



# Ethylene Oxide Virtual Public Meeting

April 13, 2022

6:00 PM – 8:00 PM

# Agenda

- Introductions
- Cancer Analysis – Delaware Division of Public Health
- Exposure and Risk – EPA Region III
- Facility Equipment and Emissions – Croda, Inc.
- Ethylene Oxide Compliance Strategies – Delaware Division of Air Quality
- Questions and Answers



# MEETING WITH ROUTE 9 COMMUNITY

APRIL 13, 2022

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Delaware Division of Public Health

# DELAWARE CODE



Office of the Registrar of Registrations,  
Legislative Council,  
State of Delaware

## TITLE 16 HEALTH AND SAFETY DELAWARE ADMINISTRATIVE CODE

1

### DEPARTMENT OF HEALTH AND SOCIAL SERVICES DIVISION OF PUBLIC HEALTH Health Promotion and Disease Prevention

#### 4201 Cancer Registry

#### 1.0 Purpose

These regulations are promulgated by the Department pursuant to Senate Bill 372 of the 141<sup>st</sup> General Assembly. These regulations are also independently authorized by 29 **Del.C.** §7903. The purpose of the regulations is to implement 16 **Del.C.** Ch. 32.

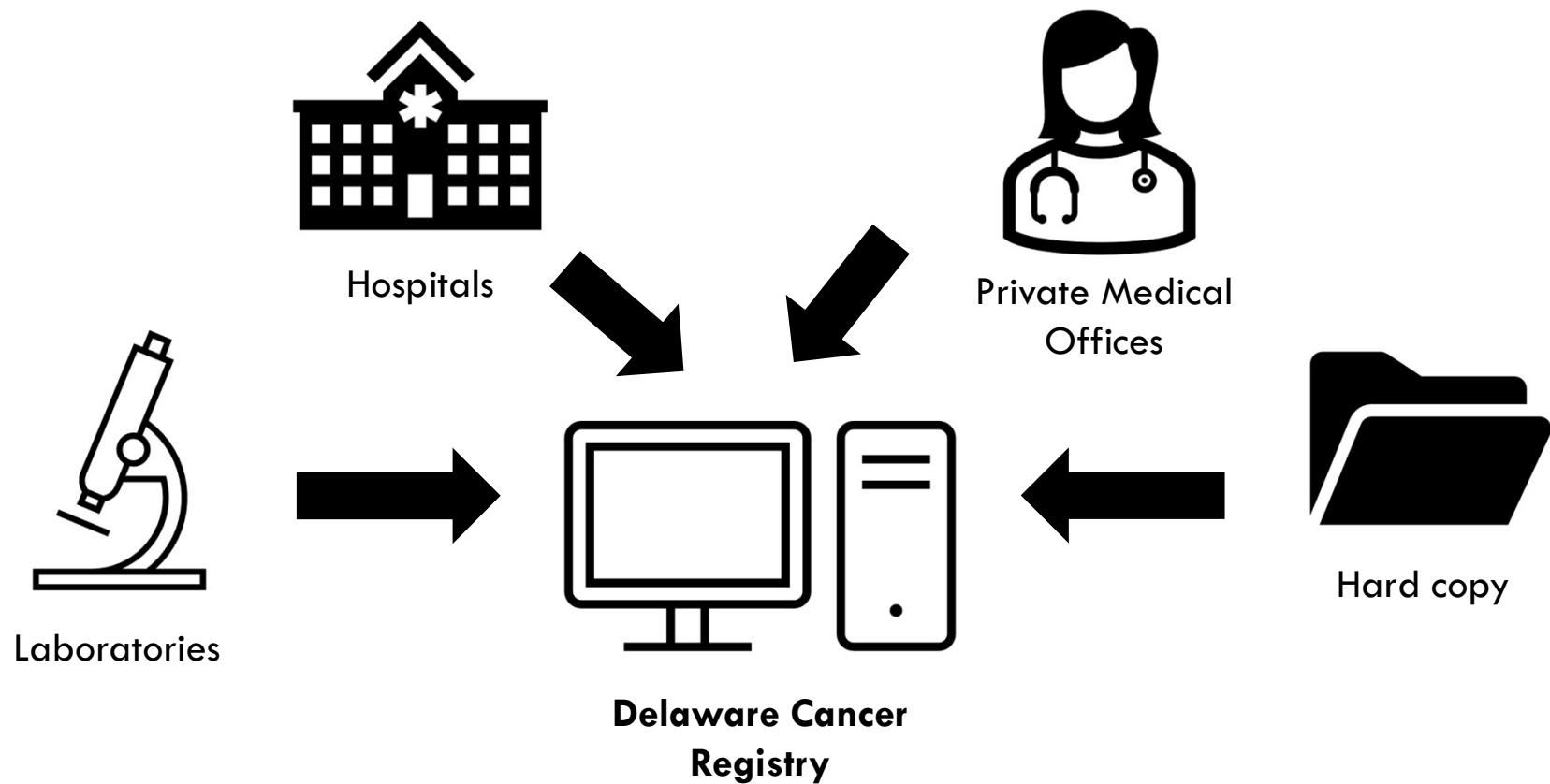
**6 DE Reg. 958 (2/1/03)**

#### 2.0 Definitions

**"Benign Tumor"** means any nonmalignant neoplasm, regardless of the tissue or origin, that appears on the American College of Surgeons most recently published list of reportable cancers and benign tumors.

**"Cancer"** means any malignant neoplasm, regardless of the tissue origin, that appears on the American College of Surgeons most recently published annual list of reportable cancers and benign tumors.

