ETHYLENE OXIDE:

A CONVERSATION WITH EPA AND WVDEP

For the Communities of South Charleston and Institute, West Virginia

September 23, 2021

GOALS

- Share information on Ethylene Oxide
- Present EPA and WVDEP actions
- Discuss Next Steps
- Answer Questions

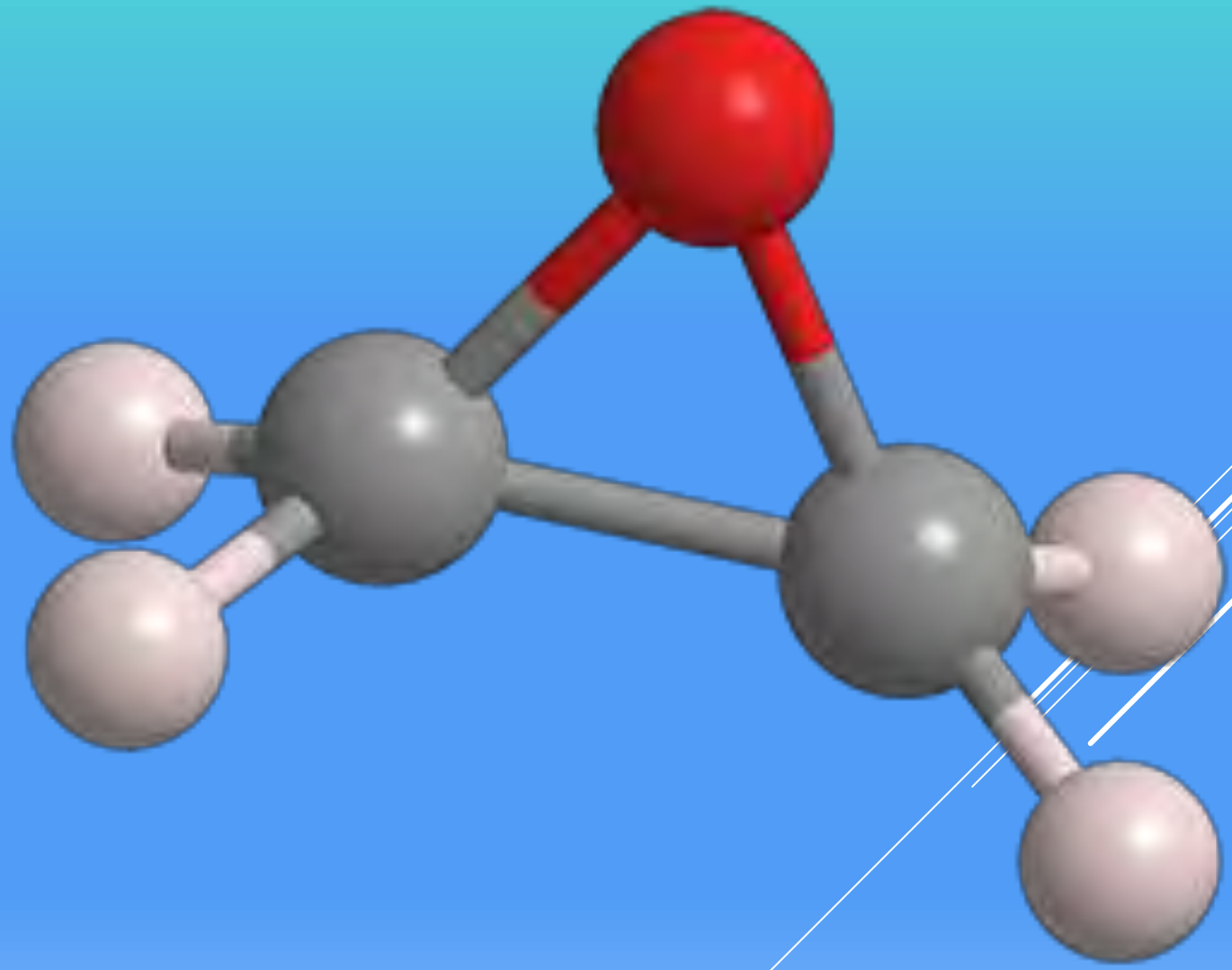
Ethylene Oxide

- What is Ethylene Oxide (EtO)?
- What are its uses, and why is it important?
- What are the findings for S. Charleston and Institute, WV?
- What are EPA and WVDEP doing about EtO?
- Where can I find more information about EtO?

