

# Clean Air Laredo Coalition

## *Ethylene Oxide Fenceline Study (Fall 2023)* & *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)
- Marvin C. Brown, IV, Senior Attorney (Earthjustice)



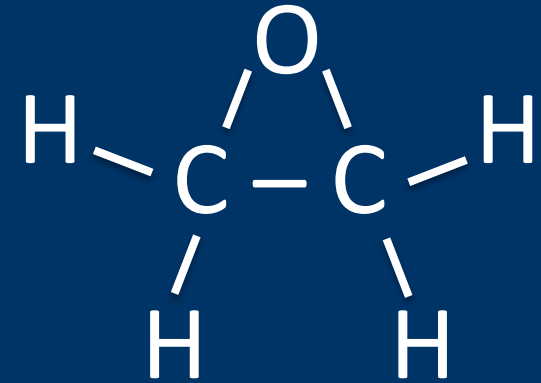
# What is Ethylene Oxide?

- Toxic, colorless gas
- Chronic exposure linked to
  - Lymphoma
  - Breast cancer
  - Leukemia
  - Myeloma
  - 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 or a virus
  - Past exposures affect future health



# 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 standards for any facility that uses EtO to sterilize medical equipment, or spices.
- The EPA is required to review these regulations every 8 years.



# EtO Toxicity

- The EPA has an “Acceptable” cancer risk threshold for carcinogens of 1-in-10,000.
- To achieve that level of acceptability, EtO concentrations in the air must be less than 11 parts per trillion.
- That is the equivalent of having 1 penny in a bank with \$11 billion.
- EtO is dangerous in extremely small amounts.



