Letter Health Consultation

"Evaluation of Potential Health Impacts from Ethylene Oxide Emissions"

STERIGENICS INTERNATIONAL, INC.

WILLOWBROOK, ILLINOIS

AUGUST 21, 2018

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order 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; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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LETTER HEALTH CONSULTATION

"Evaluation of Potential Health Impacts from Ethylene Oxide Emissions"

STERIGENICS INTERNATIONAL, INC.

WILLOWBROOK, ILLINOIS

Prepared By:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Agency for Toxic Substances and Disease Registry, Region 5

Public Health Service
77 W. Jackson Blvd., Room 413
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July 26, 2018 *

Ed Nam
Director, Air and Radiation Division
United States Environmental Protection Agency, Region 5
77 W. Jackson Blvd., MS A-18J
Chicago, IL 60604

Dear Mr. Nam:

Since February 2018, ATSDR has met with U.S. EPA Region 5 Air and Radiation Division (ARD) staff regarding a change in the cancer risk basis for ethylene oxide (EtO) in the EPA Integrated Risk Information System (IRIS) and how that change affects general population risks estimated from EtO-emitting facilities in the draft 2014 National Air Toxics Assessment (NATA) update[1]. In December 2016, IRIS changed EtO's adult-based inhalation unit risk from 0.0001 per microgram per cubic meter ($\mu g/m^3$) to 0.003 per $\mu g/m^3$, a 30-fold increase in cancer potency. It also changed EtO's cancer weight-of-evidence descriptor from "probably carcinogenic to humans" to "carcinogenic to humans". These changes could result in many census tracts having estimated cancer risks that are greater than 1 in 10,000 from EtO exposure identified through the draft NATA modeling of air emissions across the United States.

Specifically, ARD decided to evaluate the implications of this change at two sites, Sterigenics International, Inc. (referred to in the letter as "*Sterigenics*") in Willowbrook, IL and the Elé Corporation in McCook, IL. This letter addresses EtO emissions from the Sterigenics facility. In June 2018, after the monitoring results were received and reviewed, ARD requested that ATSDR review air measurements of EtO and modeling results of EtO emissions from Sterigenics and specifically answer the question: *If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?*

The air modeling data that U.S. EPA provided to ATSDR estimated potential short-term and long-term concentrations of EtO in ambient air surrounding the Sterigenics Corporation. Follow-up air monitoring data confirm the presence of elevated EtO at concentrations within a similar range to those estimated by the air modeling of Sterigenics emissions. Based on these measured and modeled concentrations and the proximity to residences and other commercial structures, cancer risks higher than 1 in 10,000 people may exist for some community members and workers exposed to airborne EtO in this community. If these measured and estimated concentrations represent chronic exposures

* Minor edits to the reference list have been incorporated into the final posted ATSDR Letter Health Consultation.

[1] The 2014 NATA is expected to be publicly available in the fall of 2018.

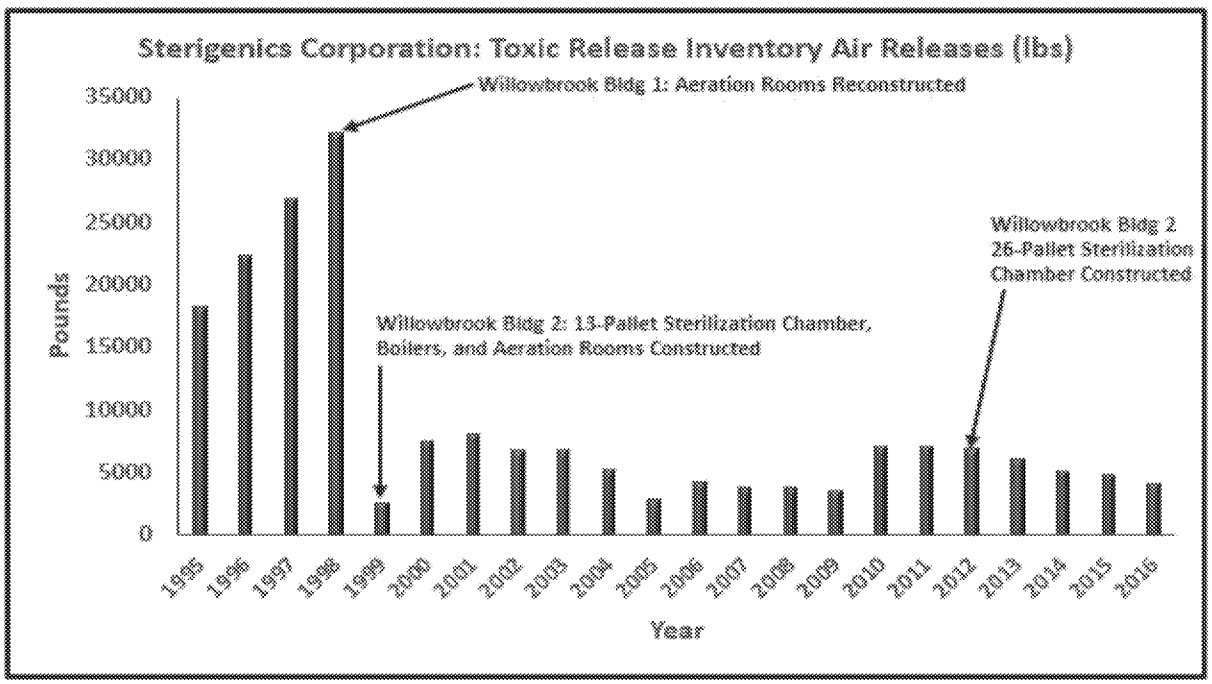
in the surrounding community (with higher exposures likely for workers of the facility), EtO emissions from the Sterigenics Corporation poses a public health hazard.

