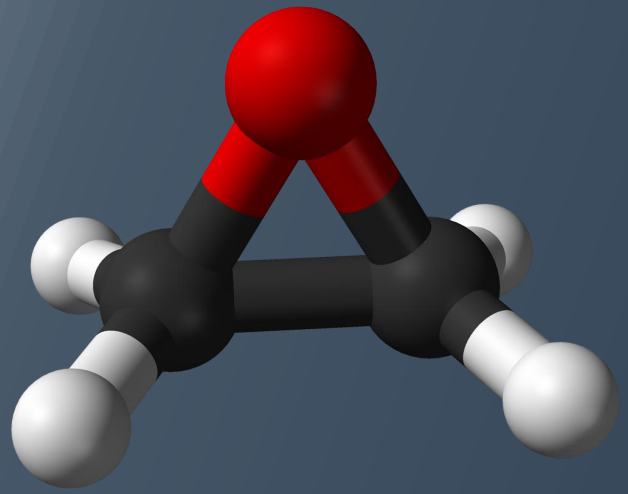
Working Group Meeting #1



Proposed Amended Rule 1405

Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

Wednesday August 17, 2022
1:00 PM

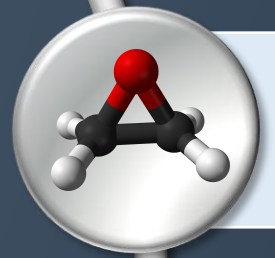
Zoom Meeting Link:
https://scaqmd.zoom.us/j/99006686880

Dial In: (669) 900 6833

Meeting ID: 990 0668 6880

Agenda

Introduction



Overview of Ethylene Oxide

Regulatory Background

Rule Development Process

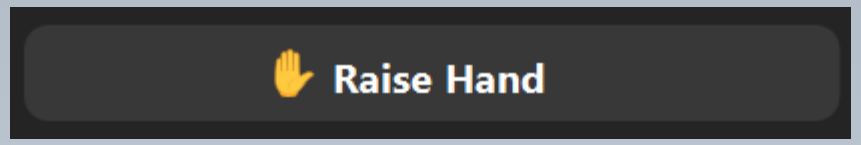
Proposed Amended Rule 1405

Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

Introduction

Meeting Information

- To speak in today's meeting:

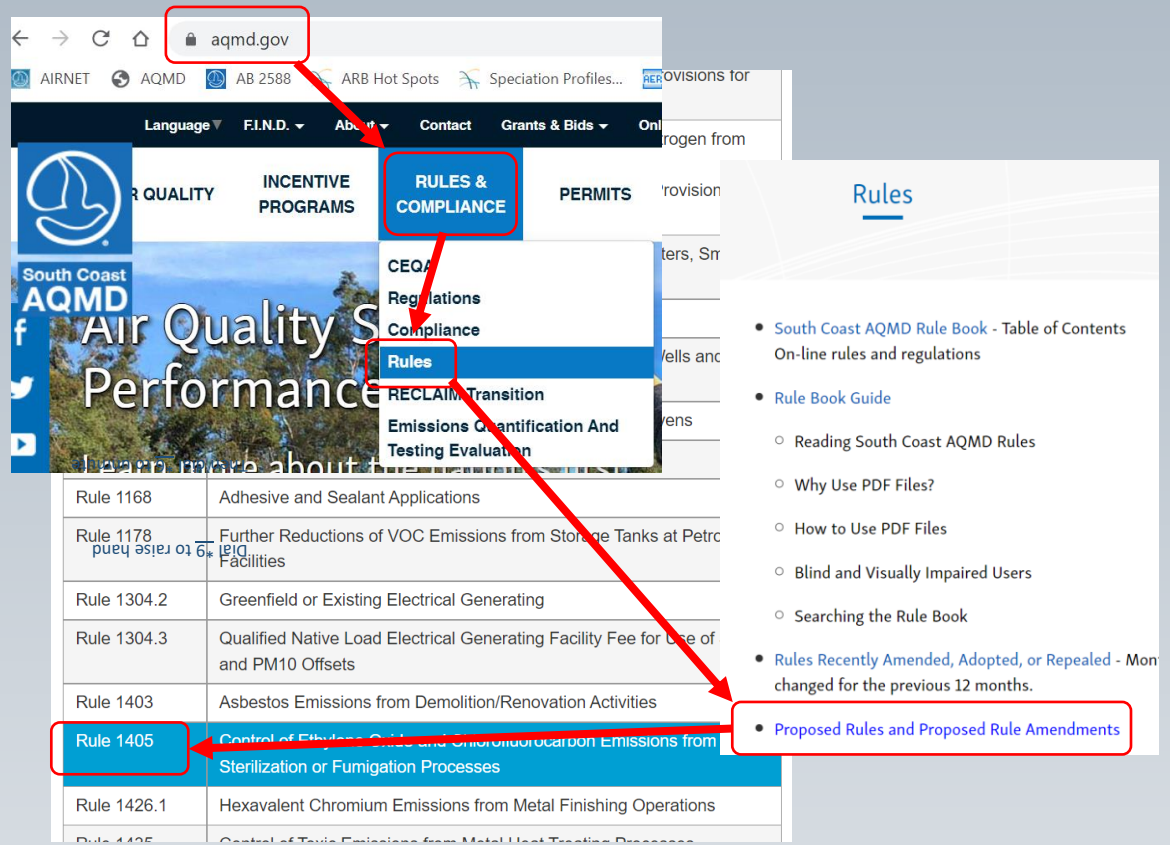


OR

Dial *9 to raise hand

Then dial *6 to unmute

- For meeting materials:

