Ethylene Oxide: An Emerging Air Quality Issue

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Ethylene Oxide:

- Background, Uses, and Risks
- Toxicity: Studies on Cancer Risk
- Regulations in the US
- Monitoring in the US
- Regulations in Canada
- Monitoring in Canada

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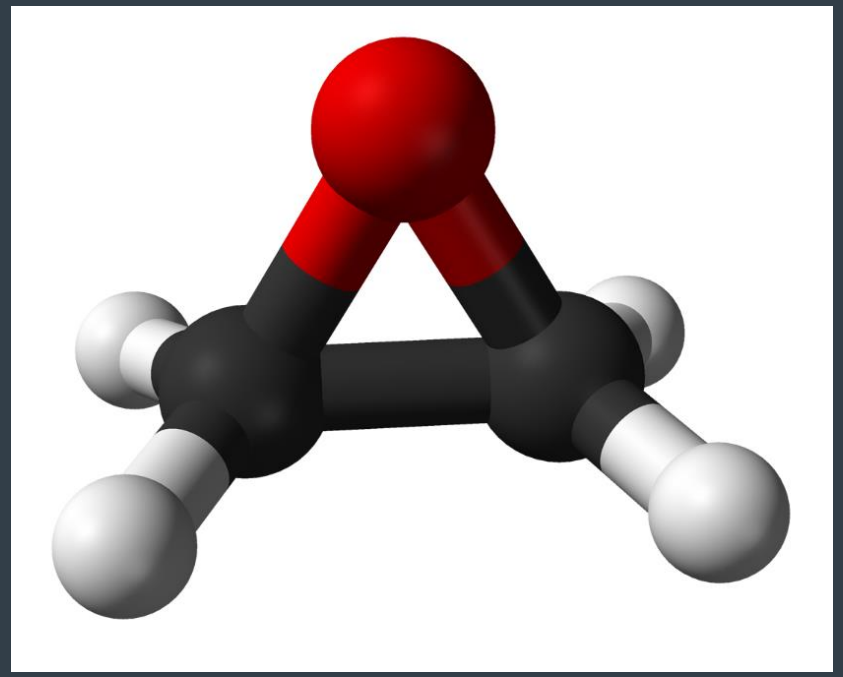
Properties of Ethylene Oxide



- Chemical Formula: C_2H_4O
- Colorless, flammable gas
- Faintly sweet odor
- Made from petroleum or natural gas
  - Derivative of ethylene
- In ambient conditions:
  - ***Carcinogenic***
  - Mutagenic (DNA Altering)

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Uses of Ethylene Oxide

- Chemical intermediate in the manufacture of:
  - Ethylene glycol
    - Antifreeze
    - Coolant for cars, gas compressors, and air conditioners
  - Plastics
  - Adhesives
  - Pharmaceuticals
  - Pesticides
- Sterilizing agent, primarily in the medical industry
  - Approximately 50% of the medical field use EtO

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Ethylene Oxide Risks

- Short-term effects
  - Central nervous system depression
  - Irritation of eyes and mucous membranes

- Long-term effects
  - Carcinogenic
    - Leukemia
    - Lymphoid
    - Breast

- It was found that EtO is *30x more carcinogenic* than originally thought

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Ethylene Oxide in the Atmosphere

Ethylene Oxide Emissions - US

Letting it out

Eight of the top 10 US emitters of ethylene oxide in 2017 were chemical manufacturing plants.

Ranking	Facility	Location	Ethylene oxide emitted (kg)
1	Huntsman Petrochemical[a]	Port Neches, TX	18,420
2	Sasol Chemicals	Westlake, LA	7,461
3	BASF	Geismar, LA	6,895
4	Midwest Sterilization	Laredo, TX	6,734
5	Union Carbide (owned by Dow)	Hahnville, LA	6,584
6	Eastman Chemical	Longview, TX	6,069
7	Union Carbide (owned by Dow)	Seadrift, TX	5,080
8	Shell Chemical	Geismar, LA	4,275
9	Sterilization Services of Virginia	Richmond, VA	3,515
10	Celanese	Pasadena, TX	2,870

Source: EPA Toxics Release Inventory. a Huntsman announced in August the sale of this plant to Indorama Ventures.