BACKGROUND

Sterigenics provides sterilization processes using gamma, ethylene oxide, Ebeam, and X-ray sterilization and operates 46 facilities in 13 countries (Sterigenics, 2018). The facility stores ethylene oxide that is sprayed into sealed chambers to sterilize medical equipment, pharmaceuticals, and food/spice products contained on 40" x 48" pallets. The sterilization chambers are contained in two buildings. Building 1 has fifteen chambers that can hold 1 to 13 pallets, while Building 2 has four sterilization chambers that can hold 13 to 26 pallets (Illinois EPA, 2017). Building 1 chambers were constructed in 1984, while Building 2 chambers were built in 1999 and 2012. Pollution control technology includes acid water scrubbers and dry bed reactors that convert the ethylene oxide to ethylene glycol after the sterilization process (Illinois EPA, 2015). Although back vents on the units have historically been uncontrolled, Sterigenics is currently in the process of installing pollution controls to control passive releases (ATSDR, 2018).

Figure 1 illustrates the total reported emissions in pounds per year (lbs/yr) of EtO from Sterigenics.

Figure 1. TRI Total Air Emissions Reported (in pounds), by Sterigenics Corporation for Ethylene Oxide, 1995-2016



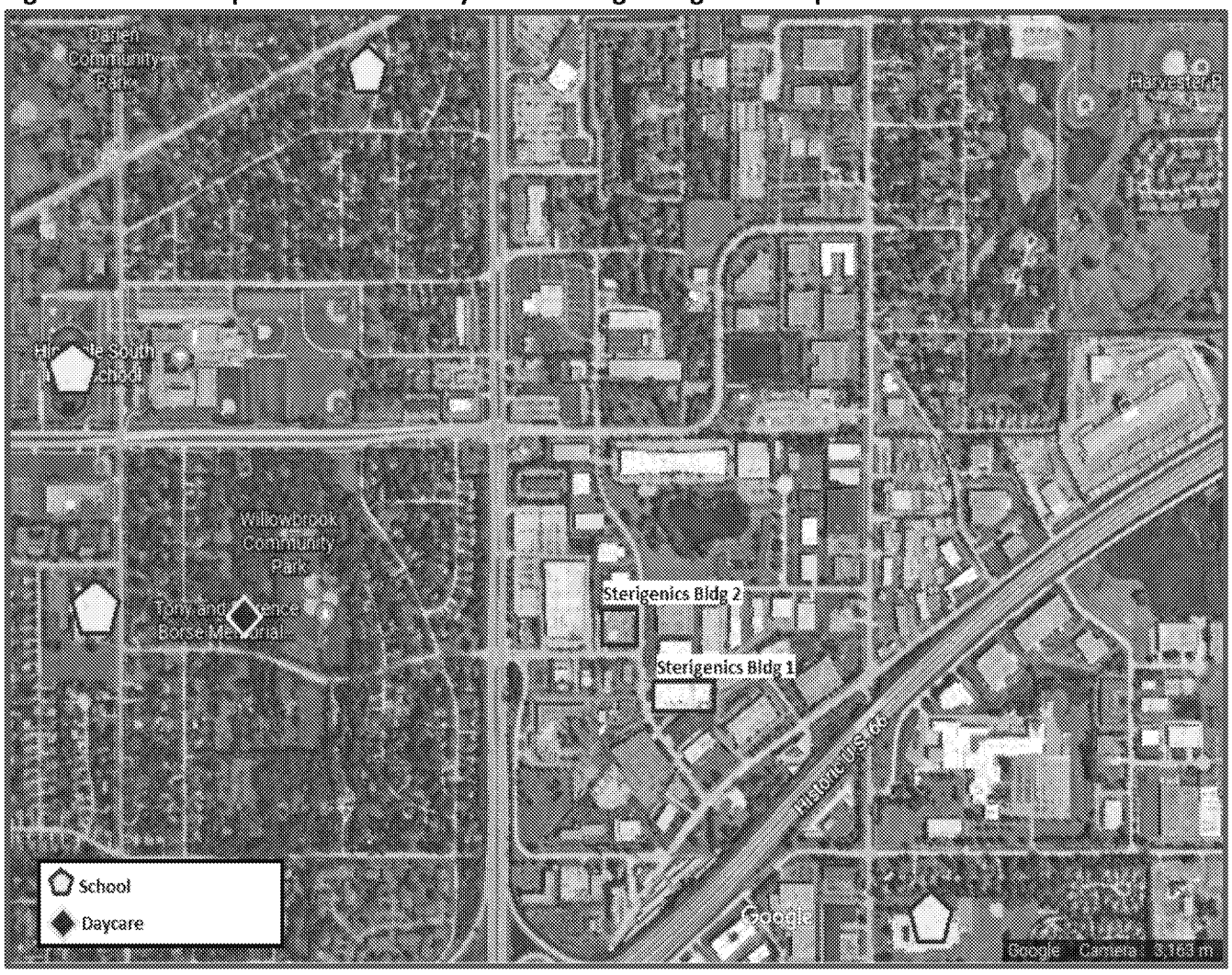
[a]*Source: Toxic Release Inventory (TRI): https://www.epa.gov/enviro/tri-overview*