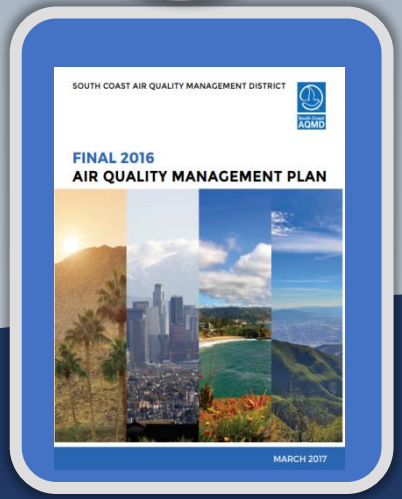


South Coast AQMD

Cleaning The Air That We Breathe…

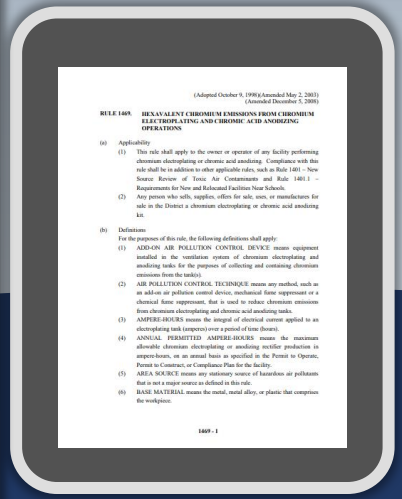
- Local air pollution control agency
  - Largest of the 35 local air agencies in CA and in the U.S.
  - 10,743 square miles
  - 17 million residents
- Responsibilities
  - Regulate emissions from stationary sources
  - Develop and implement plans to meet national air quality standards
  - Permit and inspect 28,400 affected businesses
  - Administer over $100 million of incentive funding annually

Key South Coast AQMD Activities



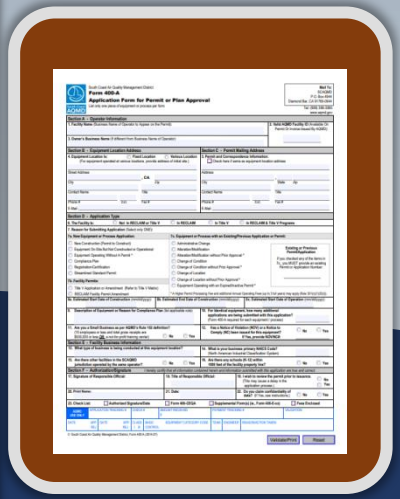
Air Quality Management Plans

Blueprint to comply with clean air standards



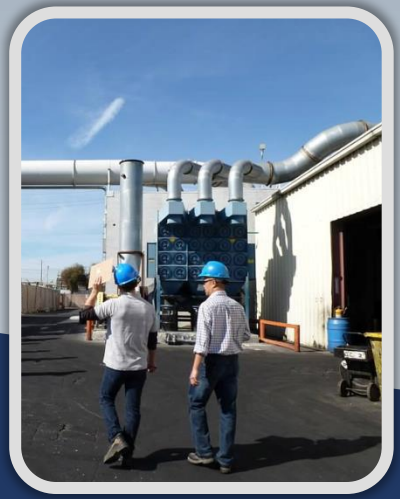
Rules and Regulations

Reducing emissions from facilities or equipment



Permits to Operate

Issuance of Permits to limit the amount of emissions per equipment/ facility



Compliance Inspections

Periodic inspections to enforce rules and permits

Complaint Investigations

Responses to air quality concerns received from the public

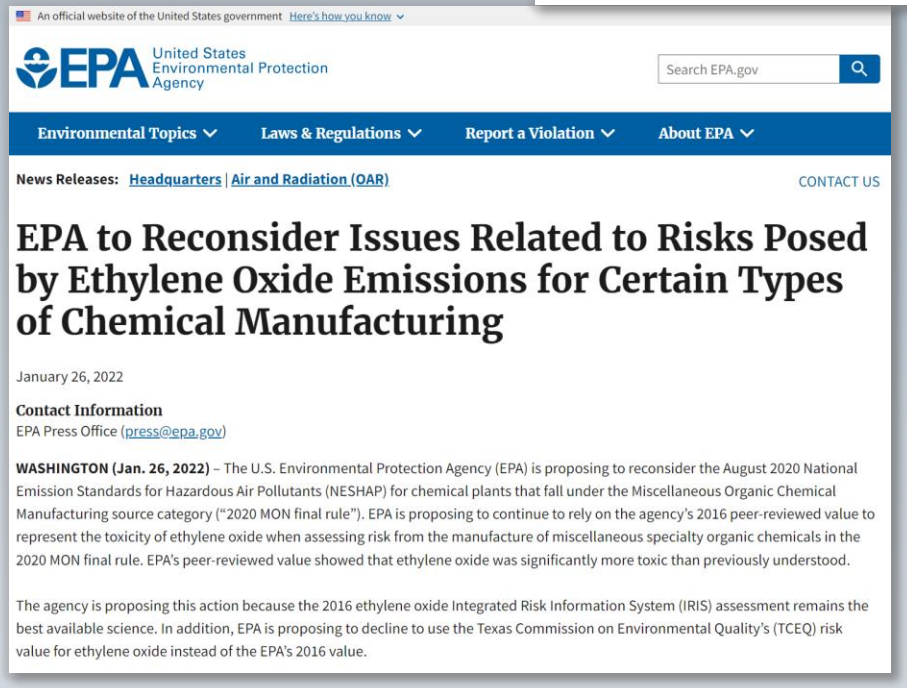
Ambient Air Monitoring

Quantification of air quality including special studies

Background

- United States Environmental Protection Agency (U.S. EPA) and California's Office of Environmental Health Hazard Assessment (OEHHA) reassessing toxicity of ethylene oxide (EtO)
- Prompted South Coast AQMD to monitor near large sterilization facilities
  - Began monitoring March 2022

January 26, 2022



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EPA to Reconsider Issues Related to Risks Posed by Ethylene Oxide Emissions for Certain Types of Chemical Manufacturing

January 26, 2022

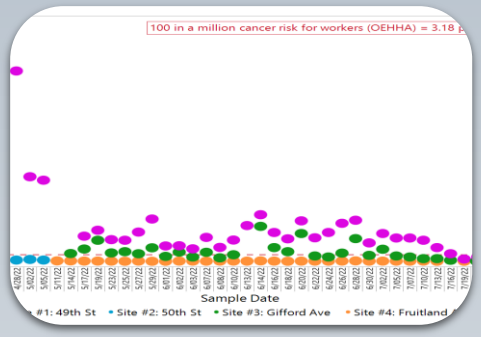
Contact Information
EPA Press Office (press@epa.gov)

WASHINGTON (Jan. 26, 2022) – The U.S. Environmental Protection Agency (EPA) is proposing to reconsider the August 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP) for chemical plants that fall under the Miscellaneous Organic Chemical Manufacturing source category ("2020 MON final rule"). EPA is proposing to continue to rely on the agency's 2016 peer-reviewed value to represent the toxicity of ethylene oxide when assessing risk from the manufacture of miscellaneous specialty organic chemicals in the 2020 MON final rule. EPA's peer-reviewed value showed that ethylene oxide was significantly more toxic than previously understood.