- 75% of EtO emissions come from chemicals and plastics manufacturing
  - 84 metric tons (165,000 lbs) released in 2017
  - Uncontrolled fugitives
  - Process vents
- Long half-life (emissions accumulate)
  - Still under study (4-7 months)
  - Season and Location dependent (OH radical)
  - Reacts to form formic acid
- 5 of 10 top emitters are in Texas (2017)

Studies on Cancer Risk
Updates to State Regulations

Basis of Study

- Exposure estimates based on
  - 17,530 workers in 13 sterilizing facilities
    - Derived for individual workers using a comprehensive exposure assessment
    - Large and diverse cohort (55% female)
    - Little exposure to chemicals other than EtO

- Limitations
  - Not enough long-term sampling data
  - Regression model extrapolated exposure for each individual

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EPA Conclusions

- EPA Updated Integrated Risk Information System (IRIS)
  - IRIS changed EtO's adult based inhalation unit risk from:
    - 10^{-4} cancer risks per ug/m^3 -> $3x10^{-3}$ cancer risks per ug/m^3
    - 30x higher cancer potency in adults
    - If risk > 1 in 10,000 => higher than acceptable
    - For reference, benzene's inhalation unit risk = $2.2x10^{-6}$ cancer risks per ug/m^3

- Translates to an ambient concentration of 0.02 ug/m^3 (0.01 ppb)