[b]*Dates for facility constructed and upgrades were identified according to Illinois EPA (2017) DRAFT/PROPOSED Clean Air Act Permit Program (CAAPP) Permit*

The emissions data show a substantial reduction in total air releases after 1998. No data are available before 1995 on ambient air releases, but the available data suggests that substantially higher ambient releases prior to 1995 were likely. The Building 1 sterilization chambers were constructed in 1984, therefore EtO has been emitted over the past 34 years from the Willowbrook facility.

Willowbrook, Illinois is a small suburb of Chicago with approximately 8,500 residents (U.S. Census, 2016). The Willowbrook industrial complex where Sterigenics is located is in a densely populated metropolitan area, with 19,271 people living within 1 mile of the facility boundary. There are four schools and one daycare facility within 1 mile of the facility. According to 2016 Census estimates, Willowbrook residents are predominately white (73.3%), non-Hispanic (66.6%), educated (97.7% graduate high school, and 48.9% graduated with a bachelor's degree or higher), and middle class (median household income was over $67,000 per year). Approximately 18.5% of the population is identified as Asian, and 6.3% as black.

Figure 2. Aerial map of the community surrounding Sterigenics Corporation



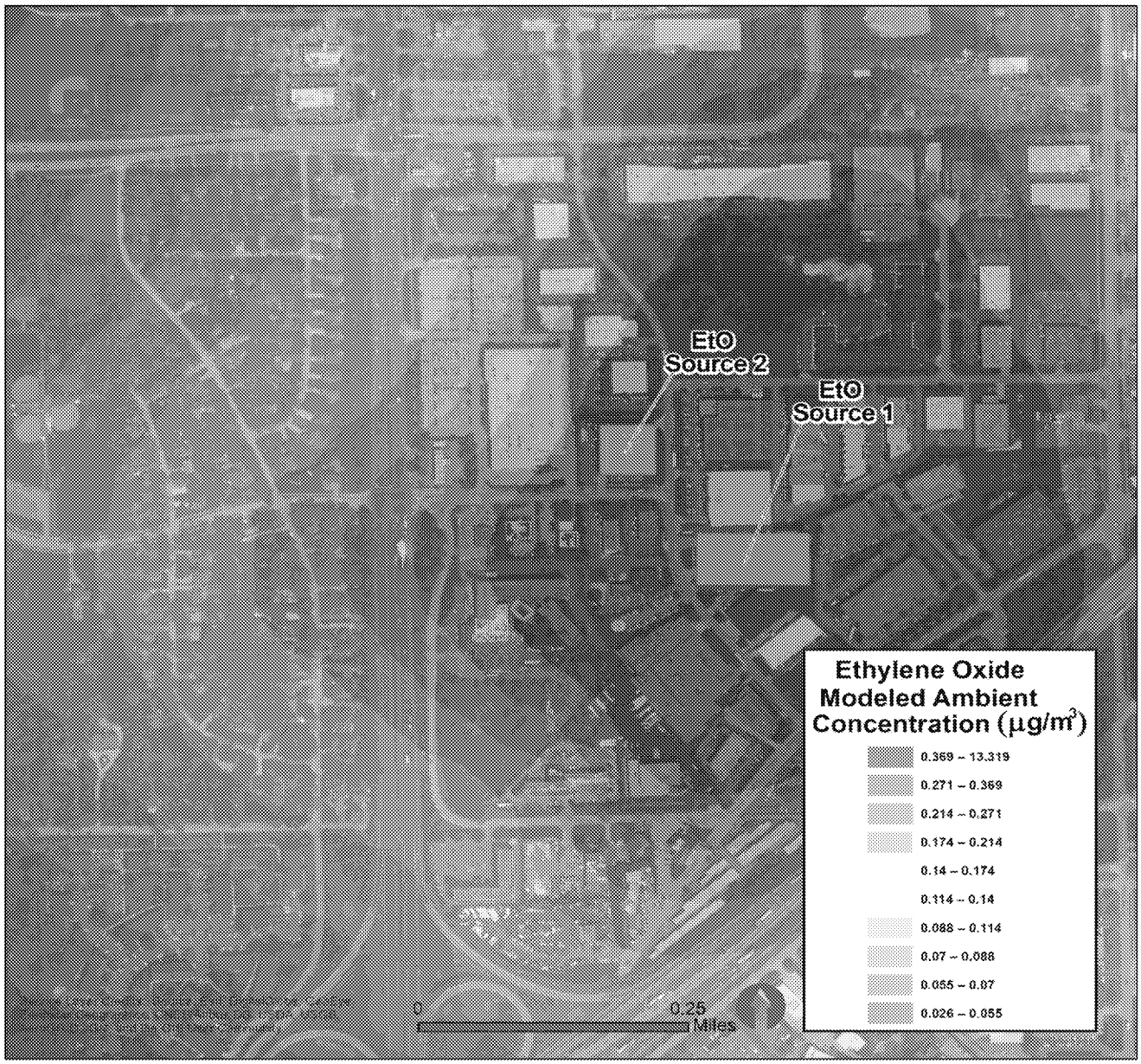
Source: Google Earth

ENVIRONMENTAL DATA

Air Modeling

U.S. EPA modeled short and long-term ambient EtO concentrations (AERMOD version 18081) to evaluate the potential impact of site emissions. These scenarios estimated a 5-year average to represent chronic exposures and maximum 1- and 8-hour averages to represent acute exposures at 882 community receptor points. An overlay of the modeling output is displayed in Figure 3, below. The statistical distributions of the modeled air concentrations are presented in Table 1.

Figure 3. AERMOD modeling output: 5-year average exposure estimates



Source: U.S. EPA Air and Radiation Division, Region 5
Note: Source 1 is Sterigenics Willowbrook Building 1, and Source 2 is Sterigenics Willowbrook Building 2

Table 1. Statistical distribution of EtO modeling*