WHAT IS ETHYLENE OXIDE?

What is EtO?

- A colorless gas at room temperature
- Flammable
- Used to make other chemicals
- Sterilizing agent
- Created naturally



What is EtO used for?

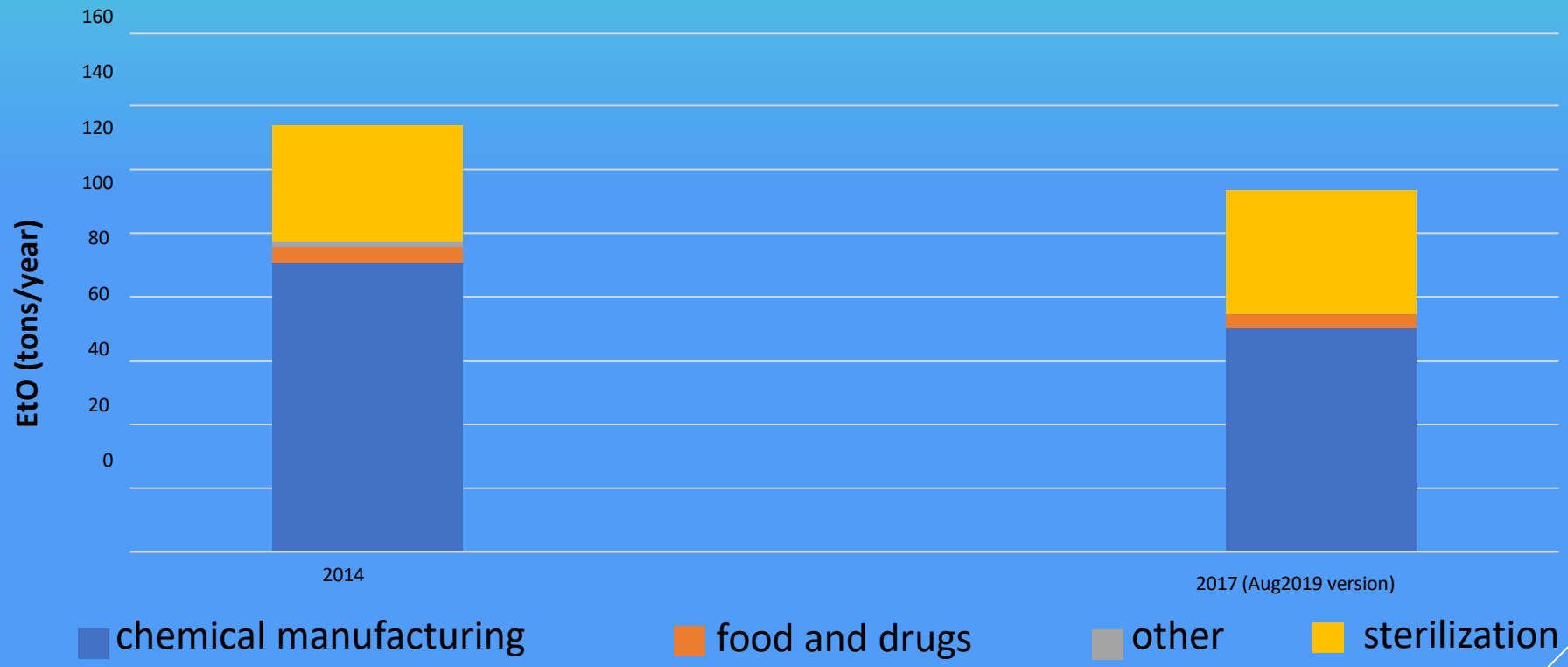
- Chemical facilities manufacture EtO to produce things we use every day

- Makes ethylene glycol, which is a key ingredient in a variety of consumer household products

What is EtO used for?