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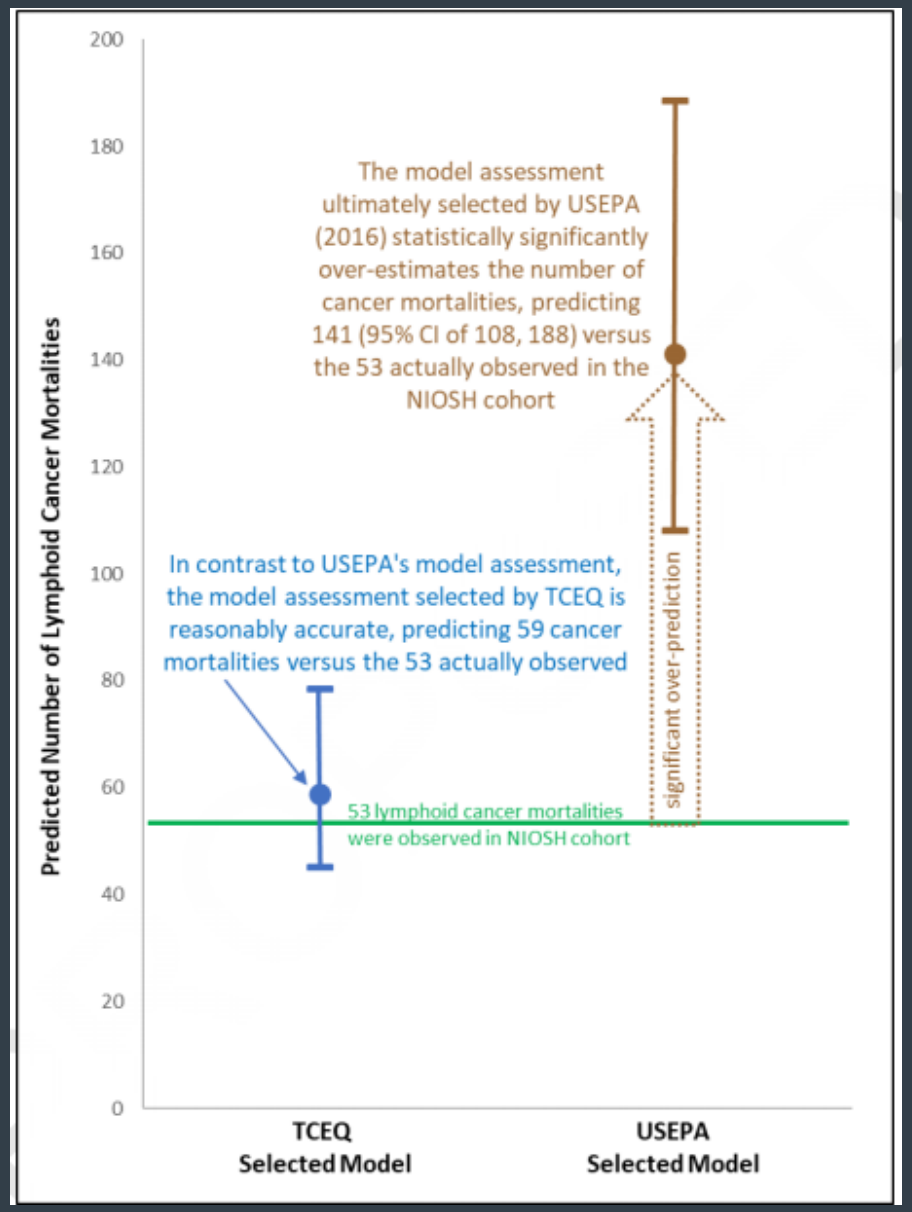
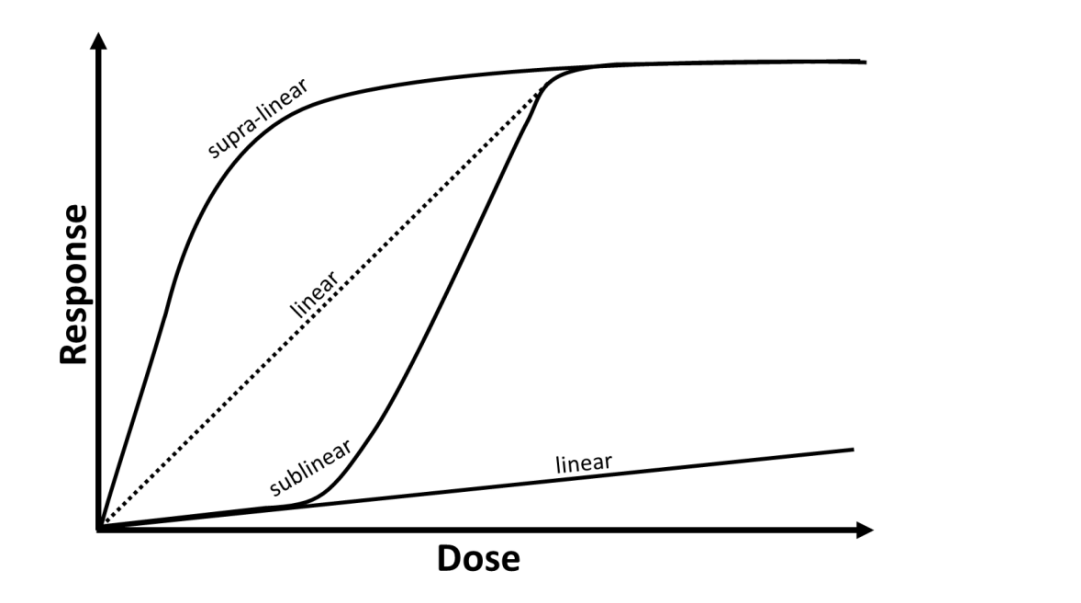
TCEQ Conclusions



- TCEQ believes EPA has overestimated the risk associated with exposure to EtO
- Increase toxicity of EtO to
  - **4.3 ug/m^3 (2.4 ppb)**