Statistics	Modeled 1-hour ($\mu g/m^3$)	Modeled 8-hour ($\mu g/m^3$)	Modeled 5-year ($\mu g/m^3$)
Minimum	2.17	1.02	0.03
25th Percentile	4.62	2.26	0.09
50th Percentile	9.72	4.07	0.17
75th Percentile	18.88	7.29	0.31
90th Percentile	33.90	12.62	0.57
95th Percentile	45.22	18.83	0.91
99th Percentile	134.73	61.39	2.97
Maximum	249.77	123.89	13.32
Mean	15.75	6.72	0.32
Geometric Mean	10.13	4.41	0.18

N= 882 modeled receptors

Air Measurements

U.S. EPA collected 39 validated samples May 16th and May 17th, 2018. These samples were collected using SUMMA® canisters, and analyzed using U.S. EPA Compendium Method TO-15, Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air. A SUMMA® canister is an airtight, stainless-steel container with an inner surface that has been electro-polished and chemically deactivated. The laboratory is required to clean each canister and evacuate it to a high vacuum prior to shipping it to the sampling location. A canister can hold the vacuum for up to 30 days. The air being sampled is "drawn" into the canister by the high vacuum, thus eliminating the need for a pump. While opening the inlet orifice fills the canister in less than a minute, yielding an instantaneous "grab" sample, regulators can be added to the inlet orifice to draw the air into the canister over a designated period, ranging from 1 to 24-hours.

Of the 39 samples collected at 26 discrete locations (Figure 4), 18 were 12-hour samples, and 21 were grab samples (Table 2). Three of the 12-hour samples were collocated duplicates, and three of the grab samples were collocated duplicates. Grab samples generally had lower EtO concentrations than 12-hour averaged samples (U.S. EPA, 2018). However, all grab samples were collected between 10:20 am and 3:05 pm. ARD staff noted that higher EtO concentrations were measured overnight than during the day, and 12-hour samples were collected overnight in some locations. Since Sterigenics is a 24-hour operation, this may be due to calm meteorological conditions overnight with a higher potential for inversions. Given the elevated detections over a limited duration, additional long-term sampling is warranted to better characterize residential exposure to EtO.