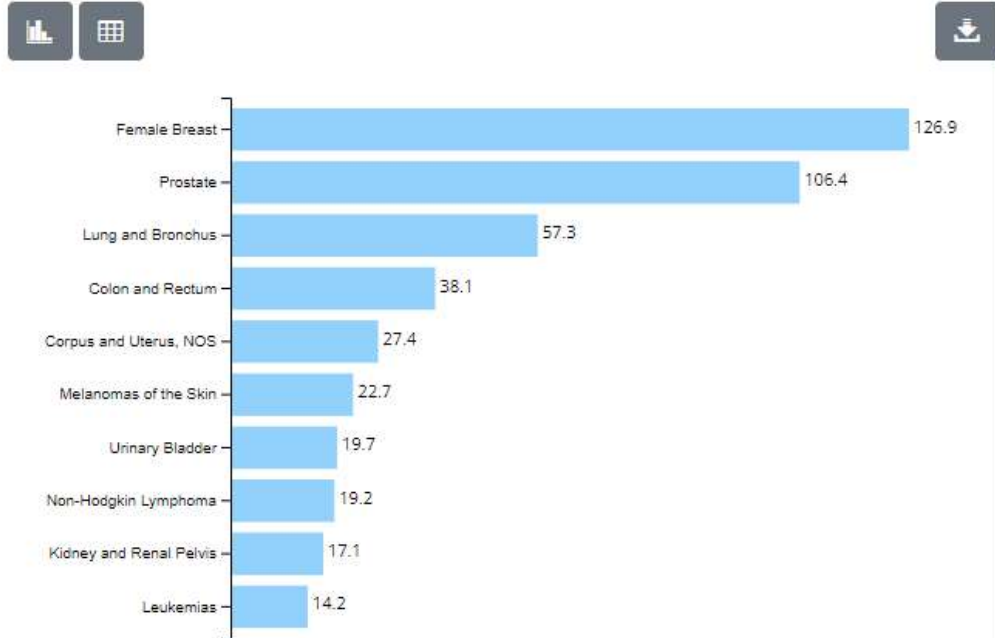
# DATA: DELAWARE CANCER REGISTRY



# UNITED STATES TOP TEN CANCERS 2014-2018

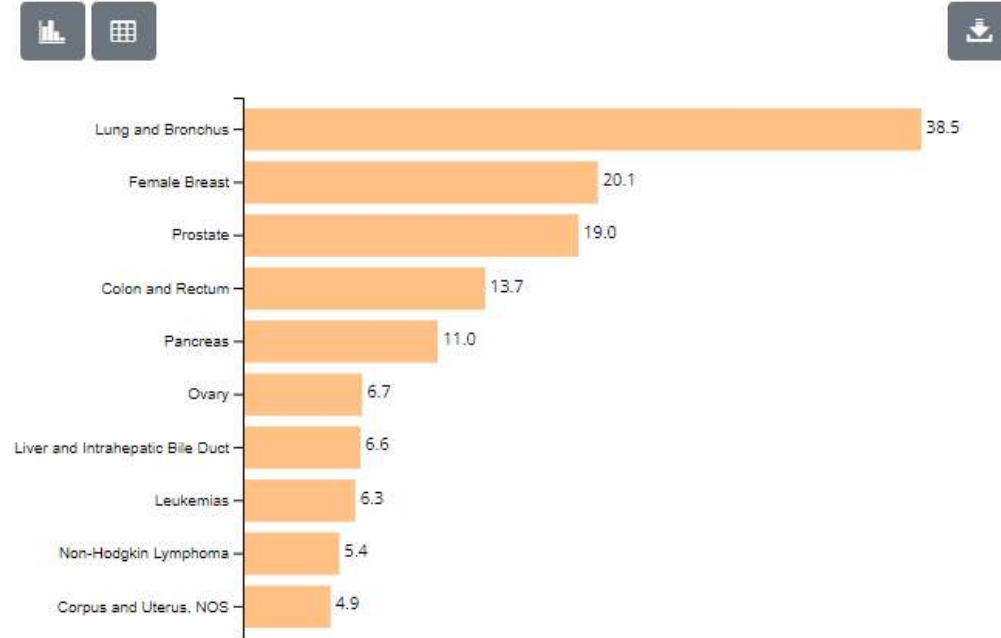
## Top 10 Cancers by Rates of New Cancer Cases

United States, 2014-2018, All Races and Ethnicities, Male and Female  
Rate per 100,000 people



## Top 10 Cancers by Rates of Cancer Deaths

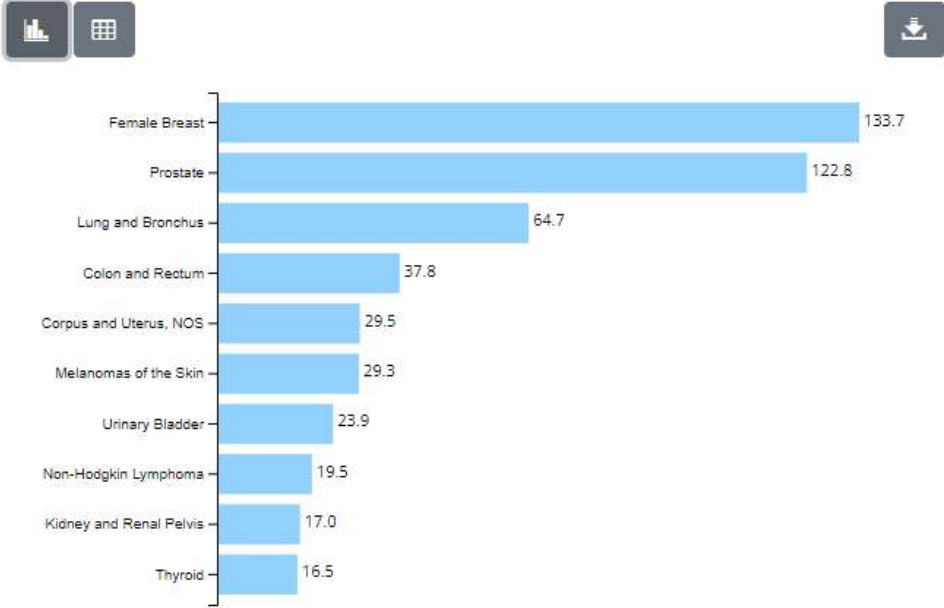
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# DELAWARE TOP TEN CANCERS 2014-2018

