Clinician Brief: Ethylene Oxide
- ATSDR Clinician Overview: Ethylene Oxide

7. Conclusions

7.1. Conclusion Number One

ATSDR concludes that breathing EtO concentrations in outdoor air near Sterigenics is not expected to cause noncancer health effects. The lifetime excess risk of cancer from breathing EtO for people who live, work, or attend school near Sterigenics is similar to lifetime excess cancer risk from breathing background EtO concentrations in Georgia and other areas of the country with no known source of EtO emissions. This finding was based on EtO concentrations measured from April 2020 to October 2022.

7.2. Basis for Conclusion Number One

- EtO concentrations measured in the outdoor air at sampling locations within about one mile of Sterigenics from April 2020 to October 2022 are similar to background EtO concentrations measured elsewhere in Georgia and in the U.S. with no known source of EtO emissions nearby.
- After adjusting for seasonal variation and positive bias, EtO concentrations measured at sampling locations near Sterigenics after Sterigenics reopened in April 2020 with new emissions controls were not statistically significantly greater than the background EtO concentrations measured at the same locations from September 2019 to April 2020 when Sterigenics was closed.
- Adjusted EtO concentrations in outdoor air near Sterigenics from April 2020 to October 2022 were not statistically significantly greater than outdoor EtO concentrations at Georgia EPD's two background locations (South DeKalb and General Coffee).
- Calculated, high-end, lifetime excess cancer risk estimates were similar at sampling locations near Sterigenics and at the two Georgia background locations. EtO concentrations at background sites while the Sterigenics facility was operating were associated with an estimated 5 additional cases in 10,000 people, while sites near Sterigenics ranged from 4 to 7 estimated additional cases in 10,000 people during the same time period.
- The highest EtO concentrations measured near Sterigenics are well below the ATSDR noncancer health guidelines and significantly below the lowest concentrations that have been reported to result in noncancer health effects in scientific studies of acute (less than 2 weeks), intermediate (2 weeks to 1 year), and chronic (greater than 1 year) exposure to EtO.

7.3. Conclusion Number Two

ATSDR cannot determine whether breathing EtO concentrations near Sterigenics could have harmed people's health before September 2019 when Sterigenics closed to upgrade emissions controls.

7.4. Basis for Conclusion Number Two

- There are no outdoor EtO air sampling data available prior to Sterigenics temporarily shutting down in September 2019. Sterigenics subsequently re-opened with new emissions controls in April 2020.
- Before Sterigenics closed to install new emissions controls, emissions from Sterigenics may have been higher than they are now.

7.5. For More Information

If you have questions about this document or ATSDR's work on EtO, call our toll-free number at 1-800-CDC-INFO, and ask for information on the Sterigenics EtO health consultation in Cobb County, Georgia.

8. Recommendations and Public Health Action Plan

- ATSDR recommends EPA continue to improve the analytical methods to accurately measure EtO at lower concentrations and identify potential background EtO sources. Research on this topic is currently underway (Yelverton, Hays and Rice 2024; EPA 2024).
- ATSDR recommends community members keep up to date with routine medical checkups and recommended age-appropriate health screening tests.
- Clinicians interested in learning more about EtO exposure and health may access ATSDR's online resources on EtO for clinicians at the website links below. Community members who wish to speak to their doctors about their exposure may share the following resources:
    - **ATSDR Clinician Brief: Ethylene Oxide**
    - **ATSDR Clinician Overview: Ethylene Oxide**

9. Authors, Site Team, and Contributors

Lydia Hoadley, MSPH
Health Assessor, Central Section, Office of Community Health Hazard Assessment, ATSDR/CDC

James S. Pyon, MS
Associate Service Fellow, Exposure Investigation Section, Office of Community Health Hazard Assessment, ATSDR/CDC

James Durant, MSPH, CIH
Senior Environmental Scientist and Data Analyst, Exposure Investigation Section, Office of Community Health Hazard Assessment, ATSDR/CDC

Leann Bing
Region 4 Representative, Central Section, Office of Community Health Hazard Assessment, ATSDR/CDC

Michelle Zeager, DO, MPH, FAAP
Medical Officer, Exposure Investigation Section, Office of Community Health Hazard Assessment, ATSDR/CDC

10. References

American Cancer Society. 2025. Lifetime Risk of Developing or Dying from Cancer. Available at: https://www.cancer.org/cancer/risk-prevention/understanding-cancer-risk/lifetime-probability-of-developing-or-dying-from-cancer.html . Accessed April 14, 2025.

[ATSDR] Agency for Toxic Substances and Disease Registry. 2022a. Public Health Assessment Guidance Manual (PHAGM). Atlanta: US Department of Health and Human Services. Available at: https://www.atsdr.cdc.gov/pha-guidance/index.html. Accessed October 14, 2022.

[ATSDR] Agency for Toxic Substances and Disease Registry. 2022b. Toxicological Profile for Ethylene Oxide. Available at: https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=734&tid=133#:. Accessed October 14, 2022.

[ATSDR] Agency for Toxic Substances and Disease Registry. 2023a. Evaluation of Ethylene Oxide Concentrations in Outdoor Air Near Sterigenics, Willowbrook, DuPage County, Illinois. Available at: https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics-HC-Public-Comment-508.pdf . Accessed August 21, 2024.

[ATSDR] Agency for Toxic Substances and Disease Registry. 2023b. Public Health Assessment Site Tool (PHAST), v2.2.1.0. Available at: https://csams.cdc.gov/PHAST/Home/Index . Accessed August 18, 2023.

[ATSDR] Agency for Toxic Substances and Disease Registry. 2024. Evaluation of Ethylene Oxide Concentrations in Outdoor Air Near Medline Industries and Vantage Specialty Chemicals Lake County, Illinois. Available at: https://www.atsdr.cdc.gov/HAC/pha/EtO/Lake-Co-HC-508.pdf . Accessed August 21, 2024.

Carslaw, D. 2019. The Openair Manual. Available at: https://davidcarslaw.com/files/openairmanual.pdf . Accessed July 24, 2025.

[EPA] United States Environmental Protection Agency. 2016a. "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide." Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf . Accessed August 15, 2023.

[EPA] U.S. Environmental Protection Agency. 2016b. Definition and Procedure for the Determination of the Method Detection Limit Revision 2. https://www.epa.gov/sites/default/files/2016-12/documents/mdl-procedure_rev2_12-13-2016.pdf . Accessed July 24, 2025.

[EPA], United States Environmental Protection Agency. 2021b. EPA's Work to Understand Background Levels of Ethylene Oxide. Research Triangle Park, NC. April 11, 2023. https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/epas-work-understand-background-levels-ethylene-oxide Accessed August 15, 2023.

[EPA], United States Environmental Protection Agency Office of Air and Radiation. 2021c. "Technical Note: The Ethylene Oxide (EtO) Canister Effect." Available at: https://www.epa.gov/sites/default/files/2021-05/documents/technical-note-on-eto-canister-effect-052521.pdf . Accessed August 15, 2023.

[EPA], United States Environmental Protection Agency Office of Research and Development. 2021b. "Effect of Canister Type on Background Ethylene Oxide Concentrations." https://www.epa.gov/sites/default/files/2021-05/documents/ord-eto-canister-background-memo-05072021.pdf . Accessed August 15, 2023.

[GA EPD] Air Protection Branch, Georgia Environmental Protection Division. 2020. Memorandum: Modeling Analysis for Ethylene Oxide Sterigenics U.S., LLC, Atlanta, Cobb County, GA (Permit Application #27153). Available at: https://epd.georgia.gov/draft-sterigenics-air-quality-permit . Accessed October 12, 2022.

[GA EPD] Air Protection Branch, Georgia Environmental Protection Division. 2021. Sterigenics Air Quality Permit Narrative. Available at: https://epd.georgia.gov/ethylene-oxide-information. Accessed October 16, 2023.

[GA EPD] Air Protection Branch, Ambient Air Monitoring Program, Georgia Environmental Protection Division. 2023. Ethylene Oxide Monitoring Report, Data through October 2021. Available at: https://epd.georgia.gov/ethylene-oxide-information . Accessed July 24, 2025.

Goodman, B. Miller, A. 2019. 'Residents unaware of cancer-causing toxin in air'. Georgia Health News and WebMD. https://www.webmd.com/special-reports/ethylene-oxide/20190719/residents-unaware-of-cancer-causing-toxin-in-air . Accessed September 6, 2023.

Hornung, Richard W., Alice Greife, Leslie Thomas Stayner, Nelson Kyle Steenland, Robert F. Herrick, Larry J. Elliott, V. L. Ringenburg, and J. S. Morawetz. 1994. 'Statistical model for prediction of retrospective exposure to ethylene oxide in an occupational mortality study', American journal of industrial medicine, 25 6: 825-36.

[IEPA] Illinois Environmental Protection Agency. 2019. Cancer Incidence Assessment near Sterigenics in Willowbrook, Illinois, 1995–2015. https://dph.illinois.gov/content/dam/soi/en/web/idph/files/publications/sterigenicswillowbrookcancer-investigation-final-0.pdf . Accessed July 24, 2025.

McClenny WA, Holdren MW. 1999. 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). Washington, DC. https://www.epa.gov/sites/default/files/2019-11/documents/to-15r.pdf.

Mei EJ, Moore AC, Kaiser J. 2023. Suitability of new and existing ambient ethylene oxide measurement techniques for cancer inhalation risk assessment. Environmental Pollution. 336:122481. doi:https://doi.org/10.1016/j.envpol.2023.122481

Mikoczy, Z., H. Tinnerberg, J. Björk, and M. Albin. 2011. 'Cancer incidence and mortality in Swedish sterilant workers exposed to ethylene oxide: updated cohort study findings 1972-2006', Int J Environ Res Public Health, 8: 2009-19.

2004[NTP], National Toxicology Program. 2021. "Report on Carcinogens: 1998 Background Document for Ethylene Oxide." In, edited by Department of Health and Human Services. Research Triangle Park, NC: NTP.

Steenland, K., L. Stayner, and J. Deddens. 2004. 'Mortality Analyses in a Cohort of 18 235 Ethylene Oxide Exposed Workers: Follow up Extended from 1987 to 1998', Occupational and Environmental Medicine, 61: 2-7.

Steenland, K., E. Whelan, J. Deddens, L. Stayner, and E. Ward. 2003. 'Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States)', Cancer Causes Control, 14: 531-9.

Sterigenics. 2022. Sterigenics Atlanta Facility Leak Detection and Repair Program. Available at: https://epd.georgia.gov/sterigenics-orders-notices-and-response-letters . Accessed August 14, 2023.

United States Preventative Services Taskforce. Breast Cancer: Screening. 2024. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast- cancer-screening . Accessed July 24, 2025.

Yelverton, T., M. D. Hays, J. Rice. 2024. ‘Ethylene oxide: an air contaminant of concern’, ACS ES&T Air, 1(8): 747-754.

Appendices

Appendix A: Community Questions and Answers

Topic: Non-cancer health effects

Question: Does EtO have an impact on fertility or risk of stillbirth?

Answer: More research is needed to better understand the risk of exposure during pregnancy. There is limited research that looked at pregnant women who were exposed to high levels of EtO in the workplace, where levels of exposure are typically much higher than in a community setting. It showed that some women had miscarriages. Another study did not find this. With limitations in these studies, definitive conclusions regarding the associations between EtO exposure and pregnancy outcomes cannot be drawn.

There is some evidence from research studies that EtO exposure may adversely affect fertility in laboratory animals. Breathing EtO has been associated with decreased sperm count and other reproductive effects in males as well as fewer pups born for pregnant female rodents.

The workers and animals in these studies were exposed to much higher concentrations of EtO than what might be found in outdoor air near a sterilization facility. The concentrations of EtO measured in Cobb County are not at a level where noncancer health effects would be expected.

Question: My daughter and I both have breathing issues. We have lived in this home for decades, since before my daughter was born. I didn't have this issue before I move in, and it has gotten worse over time. I am worried that this might be caused by EtO in our area.