The agency is proposing this action because the 2016 ethylene oxide Integrated Risk Information System (IRIS) assessment remains the best available science. In addition, EPA is proposing to decline to use the Texas Commission on Environmental Quality's (TCEQ) risk value for ethylene oxide instead of the EPA's 2016 value.

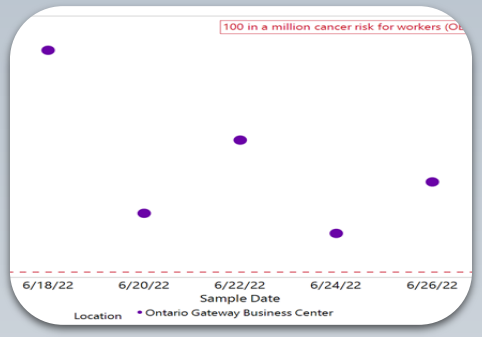
Overview of Initial Monitoring Efforts

- Initial air monitoring results show:
  - Elevated levels of EtO at off-site monitoring sites (directly outside of facilities)
  - EtO levels drop significantly a few hundred feet away from source
  - EtO levels at nearby residential communities within typical background levels



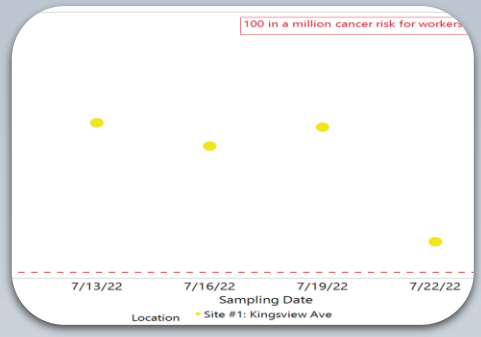
Vernon Air Monitoring

- Began April 22, 2022



Ontario Air Monitoring

- Began June 16, 2022



Carson Air Monitoring

- Began July 10, 2022

- Monitoring efforts ongoing
- Further details on monitoring efforts to be presented in upcoming Working Group Meetings

PAR 1405 Rule Development

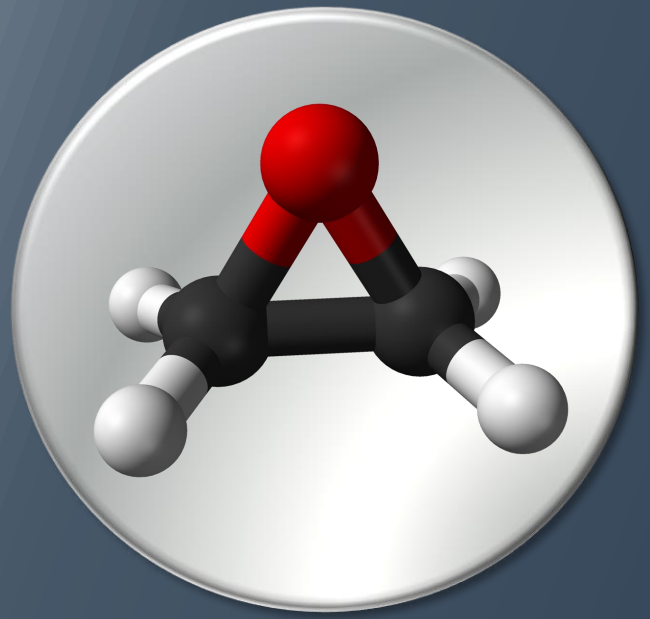
- Rule 1405 requires emission controls from sterilization operations
  - Emission control requirements more stringent than federal regulations
- As part of the rule amendment, staff will assess potential technologies and methods to further reduce EtO emissions based on latest scientific findings

Source: picarro.com

Source: picarro.com

Proposed Amended Rule 1405

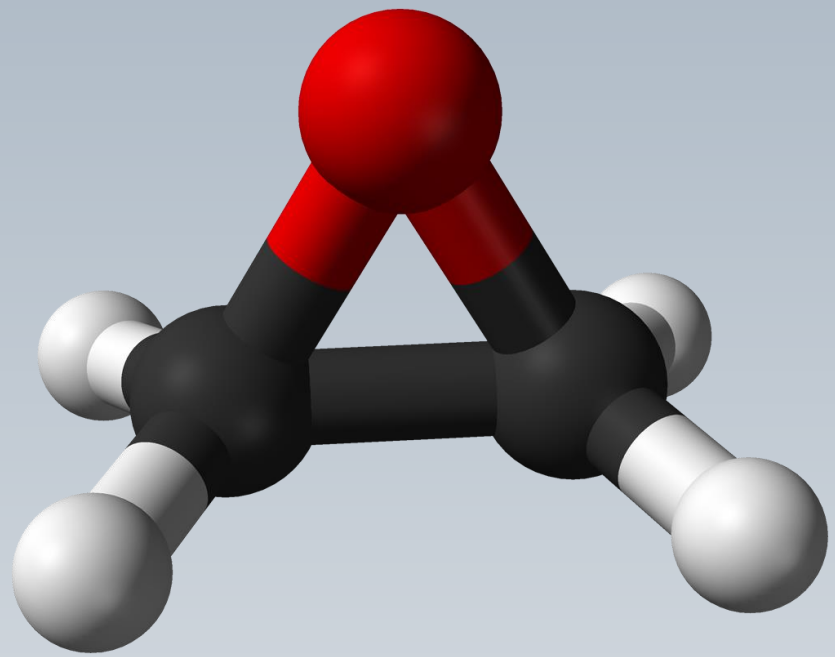
Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes