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Table 2. Statistical distribution of residential and commercial EtO air sampling*

Statistics	Grab samples (µg/m^3)	12-hour samples (µg/m^3)
Min	0.16	0.34
25th Percentile	0.24	0.69
50th Percentile	0.45	1.56
75th Percentile	1.34	4.39
90th Percentile	2.28	8.26
95th Percentile	4.27	8.44
99th Percentile	4.33	8.96
Max	4.34	9.09
Mean	1.07	3.02
Geo Mean	0.62	1.74

N=21 grab samples, 18 12-hour samples

Figure 4. Ambient air samples near the Sterigenics facility, Willowbrook, IL

Source: U.S. EPA, Region 5

Figure 4, shows the location of discrete samples collected in the community. Given limited measured data presented in Table 2, ATSDR used the maximum 12-hour residential sample concentration and the maximum 12-hour commercial sample concentration to represent chronic upper bound residential (2.1 $\mu g/m^3$) and occupational (9.1 $\mu g/m^3$) exposures in the community. These concentrations represent maximums identified during a very temporally and spatially limited sampling campaign and actual average long-term exposures may be higher or lower.

HEALTH IMPLICATIONS

Overview for identifying contaminants of concern and evaluating risk

To evaluate EtO exposures near Sterigenics, ATSDR considered its own health-based comparison values as well as those published by other agencies. ATSDR uses comparison values for screening purposes to determine whether a pollutant should be evaluated further. A CV was identified for both an intermediate exposure duration (for non-cancer evaluation) as well as for a long-term (chronic) exposure duration (for which we considered both cancer and non-cancer health effects). In this evaluation, the air sampling results were compared to the ATSDR Cancer Risk Evaluation Guide (CREG) and environmental media evaluation guide (EMEG) and California EPA Reference Exposure Level (REL) for EtO.

- ***ATSDR CREGs*** are estimates of the concentrations of a carcinogen at which there is an elevated risk for one additional case of cancer in one million people exposed over a lifetime. ATSDR's CREG for EtO is calculated from the current U.S. EPA's adult-based inhalation unit risk value (0.003 $(\mu g/m^3)^{-1}$) and is based on U.S. EPA evaluations and assumptions about hypothetical cancer risks at low levels of exposure. ATSDR's CREG for EtO is 0.00021 $\mu g/m^3$.
- ***ATSDR inhalation minimal risk levels (MRL)/EMEGs*** are estimates of the concentrations of pollutants calculated that anyone could be exposed to where health effects are unlikely, based on chronic, intermediate, and acute exposures (those occurring longer than 365 days, between 14-365 days, and 14 days of exposure or less, respectively). For EtO, ATSDR only has an intermediate EMEG of 160 $\mu g/m^3$ (ATSDR, 1990).
- ***California RELs*** are concentrations that are unlikely to result in adverse non-cancer health effects. The chronic California REL for EtO is 30 $\mu g/m^3$ (California EPA, 2008).

All 5-year modeled and 12-hour measured averages exceeded the ATSDR CREG. Only maximum modeled concentrations exceeded intermediate or chronic non-cancer screening values. The following sections evaluate chronic non-cancer and cancer risks further.

Ethylene oxide properties

Ethylene oxide is a highly flammable gas that is highly reactive with nucleophilic substances such as water, alcohols, halides, amines, and sulfhydryl compounds. It is used as an intermediate in the production of ethylene glycol and surfactants as well as a fumigant for sterilizing foods and heat-sensitive medical equipment.

EtO is highly reactive, readily absorbed, and easily distributed in the human body. The absolute odor threshold has been reported in several studies to be about 470 milligrams per cubic meter (mg/m^3)

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(or 470,000 μg/m^3), with acute health effects possible in the range of the odor threshold (NRC, 2010). Chronic exposures can result somatic cell damage at much lower concentrations (California EPA, 2008). EtO is mutagenic and causes chromosome damage in many species, including humans. EtO exposure has widely been studied in scientific literature and its adverse health impacts are well understood. The carcinogenic effects of EtO have been documented in human and animal studies (U.S. EPA 2016).

Acute and intermediate exposure and health effects

Acute and intermediate effects have mostly been documented in hospital workers or in other occupational settings that include sterilizing chambers. Short-term exposure (minutes to weeks or months) above the odor threshold of 470 mg/m^3 (into the thousands of mg/m^3) include primarily neurological effects (headache, dizziness, nausea, lethargy, fatigue, muscle weakness, numbness, memory loss, incoordination, etc.), respiratory irritation (irritation of the nasal cavity, sinuses, coughing, shortness of breath, wheezing, and bronchial constriction and hyperreactivity), excessive thirst and dry mouth, and gastrointestinal effects (vomiting, diarrhea, stomach spasms, etc.). Some studies reported skin rashes with short-term exposures (NRC, 2010).

All studies with documented health effects summarized above had substantially higher EtO concentrations than what was observed in measured and modeled data in this assessment. ATSDR does not have an acute health-based comparison value but does have an intermediate-duration health-based comparison value of 160 μg/m^3. No measured data and only the maximum 1-hour modeled concentration of EtO exceeded this value and modeled and measured concentrations of EtO in this investigation were well below the odor threshold. Thus, it is unlikely that the non-cancer health effects noted above would occur in the general or off-site worker populations.