- **To sterilize things that cannot be sterilized by other methods**
  - Medical equipment
  - Surgical equipment and supplies
- **To fumigate certain items that cannot get wet**

Sources of EtO Emissions Nationwide



Ethylene Oxide Emissions (tons)
from National Emission Inventory Point Data Category

WHY IS ETHYLENE OXIDE IMPORTANT?

EtO Health Impacts

EtO is a carcinogen and can damage the nervous system:

Acute symptoms (short term): May cause eye/skin/respiratory irritation, headache, nausea

Chronic symptoms (long term): May cause cancer, mutagenic (it can damage DNA) changes, neurotoxicity

EtO History

- **1985**: Integrated Risk Assessment (IRIS) completed based on animal exposure studies
- **2016**: Integrated Risk Information System (IRIS) completed based on human occupational studies
- **2018**: EPA's National Air Toxics Assessment (NATA) alerted state and local agencies to potential elevated cancer risks from its screening analysis
- **2020**: EPA Office of Inspector General's Management Alert advised EPA to conduct meetings to communities

Exposure to EtO

- Workers may be exposed to EtO if they work in places where EtO is produced or used, such as chemical plants and commercial or hospital sterilizers.
- People who live near facilities that emit EtO may be exposed to EtO in the outdoor air.
- It is unlikely that EtO would remain in or on food or remain dissolved in water long enough to be eaten or swallowed.
- There is limited information on levels of EtO at hazardous waste sites - in air, water, or soil.

EtO Health Risks

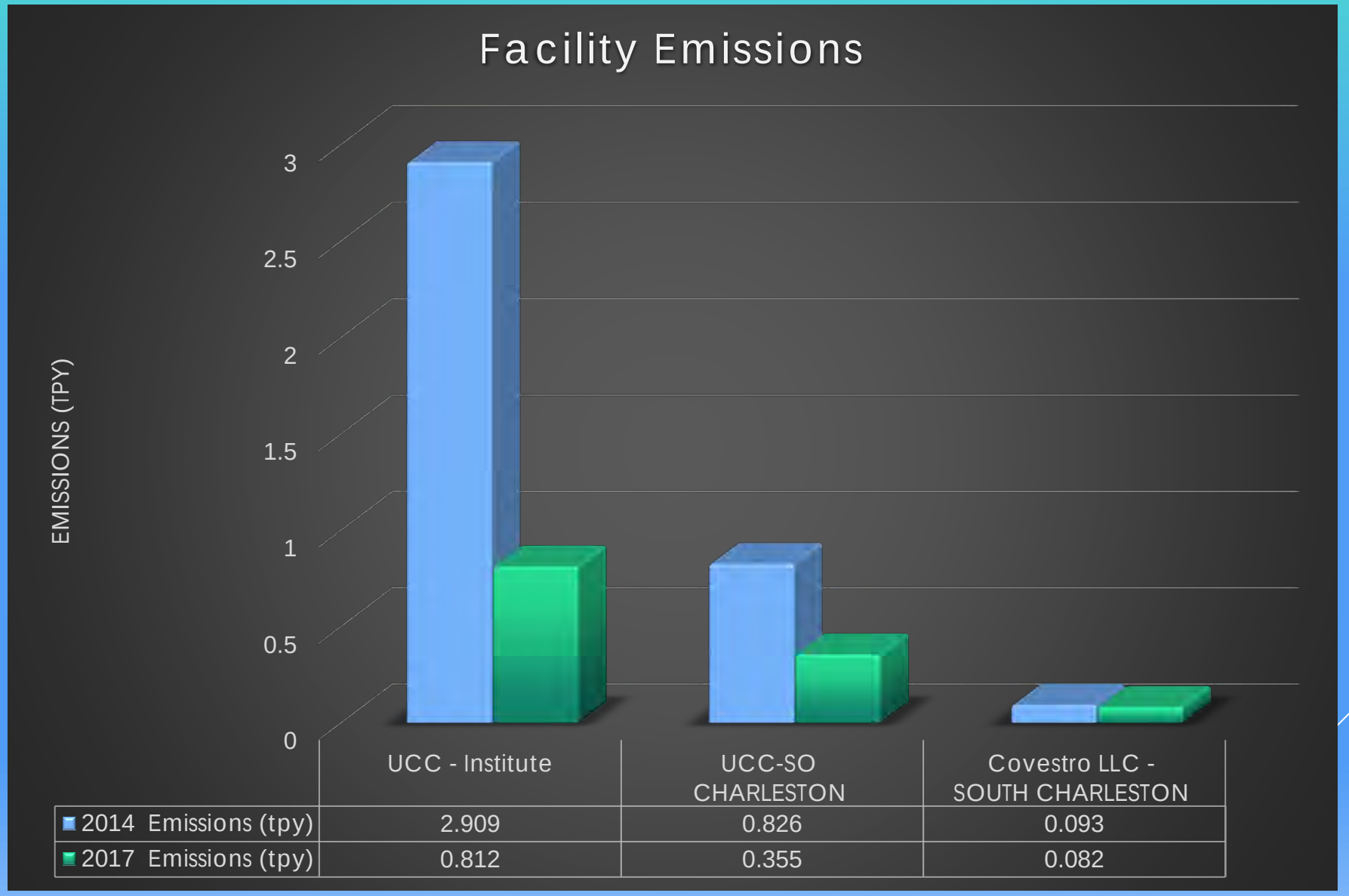
- Risk to get cancer from breathing ethylene oxide is based on exposure for 24 hours a day for 70 years