TCEQ Conclusions



- TCEQ argues that:
  - Very high exposure cohort
  - Linear response fit
    - EPA: Supralinear: steep at low doses – too conservative?
    - TCEQ argues sub-linear fit
      - Less steep at low doses, steep at higher doses

Illinois EPA Conclusions

- Closed facilities and strictest rules for highest emitters
  - Medical sterilization facilities
  - Expecting emissions to reduce by 10x-30x

- Laws specific to industries and the highest polluters (2019):
  - Controls/capture for EtO emissions
  - Emission limitations
  - Quarterly ambient air testing
  - Distance requirements from schools and parks
  - Ambient Air Monitoring
    - Daily data from June 2019-April 2020
    - Average concentration is 0.4 ug/m^3

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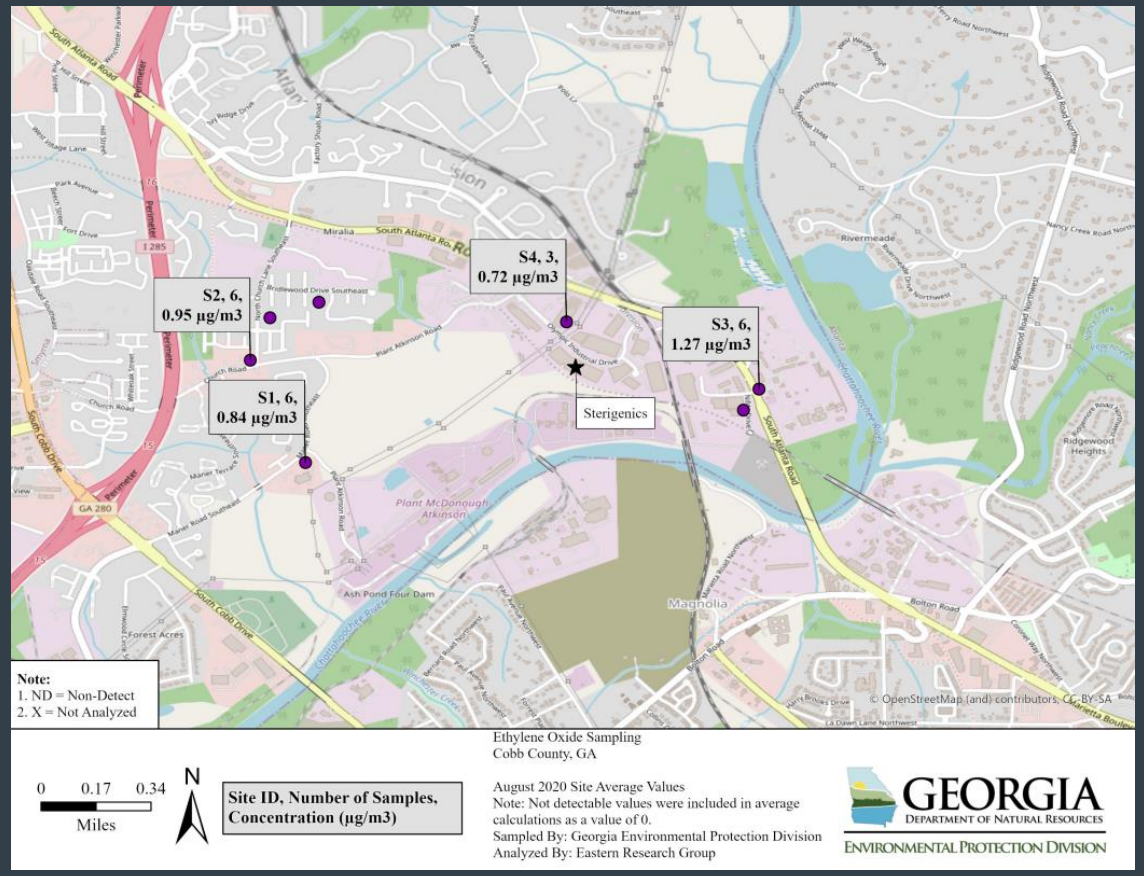
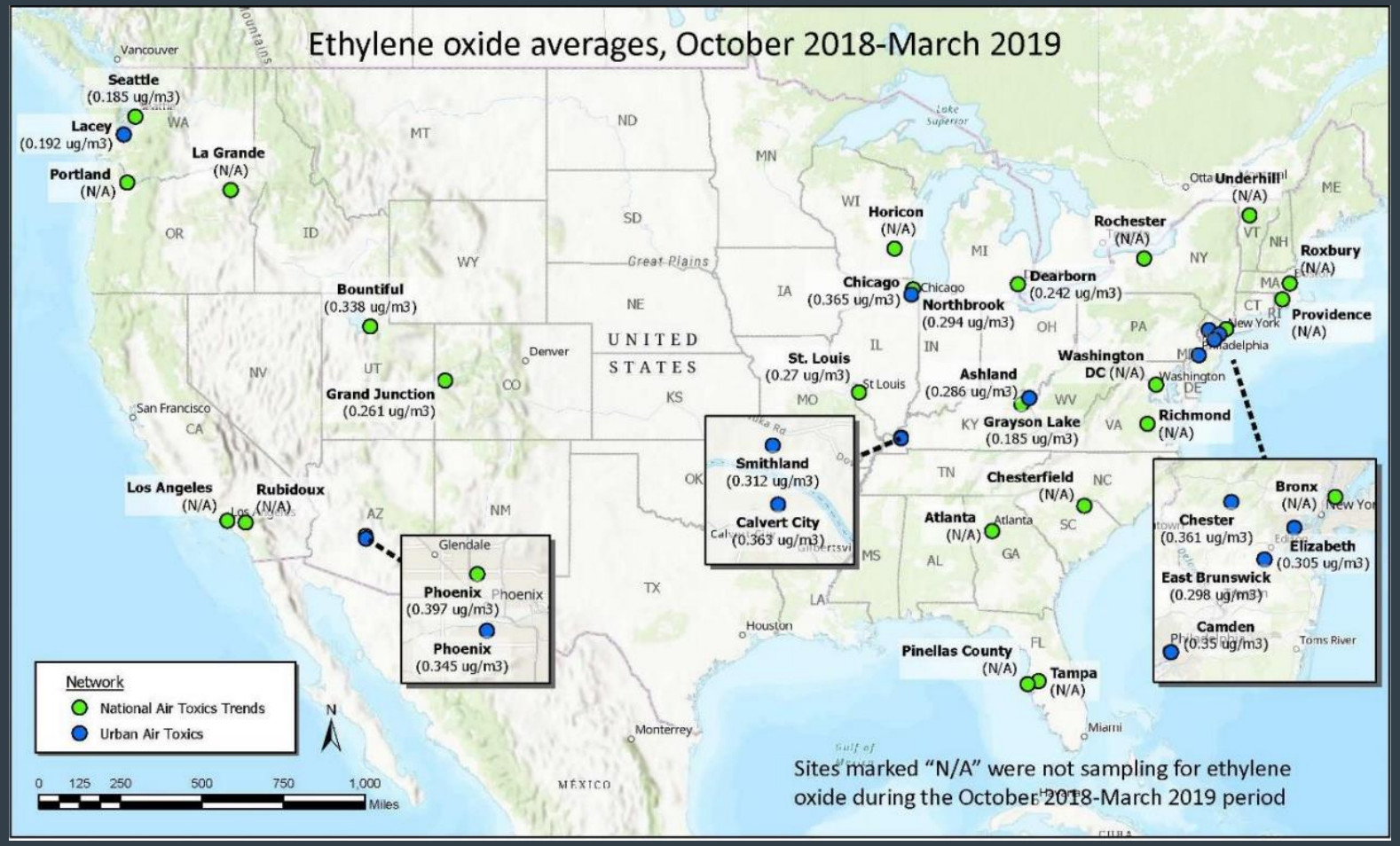
Georgia EPD Conclusions