Overview of Ethylene Oxide

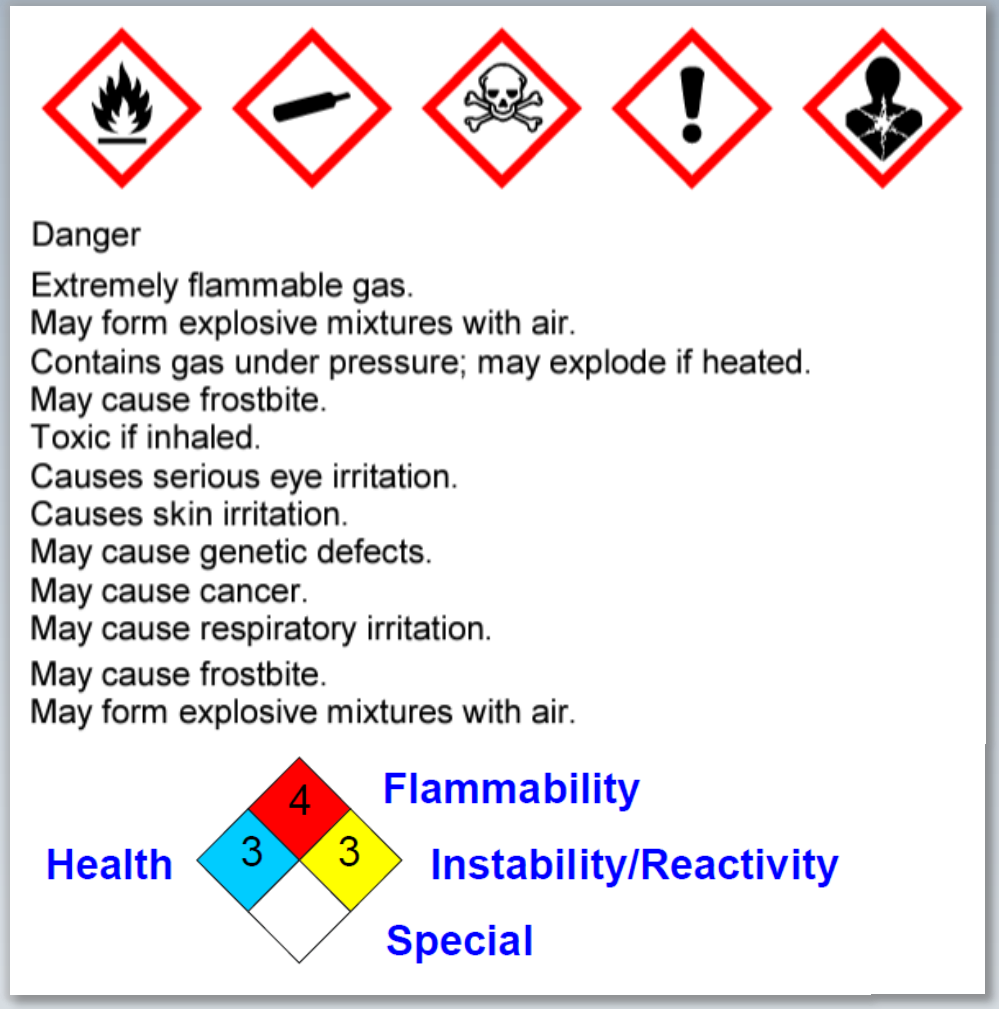
Ethylene Oxide Background

- EtO (or EO) Characteristics:
  - Flammable and colorless gas at room temperature
  - EtO released into the air stays for several months
- Key EtO Uses:
  - Antifreeze, textiles, solvents, detergents, and adhesives production
  - Ensure safety by fumigating cosmetics and some foodstuffs like spices
  - Sterilize medical devices and equipment
- Almost all EtO used in the air district is for medical or veterinarian use



Health Effects of EtO

- EtO is closely associated with:
  - Hematopoietic (blood) cancer
  - Breast cancer in women
- Other long-term, chronic effects
  - Reproductive harm
- Immediate, acute effects
  - Eye irritation and skin burns
  - Breathing problems
  - Neurological difficulties
  - Gastrointestinal distress



How Commercial EtO Sterilization Works

Step 1: **Preconditioning**

Medical devices, still wrapped and packaged on pallets, brought up to optimal temperature and humidity

Examples of **medical devices** are gloves, IV needles and catheters, and implantable pacemakers

Step 2: **Sterilization**

Medical devices transferred to heated chambers where EtO is introduced inside then sent to control devices after use

Source: steris-ast.com

Step 3: **Aeration**

Medical devices transferred to aeration room where residual EtO off-gassed and sent to control devices

Step 4: **Post-aeration**

Medical devices await pickup for delivery to distributors or end-users

Alternatives to EtO Sterilization

- Currently in commercial use
  - Moist heat (steam) or dry heat
  - Electron Beam (E-beam)
  - Gamma Irradiation
  - X-Ray
  - Vaporized hydrogen peroxide (VHP)
- In development
  - Nitrogen dioxide gas
  - Chlorine dioxide gas
  - Vaporized peracetic acid

"More than 20 billion devices sold in the U.S. every year are sterilized with ethylene oxide, accounting for approximately 50 percent of devices that require sterilization."

