Ethylene Oxide Fenceline Study (Fall 2023)

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National Academies of Sciences Report on TCEQ's Risk Assessment Methodology (March 2025)

> Presented by Tricia Cortez Rio Grande International Study Center

Sources:

- Kimberly Terrell, PhD., Staff Scientist & Director of Community Engagement (Tulane Environmental Law Clinic)
- Richard Peltier, PhD, Professor of Environmental Health Science (University of Massachusetts at Amherst)

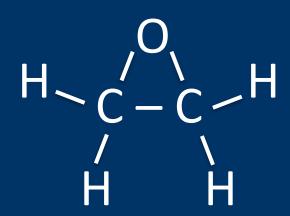
What is Ethylene Oxide?

- Toxic, colorless gas
- Chronic exposure linked to
 - Lymphoma
 - Breast cancer
 - Leukemia
 - Birth defects
 - Respiratory harm
 - Brain & nerve damage



Ethylene Oxide in the Air

- Small, lightweight molecule
- Travels long distances in air
- Takes months to break down in air (half-life in air is 2-5 months)



Ethylene Oxide in the Body

- EtO in the air enters lungs, then bloodstream
- Same properties that make EtO an effective sterilizer make it dangerous to human health
 - Highly reactive molecule
 - Attacks DNA and protein (mutagenic)
 - EtO can't tell the difference between you and bacteria
 - Past exposures affect future health (as in smoking)



EtO as a Carcinogenic Air Toxic

 EtO is one of 188 Hazardous Air Pollutants (HAPs) regulated by the U.S. EPA.

 The EPA sets emission limits for each polluting facility (i.e. Midwest Sterilization).

 The EPA is required to review these regulations every 8 years.



EtO Toxicity

• The EPA has an "Acceptable" cancer threshold for carcinogens of 1-in-10,000.

 For EtO, the safe level of EtO for Laredo = 11 parts per trillion.

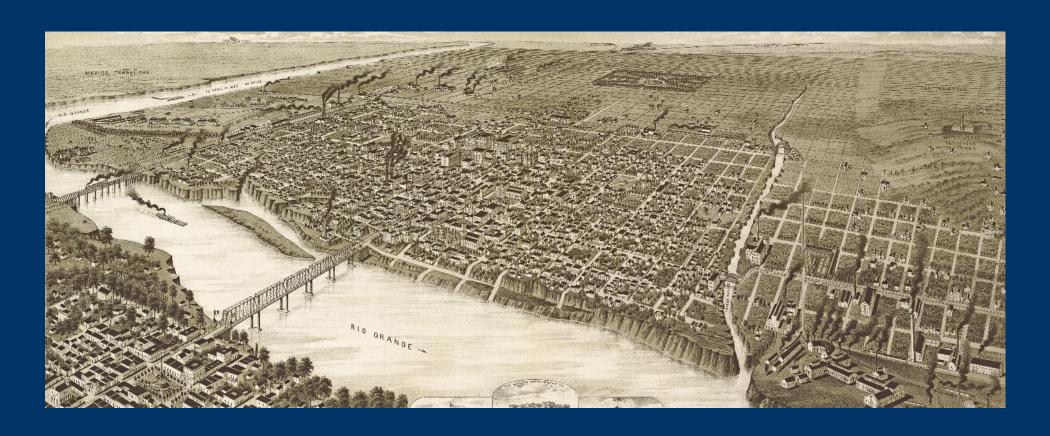
 That is the equivalent of having 1 penny in a bank with \$11 billion.

Laredo EtO Levels & Midwest Sterilization

- Midwest Laredo opened in 2005.
- It has ranked among the highest emitters of ethylene oxide among nearly 90 commercial sterilizer facilities.
- In 2019, for example, it ranked 2nd nationally among all facilities emitting nearly 16,400 pounds into the air (self-reported data)
- In 2022, EPA placed Midwest Laredo on its list of 23 high risk EtO sterilizer facilities with an "Unacceptable" cancer risk rate.

Ethylene Oxide in Laredo Summary of Fenceline Air Monitoring Study

Clean Air Laredo Coalition

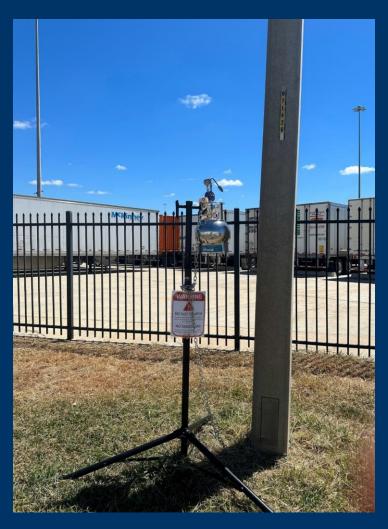


About the Clean Air Laredo fenceline study

- <u>Purpose:</u> Community-driven concerns about our limited understanding of EtO emissions in Laredo.
- **Duration:** 7 weeks (Sept. 2023-Nov. 2023)
- Sites: 14 total sites; 6 primary + 1 primary background
- Contractor: Dallas-based BAIR collected samples in a method that is consistent with US EPA best practices approach (QAPP).
- External Review: Atmospheric scientist, Dr. Peltier.
- Funding Support: City of Laredo, Webb County, UISD, LISD