- Plant shut-down due to high detection of EtO
- Air monitoring plans by Georgia EPD
  - Air sample collected every 6 days
  - Five monitoring locations: 0.25 mi -> 1 mi
    - Identifying baseline levels of air pollution in areas with no expected EtO
  - Working with EPA to better understand non-industrial sources of EtO

Ethylene Oxide Monitoring Data

Monitoring Results



- 18 sites across US
- No significant change in background concentration over past year
- High ambient background concentration
  - 0.2 – 0.4 ug/m^3
  - 10-21x higher than EPA limit (0.02 ug/m^3)
    - Need monitors able to detect very low concentrations
  - Lower than TCEQ limit (4.3 ug/m^3)

US Federal Regulations

US Federal Regulations

- EPA proposed Information Collection Request (ICR) for Ethylene Oxide Commercial Sterilization Facilities

- HAP Regulations
  - NESHAPs
  - MACT

- Currently associated with:
  - Commercial Sterilizers
  - Miscellaneous Organic Chemical Manufacturing (MON)
  - Hospital Ethylene Oxide Sterilizers
  - Polyether Polyols Production
  - Synthetic Organic Chemical Manufacturing Industry (SOCMI)

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US Federal Regulations

- MON Updated *(May 2020)*
- Process vents and equipment leaks in EtO service
- Control device
- 93% reduction in emissions
- 3 years to come into compliance
  - Shorter periods for some requirements
    - One year for equipment leak reductions
    - Two years for process vent and storage modifications
- Include:
  - Emission Limitations
  - Controls
  - Reporting
  - Fenceline Monitoring
  - Distance Requirements

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Ethylene Oxide - Canada

Canada Regulations

- Type 1 Carcinogen by IARC
- Limited data in Canada on general population's exposure to EtO
- Guidelines:
  - Guidelines for the reduction of EtO releases from sterilization applications
  - In 2019, Health Canada introduced "significant change" to qualifications to Medical Device Licenses following Sterigenics shut-down
  - Removed from list of permitted food additives with other accepted uses in 2017

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Ethylene Oxide - Canada

Jurisdiction	Limit	Year
Alberta	1 hour: 15 ug/m^3	2016
Ontario	Annual: 0.04 ug/m^3 24-hour: 0.2 ug/m^3	2016

- US EPA argues Ontario's standards are
  - Based on animal carcinogenicity data
  - Does not factor data on occupational exposures to EtO
- 2.8 tons released to environment based on 2017 NPRI

Facility	City	Pr	Total Releases (atmospheric) (tons)
MEGlobal Canada ULC – Prentiss Chemical Manufacturing Facility	Lancombe County	AB	1.60
Sterigenics	Scarborough	ON	0.57
ME Global Canada ULC – Fort Saskatchewan EOEG	Fort Saskatchewan	AB	0.53
Shell Chemicals Canada – Scotford Chemical Plant	Fort Saskatchewan	AB	0.03
Clean Harbors Canada, Inc.	Corunna	ON	0.003
		Total	**2.8**