Answer: Breathing issues have been observed in studies of animals who breathe very high levels of EtO, tens of thousands of times higher than EtO concentrations measured in Cobb County. The concentrations of EtO measured in Cobb County are not expected to cause noncancer health effects and are not measurably different from EtO in other parts of Georgia. We have less information about EtO concentrations near Sterigenics in the past.

Question: I started having issues as soon as moving here. I had colds that took forever to go away, persistent cough and a reoccurring eye rash. In the summer of 2018 while going to the park or our local neighborhood pool, I'd get a headache within an hour or two of going outside. There was a leak at the plant in April of 2018. Within a week, I was at my eye doctor complaining about eye problems. I moved from the neighborhood and the inflammation around my eye had gone away. I'm not sure if my health issue was caused by that but it does seem telling that I moved and then it went away.

Answer: ATSDR is not able to determine if EtO could have contributed to health problems in the past because we don't have air measurements. The EtO concentrations measured now are not high enough to be a concern for noncancer health effects.

Topics: Cancer and cancer incidence studies

Questions: We used to live in a subdivision very close to Sterigenics for over 13 years. Recently my daughter was diagnosed with bladder cancer. She doesn't have any of the typical risk

factors. Is there a link between EtO exposure and cancer? I understand a cancer study in Willowbrook, Illinois found an elevation in bladder cancer near Sterigenics in Illinois.

Did studies done in Illinois show other causes of cancer?

Answer: ATSDR is sorry to hear about your daughter's cancer diagnosis. Breathing EtO for many years may cause cancer. EtO is classified as a carcinogen by the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC) and by the U.S. Environmental Protection Agency (EPA). As described in greater detail in section 6.3.2 "Cancer risk evaluation" there is some evidence in studies of workers exposed to much higher levels of EtO than found in communities for associations between EtO exposure and non-Hodgkin's lymphoma, myeloma, lymphocytic leukemia, and breast cancer. ATSDR is unaware of direct evidence that breathing EtO may cause bladder cancer specifically.

One study (Mikoczy 2011) of 2,171 males and females who worked at one of two sterilization facilities in Sweden did not find statistically significantly higher incidence of cancers of urinary organs (which includes bladder cancers) in workers exposed to EtO fifteen years after their exposure. The best information we have on EtO exposure and cancer comes from studies in workers; less is known about children or exposure at community levels.

The Illinois Department of Public Health (IDPH) Division of Epidemiologic Studies conducted a cancer incidence assessment to determine if there is elevated cancer incidence in the population surrounding the Sterigenics facility in Willowbrook, Illinois. This type of assessment is not intended to and cannot determine cause-and-effect relationship with site related contaminants but rather is a screening to identify unusual patterns. IDPH obtained cancer cases from the Illinois State Cancer Registry (ISCR) for diagnosis years 1995-2015. In the assessment, two study groups were identified: 1) study area 1 was comprised of cases in nine census tracts immediately surrounding the Sterigenics facility; 2) study area 2 was comprised of an area approximating the entire 60527 zip code. The population comprising study area 1 was included in study area 2. The IDPH cancer incidence assessment report was released on March 29, 2019 (IDPH 2019).

The conclusion of their report, IDPH Cancer Incidence Assessment near Sterigenics, Willowbrook, Illinois (1995-2015) states the following regarding the findings for bladder cancer and other cancer sites:

In conclusion, this cancer assessment examined a number of cancer sites that included cancers that have a recognized association with EtO (lymphohematopoietic and breast cancers), and other common cancer sites that have no such association with EtO, in both adult and pediatric [populations] surrounding the Sterigenics facility in Willowbrook, Illinois, over the years 1995 through 2015. For lymphohematopoietic and breast cancers the study found increases in Hodgkin lymphoma, and in recent years, non-Hodgkin lymphoma. Pediatric lymphoma was also elevated during the study period. For other common cancer sites, the study found increased cancer in prostate for males, and increased cancers of the pancreas, ovary, and bladder in females. However, many apparent differences and inconsistences existed between genders, across study areas, and among cancer sites. A number of limitations in methodology and data

also exist. Future studies with larger populations and preferably involving multiple EtO emissions sites are strongly recommended to confirm this assessment's findings. (IDPH 2019)

Question: When will a cancer incidence report be done?

Answer: The Georgia Department of Public Health is conducting a cancer incidence assessment using data from the Georgia Comprehensive Cancer Registry. Please direct questions about this assessment to: contactpublichealth@dph.ga.gov

Question: There haven't been many studies in communities. The University of Illinois Chicago's study showed people living near plants were absorbing EtO. How are you tracking the people who have cancer? Our neighborhood tends to be transient. You're not going to capture the people who moved away if you're just looking at zip codes. Several of us have been diagnosed with irritant asthma. My pulmonologist says it's caused by EtO. When Sterigenics had leaks, I was at urgent care having issues. Are you going to pull hospital records to conduct a study?

Answer: ATSDR does not have plans to conduct a study near the Sterigenics facility in Cobb County. The Georgia Department of Public Health is conducting a cancer incidence assessment using data from the Georgia Comprehensive Cancer Registry. Please direct questions about this assessment to: contactpublichealth@dph.ga.gov

Question: The Sterigenics facility under Sterigenics and previously under Griffin Microsystems has been operating since 1970 and we have data that they self-reported their emissions during that time. Is the ATSDR engaging in looking at that historic data to also consider the impacts within our community? I hear from people on a regular basis who have gotten cancer or who've lost folks with multiple myeloma cancers that we know are connected to long term ethylene oxide exposure.

Answer: The information we have about past EtO emissions is very limited. Figure 1 in this health consultation displays EtO emissions Sterigenics self-reported to the Toxic Release Inventory (TRI). These data indicate emissions may have been higher in the past. However, they do not give us information about EtO concentrations in the community and cannot be used to make conclusions about whether EtO from Sterigenics could have harmed people's health in the past. Cancers such as multiple myeloma have many risk factors. ATSDR cannot determine whether any one case of cancer was caused by past EtO exposure.

Topic: Locations near Sterigenics with special exposure scenarios

Question: Is ATSDR aware that there is a homeless shelter and daycares near Sterigenics?

Answer: We are aware of the homeless shelter and daycares near Sterigenics. In Appendix F, we calculate cancer risk specifically for any long-term residents of the shelter or children who attend the daycare.

The EtO concentrations measured at the nearest monitor to the shelter and the nearest daycare (S4) were similar to background concentrations measured elsewhere in the U.S. There was no evidence that Sterigenics influenced EtO concentrations at S4. The current risk of cancer from EtO for people who live at the shelter, attend daycare, or work at the daycare or other

facilities nearby is the same as the risk of cancer from breathing background EtO in other parts of the U.S.

Recommendation: I would recommend looking at Whittier Mill Park which is about 1.7 miles away from the plant. People work out there and kids that play out there. I think when they did that test initially that test had contamination which is why I think it should be looked at.

Answer: Based on ATSDR's analysis, there is no evidence that Sterigenics was contributing to EtO concentrations closest to the facility at Georgia EPD's air monitors (less than 1 mile). It is therefore unlikely that there are any long-term measurable effects from Sterigenics at Whittier Mill Park after the facility re-opened with new emissions controls in April of 2020. GHD conducted one week of sampling near Whittier Mill Park and in other locations while Sterigenics was operating. This shorter-term air sampling was used to evaluate that potential for health effects from breathing EtO for acute (less than two weeks) and intermediate (two weeks to less than one year) durations. GHD did find elevated concentrations at their Whittier Mill Park in June 2020, but the highest EtO concentration measured by GHD (52 µg/m^3) was flagged for isobutane interference, meaning isobutane was likely incorrectly measured as EtO and the measured result may have been higher than what was truly in the air. The highest valid EtO concentration measured was 7.1 µg/m^3. EtO concentrations below ATSDR's minimal risk levels (MRLs) do not pose a detectable risk of non-cancer health effects for the specified duration of exposure. These concentrations do not exceed ATSDR's acute MRL (720 µg/m^3) or intermediate MRL (130 µg/m^3).

Topic: Blood testing

Questions: Would you do a blood draw from members of the community to determine exposure levels?

I have lived near Sterigenics for decades. My son was born here. I had thyroid cancer. I hope that we can get the blood test for a study. Please consider the blood test. There's a doctor in Emory who is willing to help.

Answer: There are medical tests that can show if an individual has been exposed to EtO, but these tests won't predict if you will have health problems. ATSDR does not recommend using a blood test to determine if community members have been exposed to EtO.

EtO is a highly reactive chemical that can bind to proteins in cells and blood. The reaction and binding of EtO with hemoglobin protein in red blood cells forms what is referred to as hemoglobin adducts of EtO (HbEO). HbEO can be measured in a person's blood, and because red blood cells stay in circulation for about four months before the body naturally removes them, HbEO can be an indicator of total EtO exposure over the past several months. It is important to know that:

HbEO blood testing is not a routine test commonly available to the public and is not a feasible biomarker to assess the level of EtO exposure in community settings.

HbEO blood levels cannot determine the source of EtO exposure, how long a person was exposed, or if past, current, or future medical problems are associated with exposure.

Other factors besides EtO exposure from a facility that can influence the level of HbEO found in a person's blood include smoking habits and genetic differences that affect metabolism.

These factors limit the utility of this test for individuals who may be exposed in the community.

Topic: Other potential exposures

Question: Are you aware of accusations of Sterigenics dumping ethylene glycol into sewers in Illinois? Have you considered looking at the local water reclamation plant on the Chattahoochee River which backs up to Sterigenics?

Answer: Liquid ethylene glycol is a byproduct of the air emissions control system at Sterigenics. Ethylene glycol is captured in containers designed to store hazardous waste and then disposed. ATSDR is not aware of any reports or evidence that ethylene glycol was improperly handled, spilled, or released from Sterigenics in Cobb County.

Topic: Future air sampling

Question: Does ATSDR recommend fence line sampling at Sterigenics? We are concerned that data are reported to EPD by Sterigenics.

Answer: Based on our analysis of three years of air sampling from Georgia EPD, Sterigenics is not contributing measurable levels of EtO in the air. In 2020 Sterigenics installed a CEMS that measures the amount of EtO emitted from the stack in real time. This information is reported to Georgia EPD. The Georgia EPD conducts unannounced inspections to ensure fugitive emissions continue to be captured, the CEMS is in working order and Sterigenics is complying with the conditions of their permit.

Topic: Levels of concern

Question: Why is the level of EtO you are using so much higher than the 0.0036 µg/m^3 that was established by EPA IRIS?

Answer: ATSDR uses EPA's IUR to calculate theoretical cancer risks and to make health decisions. Based on EPA's IUR, ATSDR's screening level for EtO is 0.00021 µg/m^3. When EtO is above the screening level, we need to do further evaluation to determine if it is a health risk. More information about how we calculate that screening level is in Appendix E: ATSDR Screening Values, information about how ATSDR uses EPA's IUR to calculate cancer risks is in Appendix F, and our in-depth tox evaluation is in section 6.3.2 Cancer Risk Evaluation. Factors that affect the EtO concentrations that may be considered a health risk include how many years someone is exposed, how often (hours per day, days per week and weeks per year) that person is expected to breathe in EtO and whether the exposure occurs in childhood or as an adult.

Topic: Explosions

Question: What is being done about the risk of explosions at Sterigenics?

Answer: The Clean Air Act requires facilities that use hazardous substances such as EtO to develop a Risk Management Plan (RMP) that evaluates worst-case scenarios, details prevention measures, and outlines emergency response plans. RMPs must be submitted to EPA. In 2019,

Cobb County initiated an investigation of Sterigenics's compliance with applicable fire codes. After voluntarily closing in September of 2019, Sterigenics was required to remain closed through March of 2020 as a result of this investigation. As a condition of re-opening, Sterigenics agreed to install a 2-hour rated fire wall between the room containing the sterilization chambers and the remaining interior of the building and the facility replaced components of their sprinkler system. ATSDR recommends that regulators continue to monitor and work with Sterigenics to mitigate the risk of explosions in the future to the fullest extent possible.