# 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.

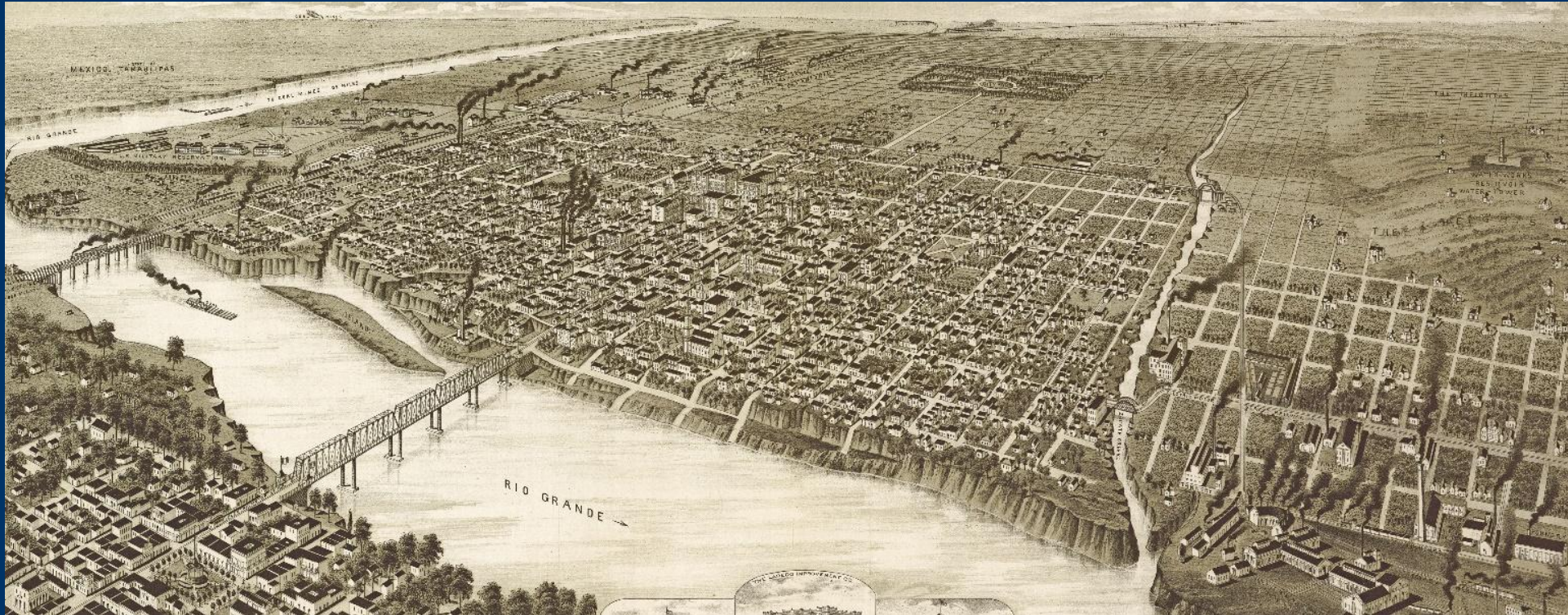




# Ethylene Oxide in Laredo

## Summary of Fenceline Air Monitoring Study

*Clean Air Laredo Coalition*





# About the Clean Air Laredo fenceline study

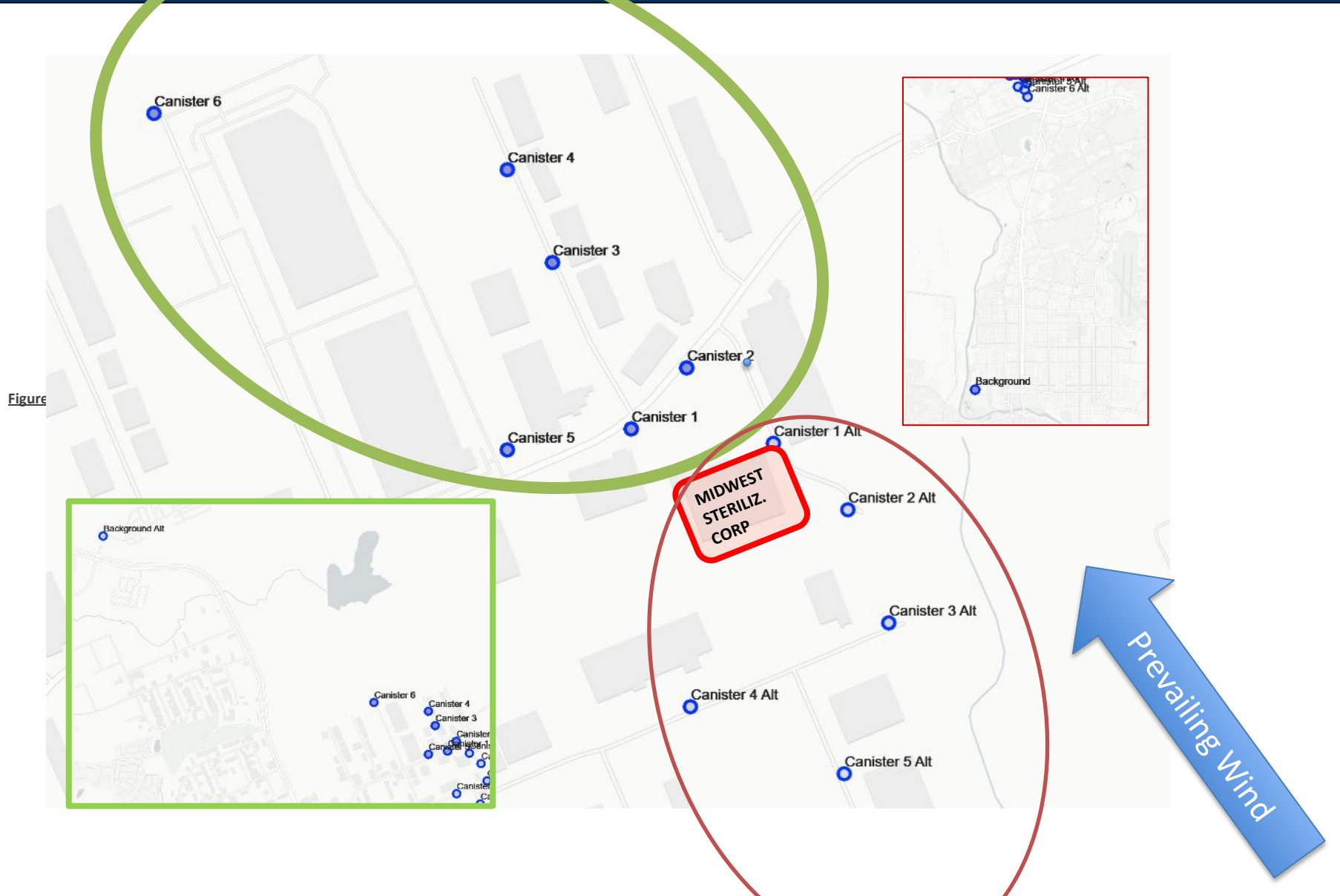
- **Purpose:** Community-driven concerns about our limited understanding of EtO emissions in Laredo.
- **Duration:** 7 weeks (Sept. 2023-Nov. 2023)
- **Sites:** 14 total sites; 6 primary + 1 primary background
- **Contractor:** Dallas-based BAIR collected samples in a method that is consistent with US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