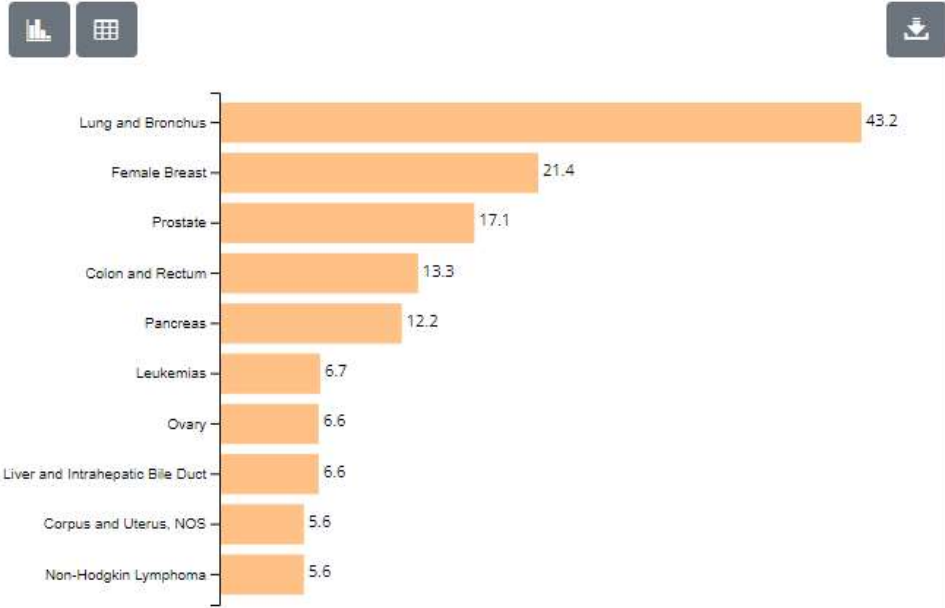
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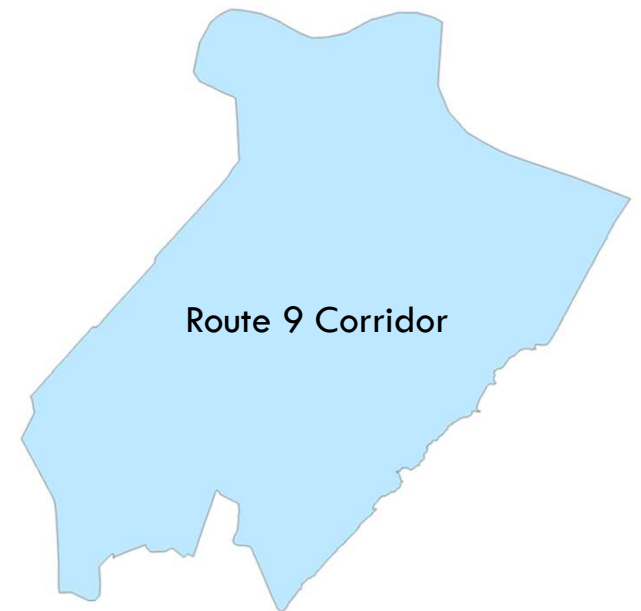
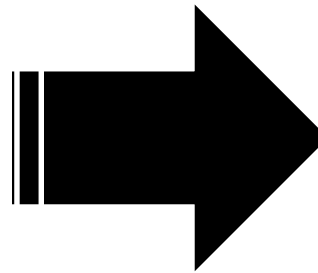
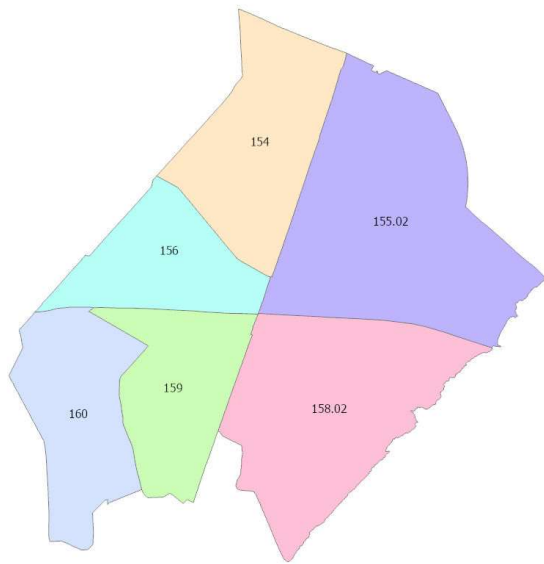


## Top 10 Cancers by Rates of Cancer Deaths

Delaware, 2014-2018, All Races and Ethnicities, Male and Female  
Rate per 100,000 people



# DATA ANALYSIS FOR ROUTE 9





**Table 1: Five Year Age-Adjusted Cancer Incidence Rates by Area and Cancer Type, Route 9 Corridor, Delaware, and US, 2011-2017**

|                          | 2011-2015   |                | 2012-2016   |                | 2013-2017   |                |
|--------------------------|---|----------------|---|----------------|---|----------------|
|                          | Age-adjusted Incidence Rate with Confidence Intervals | Count of Cases | Age-adjusted Incidence Rate with Confidence Intervals | Count of Cases | Age-adjusted Incidence Rate with Confidence Intervals | Count of Cases |
| <b>Route 9</b>           |   |                |   |                |   |                |
| All-site                 | 489.3 [446.5, 535.2]                                  | 499            | 481.4 [439.4, 526.5]                                  | 504            | 469.7 [428.2, 514.3]                                  | 497            |
| Lymphoma                 | 20.3 [12.3, 31.6]                                     | 20             | -----   | <16            | 19.8 [11.9, 31.0]                                     | 20             |
| Leukemia                 | -----   | <16            | -----   | <16            | -----   | <16            |
| Female Breast            | 122.0 [94.1, 155.8]                                   | 68             | 103.4 [77.8, 135.1]                                   | 58             | 107.0 [80.4, 139.9]                                   | 59             |
| <b>New Castle County</b> |   |                |   |                |   |                |
| All-site                 | 486.3 [478.3, 494.3]                                  | 14,820         | 485.3 [477.4, 493.3]                                  | 15,098         | 481.5 [473.8, 489.4]                                  | 15,290         |
| Lymphoma                 | 23.3 [21.5, 25.1]                                     | 693            | 23.2 [21.4, 25.0]                                     | 704            | 23.6 [21.9, 25.4]                                     | 728            |
| Leukemia                 | 13.5 [12.2, 14.9]                                     | 400            | 12.8 [11.5, 14.2]                                     | 384            | 11.7 [10.5, 13.0]                                     | 359            |
| Female Breast            | 136.2 [130.5, 142.1]                                  | 2,233          | 139.1 [133.3, 145.0]                                  | 2,306          | 140.6 [134.8, 146.5]                                  | 2,365          |
| <b>Delaware</b>          |   |                |   |                |   |                |
| All-site                 | 495.3 [489.4, 501.3]                                  | 28,028         | 491.5 [485.7, 497.4]                                  | 28,581         | 484.3 [478.5, 490.0]                                  | 28,938         |
| Lymphoma                 | 24.0 [22.7, 25.3]                                     | 1,306          | 24.0 [22.7, 25.4]                                     | 1,345          | 23.4 [22.1, 24.7]                                     | 1,339          |
| Leukemia                 | 14.4 [13.4, 15.5]                                     | 784            | 14.0 [13.0, 15.0]                                     | 779            | 13.0 [12.0, 14.0]                                     | 744            |
| Female Breast            | 134.2 [130.0, 138.6]                                  | 4,008          | 136.5 [132.2, 140.8]                                  | 4,146          | 135.4 [131.1, 139.7]                                  | 4,203          |

Source: Delaware Health and Social Services, Division of Public Health, Delaware Cancer Registry, December 2021.