Appendix B: Descriptive Statistics of EtO Air Sampling Data in Georgia Reviewed by ATSDR

ATSDR used Georgia EPD's air sampling near Sterigenics and at a background sampling location in South DeKalb, Georgia to calculate EPCs and lifetime excess cancer risk. Georgia EPD had an additional sampling location in General Coffee, Georgia. Table B1 below presents descriptive statistics of EPD's air sampling at South DeKalb and General Coffee background sampling locations and locations near Sterigenics (S1 through S7) when the facility was closed and after it re-opened. Both the original measured EtO concentrations and GAM-adjusted concentrations are presented. The GAM controls for holding time and canister lining types that make EtO formation in the canister more likely. GAM-adjusted EtO concentrations will tend to be lower than the measured values because the model is reducing the effect of positive sampling bias.

Table B1. Descriptive statistics of raw and adjusted ethylene oxide outdoor air concentrations collected by Georgia EPD when Sterigenics was closed (September 2019–April 2020) and after Sterigenics re-opened (April 2020–October 2022)

Air Sampling Location	Sterigenics Operating Status	Number of Samples	Raw Median EtO (µg/m³)	Raw Mean (90% CI) (µg/m³)	Adjusted Median EtO (µg/m³)	Adjusted Mean (90% CI) (µg/m³)
S1	Open	49	0.32	0.46 (0.37–0.57)	0.10	0.11 (0.09–0.12)
S2	Open	86	0.20	0.42 (0.31–0.57)	0.10	0.16 (0.11–0.22)
S3	Open	67	0.37	0.54 (0.44–0.64)	0.12	0.15 (0.13–0.17)
S4	Open	50	0.33	0.40 (0.33–0.48)	0.12	0.13 (0.11–0.15)
S5*	Open	0	NA	NA	NA	NA
S6§	Open	17	0.21	0.31 (0.21–0.44)	0.11	0.17 (0.11–0.21)
S7¶	Open	21	0.24	0.41 (0.27–0.57)	0.14	0.14 (0.12–0.16)
General Coffee (GC)	Open	59	0.14	0.31 (0.22–0.41)	0.08	0.13 (0.10–0.17)
South DeKalb (SD)	Open	222	0.17	0.29 (0.25–0.34)	0.11	0.14 (0.12–0.16)
S1	Closed	17	0.21	0.28 (0.21–0.39)	0.13	0.15 (0.12–0.19)
S2	Closed	18	0.25	0.30 (0.21–0.43)	0.13	0.13 (0.11–0.16)
S3	Closed	23	0.28	0.33 (0.26–0.41)	0.14	0.16 (0.13–0.20)
S4	Closed	24	0.34	0.39 (0.29–0.52)	0.15	0.21 (0.14–0.29)

Air Sampling Location	Sterigenics Operating Status	Number of Samples	Raw Median EtO (µg/m³)	Raw Mean (90% CI) (µg/m³)	Adjusted Median EtO (µg/m³)	Adjusted Mean (90% CI) (µg/m³)
S5*	Closed	1	NA	NA	NA	NA
S6§	Closed	0	NA	NA	NA	NA
S7¶	Closed	2	0.25	0.25	0.18	0.18
General Coffee (GC)	Closed	15	0.14	0.21 (0.14–0.32)	0.07	0.11 (0.08–0.13)
South DeKalb (SD)	Closed	34	0.23	0.27 (0.22–0.32)	0.11	0.13 (0.11–0.15)

*S5 was discontinued during the closure period due to a roof collapse in October 2019

§Data collection at S6 began in December 2019 and ended in December 2020

¶Sampling at S7 began in December 2019

Table B2 provides descriptive statistics for sampling conducted by GHD that took place over two non-consecutive weeks (about one week when Sterigenics was closed and about one week after it re-opened). EPD's data were more appropriate for estimating the long-term average concentration of EtO that someone might breathe in for many years because they were collected over a much longer time period and had many more samples per sampling location than GHD's data. GHD's data were considered suitable for assessing short (acute) and intermediate (medium) term exposures. About 30% of samples collected by GHD after Sterigenics re-opened were invalidated due to isobutane interference, meaning the gas isobutane was incorrectly measured as EtO, causing the reported concentration of EtO to be higher than the amount of EtO actually in the air.

Table B2. Descriptive Statistics of GHD air sampling conducted for five days in September 2019 when Sterigenics was closed and for nine days in July 2020 after Sterigenics re-opened

Air Sampling Location	Sampling Location Description	No* of Valid Samples [No Detected], Closed§	Mean of Valid, Detected, Closed (µg/m³)	No of Valid Samples [No Detected], Open*	No of Invalid Samples, Open†	Mean, Open (µg/m³)
Smyrna 1	Nickajack Park	5 [2]	0.8	7 [7]	2	1.4
Smyrna 2	N Cooper Lake Park	4 [2]	0.30	7 [7]	2	1.3
Smyrna 3	Fire Station # 3	5 [1]	0.17	6 [6]	3	1.2
Smyrna 4	City Hall – Outdoors	5 [0]	NA	6 [6]	3	1.5
Smyrna 5	Fire Station # 4 – Outdoors	4 [2]	0.2	8 [8]	1	2.1
Smyrna School 1	Teasley Elementary	5 [1]	0.35	6 [6]	3	1.2

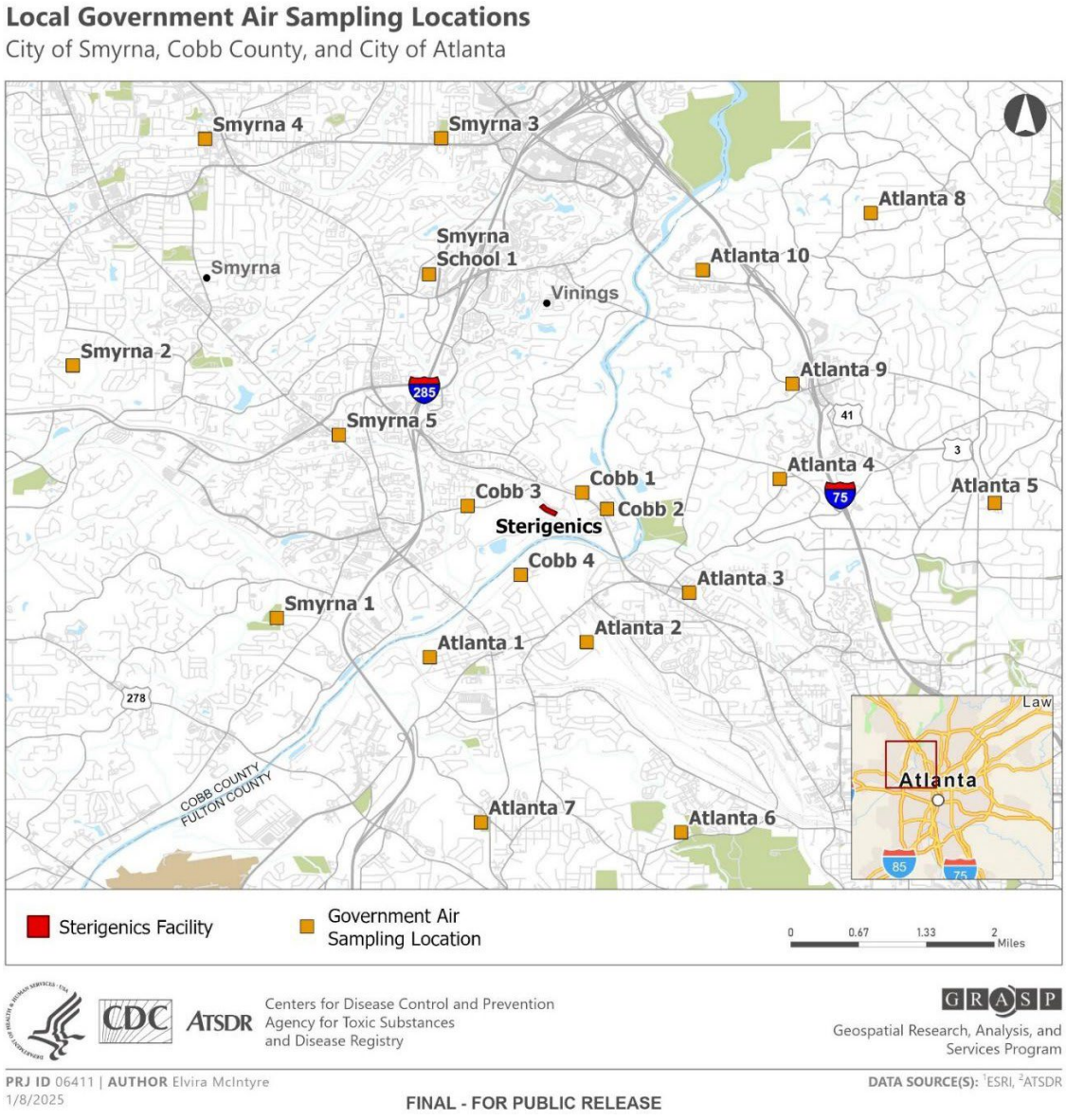
Air Sampling Location	Sampling Location Description	No* of Valid Samples [No Detected], Closed§	Mean of Valid, Detected, Closed (µg/m³)	No of Valid Samples [No Detected], Open*	No of Invalid Samples, Open†	Mean, Open (µg/m³)
Cobb 1	RL Sutton Property (North)	5 [2]	0.2	6 [6]	3	1.4
Cobb 2	RL Sutton Plant (East)	5 [2]	0.2	7 [7]	2	1.9
Cobb 3	Plant Atkinson Rd	5 [1]	0.33	6 [6]	3	2.0
Cobb 4	Argos Plant	5 [2]	4.0	5 [5]	4	2.4
Atlanta 1	Whitter Mills Park	5 [1]	0.4	1 [1]	8	7.1
Atlanta 2	Spink Collins Park	5 [1]	0.55	5 [5]	5	2.3
Atlanta 3	Coronet Way Park	5 [1]	0.21	6 [6]	4	2.7
Atlanta 4	Margaret Mitchell School	5 [0]	NA	8 [8]	1	1.8
Atlanta 5	Sutton Middle School	5 [0]	NA	8 [8]	1	1.4
Atlanta 6	Boyd Elementary	5 [0]	NA	5 [5]	4	2.2
Atlanta 7	A.D. Williams Park	5 [1]	0.78	7 [7]	2	1.8
Atlanta 8	Warren T. Jackson Elementary	5 [0]	NA	7 [7]	2	1.3
Atlanta 9	W Paces Ferry Rd.	5 [2]	1.9	7 [7]	2	1.9
Atlanta 10	North Atlanta High School	5 [1]	0.24	7 [7]	2	1.2

*No=number

§Duplicates were averaged and counted as one unique sample

†There were no invalid samples when the facility was closed

Figure B1. GHD outdoor air sampling locations where air sampling was conducted for five days in September 2019 when Sterigenics was closed and for nine days in July 2020 after Sterigenics re-opened



Appendix C: Statistical Tests and Plots Supporting Exposure Pathway Analysis with Adjusted Data

1. Ambient pressure canisters

ATSDR conducted a Mann-Whitney U test comparing EtO concentrations in canisters that reached ambient pressure before being collected to canisters that were still pressurized at collection. We could not reject the null hypothesis that there was no difference in concentrations between the ambient pressure canisters and canisters with remaining pressure ($p= 0.53$). Georgia EPD also presented their data with and without the ambient pressure canisters and observed no substantial differences between the two datasets. Based on this evidence, ATSDR concluded that it was unlikely the decision of whether or not to include the ambient canisters in the analysis would influence public health conclusions.

2. Comparing operating vs closed

ATSDR analyzed GAM-adjusted EtO concentrations to determine if there was a difference in EtO concentrations when the facility was closed (prior to April 8, 2020) compared to when it re-opened (on or after April 8, 2020). ATSDR performed a Kruskal-Wallis test, with an alternative hypothesis that adjusted EtO concentrations at locations near Sterigenics were greater when the facility was operating compared to when it was closed. None of the five locations with sufficient data to perform this statistical comparison had statistically significantly greater EtO concentrations during facility operations (Table C1).