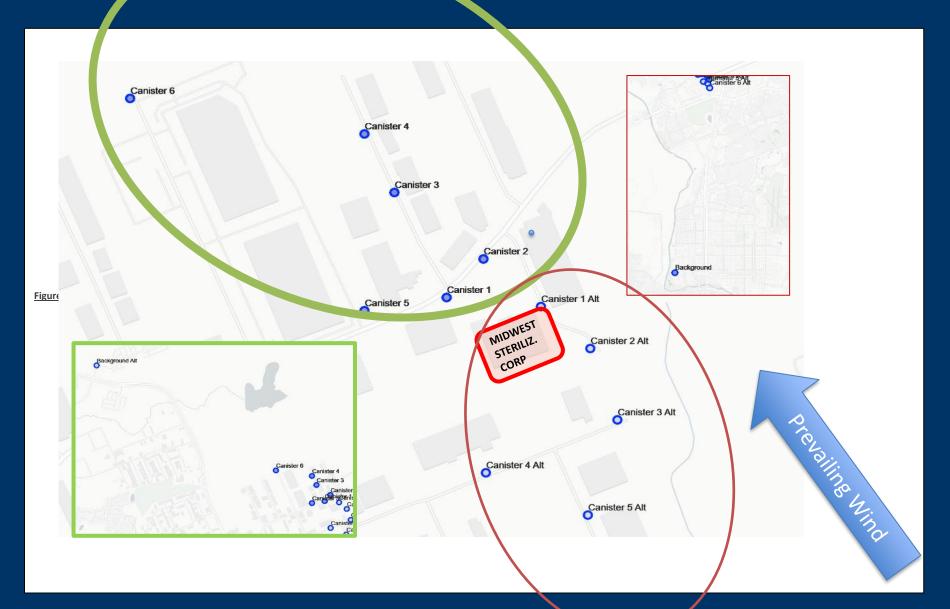
Canister Sampling



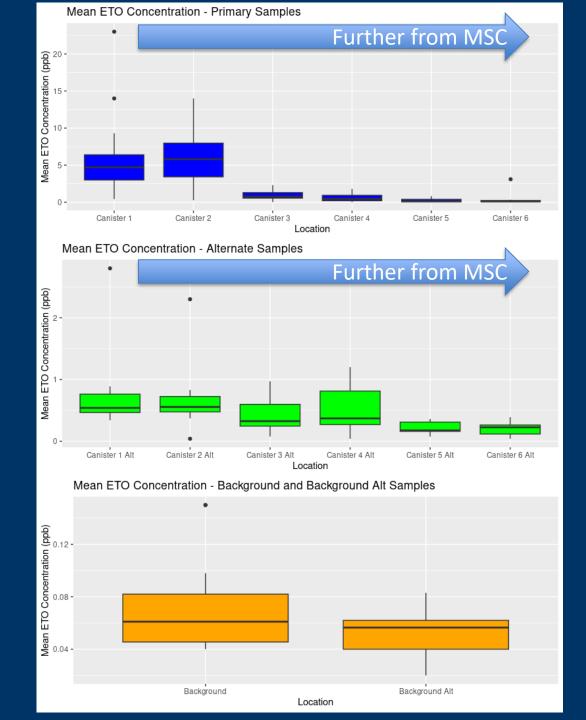




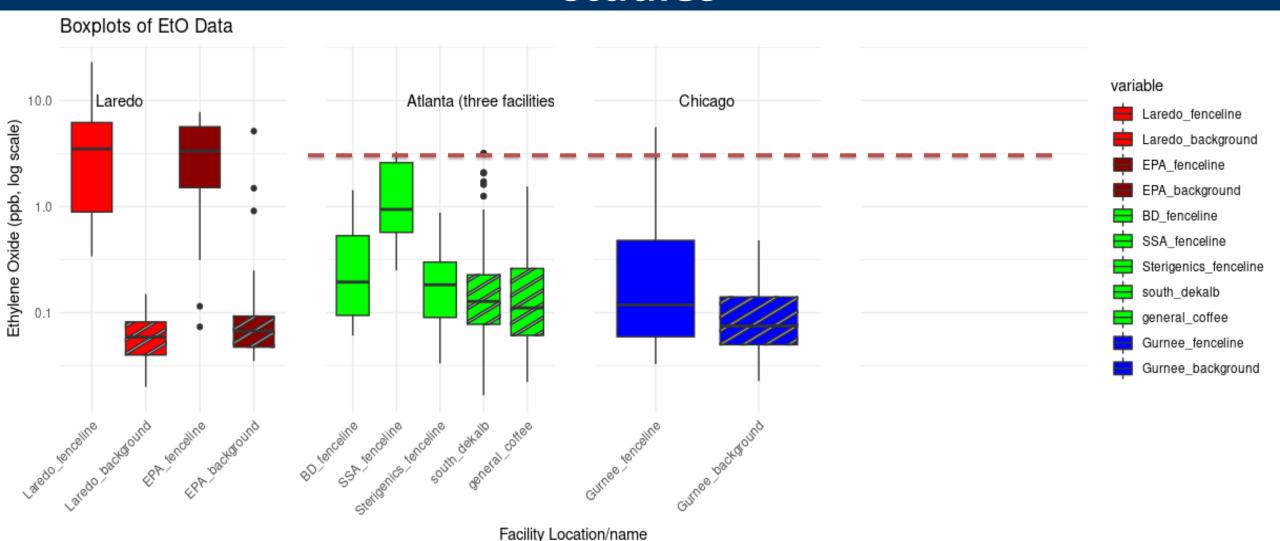
Site Orientation



- The CAL study detected concentrations as high as 23 ppb. (23,000 ppt)
- Background average ~0.05-0.07 ppb (50 ppt).
- Canister 1 average ~5.5-6 ppb (5,000-6,000 ppt)
- Canister 6 average ~0.20-0.25 ppb (200-250ppt).
- Distance and wind direction are very important.



Comparing Laredo with other fenceline studies



Clean Air Laredo Conclusions

- Elevated EtO concentrations found at the fence line, and extending a significant distance from that fence line; much higher than the urban background.
- Even though concerns are relatively recent, EtO has always been a potent carcinogen.
- Remains unclear what specific industrial activity at Midwest Sterilization is driving these significant emissions; more data are required.

Why the concern now?

1985: EtO deemed 'reasonably anticipated as a carcinogen'.

1998: EPA begins a new review.

2006: Internal review completed.

2011-2013: Assessment finalized and publicly released.

2016: IRIS determination: "sufficient to conclude that ethylene oxide is carcinogenic to humans."

2018: NATA released that identified many communities at risk, including Laredo.

2022: EPA placed Midwest Laredo on its list of 23 high risk EtO sterilizer facilities with an "Unacceptable" cancer risk rate.

2022: RGISC sues EPA for failing to revise the rule, by law.

2024: Revised sterilizer rule released by EPA.



- EPA was required to update the sterilizer rule in 2014
 - EPA failed to meet this legal requirement.
 - The rule had not been updated since 1994.
- In 2022, RGISC and several other plaintiffs sued EPA over its failure to update the sterilizer rule.
 - In 2023, RGISC settled the case.
 - RGISC put EPA on a deadline to revise the sterilizer rule by March 1, 2024.



New Sterilizer Rule: Compliance