Note: Rates are per 100,00 population. All-site refers to all cancer types. Population estimates are from Woods & Poole Economics, Inc. Census Tract Estimates Controlling to Vintage 2017, 2000-2017

'-----' indicates suppression of rates and counts for privacy protection with small numbers

Route 9 Corridor includes tracts 154, 155.02, 156, 158.02, 159 and 160.



NATIONAL CANCER INSTITUTE

Surveillance, Epidemiology, and End Results Program

# DIVISION OF PUBLIC HEALTH REPORTS ON CANCER

- The Delaware Division of Public Health (DPH) currently produces two annual reports on cancer incidence and mortality in Delaware. The reports are made publicly available here: <https://www.dhss.delaware.gov/dhss/dph/dpc/cancer.html>
- Moving forward, DPH will begin producing a Route-9 specific cancer data brief with the new Route 9 grouping as described in the previous slide. DPH will make these reports available to the public





**Ways to connect to services:**

- Visit Henrietta Johnson Medical Center
- Visit Healthy Delaware website:  
<https://www.healthydelaware.org/Individuals#healthy-living>
- Call Division of Public Health at 302-744-1040

# RESOURCES

To learn more about cancer risk factors: <https://youtu.be/mufb0Hx2438>

More about cancer causing substances in the environment: [Cancer-Causing Substances in the Environment - National Cancer Institute](#)

Want to know cancer statistics in the other states and Delaware: [USCS Data Visualizations - CDC](#)

Want to know which census-tract you reside in: <https://geocoding.geo.census.gov/geocoder/geographies/address?form>

For information on Delaware's cancer reports: <https://www.dhss.delaware.gov/dhss/dph/dpc/cancer.html>

For information on how to get a cancer screening: <https://www.healthydelaware.org/Individuals#healthy-living>



# EPA Risk Discussion

Alice H. Chow, Chief

Carol Ann Gross-Davis, PhD

Air Quality Analysis Branch

EPA Region 3

# Agenda

- What is Risk?
- How does EPA estimate Risk?
- 2014 National Air Toxics Assessment
- How does EPA communicate Risk?
- What are the latest modeling results?

# What is Risk?

| <b>Hazard</b>   | <b>vs.</b> | <b>Risk</b>  |
|---|------------|--|
| <p>A Hazard is something that has the potential to harm you</p> <p>A shark in the sea is a hazard</p> |            | <p>Risk is the likelihood of a hazard causing harm.</p> <p>Swimming with a shark is a risk</p> |



- Rules and Regulations for
- Process Safety
  - Technical Safety
  - Occupational Safety
  - Community Alerts

# What is Risk?

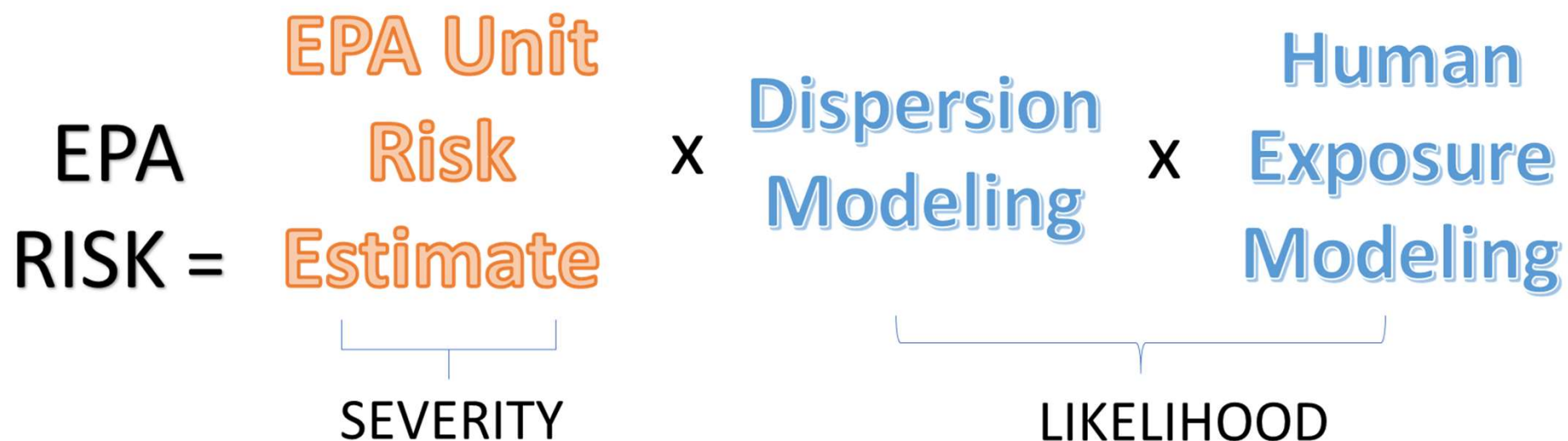
Severity that can be caused  
by the event or exposure