Table C1. Statistical test results comparing adjusted EtO concentrations when Sterigenics was operating (April 8, 2020 through October 31, 2022) compared to when it was closed (September 6, 2019 through April 7, 2020)

Sampling Location	Test Statistic	p-value
South Dekalb	-0.90	0.813
S1	-2.05	0.980
S2	-1.55	0.939
S3	-1.23	0.890
S4	-1.62	0.947
S7	-0.55	0.707

3. Comparing near source to background

ATSDR used a nonparametric Dunn's test with a Benjamini-Hochberg (BH) correction for multiple comparisons and a one-sided alternative hypothesis (alternative="greater") to compare near site sampling to background sampling at South DeKalb. EtO concentrations were not significantly greater compared to background either when the facility was open (Table C2) or when it was closed (Table C3). General Coffee was not used for this comparison because unlike near source, General Coffee used exclusively pressurized canisters and was in a more rural location.

Table C2. Dunn's test results comparing GAM-adjusted EtO concentrations at sampling locations near Sterigenics (S1-S4 and S7) to background sampling at South DeKalb when Sterigenics was open (April 2020 through October 2022).

Sampling Location	Z value	p-value
S1	-1.71	0.96
S2	-1.31	0.96
S3	0.79	0.64
S4	0.08	0.70
S7	1.20	0.64

Table C3. Dunn's test results comparing GAM-adjusted EtO concentrations at sampling locations near Sterigenics (S1-S4 and S7) to background sampling at South DeKalb when Sterigenics was closed (September 2019 through April 2020).

Sampling Location	Z value	p-value
S1	0.76	0.28
S2	0.38	0.35
S3	1.02	0.26
S4	1.27	0.26
S7	1.06	0.26

4. Polar plots of EtO concentrations near Sterigenics

Polar plots visualize the relationship between EtO concentrations, wind speed on the day a given concentration is observed, and wind direction. EtO concentrations are visualized on a color thermometer scale with dark blue representing the lowest EtO concentrations and deep red the highest EtO concentrations. This scale is displayed at the bottom of Figures C1 and C2. The locations of observed EtO concentrations on the radial plot depend on the directions from which the wind was blowing and the wind speeds associated with each observation. The openair manual describes the basis of these plots in more detail (Carslaw 2019).

When facilities are emitting significant amounts of air pollutant, in most cases we would expect to see higher concentrations on days when the wind is blowing from the facility towards the monitor and the wind speed is higher. That would be represented on a polar plot by higher EtO concentrations (colors closer to the red end of the scale) facing in the direction of the facility.

Polar plots of EtO concentrations near Sterigenics based on Georgia EPD's air sampling data collected when the facility was open did not demonstrate clear evidence of facility contribution. There is no clear trend of higher EtO concentrations in the direction of the facility on the plots. The polar plots when the facility was open look about as random in terms of concentration, wind direction, and wind speed trends as the plots based on data measured when the facility was closed and the plots for background locations.

Figure C1. Polar plots of EtO concentrations measured near the Sterigenics facility in Cobb County Georgia by Georgia EPD after the facility re-opened (April 2020 through October 2022).

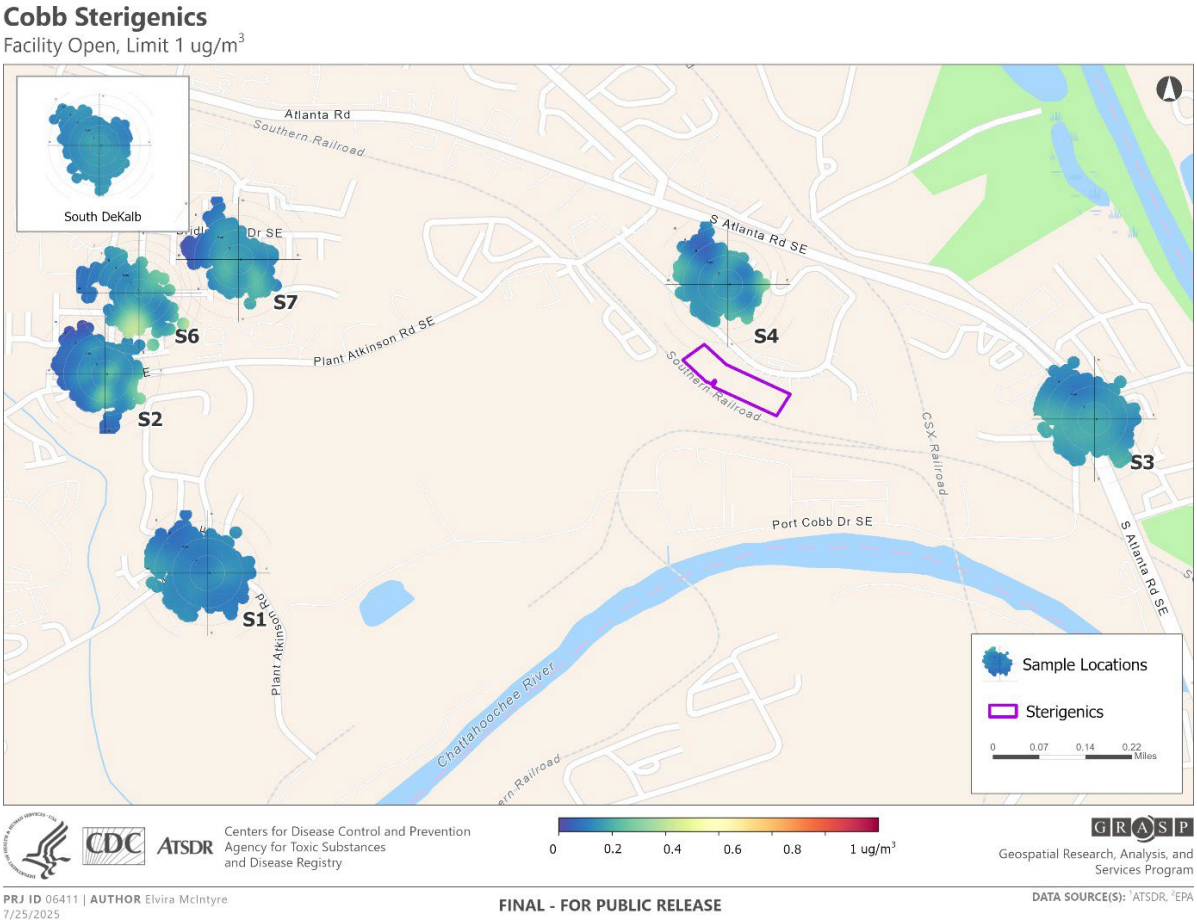
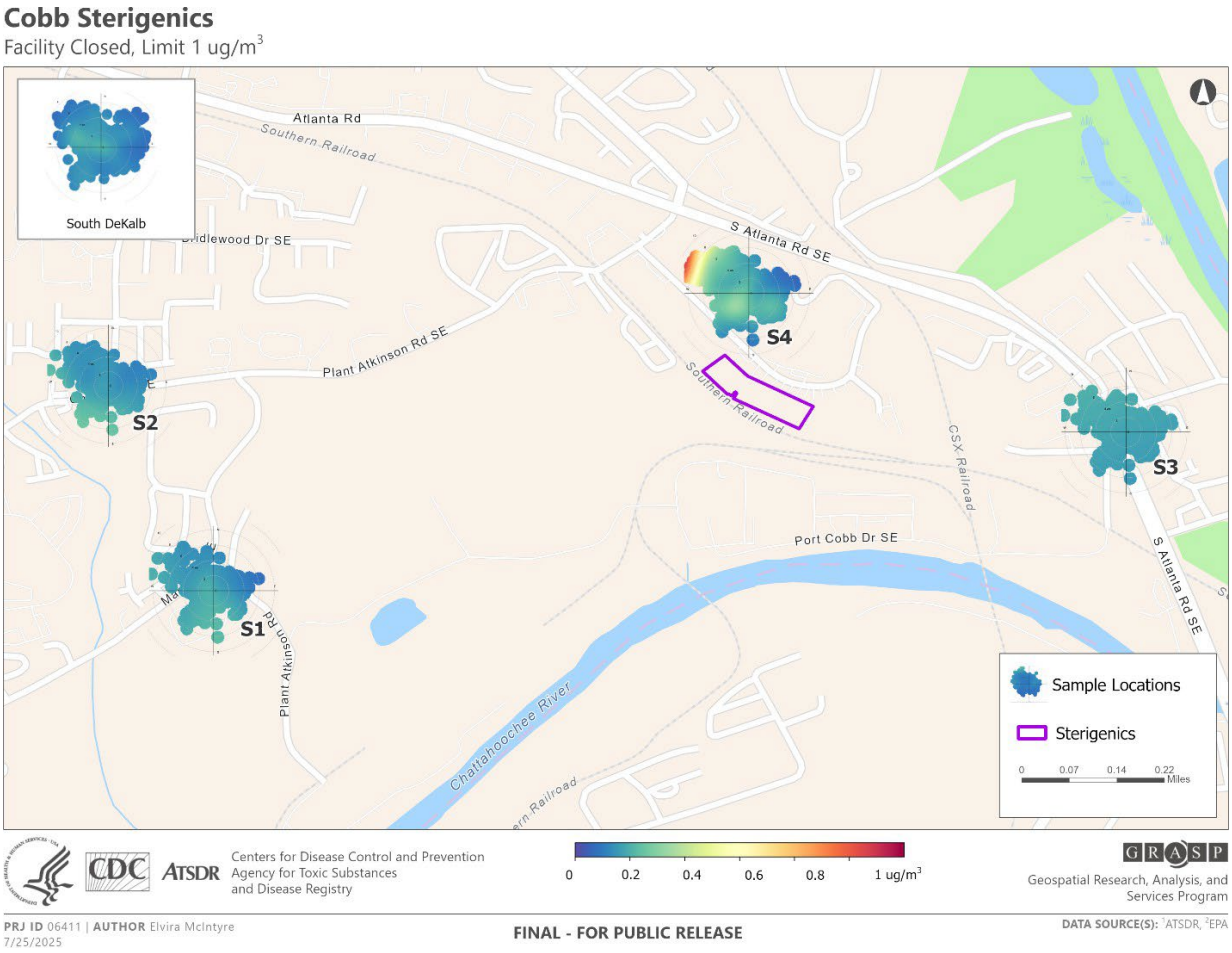


Figure C2. Polar plots of EtO concentrations measured near the Sterigenics facility in Cobb County Georgia by Georgia EPD when the facility was closed (September 2019 through April 2020).



Appendix D: Statistical Tests and Plots of Exposure Pathway Analysis with Raw (Unadjusted) Data

ATSDR used unadjusted EtO concentrations analyzed at the ERG laboratory (collected from September 2019 through October 2021) to repeat the analyses conducted above with adjusted data. We used only data analyzed by the ERG laboratory because after October 2021 the South DeKalb site used more pressurized canisters for EtO sampling. Without model adjustment, EtO concentrations measured in pressurized canisters may not be directly comparable to the passive canister sampling conducted at locations near Sterigenics.