Chronic exposure and health effects

Cancer effects

The U.S. EPA IRIS released an "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" in December 2016. This evaluation summarizes the evidence that EtO is "carcinogenic to humans" through a mutagenic mode of action (MOA) and derives an inhalation unit risk value for EtO (U.S. EPA, 2016). Many studies have identified the genotoxic potential and mutagenic mode of action of EtO exposure via inhalation. There is clear evidence from multiple studies that EtO causes chromosomal aberrations, sister chromatic exchanges, and micronuclei in peripheral blood lymphocytes and bone marrow cells. Chromosomal aberrations and micronucleus frequency have been linked to increased risk of cancer in a number of large human studies (Jinot et al., 2017). Mice and rats exposed to EtO demonstrate cancers of the lymphohematopoietic system (cells involved in the production of lymphocytes and cells of blood, bone marrow, spleen, lymph nodes, and thymus), brain, lung, connective tissue, uterus, and mammary gland.

In humans, an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers in the EtO manufacturing and in sterilizing facilities (U.S. EPA, 2016). U.S. EPA identified six studies evaluating breast cancer in women, with the largest being a study from the National Institute of Occupational Safety and Health (NIOSH) of over 18,000 workers (45% male, 55% female) in 14 commercial sterilization plants. The NIOSH study reported statistically significant

exposure-response relationships for breast cancer incidence and mortality (Steenland et al., 2003 and Steenland et al., 2004). From assessing these studies, U.S. EPA (2016) determined that there is sufficient evidence of a causal relationship between EtO exposure and breast cancer in women.

U.S. EPA used the cancer incidence data from the NIOSH study, using individual exposure estimates for 17,530 workers from 13 plants, to calculate an inhalation unit risk value. A linear low-dose extrapolation of the lowest effective concentration (LEC; defined here as the lower 95% confidence limit on the EC_{01}, the estimated effective concentration associated with 1% extra risk) for lymphoid cancer was calculated as 2.9×10^{-3} per $\mu g/m^3$. Using the same approach, the lifetime unit risk for breast cancer was calculated as 8.1×10^{-4} per $\mu g/m^3$. Combining the risk for lymphoid and breast cancers in females U.S. EPA adopted an inhalation unit risk of 2.99×10^{-3} per $\mu g/m^3$ (rounded to 3.0×10^{-3} per $\mu g/m^3$). These adult-exposure only unit risk estimates were then rescaled to a lifetime, using age-dependent adjustment factors (ADAF). ADAFs are used to incorporate the greater risk of early life exposure to chemicals that have a mutagenic MOA. When applying the ADAFs, EPA calculated an inhalation unit risk value over a 70-year lifetime of 5.0×10^{-3} per $\mu g/m^3$ (U.S. EPA, 2016). Cancer risk from measured and modeled EtO concentrations are estimated by multiplying the IUR by the EtO concentrations.

U.S. EPA Cancer Risk Estimates Reviewed by ATSDR

U.S. EPA Region 5 air modelers estimated cancer risk assuming a 70-year lifetime from measured and modeled data. Based on modeled EtO concentrations at over 882 specific locations around the Sterigenics facility, U.S. EPA used the 5-year average EtO concentrations to calculate lifetime cancer risks between 1.3×10^{-4} to 6.7×10^{-2}, with a geometric mean risk of 9.1×10^{-4}. Even though cancer risks are not generally calculated for short term exposures, the estimated cancer risks associated with the *measured* EtO air concentration (19 samples collected for 12 hours each) were similar (range: 7.9×10^{-4} to 4.5×10^{-2}, geometric mean: 7.7×10^{-3}; Table 3). Note that these cancer risks were calculated using the lifetime ADAF-adjusted IUR of 5.0×10^{-3} per $\mu g/m^3$.

Table 3. Range of measured and modeled EtO concentrations: U.S. EPA Cancer Risk Estimates

Statistics	Modeled 5-year ($\mu g/m^3$)	Modeled cancer risk range	12-hour samples ($\mu g/m^3$)	Measured cancer risk range*
Minimum	0.03	1.3E-04	0.16	7.9E-04
Maximum	13.32	6.7E-02	4.34	4.5E-02
Mean	0.32	1.6E-03	1.04	1.4E-02
Geometric Mean	0.18	9.1E-04	0.61	7.7E-03

**Cancer risk was calculated to estimate what long term exposures to the 12-hour concentration could look like if sustained long term and does not represent actual exposures.*

Cancer Risk Estimates Calculated by ATSDR

For ATSDR assessments, the reasonable maximum exposure (RME) scenario for residential exposure duration is 33 years over a lifetime of 78 years, so ATSDR calculated an IUR based on 33-year residential exposure using ADAFs. As mentioned previously, ATSDR's RME exposure point concentration (EPC) of 2.1 $\mu g/m^3$ was used as a reasonable estimate of exposure for the most exposed individual in the community. This EPC is the maximum residential sample concentration of EtO in the May 2018 data collection period. Given these assumptions, the cancer risk for this residential sample

location is **6.4 x 10^{-3}**—an additional lifetime risk of 6.4 cancers in a population of 1,000 residents who could be exposed to EtO emissions from Sterigenics. This cancer risk exceeds U.S. EPA's decision-making cancer risk range of 1.0 x 10^{-6} to 1.0 x 10^{-4}, and adds to the lifetime background cancer risk of an average American of 1 in 3 people (American Cancer Society, 2018).