$$\text{RISK} = \text{SEVERITY} \times \text{LIKELIHOOD}$$

Likelihood of an occurrence  
of a hazardous event of  
exposure

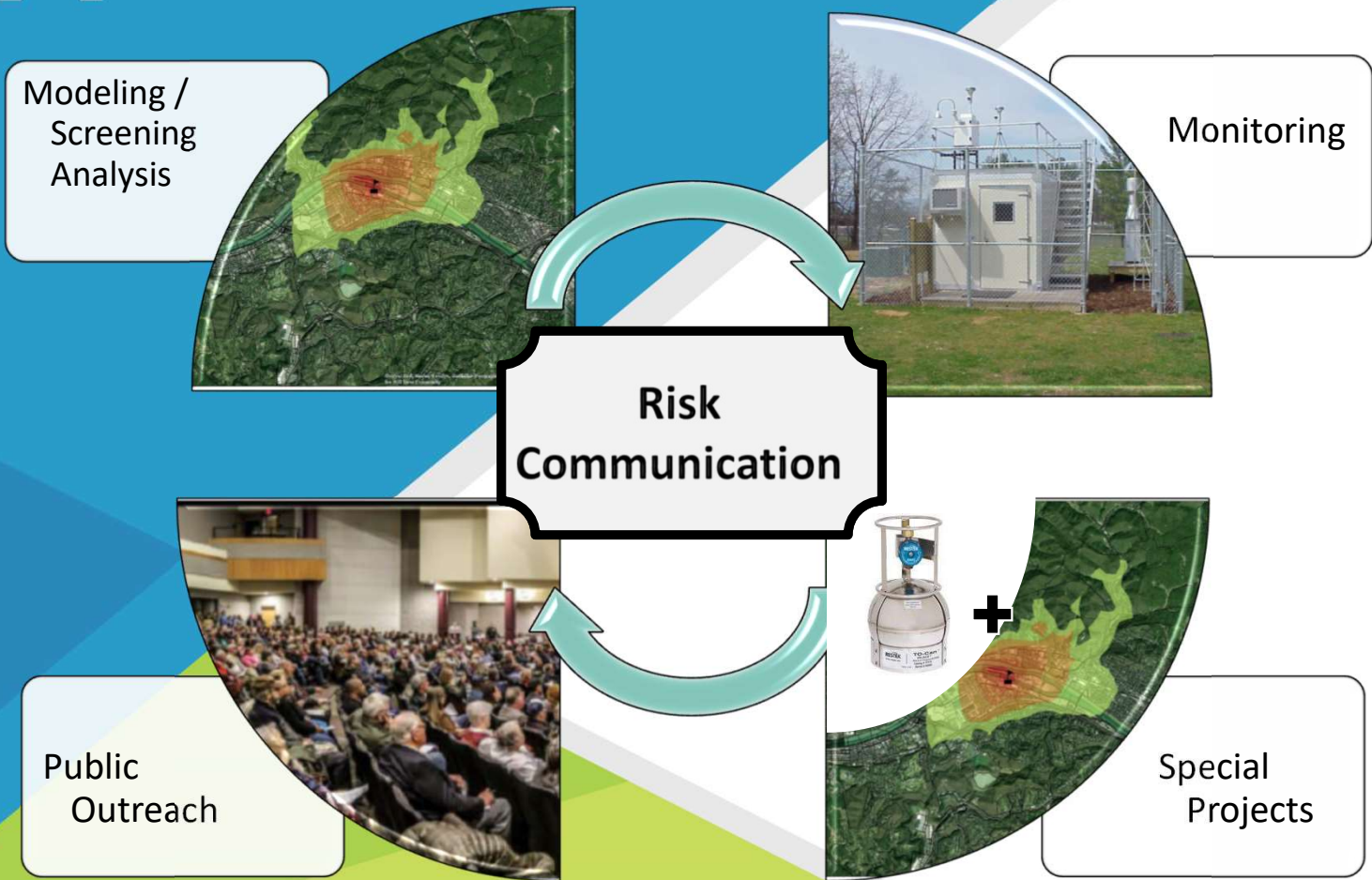


# How does EPA estimate Risk?



# 2014 National Air Toxics Assessment (NATA)

- In 2016, EPA's Office of Research and Development (ORD) determined that Ethylene Oxide (EtO) is a human carcinogen (breast cancer, lymphoma)
- ORD changed the unit risk estimate—increased 30-60 fold
- The 2014 NATA is a screening tool used the 2016 unit risk estimate to model risk exposure
- The 2014 NATA identified high risk areas ( $\geq 100$  in a million) for further study



# Human Exposure Model for 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: <https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem>

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

$$\text{EPA RISK} = \underbrace{\text{EPA Unit Risk Estimate}}_{\text{SEVERITY}} \times \underbrace{\text{Dispersion Modeling} \times \text{Human Exposure Modeling}}_{\text{LIKELIHOOD}}$$

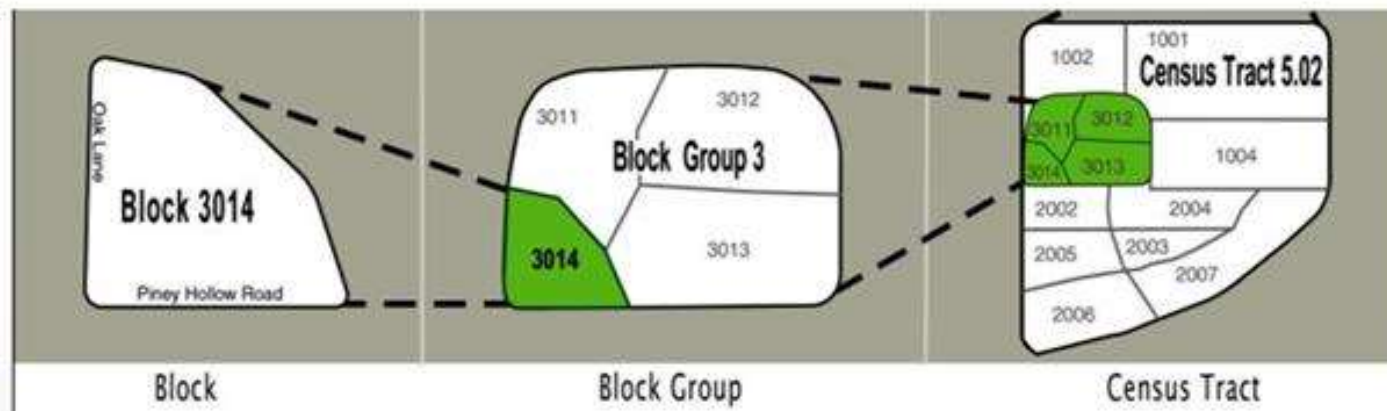
- A cancer risk level of 1-in-1 million implies that,
  - If 1 million people are exposed to the same concentration of EtO continuously (24 hours per day) over 70 years (an assumed lifetime)
  - One person would likely contract cancer from this exposure.
- This risk would be in addition to any cancer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

# Estimated Risk above background

- Using 2021 emissions data provided by Croda EPA used the Human Exposure Model 4 (HEM 4) to estimated the potential cancer risk from breathing EtO emissions from this facility
  - The highest block tract or area was estimated to be **70 cases in one million**

# Census Tracts vs. Census Blocks

- AirToxScreen (screening level assessment) is performed at the census tract.
- Risk assessment for the EtO was performed at the census block.




# What are the Background levels


- We don't know what background levels are for ethylene oxide – we can't put an exact number on it.
  - This is because the current measurement methods are not sensitive enough to be used for this purpose.
  - These methods are more reliable at higher concentrations that we see close to many industrial facilities that use or produce EtO, they are less reliable (and somewhat uncertain) at lower concentrations.