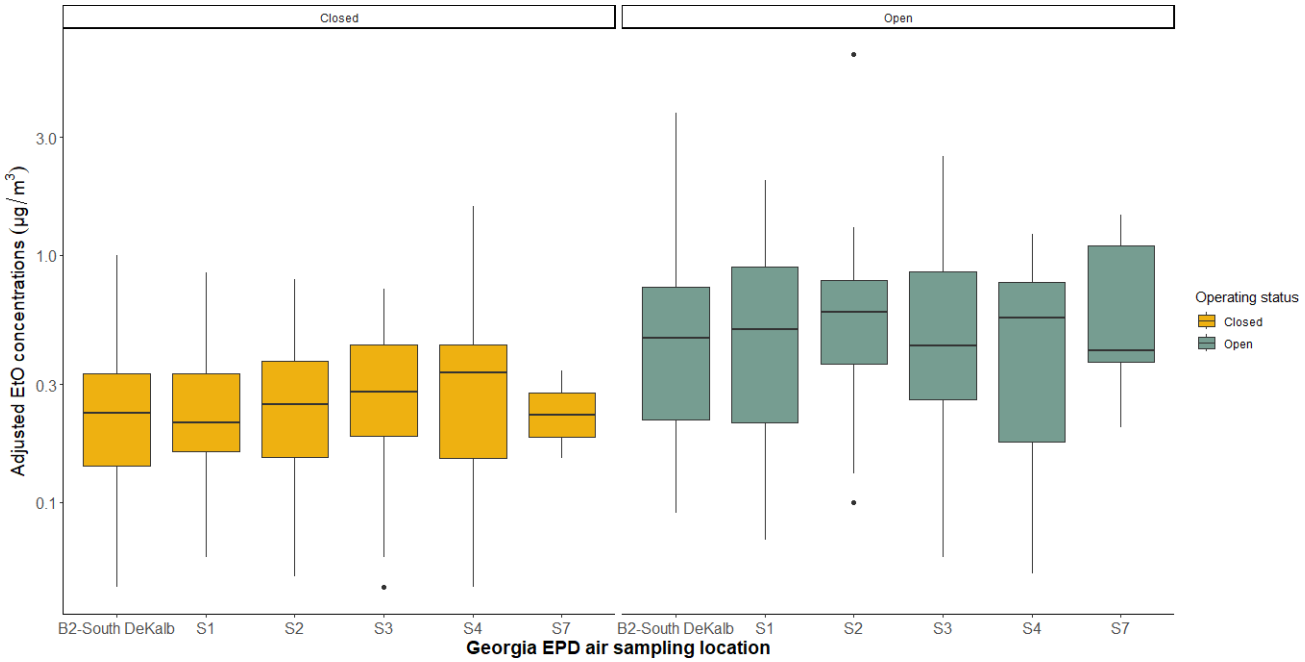
1. Comparing operating vs closed

ATSDR performed a Kruskal-Wallis test, with an alternative hypothesis that raw EtO concentrations at locations near Sterigenics were greater when the facility was operating compared to when it was closed. None of the five locations with sufficient data to perform this statistical comparison had statistically significantly greater EtO concentrations during facility operations (Table D1). The background South DeKalb location and the S3 location were slightly greater than the $p<0.05$ cut off for statistical significance (Table D1). Raw EtO concentrations were similar when the facility was closed compared to when it was open. Although raw EtO concentrations were visually slightly higher during the open period, this was likely due to the seasonal effect resulting in EtO concentrations during the closure period (which took place a few weeks before the beginning of fall in 2019 through a few weeks after the end of spring in 2020) being slightly lower in unadjusted data compared to the open period which included data spanning more than a year (Figure D1).

Table D1. Statistical test results comparing raw, unadjusted EtO concentrations when Sterigenics was operating (April 8, 2020 through September 30, 2021) compared to when it was closed (September 6, 2019 through April 7, 2020).

Sampling Location	Test Statistic	p-value
South Dekalb	1.62	0.05
S1	1.25	0.11
S2	1.16	0.12
S3	1.64	0.05
S4	0.24	0.41
S7	0.68	0.25

Figure D1. Boxplot of raw, unadjusted EtO concentrations measured when Sterigenics was closed (September 2019–April 2020) compared to raw, unadjusted EtO concentrations measured after Sterigenics re-opened (April 2020–September 2021).



See Appendix I: Explanation of a Boxplot for more information about boxplots

2. Comparing near source to background

ATSDR also analyzed GAM-adjusted EtO concentrations to determine if there was a difference in raw EtO concentrations measured when Sterigenics was operating (on or after April 2020) at near source locations (S1–S4 and S7) compared to a background sampling location in South DeKalb during the same time period. No statistically significant differences from background were observed either when the facility was operating (Table D2) or when it was closed (Table D3).

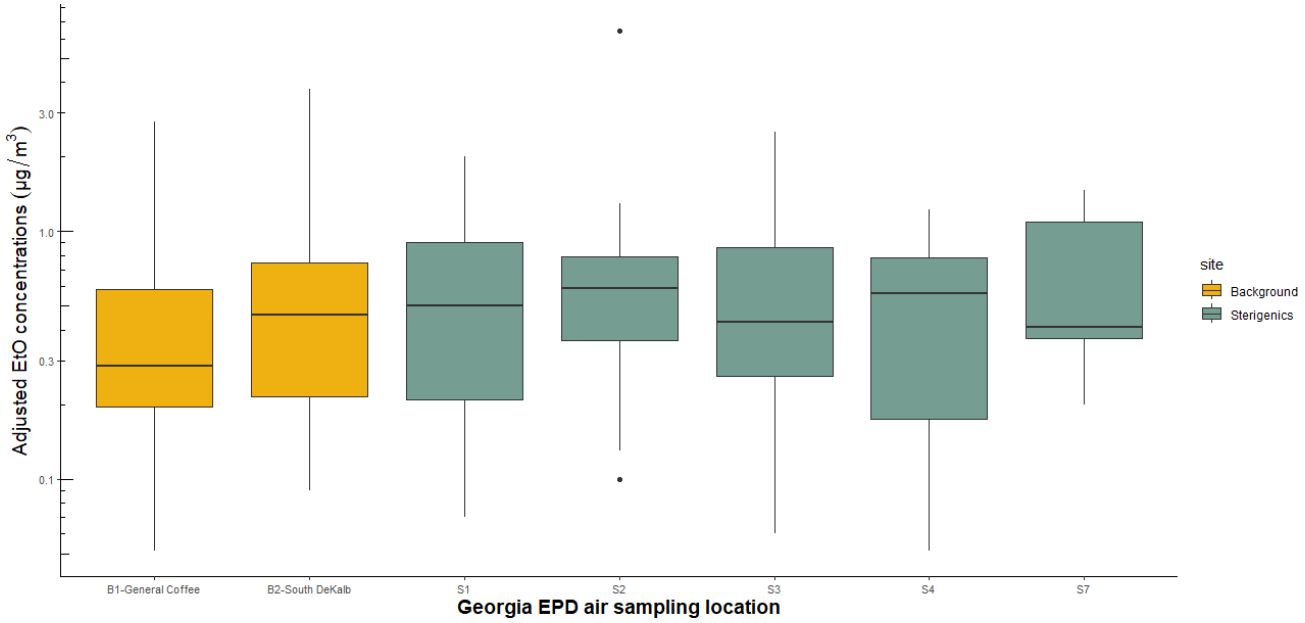
Table D2. Dunn's test results comparing raw, unadjusted EtO concentrations at Sterigenics to unadjusted concentrations at the South DeKalb background sampling location when Sterigenics was open (April 2020–September 2021).

Sampling Location	Z value	p-value
S1	-0.13	0.65
S2	-0.20	0.65
S3	1.31	0.48
S4	-0.38	0.65
S7	0.64	0.65

Table D3. Dunn's test results comparing raw, unadjusted EtO concentrations at Sterigenics to unadjusted concentrations at the South DeKalb background sampling location when Sterigenics was closed (September 2019 through April 2020).

Sampling Location	Z value	p-value
S1	-0.34	0.63
S2	-0.05	0.63
S3	0.74	0.57
S4	0.92	0.57
S7	-0.15	0.63

Figure D2. Boxplot of raw, unadjusted EtO concentrations at background locations and locations near Sterigenics after the facility re-opened (April 2020–September 2021)



See Appendix I: Explanation of a Boxplot for more information about boxplots

Appendix E: ATSDR Screening Values

ATSDR used comparison values to determine whether inhaling EtO over certain durations may pose a health hazard. When a contaminant is above a comparison value, a more in-depth analysis is needed to determine if it may pose a health risk.

For this analysis, we used three comparison values for inhaling EtO. There are two Environmental Media Evaluation Guide (EMEG) values for EtO. The EMEGs for EtO are estimated contaminant concentrations in air to which humans may inhale over specified time periods that are not expected to result in adverse non-cancer health effects. EMEGs are based on ATSDR "minimal risk levels" (MRLs). The EMEGs for EtO are for two different durations of exposure: acute duration, meaning inhaling EtO at a particular level for less than 2 weeks, and intermediate duration, meaning inhaling EtO for more than 2 weeks but less than 1 year.

To determine if further evaluation of cancer risk was needed, we compared measured levels of EtO with the Cancer Risk Evaluation Guideline (CREG). The CREG is the concentration of EtO in the air that would be expected to cause no more than 1 additional excess cancer case in 1 million persons exposed over a lifetime of exposure (78 years). ADAFs were applied to calculate the concentration that would result in 1 in 1 million lifetime, excess cancer risk. The application of ADAFs to calculate cancer risk is described in appendix F.

ATSDR's CREGs and EMEGs are listed in Table E1.

Table E1. ATSDR screening values

Screening Value Type	Exposure Duration	Concentration in Air (µg/m^3)
Environmental Media Evaluation Guide (EMEG)	Acute (>2 weeks)	720
Environmental Media Evaluation Guide (EMEG)	Intermediate (2 weeks – 1 year)	130
Cancer Risk Evaluation Guideline (CREG)	Chronic (greater than 1 year)	0.00021

Appendix F. Lifetime Excess Cancer Risk Calculations

ATSDR uses RME assumptions for residential and off-site worker scenarios outlined in our guidance when calculating lifetime excess cancer risk (ATSDR 2022a). These assumptions allow ATSDR to estimate lifetime excess cancer risk for the most exposed person living or working near each monitor. In addition to ATSDR's default assumptions for residents and off-site workers, Table F1 shows the assumptions for two custom exposure scenarios: a scenario for a nearby daycare, which offers daycare and private school through 2nd grade as well as after school programs through age 12, and a scenario for residents of the nearby homeless shelter. There was at least one adult at the shelter who had lived there long-term and who had the most potential for cancer risk based on breathing EtO. We calculated an adult's cancer risk based on 20 years exposure at monitor S4.

Table F1. Reasonable maximum exposure assumptions for different exposure scenarios in Cobb County, Georgia

Scenario	Years Exposed	Age Exposed	Hours/Day Exposed	Days/Week Exposed	Weeks/Year Exposed
Residential	33	0–21	24	7	52.14
Off-site Worker	20	Adults only	8	5	52.14
Daycare	12	0–12	depends on age*	5	depends on age*
Shelter-child	6	0–6	24	7	52.14
Shelter-adult	20	Adult	24	7	52.14

* birth to <1 year 11.8 hrs/day, 52.14 weeks/year based on daycare RME; age 1 to <2 10 hrs/day 52.12 weeks/year based on daycare RME; age 3<5 9.6 hrs/day 47 weeks/year based on pre-k scenario; age 5<6 9.6 hrs/day 47 weeks/year based on kindergarten scenario; age 6<8 9.0 hrs/day 47 weeks/year based on elementary scenario; age 8<12 3 hrs/day, 47 weeks/year, custom after school care scenario

ATSDR applies ADAFs to account for potential early life susceptibility to EtO exposure. ADAFs weight early life exposures as having more cancer risk than adult exposures. For example, ATSDR calculates an exposure that occurs between birth and two years of age as having ten times the cancer risk of two years of exposure as an adult. For the default residential scenario, ATSDR calculates a scenario where children are exposed for many years beginning at birth to inform our public health decisions as exposure from birth would result in the highest calculated cancer risk and therefore lead ATSDR to make health protective decisions. The ADAFs as they apply to each age group are shown in Table F2.

Table F2. Age-dependent adjustment factors used to calculate cancer risk

Age at Exposure	Age-Dependent Adjustment Factor (ADAF)
Birth–less than 2 years old	10
2–less than 16 years old	3
16–78 years old	1

Lifetime excess cancer risk for each age group (age group excess cancer risk) is calculated by multiplying EPA's IUR by the years of exposure for each age group (exposure duration or ED) divided by the number of years in a typical lifetime (lifetime years or LY, equivalent to 78 years) times the EPC (the appropriate EtO concentrations for the exposed population) in micrograms per cubic meter of air, times the appropriate ADAF for that age group (ATSDR 2023b).