Table 4. Site-specific ADAF calculations for residential exposure*

Age Range	ADAF	U.S. EPA unadjusted IUR	EPC (µg/m³)	Duration Adjustment	Partial Risk
0 to <2 yrs	10	2.99 x 10^{-3}	2.1	2 years/78 years	1.6 x 10^{-3}
2 to <16 yrs	3	2.99 x 10^{-3}	2.1	14 years/78 years	3.4 x 10^{-3}
16 to 33 yrs	3	2.99 x 10^{-3}	2.1	17 years/78 years	1.4 x 10^{-3}
				Lifetime Risk	**6.4 x 10^{-3}**

**Cancer risk was calculated to estimate what long term exposures to the 12-hour concentration could look like if sustained long term and does not represent actual exposures.*

Likewise, ATSDR assumed the maximum commercial 12-hour sample concentration in commercial sample locations of 9.1 µg/m³ to represent RME occupational exposures to workers in nearby facilities. Note that workers at the Sterigenics facility would be covered under the Occupational Safety and Health Administration (OSHA) EtO standard (29 CFR 1910.1047). For the off-site worker scenario, ATSDR assumed an 8.5-hour workday, 250 days a year, for 25 years (ATSDR, 2016), yielding an exposure factor (EF) of 0.08.

$$EF_{cancer,\ chronic} = \frac{8.5\,\frac{hr}{d}\,x\,5\,\frac{d}{wk}\,x\,50\,\frac{wk}{yr}\,x\,25\,yr}{24\frac{hr}{d}\,x\,7\,\frac{d}{wk}\,x\,52.14\,\frac{wk}{yr}\,x\,78\,yr} = 0.08$$

Cancer risk for workers can be calculated by multiplying the long-term air concentration by the IUR, adjusting the duration of exposure as appropriate using the exposure factor calculation, above:

$$Cancer\ risk = IUR\ x\ EPC\ (\mu g/m^3)\ x\ EF$$

For the maximum commercial concentration of 9.1 µg/m³, this risk equation yields a lifetime occupational cancer risk of 2.1 x 10^{-3}, or an increased risk of cancer for 2.1 people in a population of 1,000 workers from chronic exposures to Sterigenics emissions:

$$Cancer\ risk_{occupational} = 0.00299\ x\ 9.1\ \mu g/m^3\ x\ 0.08 = \mathbf{2.1\ x\ 10^{-3}}$$

While a more complete database from which to characterize exposure is preferable, we used U.S. EPA's limited data for the Sterigenics investigation and applied the standard ATSDR evaluation process. Note that in both ATSDR calculations, we made a very conservative assumption that a 12-hour sample represents long term exposure. We felt this assumption was warranted because the measured and modeled concentrations demonstrated consistency and provided support that this range of exposure is possible in the area surrounding Sterigenics.

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Non-cancer effects

Workers exposed to ethylene oxide over a long-term duration experienced similar health effects to those exposed over shorter durations (California EPA, 2008). Workers exposed to levels of EtO at 8,500 $\mu g/m^3$ and higher over an average of 5-6.5 years demonstrated cognitive and motor impairment compared to unexposed controls. At lower levels of EtO exposure (145-300 $\mu g/m^3$), studies have shown evidence of hemoglobin adducts, DNA damage effects (i.e. sister chromatid exchanges), and hematological effects (i.e. increases in leukocytes and decreases in neutrophil counts; decreases in hematocrit and hemoglobin) (California EPA, 2008). No measured EtO concentrations from the residential or occupational sampling approached or exceeded effect levels in the long-term modeling estimates or the 12-hour samples being used as chronic exposure surrogates, therefore, non-cancer health effects are not expected. However, air sampling in this effort was extremely limited.

LIMITATIONS

ATSDR made several assumptions as part of this assessment that could lead to the over or underestimation of risk. Some limitations of this assessment include:

1. To calculate risks, ATSDR assumed that the concentrations measured during this assessment will continue, unchanged if no actions are taken, over 33 years for residents, and 25 years for workers.
2. ATSDR assumed that the very limited sampling investigation of 26 discrete locations over 2 days throughout the community represents typical exposure conditions from Sterigenics EtO emissions. Only one 12-hour residential sample was collected, and that sample was used to represent the RME residential chronic exposure estimate. EtO concentrations from grab samples at one other residential location were slightly higher than the 12-hour averaged sample collected at this property.
3. ATSDR assumed that the highest EtO concentration in the commercial area surrounding Sterigenics represents worst case off-site worker exposures. This is likely underestimating worker exposures for some employees in this area.
4. Due to a lack of long term sampling, the temporal trends of EtO emissions could not be evaluated. Fluctuations of seasons that affect temperatures, barometric pressure, wind speed and direction, and other potential factors that could influence the transport of EtO into the surrounding community were not assessed.