# Breathing Air Containing EtO is the Main Way People are Exposed

- 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 also is limited information on levels of EtO at hazardous waste sites - in air, water, or soil. This makes it difficult to determine how likely it is that someone might be exposed to EtO at or near these sites.
- 

# Factors That Affect Whether EtO May Harm your Health

- 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
  - EPA and DE are taking steps to reduce ethylene oxide (EtO) in the air to reduce risk.
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**Contact Info:**

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**Carol Ann Gross-Davis, PhD**

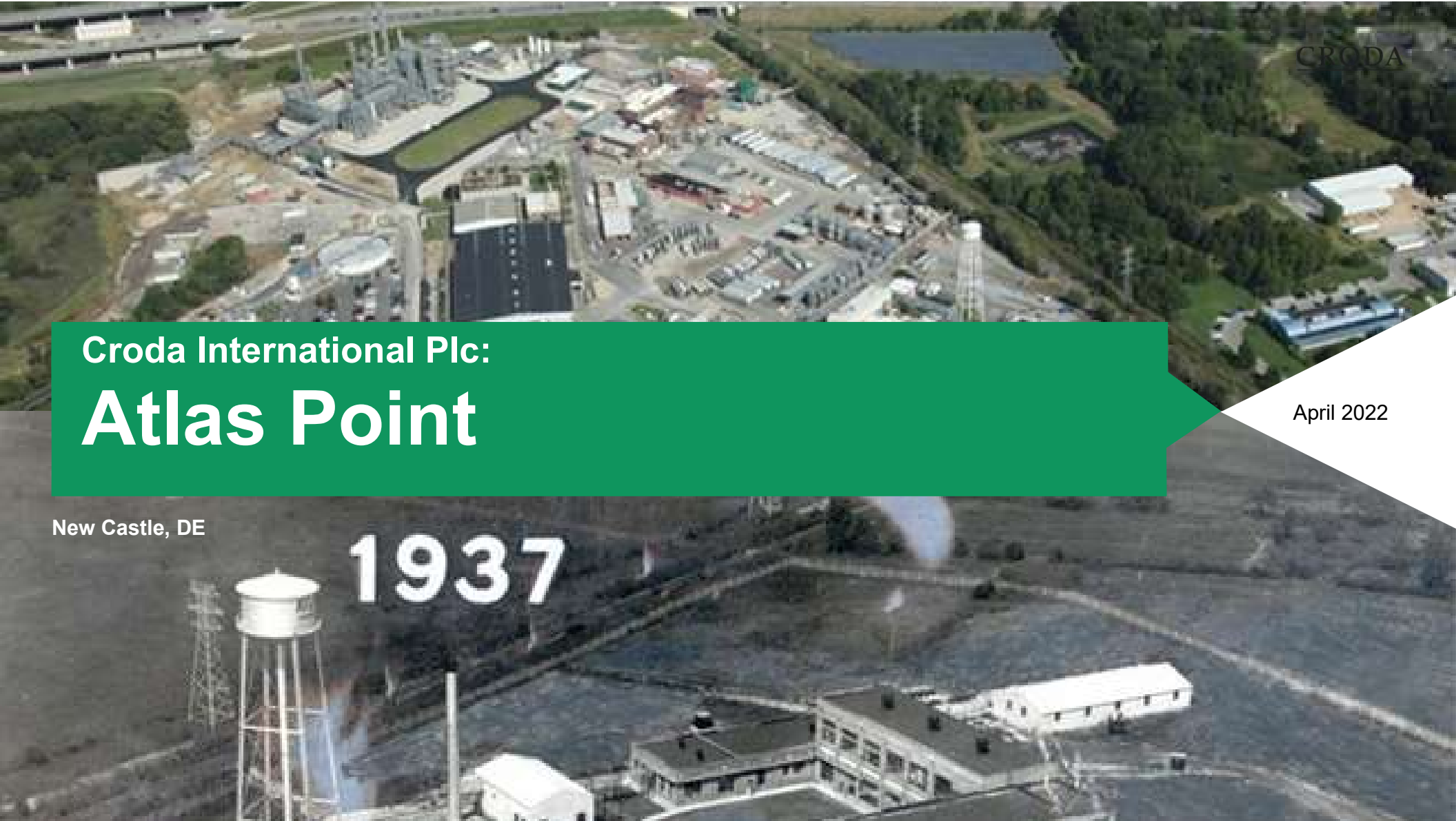
**[Gross-davis.carolann@epa.gov](mailto:Gross-davis.carolann@epa.gov)**