- One-time, short-term exposure to low amounts of ethylene oxide should not cause immediate harm to a person's health

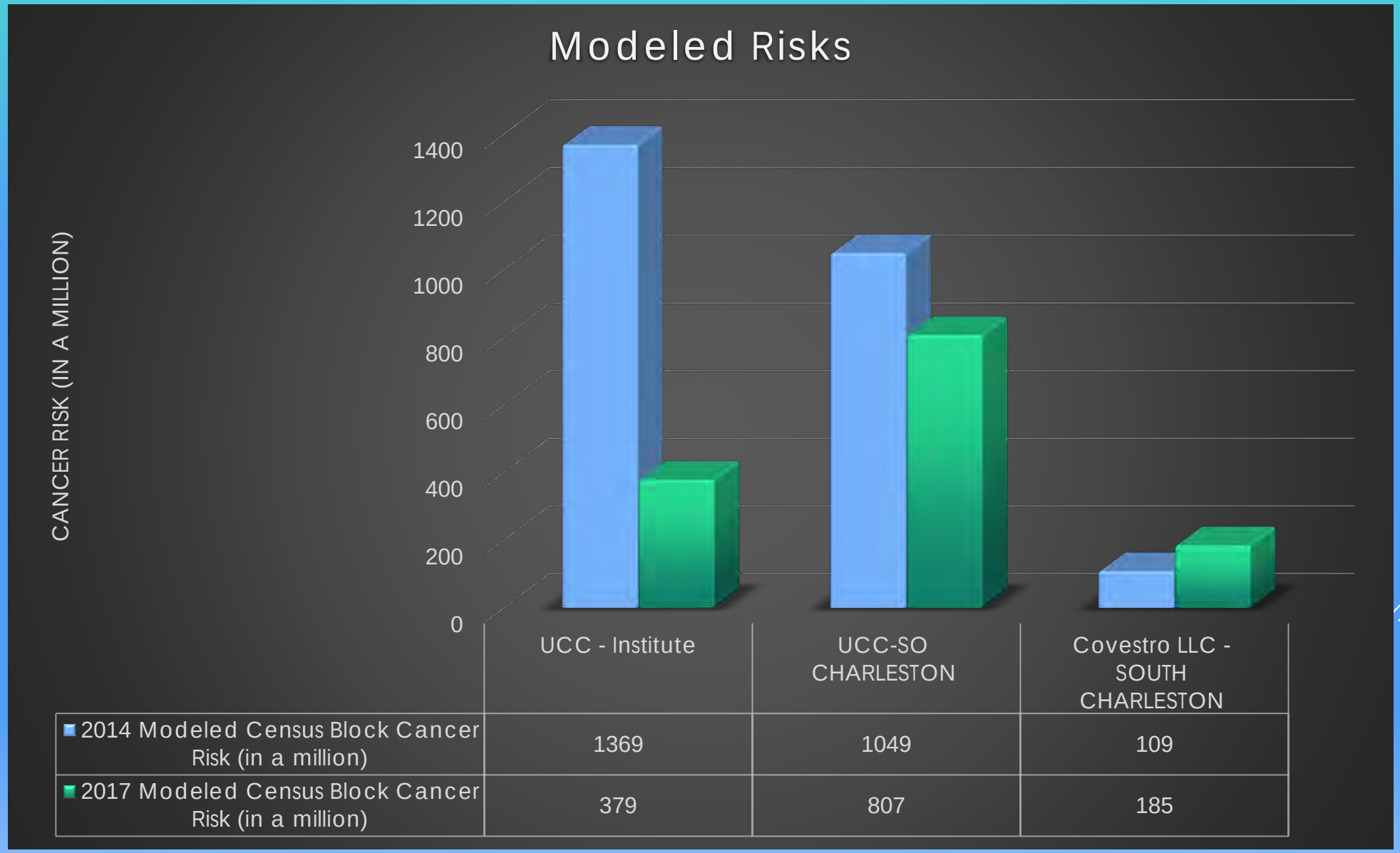
- Long-term ethylene oxide exposure increases the risk of cancers of the white blood cells including: non-Hodgkin lymphoma; myeloma; lymphocytic leukemia and breast cancer in women