# Canister Sampling

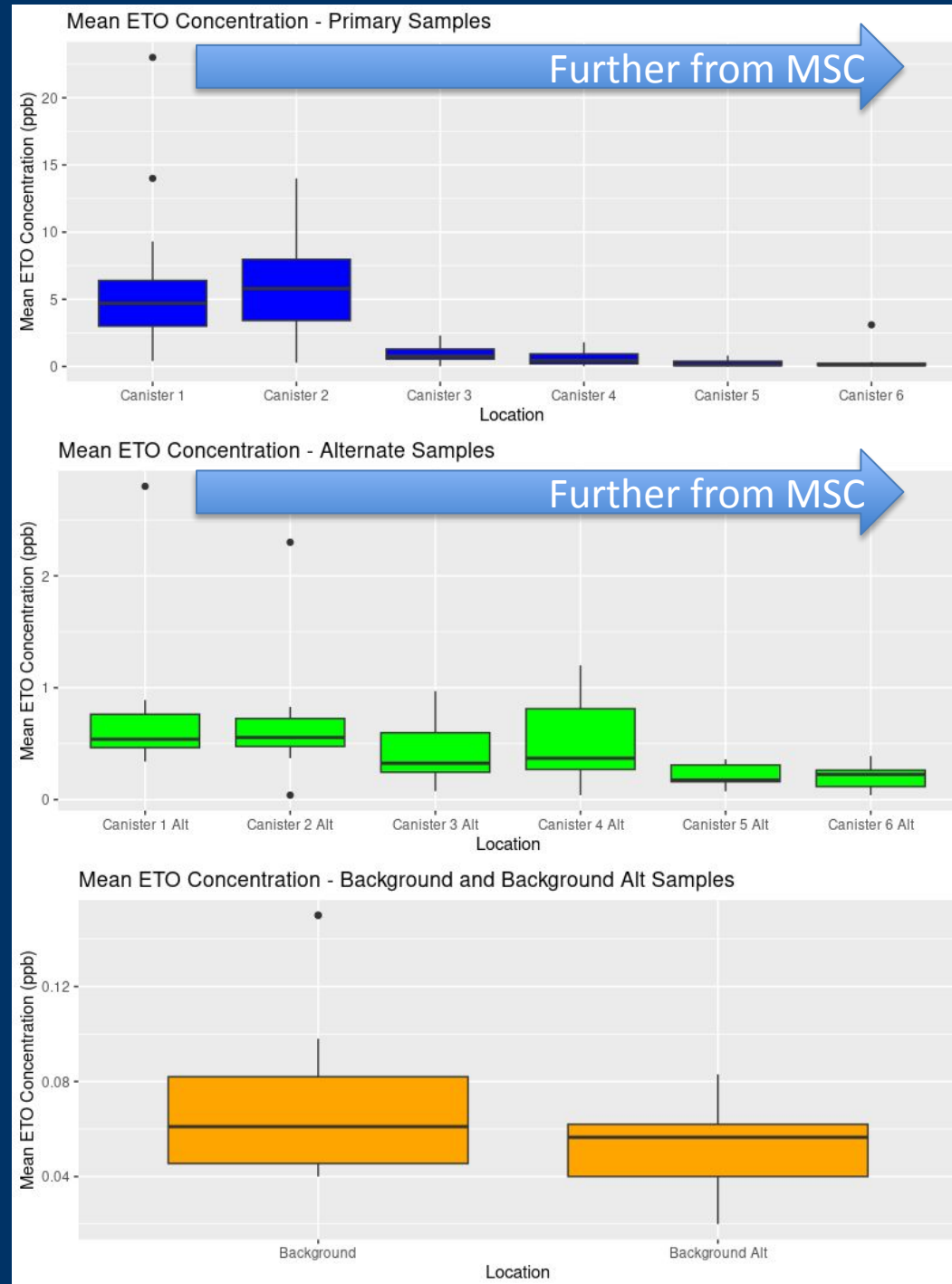




# Site Orientation

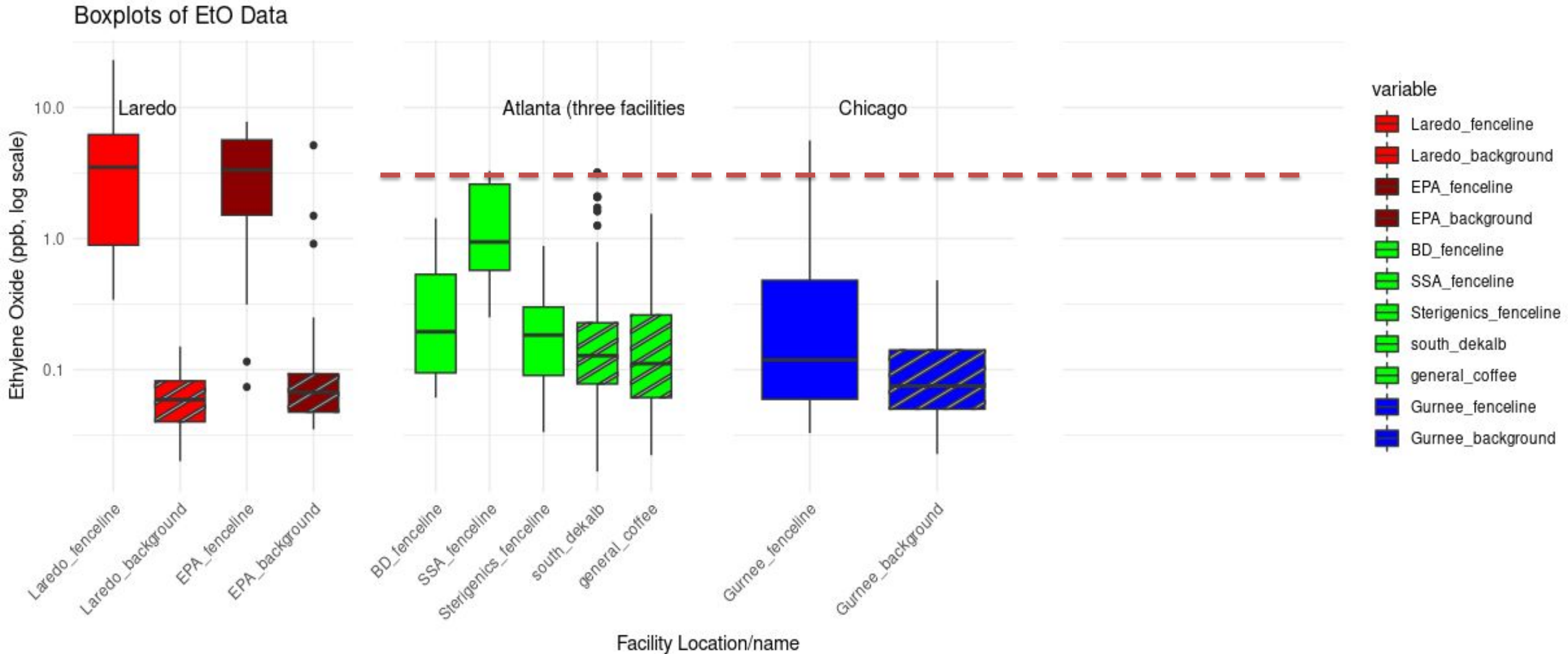


- The CAL study detected concentrations as high as 23 ppb. (23,000 ppt)
- Background average ~0.05-0.07 ppb (50 ppt).
- Canister 1 average ~5.5-6 ppb (5,000-6,000 ppt)
- Canister 6 average ~0.20-0.25 ppb (200-250 ppt).
- Distance and wind direction are very important.



# Comparing Laredo with other fenceline studies

*(Atlanta, Chicago) – Laredo has high concentration levels*





# Clean Air Laredo Study Conclusions

- Elevated EtO concentrations found at the fenceline, and extending a significant distance from that fenceline; much higher concentrations 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 in Laredo; more data are required.



# Why the Concern Now?

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

**1994:** EPA set its first set of emission standards for sterilization facilities.

**1998:** EPA begins a new review.

**2006:** Internal review completed.

**2011-2013:** Assessment finalized and publicly released.

**2016:** EPA 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 review and revise the rule, as required by law.

**2024:** Revised sterilizer rule released by EPA.



# RGISC's Legal Success

- 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 (2024): 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

# New Sterilizer Rule: Compliance

- Midwest Sterilization 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%.
- *NOTE: In 2024, EPA found that 1 in 17 employees at commercial sterilization facilities are at risk of developing cancer from breathing in EtO emissions at their job.*





# City Council Question to Midwest

- EPA has announced that any facility that does not want to comply with the new rule may get a presidential exemption.
- 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?**



# National Academies of Science Review of TCEQ Methodology

- TCEQ created its own cancer risk assessment for EtO, in 2020.
- TCEQ's alternative assessment was significantly more lenient than the EPA's assessment.
- Texas is the nation's top EtO polluter.
- Texas is home to nearly 26 facilities that emit EtO, some of which are commercial sterilizers.
- Midwest Sterilization in Laredo uses the most ethylene oxide of all sterilizer facilities in the nation (*more than 1 million pounds per year*).

# National Academies of Science Review of TCEQ Methodology

- NAS issued a report (March 2025) upon reviewing TCEQ's methodology to determine EtO's carcinogenic hazards; strongly criticized the TCEQ alternative risk assessment.
- 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 and failed "to provide a credible basis for its hazard conclusions."



# 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.”