Croda International Plc:  
**Atlas Point**

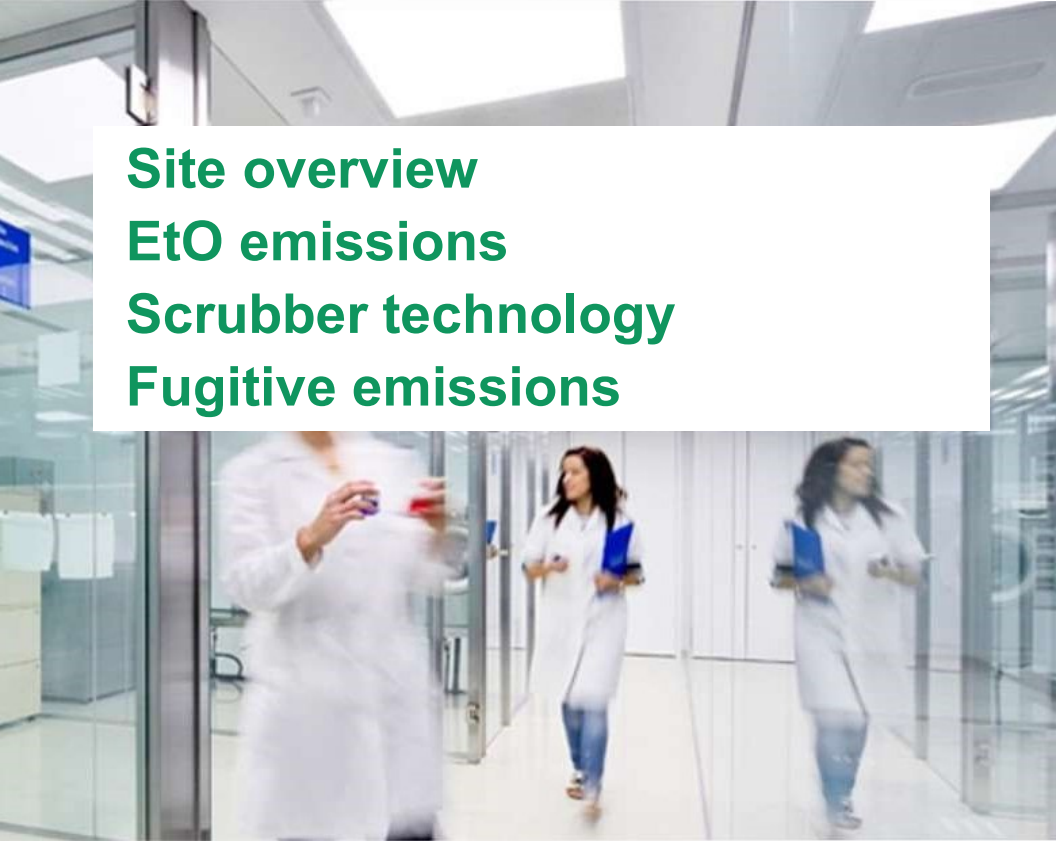
April 2022

New Castle, DE

1937



# Topics



Site overview  
EtO emissions  
Scrubber technology  
Fugitive emissions



Smart science  
to improve lives™

## Site overview

Atlas Point first started **1937**

Croda purchased Atlas Point in 2006

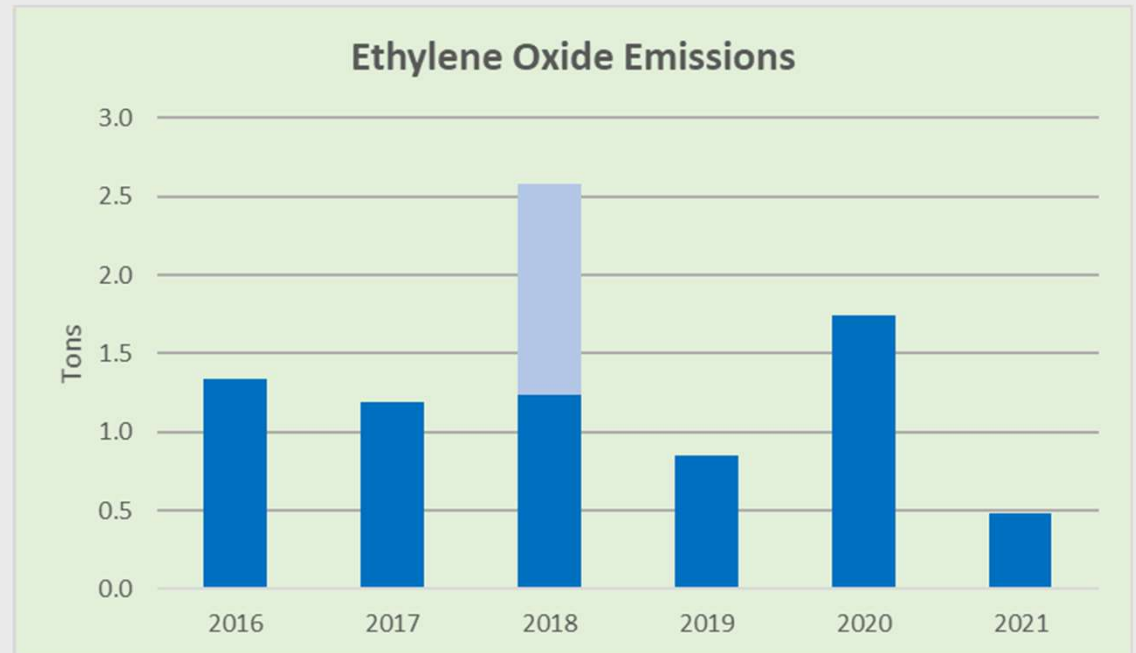
- Main product – Surfactants – help things mix together
  - Cosmetics, lotions, soaps, hair treatments
  - Cleaners, detergents
  - Mixing agents for crop protective materials
- Ethylene Oxide (EtO) plant constructed 2016
  - Provide ethanol based “renewable” EtO
  - Minimize petroleum EtO for sustainability
  - Only plant of its kind in US



# EtO emissions

- Overall reduction of emissions since 2016
- Two notable outliers
  - 2018: Release of EtO (*In light blue in chart*)
  - 2020: Plant control system design deficiencies
    - Found during stack testing
    - Corrected via design changes confirmed by follow-up test

- Typical data contains two types of emissions
  - “Point source” emissions
  - “Fugitive emissions”



# Emission reduction improvements at Atlas Point

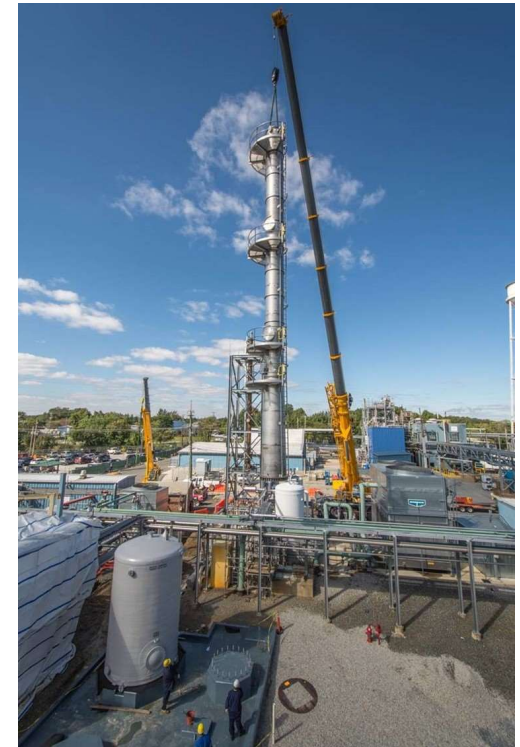
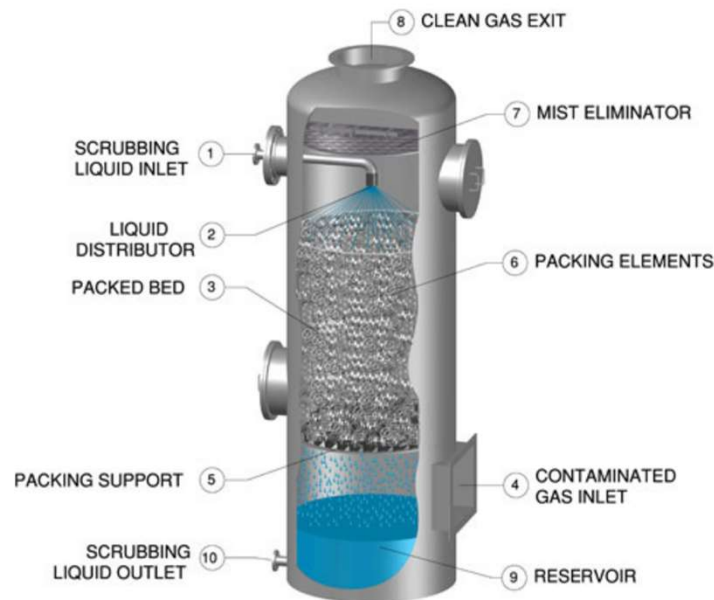
Smart science to improve lives™