Despite these limitations, ATSDR acknowledges that the U.S. EPA modeling demonstrates similar concentration ranges to community air measurements. Thus, ATSDR believes the exposure estimates assumed in this assessment are reasonable. Historical emissions were higher before a substantial drop in 1999 with the construction of aeration rooms in Building 1. EtO cancer risks may have been substantially greater for the 14 years the facility operated before these emission controls were implemented, but historical risk cannot be evaluated with available emissions data.

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Conclusions:

U.S. EPA asked ATSDR to answer the following question: "*If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?*" U.S. EPA provided modeled and measured data for ATSDR to evaluate and render a health opinion.

It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:

1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated risks *present a public health hazard to these populations*.
2) Measured and modeled ethylene oxide concentrations in ambient air indicate that non-cancer health effects are unlikely for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility.

Recommendations:

1) ATSDR recommends that Sterigenics take immediate action to reduce EtO emissions at this facility.
2) ATSDR recommends that U.S. EPA work with the Sterigenics facility to initiate long-term air monitoring as soon as possible to measure ambient air levels of EtO. Ongoing air monitoring can demonstrate the effectiveness of actions taken by the company to reduce emissions and subsequent exposures in the community.
3) ATSDR recommends that IDPH investigate whether there are elevated cancers in the population surrounding the Sterigenics facility that are consistent with those associated with chronic EtO exposures.

Please do not hesitate to contact ATSDR Region 5 to discuss this assessment further or to request further public health assistance.

Sincerely,

Michelle A Colledge

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Central Branch, Region 5

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Rick Gillig, ATSDR/ DCHI/CB
Tina Forrester, ATSDR/ DCHI/OD

References:

Agency for Toxic Substances and Disease Registry (ATSDR). 2018. Discussion between ATSDR and U.S. EPA Region 5 Air and Radiation Division on 7/23/2018.

Agency for Toxic Substances and Disease Registry (ATSDR). 2016. Exposure Dose Guidance for Determining Life Expectancy and Exposure Factor. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

Agency for Toxic Substances and Disease Registry (ATSDR). 1990. Toxicological Profile for Ethylene Oxide. Health and Human Services: Atlanta, GA. Accessed from: https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=734&tid=133

American Cancer Society (ACS). 2018. Lifetime probability of developing or dying of cancer. Accessed from: https://www.cancer.org/cancer/cancer-basics/lifetime-probability-of-developing-or-dying-from-cancer.html

California Environmental Protection Agency (California EPA). 2008. Determination of Noncancer Chronic Reference Exposure Levels, Appendix D3, Ethylene Oxide. Accessed from: https://oehha.ca.gov/chemicals/ethylene-oxide.

Illinois Environmental Protection Agency (Illinois EPA). 2017. DRAFT/PROPOSED Clean Air Act Permit Program (CAAPP) PERMIT. Permit No. 95120085. Bureau of Air, Permit Section. April 17, 2017.

Illinois Environmental Protection Agency (Illinois EPA). 2015. *Statement of Basis* for the DRAFT CAAPP Permit for: Sterigenics. Statement of Basis No.: 95120085. February 25, 2015.

Jinot, J., Fritz, J., Vulimiri, S., and Keshava, N. 2017. Carcinogenicity of ethylene oxide: key findings and scientific issues. *Toxicol Mech Methods*, Jun;28(5):386-396.

National Research Council (NRC). 2010. Committee on Acute Exposure Guideline Levels. Washington (DC): National Academies Press (US). ISBN: 978-0-309-15944-9.

Steenland, K; Stayner, L; Deddens, J. 2004. Mortality analyses in a cohort of 18 235 ethylene oxide exposed workers: Follow up extended from 1987 to 1998. Occup Environ Med 61: 2-7.

Steenland, K., Whelan, E., Deddens, J., Stayner, L., Ward, E. 2003. Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States). *Cancer Causes Control*. 14:531–539.

Sterigenics International, LLC. 2018. Willowbrook, IL: Ethylene Oxide Sterilization. Accessed from: https://www.sterigenics.com/facilities_pdfs/2018/eo/n_amer/Willowbrook.pdf.

United States Census (Census). 2016. American Fact Finder: 2016 Population Estimates. Accessed from http://www.census.gov.

United States Environmental Protection Agency (U.S. EPA). 2018. Validated Raw Data Package. Provided to ATSDR by U.S. EPA Air and Radiation Division (ARD) for review on 6/6/2018.

United States Environmental Protection Agency (U.S. EPA). 2016. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide. National Center for Environmental Assessment, Washington DC. Accessed from http://www.epa.gov/iris.