Source: fda.gov, 2019

Advantages of EtO for Commercial Sterilization

Relatively low temperature and humidity method

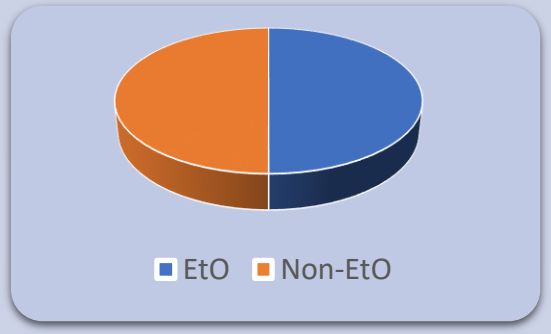
- Alternative methods not compatible with all devices

Able to penetrate most packaging

- Medical devices remain shrink-wrapped, boxed, and on pallets during process

Large capacity

- Commercial sterilizers able to accommodate many pallets of medical devices simultaneously



Established use

"For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process."
Source: fda.gov

Additional EtO Information

Visit aqmd.gov/eto for additional information including:

- Background on EtO & EtO facilities
- Ambient Air Monitoring Data
- Comments by Leaders & Community
- Enforcement Activity

Proposed Amended Rule 1405

Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

Regulatory Background

EtO Risk Assessment History

1980s

- **Jun 1985**: U.S. EPA published first EtO health assessment
- **Feb/Jul 1987**: OEHHA* listed EtO as cancer causing agent and causing female reproductive toxicity

1990s

- **Nov 1990**: Clean Air Act Amendments of 1990 listed 189 hazardous air pollutants and mandated their emissions must be reduced, including EtO

2000s

- **Sep 2006**: U.S EPA released draft report on risk of EtO
- **Aug 2009**: OEHHA updated listing to include developmental and male reproductive toxicity to EtO

2010s

- **Dec 2016**: U.S. EPA posted finalized evaluation of the inhalation carcinogenicity of EtO

2020s

- **Jan 2022**: U.S. EPA confirmed 2016 findings after review of TCEQ** study of EtO risk

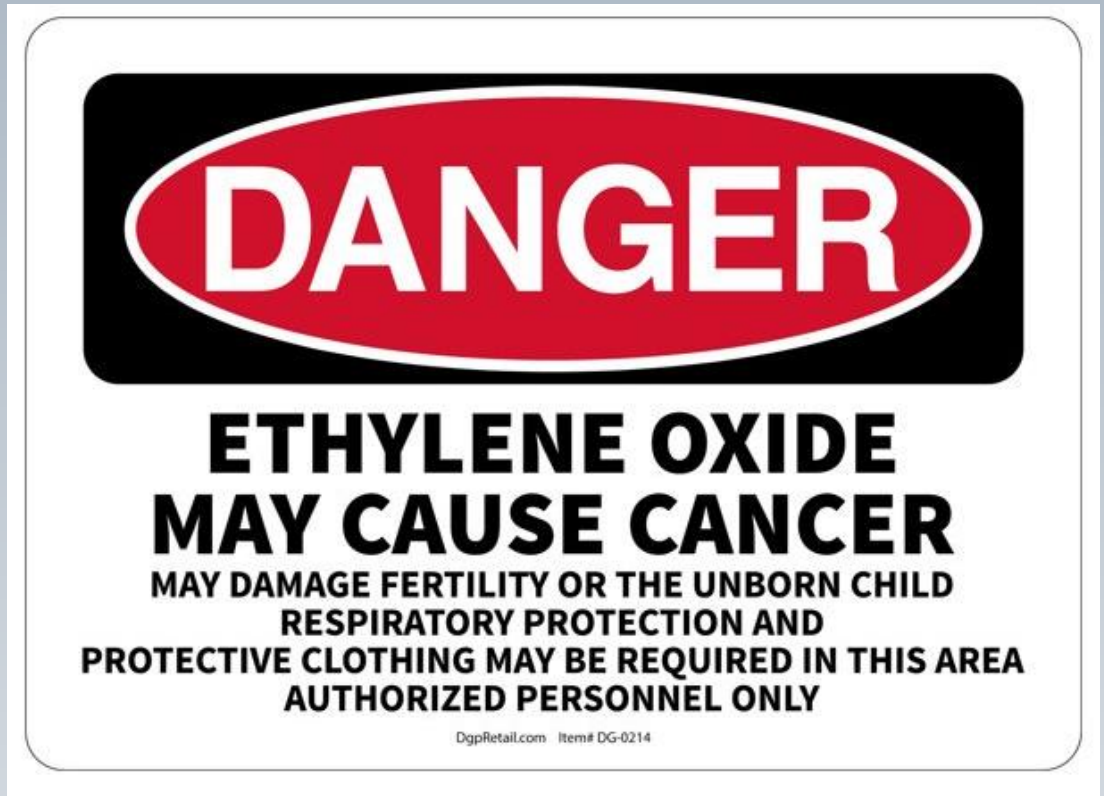
Inhalation cancer risk associated with EtO is 30 to 50 times higher than previously reported by U.S. EPA.

*OEHHA: California Office of Environmental Health Hazard Assessment

**TCEQ: Texas Commission on Environmental Quality

Present EtO Risk Understanding

- 2016 U.S. EPA risk study reveals EtO to be 30 to 50 times more carcinogenic than previously reported
- OEHHA expected to reevaluate its assessment and update EtO risk factors in the future
- South Coast AQMD bound by the California Health & Safety Code to use OEHHA risk factors



Air Quality Regulations on EtO Sterilization

NESHAP

National Emission Standards for Hazardous Air Pollutants

- Adopted in 1994
- Applicability: Uses > 1 ton EtO/year
- Last amended in 2001
- In 2019, published advanced notice of proposed rulemaking

ATCM

Air Toxic Control Measure

- Adopted in 1990
- Applicability: Uses any quantity of EtO
- Bifurcated at threshold 2,000 lbs per 12 months
- Facilities using less than 25 lbs per year exempt from controls
- Last amended in 1998

Rule 1405

Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

- Adopted in 1990
- Applicability: Uses any quantity of EtO
- Facilities using less than 4 lbs per year exempt from controls
- Last amended in 1991

Overview of Current Rule 1405 Requirements

Emission Controls
- Required for sterilizer, aeration room, and backvent control
- 95% to 99.9% control efficiency required, based on usage

Leak Checks
- Leak defined as greater than 10 parts per million (PPM) EtO
- Applies to sterilizers, aerators, collection/control equipment