- **Reduction of point source emissions**

- DNREC notice prior to EPA revised risk level
- Proactively designed scrubber
- Installed \$15 million scrubber project
- **Reduces emissions by 99%**

- **EtO Plant**

- Recycled EtO point source back to process
- Point source emissions currently zero





# Fugitive emissions

## What are fugitive emissions?

- Irregular releases of gases or vapors from pressurized equipment
  - Flanges, valve stems, tubing connections, pump seals, etc.

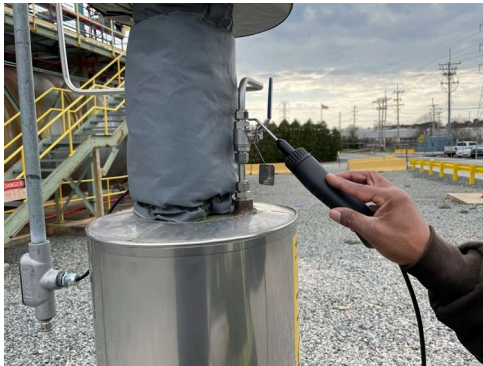
## How are they controlled?

- Routine monitoring of connections
  - Leak Detection and Repair (LDAR)
  - PPM limits with required actions
- Minimize number connections
- Low leak equipment
- Routine tightness checks
- 3<sup>rd</sup> party audits



## Next steps for Fugitives

- Focused effort on fugitive reductions
- Lowering LDAR limits
- Exploring new technology
- Best practices – Learn from others
  - DNREC, EPA
  - Industry Connections
  - LDAR Experts



### Leak Detection and Repair

A Best Practices Guide



# CRODA



Health & Safety



Sustainability



Innovation

Thanks for listening

# DNREC Division of Air Quality



# DNREC's Response to the Revised Risk

- When EPA revised the risk for ethylene oxide in December 2016, DNREC followed up with our sources to discuss paths forward to reduce emissions using existing tools.
- The change in risk did not result in new federal or state regulations.
- EPA is working on changes to federal rules for sterilizers at present.
- The change in risk did not result in updated worker exposure requirements. Ethylene oxide is currently listed as “under study” by the American Conference of Governmental and Industrial Hygienists (ACGIH).

# How DNREC/AQ worked to reduce risk...

- Permitting
- Compliance
- Enforcement

# Permitting

- Delaware issues permits prior to construction of new sources of emissions.
- Facilities request permits by submitting applications.
- The type of permits issued depend on the amount/quantity of emissions – major and minor sources receive different types of permits.
- We use computer programs to “model” (predict the offsite) emissions.
- The purpose of a permit is to tell a facility what they must do to operate in compliance with the regulations that apply to them.

# Permitting

- What is in a typical permit?
  - Emission Limitations – the amount of pollution a facility is allowed to emit
  - Operational Limitations – requirements such as limits on hours, throughput or production and requirements to operate associated control devices (equipment that reduce emissions)
  - Testing and Monitoring Requirements
  - Recordkeeping Requirements
  - Reporting Requirements
  - Compliance Certification



# Compliance

- All major sources of air emissions (Title V sources) are inspected regularly.
  - Full compliance inspection every other year – Inspection of all aspects of the facility
  - Partial compliance inspection every year – Inspection of some aspects of the facility
- Compliance work includes many types of oversight activities including:
  - Review of records and reports
  - Onsite inspections
  - Stack tests – taking samples from the area where the emissions originate to test them
  - Status meetings
- Croda's most recent full compliance inspection was conducted on 9/17/2021.
- Croda's most recent compliance activity was their annual compliance certification and semiannual report submitted on 2/4/2022
- Croda will certify their emission inventory for 2021 prior to April 30, 2022

# Enforcement

- Enforcement work includes:
  - Informal enforcement – Notice of Violation
  - Formal enforcement – Secretary’s Order
- When DAQ reviews records and test results we evaluate compliance with the regulations. If necessary, we use enforcement as a tool to address non-compliance.
- The purpose of compliance and enforcement work is to achieve ongoing long-term compliance.
- NOV List serv send a blank email to:  
[join-dnrec\\_enforcement\\_actions@lists.state.de.us](mailto:join-dnrec_enforcement_actions@lists.state.de.us)

# Croda

- DAQ increased our compliance oversight at Croda following the increase in the risk and as a result of recent enforcement matters. This includes regularly scheduled meetings to discuss facility status.
- From 2015 to present the amount of DAQ staff time spent on this facility has increased significantly. 2021 hours were 3.5 times higher than 2015.
- DAQ is committed to providing comprehensive compliance and enforcement oversight to promote compliance. When DAQ discovers issues, they will be addressed through informal and/or formal enforcement as appropriate. DAQ will also work with the facility to identify ways to continue to reduce emissions.
- As discussed by EPA, the modeled ambient concentration of ethylene oxide is far below quantifiable limits. DAQ will continue to stay informed as the technology improves and will conduct sampling when it is scientifically possible.

# What's Next?

- The work described today by the presenters will continue.
- DAQ's compliance and enforcement oversight will continue.
- DAQ will continue to engage with our partners at EPA and pursue ambient monitoring if possible.
- DAQ will work with Croda to strengthen their leak detection program and incorporate the changes into facility permits.

If you would like to follow up,  
please use the email address:

[DAQpermittinginfo@Delaware.gov](mailto:DAQpermittinginfo@Delaware.gov)

Any follow up questions will be  
posted on:

<https://dnrec.alpha.delaware.gov/air/ethylene-oxide/>

For press inquiries please contact  
the Office of Public Affairs at 302-  
739-9902