WHAT ARE THE FINDINGS FOR SOUTH CHARLESTON AND INSTITUTE, WV?

EtO Emissions Data



EtO Modeled Risks



HOW DOES EPA ADDRESS EtO RISK?

Human Exposure Model for EtO Risk

- Used primarily for sources emitting air toxics to the air
- Models inhalation exposure to predict estimated risks above background
- Produces estimates of cancer risk and noncancer hazards for air toxics
- Exposure variables are not explicitly addressed

More information can be found at:
www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem

Why are there different risk values for EtO?

- Texas has a cancer risk value substantially lower than EPA's IRIS risk value for two main reasons:
  - A smaller data set that did not include breast cancer in women as an outcome and the Texas value is based only on lymphoid cancer
  - Because we used different data, Texas selected a statistical model that both EPA and the Science Advisory Board determined does not adequately describe the relevant human cancer data

What does a 1-in-a-million cancer risk mean?

- A cancer risk level of 1-in-1 million implies that,
  - if 1 million people are exposed to the same concentration of EtO continuously (24 hours per day) over 70 years (an assumed lifetime)
  - one person would likely contract cancer from this exposure
- This risk would be in addition to any cancer risk borne by a person not exposed to EtO

Estimated Risk (Above Baseline)

- Using 2017 emissions National Air Toxics Assessment model, EPA estimated the potential increased cancer risk from breathing EtO released from the facilities
  - South Charleston area to be **807 cases in one million for Union Carbide** and **185 cases in one million for Covestro**
  - **379 in one million for Union Carbide** in Institute WV

Factors that affect EtO's health risks

- Your personal health risks (such as age, family history, lifestyle)
- How much EtO is in the air you breathe
- How long you have been breathing air with that level of EtO
- How often you breathe EtO at that level
- For everyone, including children, risks would decrease with decreased exposure

WHAT IS EPA DOING ABOUT EtO?