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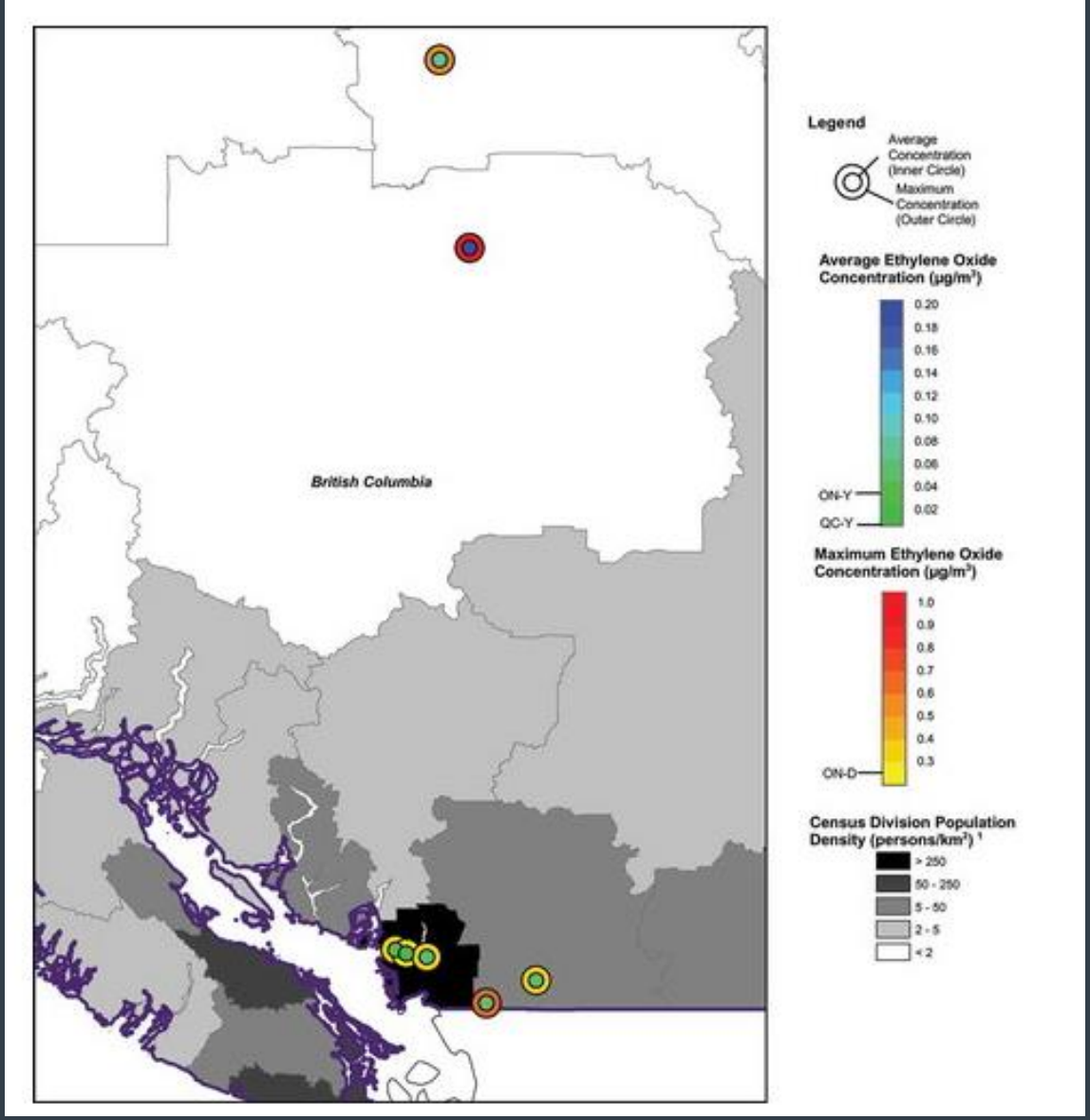
Ethylene Oxide Monitoring and Limits - Canada



- 7 sites in BC during 2009-2013
- 5 sites exceeded ON annual guideline of 0.04 ug/m^3
- Highest ethylene oxide concentration: Quesnel BC, nearly double 24-hr ON limit (0.2 ug/m^3)
- The detection limit exceeds the annual ON guideline

Standard		Year
Annual: 0.02 ug/m^3	US EPA	2016
Annual: 4.3 ug/m^3 1-hour: 20 ug/m^3	TCEQ	2020
1-hour: 15 ug/m^3	Alberta	2016
Annual: 0.04 ug/m^3 24-hour: 0.2 ug/m^3	Ontario	2016

Any questions?

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