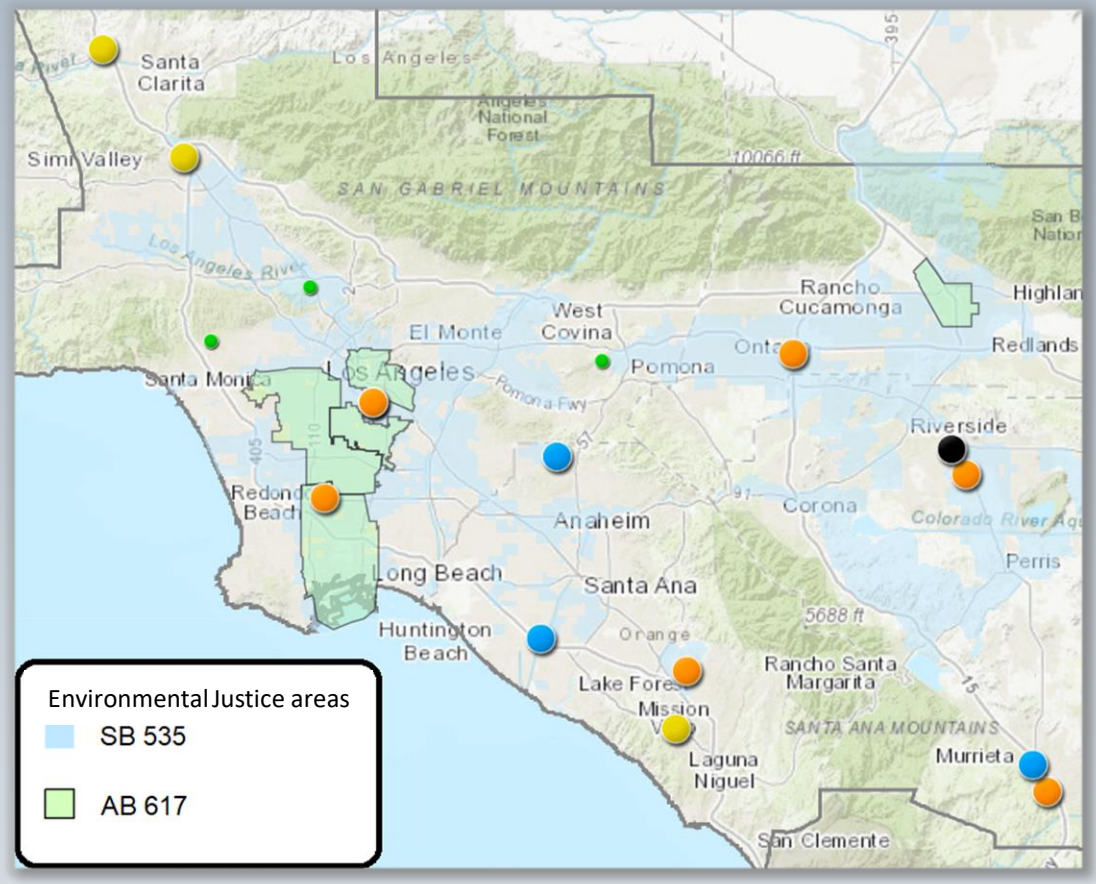
Source Testing
- Annual source tests required for some control devices
- One time performance test required for others

Record Keeping
- Leak checks, sterilization records, EtO purchased & used
- Records required to be maintained onsite

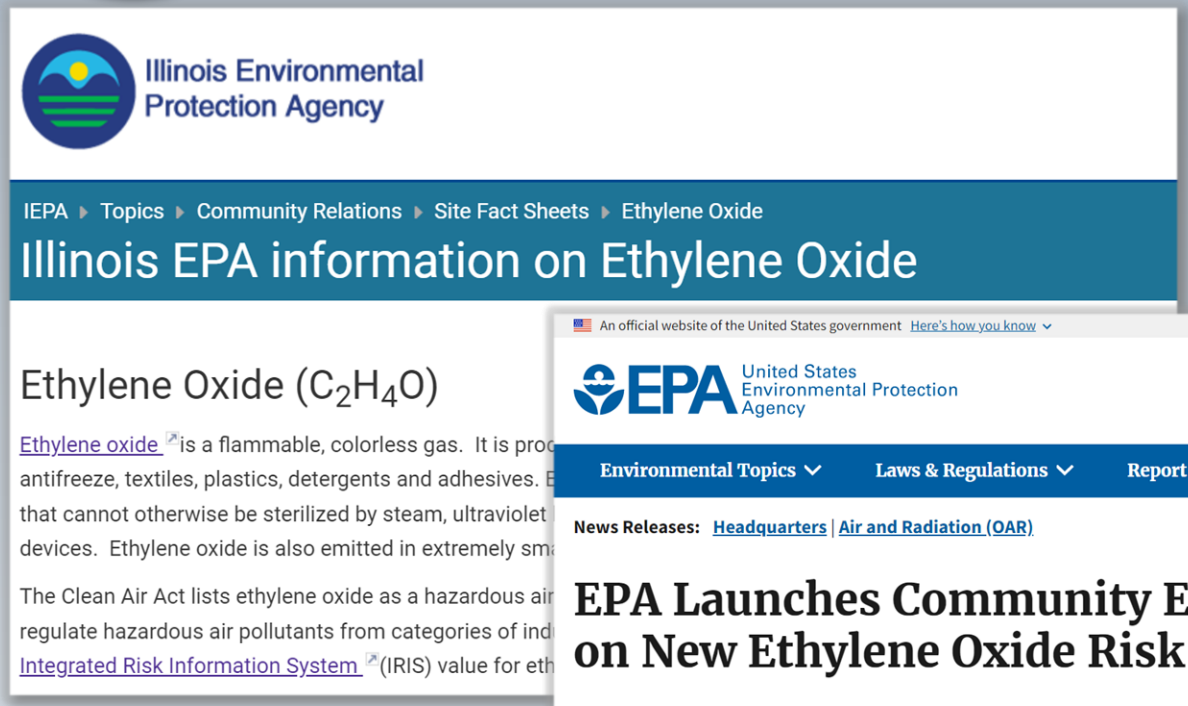
EtO Facilities Currently Permitted

17 active, permitted facilities

- Large – permitted to use more than 4,000 lbs of EtO per year
- Medium – permitted to use between 400 and 4,000 lbs of EtO per year
- Small – permitted to use between 4 and 400 lbs of EtO per year
- Exempt – permitted to use less than 4 lbs of EtO per year
- Aeration only - do not use EtO directly