MONITORED LEVELS

- EPA has monitored the air for ethylene oxide across the nation as part of our air toxics network.
- We found a range of results nationally where EtO was detected and had high levels of EtO and higher risk.
  - These high results were not in EPA Region 3—not in West Virginia.
  - However, some of these results are also not associated with a known regulated source.
- We are continuing to study the areas to better understand where the ethylene oxide is coming from.
  - For example, the Office of Transportation and Air Quality are looking into possible mobile emissions.

MONITORED LEVELS

- We are also working on getting better at measuring lower concentrations of EtO.
  - We have higher confidence in measuring at concentrations near sources.
  - We have identified and are working to improve the method to reduce issues regarding sample collection and analysis.
  - Analysis methods continue to improve so that we can reduce the uncertainty in the measurements and allow for a better understanding of EtO concentrations in ambient air.

EPA's EtO Response Strategy

- Review Clean Air Act regulations for facilities that emit ethylene oxide.
- Identify ways to reduce emissions:
  - Work with state agency partners to gather updated EtO facility emissions
  - Discuss voluntary controls with industries.
  - Continue to work and support state partners.

EPA Regulations for EtO Emissions

- 40 CFR. Part 63, Subpart FFFF: Miscellaneous organic chemical manufacturing
- **40 CFR Part 63, Subpart PPP: Polyether polyols production**
- 40 CFR Part 63, Subparts F, G, H, and I: Synthetic organic chemical manufacturing industry
- 40 CFR Part 63, Subpart EEEE: Organic liquids distribution (non-gasoline)
- 40 CFR Part 63, Subpart O: Ethylene oxide-emitting (commercial) sterilization facilities
- 40 CFR Part 63, Subpart WWWWW: Hospital sterilizers

Upcoming Regulatory Reviews

- Commercial Sterilizers: Oct.-Dec., Fiscal Year (FY) 2022
- Hospital Sterilizers: Oct.-Dec., FY 2023
- Group 1 Polymers and Resins: April-June, FY 2024
- Synthetic Organic Chemicals Manufacturing Industry: April-June, FY 2024
- **Polyether Polyols Production: Oct.-Dec., FY 2024**
- Chemical Manufacturing Area Sources: Oct.-Dec., FY 2024

EPA and West Virginia Collaboration

- R3 and the West Virginia Department of Environmental Protection (WVDEP) have been working together to refine the NATA screening analysis.
- Both R3 and WVDEP have collaborated in modeling EtO emissions from Union Carbide, S. Charleston; Union Carbide, Institute; and Covestro, S. Charleston.
- Current modeling results continue to show levels of concern, although less widespread.

Next Steps

- EPA will continue to collaborate with WVDEP to model risk impacts using more recent 2020 data to determine risk trends.
- We will support WVDEP's short term sampling to confirm modeled results.
- We will continue to hold joint meetings to inform the communities of our efforts.

INTRODUCE WVDEP

ADDITIONAL RESOURCES

Additional Resources on EtO

- The following national EPA websites have additional EtO information:
  - https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide
  - https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-health-information-about-ethylene-oxide
- A recording of these presentations and answers to questions not addressed will be posted on:
  - https://dep.wv.gov/daq/Air%20Toxics/EthyleneOxide/Pages/default.aspx
- Additional comments can be posted to:
  - DEP.Comments@wv.gov

Contacts on EtO

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THANK YOU

OTHER FEDERAL AGENCIES

- **Centers for Disease Control**
  - The Agency for Toxic Substances and Disease Registry (ATSDR) provides scientific and health effects information on EtO. https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=133.
  - The National Institute for Occupational Safety and Health (NIOSH) is a research agency focused on assuring safe and healthful working conditions. https://www.cdc.gov/niosh/topics/ethyleneoxide/default.html
- **The Food and Drug Administration (FDA)**
  - FDA reviews the sterility information for most sterile medical devices before they are on the market. Learn more at https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices#how
- **The Occupational Safety and Health Administration (OSHA)**
  - OSHA sets workplace standards for EtO exposure and provides other resources for employers. See https://www.osha.gov/ethylene-oxide; a fact sheet is available at https://www.osha.gov/OshDoc/data_General_Facts/ethylene-oxide-factsheet.pdf