The total excess cancer risk for an exposure scenario that spans multiple age groups is the sum of the cancer risk for each age group. Table F3 illustrates an example calculation of cancer risk based on an EPC calculated from Georgia EPD's air sampling data at sampling station S3.

Table F3. Example lifetime, excess cancer risks for a residential exposure scenario

Age at Exposure	EPC	IUR	ED ÷ LY	ADAF	Age group excess CR
Birth–less than 2 years old	0.174	0.003	2 ÷ 78	10	0.00013
2– less than 16 years old	0.174	0.003	14 ÷ 78	3	0.00028
16–33 years old	0.174	0.003	17 ÷ 78	1	0.00011
0-33 years old (total)	0.174	0.003	NA	NA	**0.00053**

EPC = exposure point concentration ($\mu g/m^3$) 95% upper confidence limit of concentrations at Georgia EPD's S3 station measured while Sterigenics was operating; IUR = inhalation unit risk ($(\mu g/m^3)^{-1}$); ED = exposure duration (years); LY = lifetime years (78 years); ADAF = age-dependent adjustment factor (unitless); CR = cancer risk (unitless)

Table F4 displays calculated lifetime, excess cancer risks from EtO concentrations measured by Georgia EPD while Sterigenics was closed and after Sterigenics re-opened. The excess cancer risks calculated from EtO concentrations while Sterigenics was closed represent what the estimated lifetime, excess cancer risk theoretically would have been for the same age, frequency, and duration of exposure as we assumed in the RME residential scenarios if people had only been exposed to background levels during that time period. These calculations are presented for comparison to cancer risk when the facility was open but do not represent an actual exposure. EPCs and calculated cancer risks were similar when Sterigenics was open compared to when it was closed (Table F4).

Table F4. Estimated lifetime, excess cancer risks under reasonable maximum exposure scenarios using EtO concentrations measured when Sterigenics was open (April 2020–May 2021) compared to cancer risks calculated using the same exposure assumptions using EtO concentrations measured when Sterigenics was closed (September 2019–March 2020)

Air Sampling Location	Exposure Scenario	EPC while Open	Lifetime CR (in 10,000) while Open	EPC while Closed	Lifetime CR (in 10,000) while Closed
S1	Residential	0.123	4	0.191	6
S2	Residential	0.216	7	0.162	5
S3	Residential	0.174	5	0.204	6
S4	Residential	0.145	4	0.286	9
S7	Residential	0.163	5	0.238	7
S4	Off-site Worker	0.145	0.3	0.286	0.5
S4	Daycare	0.145	0.7	0.286	1
S4	Shelter- child	0.145	2	0.286	4
S4	Shelter-adult	0.145	1	0.286	2

EPC = exposure point concentration (µg/m^3); CR = cancer risk (unitless)

Lifetime, Excess Cancer Risk Associated with Modeled EtO Concentrations

The modeled maximum EtO air concentration estimated near where people live based on air modeling Sterigenics conducted as part of the update to their air emissions permit was 0.005 µg/m^3. This value is a modeled estimate of the maximum Sterigenics contribution to EtO concentrations in nearby residential areas, which would be in addition to background EtO concentrations. The estimated lifetime theoretical cancer risk using ATSDR's RME assumptions for residents associated with that concentration would be 0.2 in 10,000.

Appendix G. Background Levels of EtO Throughout the U.S.

To evaluate outdoor EtO concentrations across the United States, ATSDR accessed data from EPA's AQS. AQS contains outdoor air pollution data collected by EPA, state, local, and tribal air pollution control agencies from thousands of monitors. AQS also contains meteorological data, descriptive information about each sampling location (including its geographic location and its operator), and data quality assurance/quality control information (EPA 2021b). EtO AQS data were initially sampled and analyzed using EPA's Method TO- 15 with gradual adoption of Method TO-15a beginning after its publication in September 2019. ATSDR evaluated the median, 95% confidence interval, and range of EtO concentrations detected across the United States at 46 air sampling stations in 16 states that have collected EtO air samples from October 2018 to March 2021 (Table G1). In general, there is a wide range of median EtO concentrations across sampling stations of 0.064-0.340 µg/m^3. The dataset has stations identified by EPA as Urban Air Toxics Strategy stations (UATS), National Air Toxics Trends Sites (NATTS), or State and Local Air Monitoring Stations (SLAMS) that are intended to inform national outdoor air quality for hazardous air pollutants in areas not believed directly impacted by industrial pollutants.

Note that the EtO concentrations reported to AQS are raw, measured values. The analysis of raw data without investigating the canister effect makes it difficult to determine whether detections of EtO are a product of the EtO canister effect (positive bias) or if EtO was actually ubiquitously present at low concentrations. Prior to the identification of this issue, different types of canisters (e.g., silicon-ceramic, SUMMA canister proprietary lining, and electropolished) were used for environmental sampling, almost always interchangeably.

Table G1. EtO detected across the United States (µg/m³) AQS[§] 2018–2021[±]

State (Station ID)	Number of Samples [Number detected]*	Median	Median 95% CI	Range
Arizona (04-013-4003)	60[49]	0.280	0.230 – 0.380	<0.108 – 0.826
Arizona (04-013-9997)	131 [107]	0.320	0.250 – 0.390	<0.108 – 1.420
Colorado (08-077-0018)	113[89]	0.230	0.180 – 0.300	< 0.108 – 1.375
Florida (12-103-0018)	59[56]	0.088	0.074 – 0.097	< 0.014 – 0.205
Florida (12-103-0026)	64[59]	0.086	0.072 – 0.100	< 0.108 – 0.256
Florida (12-057-3002)	96[89]	0.079	0.070 – 0.088	< 0.108 – 0.214
Georgia (13-089-0002)	61[58]	0.340	0.200 – 0.460	< 0.051 – 6.102
Georgia (13-069-0002)	9[5]	0.063	0.048 – 0.980	< 0.051 – 2.772
Illinois (17-031-3103)	129[92]	0.180	0.150 – 0.250	< 0.108 – 0.961
Illinois (17-031-4201)	148[103]	0.180	0.140 – 0.250	< 0.108 – 1.082
Kentucky (21-139-0004)	27[26]	0.290	0.200 – 0.340	< 0.108 – 0.828
Kentucky (21-157-0014)	30[26]	0.230	0.170 – 0.320	< 0.108 – 1.424
Kentucky (21-019-0017)	6[6]	0.230	0.085 – 0.660	0.0846 – 0.662
Kentucky (21-157-0018)	24[11]	0.120	0.076 – 0.180	< 0.108 – 0.367
Kentucky (21-157-0020)	20[7]	0.064[‡]	0.033 – 0.130	< 0.108 – 0.380
Kentucky (21-157-0021)	26[11]	0.095[†]	0.048 – 0.290	< 0.108 – 1.512
Kentucky (21-043-0500)	137[99]	0.180	0.140 – 0.220	< 0.108 – 0.864
Massachusetts (25-025-0042)	70[30]	0.081	0.069 – 0.094	< 0.090 – 0.740
Massachusetts (25-021-2004)	63[37]	0.099	0.071 – 0.120	< 0.090 – 0.824
Massachusetts (25-009-2006)	76[45]	0.094	0.082 – 0.100	< 0.090 – 0.216
Michigan (26-163-0015)	7[1]	NA	NA	< 0.108 – 0.232
Michigan (26-163-0033)	131[92]	0.170	0.140 – 0.200	< 0.108 – 1.051
Missouri (29-510-0085)	128[96]	0.200	0.170 – 0.230	< 0.108 – 0.923
New Jersey (34-007-0002)	103[82]	0.250	0.190 – 0.300	< 0.108 – 0.920
New Jersey (34-039-0004)	87[64]	0.250	0.180 – 0.300	< 0.108 – 0.706
New Jersey (34-023-0011)	107[80]	0.250	0.170 – 0.310	< 0.108 – 1.426
New Jersey (34-027-3001)	101[67]	0.200	0.150 – 0.280	< 0.108 – 0.841
New York (36-101-0003)[¶]	87[86]	0.160	0.140 – 0.170	< 0.054 – 0.402
New York (36-101-0003)[¶]	67[66]	0.140	0.120 – 0.150	< 0.054 – 0.319
New York (36-029-0005)	76[59]	0.096	0.081 – 0.110	< 0.054 – 0.411
New York (36-001-0013)	100[93]	0.110	0.098 – 0.130	< 0.054 – 0.744

State (Station ID)	Number of Samples [Number detected]*	Median	Median 95% CI	Range
New York (36-005-0110)	94[90]	0.110	0.100 – 0.120	< 0.054 – 0.303
New York (36-085-0111)	70[68]	0.110	0.100 – 0.130	< 0.054 – 1.526
New York (36-047-0118)	47[38]	0.095	0.078 – 0.120	< 0.054 – 0.629
New York (36-081-0124)	115[91]	0.080	0.069 – 0.093	< 0.054 – 0.253
New York (36-005-0133)	119[119]	0.120	0.110 – 0.130	0.066 – 0.219
New York (36-055-1007)	117[100]	0.110	0.098 – 0.120	< 0.054 – 0.397
New York (36-029-1014)	78[66]	0.100	0.090 – 0.120	< 0.054 – 1.000
New York (36-063-7001)	54[42]	0.089	0.075 – 0.110	< 0.054 – 0.183
Oklahoma (40-143-1127)	41[26]	0.280	0.210 – 0.400	< 0.108 – 0.787
Pennsylvania (42-003-0008)	13[6]	0.130†	0.073 – 0.420	< 0.108 – 0.578
Rhode Island (44-003-0002)	59[32]	0.092	0.062 – 0.100	< 0.090 – 0.569
Rhode Island (44-007-0022)	58[32]	0.072	0.064 – 0.090	< 0.090 – 0.450
Rhode Island (44-007-0026)	57[32]	0.099	0.085 – 0.100	< 0.090 – 0.1746
Rhode Island (44-007-1010)	60[25]	0.076	0.071 – 0.100	< 0.090 – 0.464
Utah (49-011-0004)	117[77]	0.180	0.140 – 0.230	< 0.108 – 1.386
Washington (53-067-0013)	47[32]	0.180	0.120 – 0.240	< 0.108 – 0.769
Washington (53-033-0080)	110[59]	0.110	0.090 – 0.130	< 0.108 – 0.679
Wisconsin (55-027-0001)	56[6]	0.068†	0.054 – 0.087	< 0.108 – 0.320
Wisconsin (55-079-0010)	14[1]	NA‡	NA	< 0.108 – 0.203

*Valid samples are samples not flagged as invalid in AQS; detected values are those reported above detection limits or alternate detection limits.

§ http://www.epa.gov/aqs

± Censored data were imputed using robust regression on order statistics.

¶ Note that NY station 0003 had noticeably higher EtO measurements than other NY stations. This station is at an atmospheric research facility, in a remote, high elevation forested area.