- All facilities (using more than 100 pounds of EtO) must use Continuous Emissions Monitoring Systems (CEMS)
 - Must record hourly averages of EtO concentration used
 - Must record weight differential in pounds of EtO used
 - Must provide notice to EPA directly when CEMS fails

 All facilities must install a permanent-total enclosure system to control EtO emissions



Midwest must:

- Install a permanent total enclosure system so that EtO does not escape the facility
- Install a continuous air monitoring system (CEMS) that will measure
 EtO within the facility.
- Install new emission control device equipment that can reduce EtO from the Sterilization Chamber Vents by 99.99%.

City Council Question to Midwest:

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President Trump has announced that any facility that does not want to comply with the new rule, can be exempted from the rules due to national security.

Commercial sterilizers were specifically called out.

To get that presidential exemption, a facility had to apply by March 31, 2025.

Q. Did Midwest submit an exemption from complying with the new rule?

NAS Report on TCEQ Methodology

- TCEQ created its own risk assessment for EtO.
- NAS found that TCEQ's methodology was insufficient and incomplete, and lacking in sound science.
- NAS found that TCEQ's risk assessment failed to capture the risk that EtO poses to communities.

NAS Report on TCEQ Methodology

Page 3 of the March 2025 report:

"While TCEQ's use of human epidemiologic data in the dose-response assessment has some merits, the report raises significant concerns regarding the overall methodology. The lack of application of systematic review methods, the exclusion of critical epidemiological data, the limitations in the modeling approach and use of unpublished validation data all contribute to a lack of confidence in TCEQ's risk assessment of ethylene oxide.

These methodological deviations underscore the need for a more rigorous and comprehensive approach in future assessments."