Other EtO Air Quality Updates


Illinois Environmental Protection Agency

IEPA ▸ Topics ▸ Community Relations ▸ Site Fact Sheets ▸ Ethylene Oxide

Illinois EPA information on Ethylene Oxide

Ethylene Oxide (C_2H_4O)

Ethylene oxide is a flammable, colorless gas. It is proc
antifreeze, textiles, plastics, detergents and adhesives. E
that cannot otherwise be sterilized by steam, ultraviolet
devices. Ethylene oxide is also emitted in extremely sm

The Clean Air Act lists ethylene oxide as a hazardous air
regulate hazardous air pollutants from categories of ind
Integrated Risk Information System (IRIS) value for eth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EPA Launches Community Engagement Efforts on New Ethylene Oxide Risk Information

August 3, 2022

Contact Information
EPA Press Office (press@epa.gov)

WASHINGTON (August 3, 2022) – Today, the US Environmental Protection Agency (EPA) announced its plans to engage and inform communities, states, Tribes, Territories, and stakeholders about up-to-date information on the risks posed by air emissions of ethylene oxide (EtO) from commercial sterilizers, as well as EPA's efforts to address these risks. EPA is releasing new information on specific facilities where lifetime risk levels are the highest to people who live nearby and is encouraging impacted communities to participate in a series of public engagements to learn more. Later this year, EPA expects to propose an air pollution regulation to protect public health by addressing EtO emissions at commercial sterilizers.


An official website of the State of Georgia. How you know

ENVIRONMENTAL PROTECTION DIVISION

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Ethylene Oxide Information

Ethylene Oxide Information

News

- Georgia EPD Comments on 2017 AirToxScreen - March 2, 2

Other Considerations

Ethylene oxide sterilization facilities are subject to requirements from other regulatory agencies such as:

- Food and Drug Administration
- Fire Departments
- Occupational Safety and Health Administration
- Building Departments

Proposed Amended Rule 1405

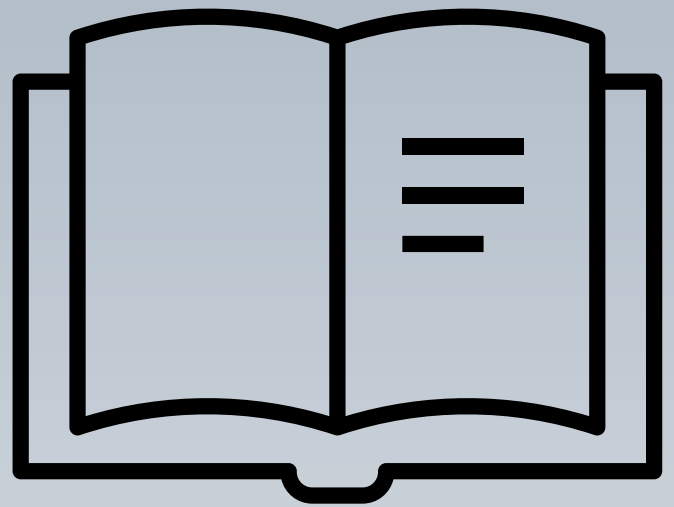
Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

Rule Development Process

Why Periodic Rule Amendments

South Coast AQMD periodically updates rules to:

- Assess current requirements
- Analyze potential for further emission reductions



Rule development of Proposed Amended Rule 1405 will review technologies and methods to further reduce emissions from EtO sterilization processes

Working Group Meetings

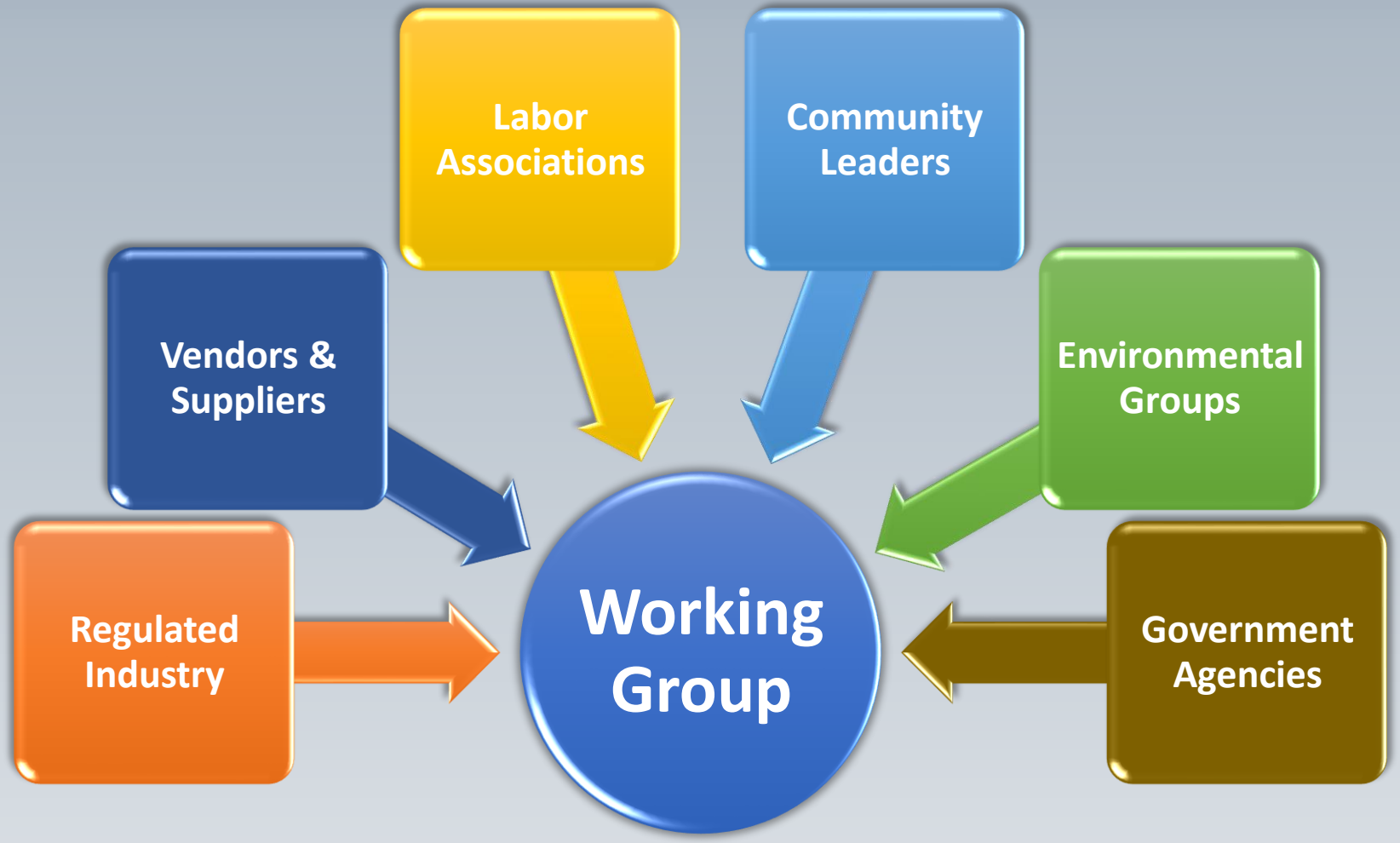
Working Group meetings are open to the public and held throughout the rulemaking process