†Less than 50% of samples were above the detection limit

‡NA= Not applicable, too few detected sample results to calculate

Appendix H: Bayesian Generalized Additive Model (GAM)

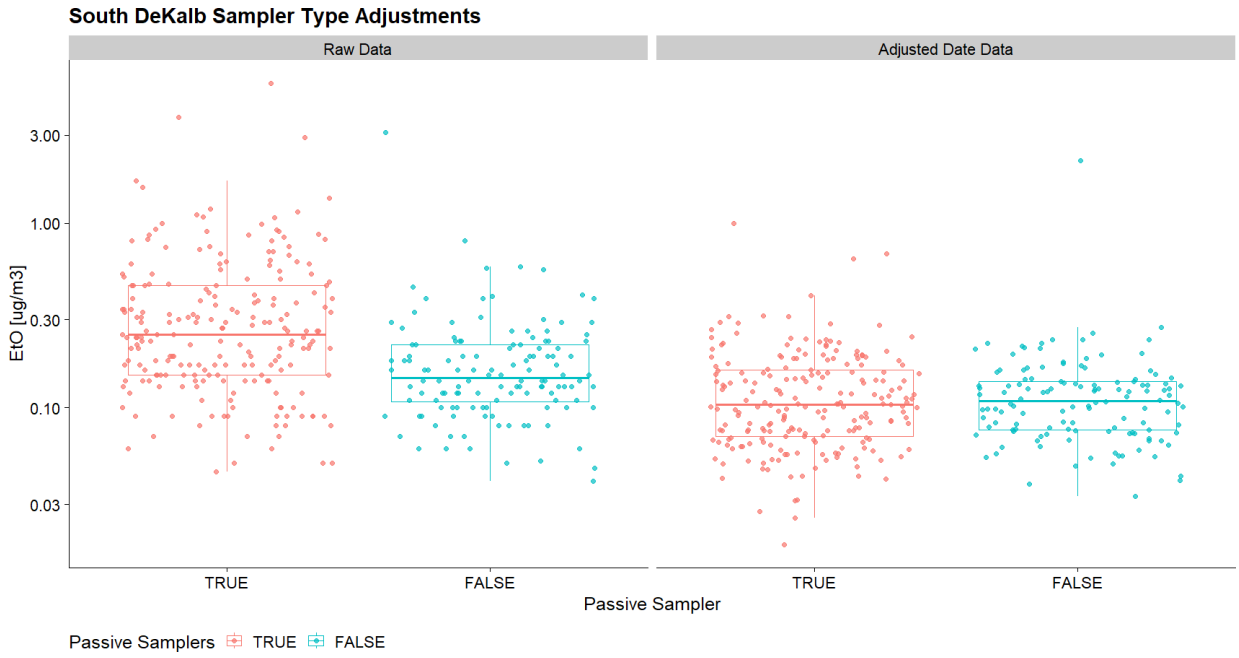
EPA has observed that in the presence of humid air, some cleaned air sampling canisters appear to form EtO through chemical reactions between humidified air and the type of inert surface lining of the canister (the canister lining). Samples collected and analyzed for EtO have one of three lining types (electropolished, proprietary SUMMA, or silicon-ceramic linings) which influence the growth of EtO from these chemical reactions. Ambient air can be collected into a canister either through the canister being under vacuum (passive) or through an electrical pump that pushes air into the canister (pressurized), which may influence canister EtO growth. The length of time between the sample collection and analysis (the holding time) is believed to facilitate more EtO growth in affected canisters because there is more time for EtO to react with the lining of the canister. This EtO growth and formation in affected canisters, called the EtO canister effect, results in positive sampling bias, which is measured concentrations of EtO that are higher than what is actually present in the air. Besides canister lining and holding time, EtO has been observed to fluctuate by season in canisters less affected by positive bias (higher in summer months).

In order to model the effects of canister lining, holding time, and seasonality, ATSDR examined EtO concentrations measured in canisters in South DeKalb, away from known sources. We did not use data collected at the General Coffee air monitor because General Coffee exclusively used pressurized canisters while sampling near Sterigenics was exclusively conducted using passive canisters. Additionally, General Coffee was more rural than Sterigenics. South DeKalb, which used a mix of pressurized and passive sampling and was located in a suburban location near Atlanta like Sterigenics served as a better basis for performing an adjustment.

Sampler type

ATSDR observed higher EtO concentrations in passive sampling conducted using canisters under vacuum compared to EtO concentrations collected in canisters using a pressurized sampling system (left side, Figure H1). ATSDR performed a statistical comparison of EtO concentrations collected at the same day in the same sampling location. We used a Paired Prentice Wilcoxon test for left censored data and found differences of medians to be significant ($p = 0.006$, difference of 0.09 ug/m3). An analysis of Georgia EPD's air sampling across multiple sites conducted by scientists affiliated with Georgia Tech also found that concentrations in pressurized canisters were lower (Mei et al. 2023). ATSDR controlled for sampler type (whether pressurized or passive sampling was used) in the GAM results with adjusted concentrations being similar regardless of sampler type (right side, Figure H1).

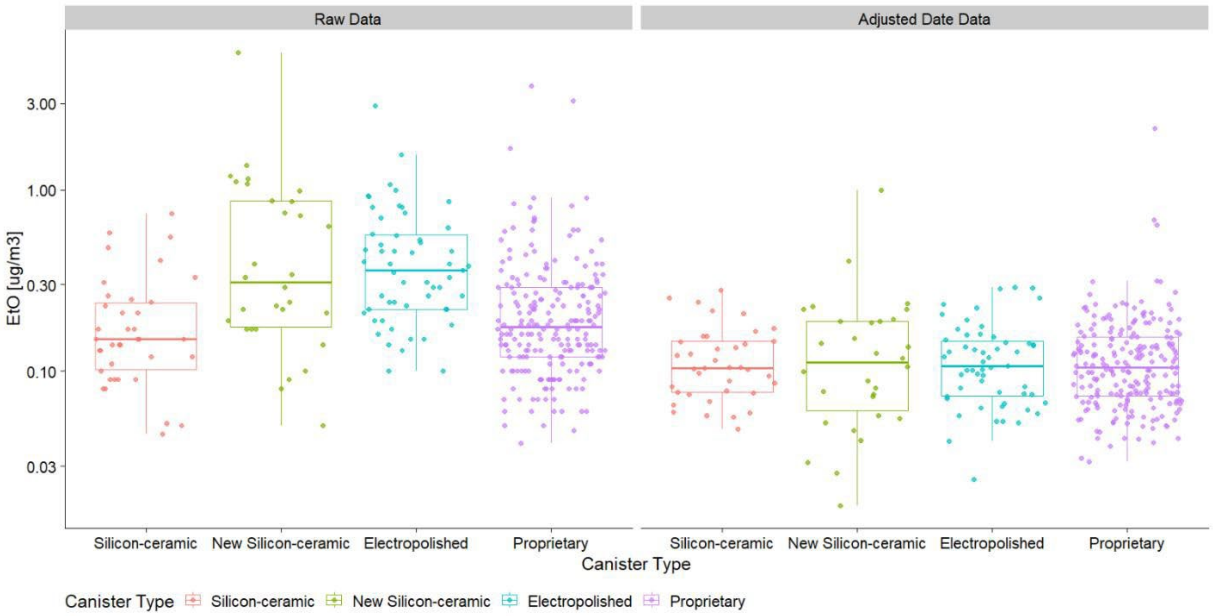
Figure H1. Unadjusted EtO concentrations (left) and adjusted EtO concentrations (right) by sampler type at the South DeKalb background sampling location September 2019 –October 2022



Canister lining

ATSDR observed higher unadjusted EtO concentrations in electropolished canisters than in canisters with a proprietary lining (Figure H2, left panel). The lowest EtO concentrations were measured in older silicon-ceramic canisters. Some newer series of silicon-ceramic canisters have EtO concentrations about as high as those measured in electropolished canisters. The GAM adjustment lowered EtO concentrations, on average, in electropolished, proprietary or newer silicon ceramic canister lining types so that they were more similar to EtO concentrations measured in older silicon ceramic canisters (Figure H2, right panel).

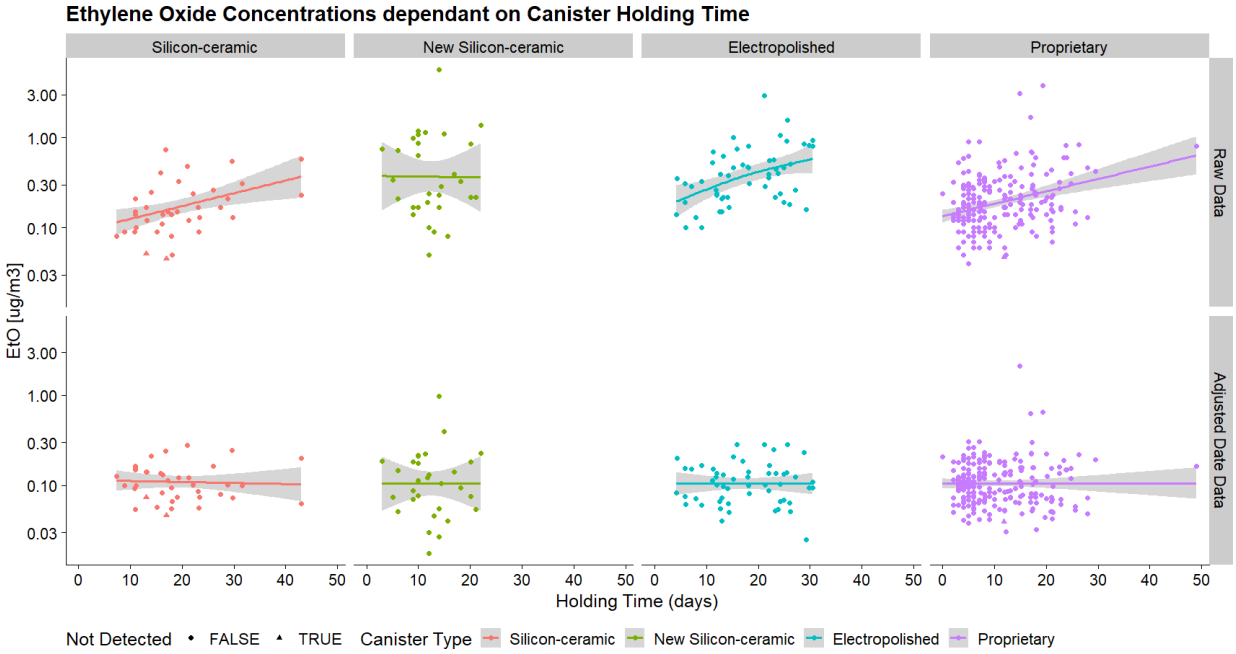
Figure H2. Boxplot of EtO concentrations by canister lining type at EPD's South DeKalb site September 2019–October 2022



Holding time

Unadjusted EtO concentrations tend to increase with longer holding times in all canister types, suggesting more EtO forms in canisters with greater wait times. The effect is most pronounced in electropolished canisters and least pronounced in silicon-ceramic canisters in EtO concentrations measured at South DeKalb (Figure H3, top panel). After GAM adjustment, there was no apparent relationship between canister holding time and EtO concentration (Figure H3, bottom panel).

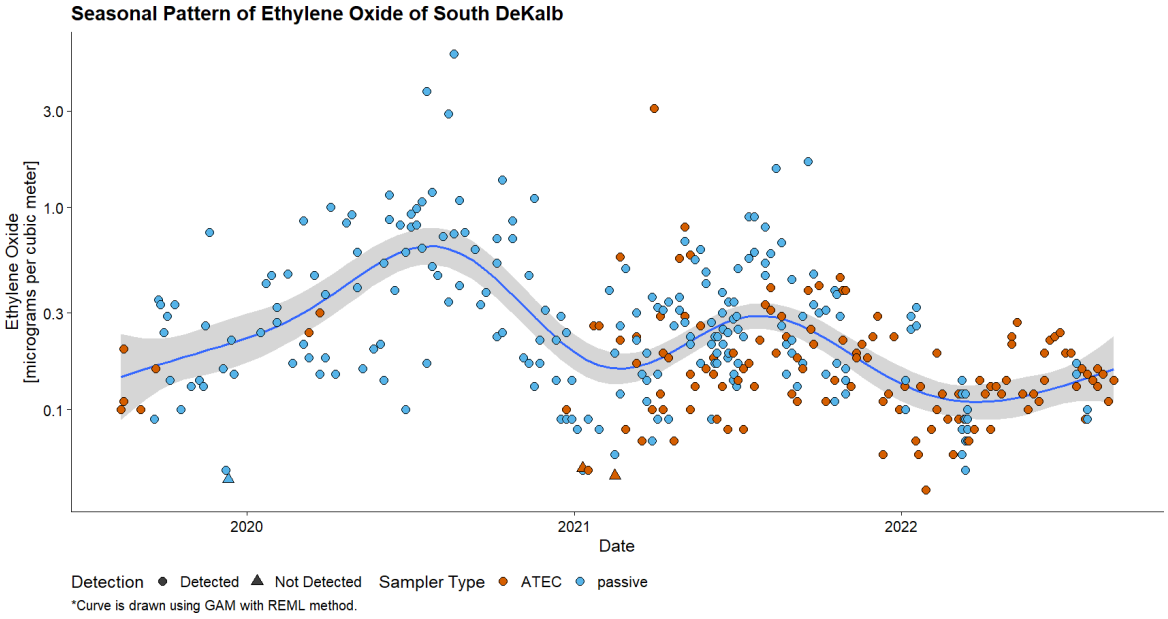
Figure H3. EtO concentrations at Georgia EPD's South Dekalb sampling location (September 2019–October 2022) by canister type and holding time



Seasonal pattern

EtO concentrations measured at South DeKalb tended to be higher in the summer and lower in the winter (Figure H4). This pattern was more pronounced from the fall of 2019 through the winter of late 2020 through early 2021 compared to later sampling.