Objectives:

1) Increase understanding of complex terms, work practices, and technology

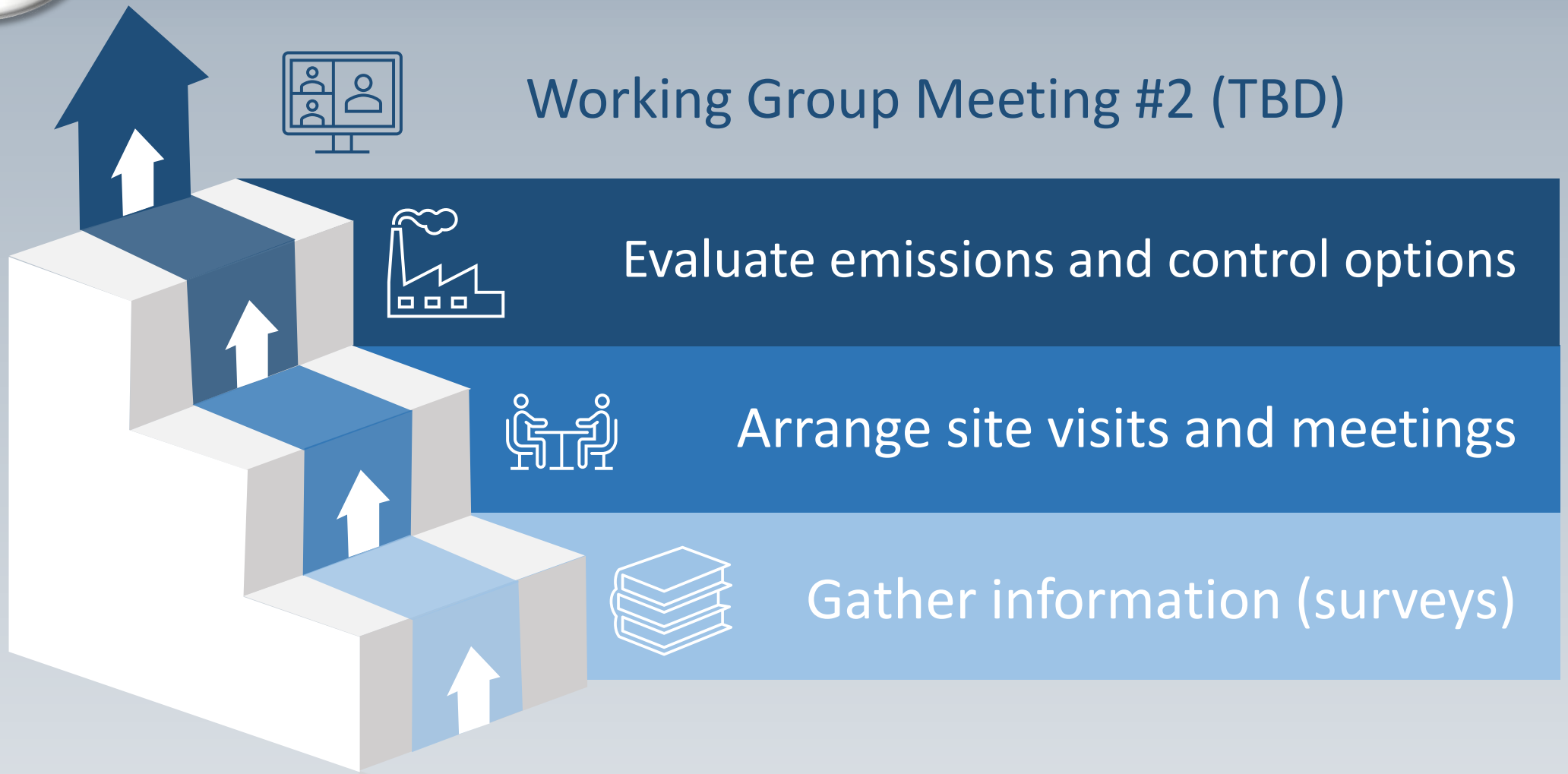
2) Build consensus and work through challenges

3) Provide input regarding concerns and solutions



Overview of Rule Development Process

Next Steps


Working Group Meeting #2 (TBD)
Evaluate emissions and control options
Arrange site visits and meetings
Gather information (surveys)

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☐ SCAQMD Advisor	SCAQMD's comprehensive bi-monthly newsletter containing the latest news, including rule

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Please contact staff with any questions or comments

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