Figure H4. Seasonal pattern in EtO concentrations at South DeKalb from September 2019–October 2022



Final model

ATSDR evaluated the optimal model of sampler type, holding time, canister lining type, lab, and seasonal effects in a stepwise fashion. Our final model (presented here) represents the optimal configuration of these variables that was generalizable to the data at Cobb County. The model had the highest Bayes factor of all models considered. The model is:

log(EtO) ~ sampler type + canister lining type + s(sample holding time, by=canister lining type) + s(decimal date) + error

Table H1. Bayesian GAM model: linear interaction of holding time by canister lining type and smoothed date (parametric coefficients) using South DeKalb air quality sampling location*

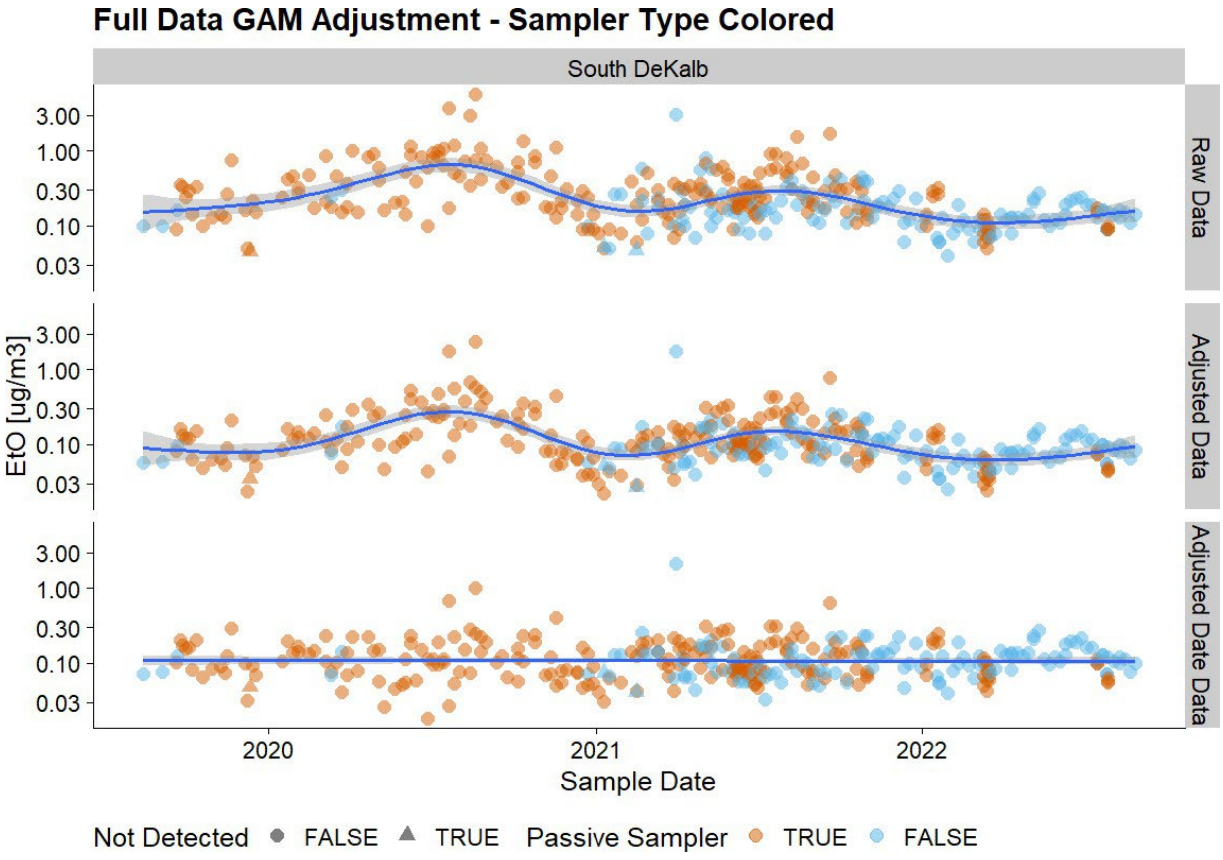
Coefficient	Median Estimate	95% Credible Interval	Probability of Direction	Rhat	Effective Sample Size
Intercept	-2.24	-2.55, -1.90	100%	1	3893
Electropolished lining	0.85	0.46, 1.22	100%	1	3914
Proprietary lining	0.55	0.20, 0.88	99.75%	1	3835
New Silicon Ceramic lining	0.72	0.29, 1.15	99.90%	1	3952
Passive Sampler	0.22	0.06, 0.39	99.75%	1	3413
Interaction of Lag: Silicon Ceramic lining	2.60	-6.98, 10.60	82.95%	1	4002
Interaction of Lag: Electropolished lining	-0.28	-19.26, 14.94	55.23%	1	3640
Interaction of Lag: Proprietary lining	2.58	-1.81, 8.67	88.83%	1	3993
Interaction of Lag: New Silicon Ceramic lining	3.88	-12.40, 21.11	77.88%	1	3914
Decimal Date	2.22	-8.34, 12.08	67.40%	1	3814
Smoothing of Lag: Silicon Ceramic lining	1.28	0.06, 4.17	NA	1	3837
Smoothing of Lag: Electropolished lining	2.44	0.17, 6.49	NA	1	3450
Smoothing of Lag: Proprietary lining	1.19	0.06, 3.61	NA	1	4087
Smoothing of Lag: New Silicon Ceramic lining	1.94	0.06, 6.49	NA	1	3981
Smoothing of Decimal Date	8.51	5.09, 13.99	NA	1	4089

* Model was built using South DeKalb background sampling from the Georgia Environmental Protection Division. Median estimate is median of Hamiltonian Monte Carlo (HMC) posterior. 95% Credible interval is the shortest interval that contains 95% of the posterior distribution and represents the uncertainty of the parameter estimate. Probability of Direction is an index which can range from 50% to 100% that measures the probability that an effect is in a particular direction. Rhat is a measure of convergence of the HMC chains and should be 1 or close to 1. Effective Sample Size is the number of independent samples with similar estimation power as the 8000 samples in HMC simulation.

Controlling for canister type and holding time limited positive bias in the dataset by predicting concentrations if they had been measured in older silicon-ceramic canisters with no time between sample collection and analysis to grow EtO. Adjusting for these two factors lowered EtO concentrations. Adjusting for sampler type made background EtO concentrations (which were collected using a mix of passive and pressurized methods) and near-site EtO concentrations more directly comparable. Adjusting for season made EtO concentrations collected at different times of the year more comparable to one another. Figure H5 illustrates the effect of model adjustment on South DeKalb background data. This model was applied to adjust concentrations measured near Sterigenics.

Adjusting for sampler type, canister lining type, and holding time lowers EtO concentrations, on average, which is illustrated by EtO concentrations in the center panel of Figure H5 being lower than the unadjusted concentrations on the top panel. Adjusting for decimal date removes seasonal and temporal patterns that make EtO concentrations less comparable over time. An apparent seasonal pattern, diminishing with time is present in unadjusted EtO concentrations (top panel, Figure H5) and EtO concentrations adjusted for everything else except decimal date (central panel, Figure H5, model log(EtO) ~ sampler type + canister lining type + s(sample holding time, by= canister lining type) + error). These changes over time are removed in the final adjusted model (bottom panel Figure H5, final model log(EtO) ~ sampler type + canister lining type+ s(sample holding time, by= canister lining type) + s(dec date) + error).

Figure H5. Time series of unadjusted (top panel), adjusted for everything except decimal date (middle panel), and fully adjusted (bottom panel) EtO concentrations at South DeKalb September 2019–October 2022

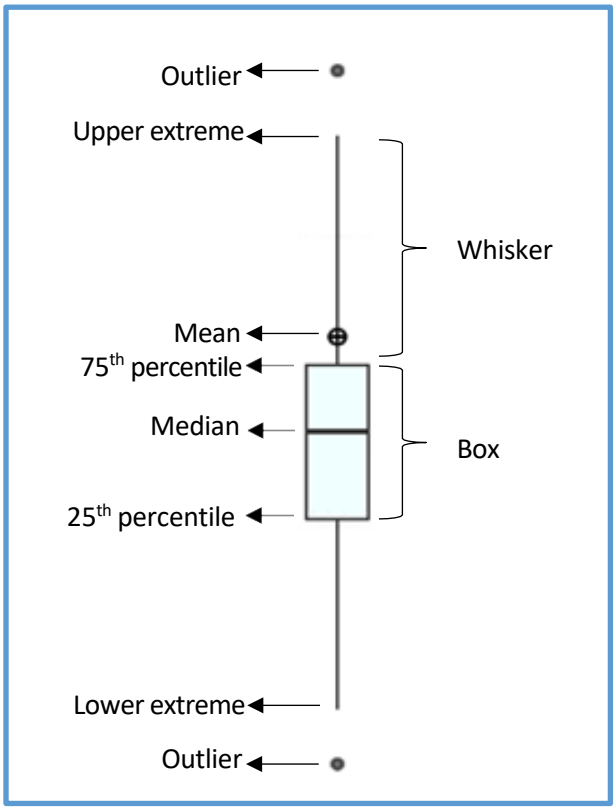


Appendix I: Explanation of a Boxplot

A boxplot is a chart that visualizes the distribution of a dataset. The components of a boxplot represent summary statistics of the dataset, as shown in Figure I1. The list below describes the statistic represented by each component of a boxplot:

- The **median** is the 50th percentile, meaning half the data is greater and half of the data is less than the median. It is represented by the line inside the box.
- The **box** is bounded by the **75th percentile** (value that is greater than three quarters of the data) at the top and **25th percentile** (value that is greater than one quarter of the data) at the bottom. The length of the box is equal to the **interquartile range (IQR)**, which is the difference of the 75th percentile minus the 25th percentile.
- The upper and lower **whisker** connect the box with the upper and lower extremes, respectively. The whisker is never longer than 1.5 times the IQR (or 1.5 times the length of the box).
- **Outliers** are values in the dataset that are either greater than the 75th percentile + 1.5 * IQR or less than the 25th percentile – 1.5 * IQR and are represented by dots above or below the upper or lower extreme.
- The value of the upper and lower **extremes** (the end of each whisker) depends on whether or not the dataset contains upper and lower outliers. If there are upper and lower outliers in the dataset, as in the example in Figure I1 then the upper extreme will be equal to the 75th percentile + 1.5*IQR and the lower extreme will be equal to the 25th percentile – 1.5* IQR. In a dataset with no outliers, the upper extreme would be equal to the maximum value and the lower extreme would be equal to the minimum value.
- The **mean,** represented in Figure I1 by a circle with a cross in the middle, is the average value of the dataset.

Figure I1. Components of a boxplot



Boxplots can help give an at-a-glance sense of several characteristics of the data. Representing boxplots from different datasets side by side can give a sense of whether observations taken at different times or in different places tended to be higher or lower than one another. They can display how much variation is in the dataset. Variation is a measure of how different observations in a dataset are from each other. More variable datasets will have longer boxes and whiskers. The boxplot can also give a sense of whether data is skewed. For example, a boxplot with a long upper whisker, a shorter lower whisker and a median towards the bottom of the box indicates a dataset that is positively skewed, meaning values less than the median tend to be closer together whereas higher values greater than the median are spread farther apart.