Message

From: Delgrosso, Karen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F5353F3A36E4B98AAC05B22BFCA8026-KDELGROS]
Sent: 11/16/2021 2:27:19 PM
To: Nitsch, Chad [Nitsch.Chad@epa.gov]
CC: White, Terri-A [White.Terri-A@epa.gov]; Koffi, LaRonda [Koffi.LaRonda@epa.gov]
Subject: RE: HQ Responses on B Braun EtO

Will do. Thanks, Chad!

From: Nitsch, Chad <Nitsch.Chad@epa.gov>
Sent: Tuesday, November 16, 2021 9:26 AM
To: Delgrosso, Karen <Delgrosso.Karen@epa.gov>
Cc: White, Terri-A <White.Terri-A@epa.gov>; Koffi, LaRonda <Koffi.LaRonda@epa.gov>
Subject: RE: HQ Responses on B Braun EtO

Yes. Yes. Thank you.

Chad Nitsch
Director, Office of Public Affairs
US Environmental Protection Agency – Region 3 (Mid-Atlantic: WV, VA, PA, MD, DE, DC, and 7 federally recognized tribes)
215-814-5434
For Region 3 employees:
Want to know what is going on in Region 3?
Click on Ollie the Owl:

From: Delgrosso, Karen <Delgrosso.Karen@epa.gov>
Sent: Tuesday, November 16, 2021 9:26 AM
To: Nitsch, Chad <Nitsch.Chad@epa.gov>
Cc: White, Terri-A <White.Terri-A@epa.gov>; Koffi, LaRonda <Koffi.LaRonda@epa.gov>
Subject: HQ Responses on B Braun EtO

Hi Chad, I assume that I can share these responses with Alice, Cristina, and Carol. Also, I assume that you want me to include these in OPA Teams under EtO and I will create a B Braun folder. I wait to hear from you. Thanks, Karen

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From: Nitsch, Chad <Nitsch.Chad@epa.gov>
Sent: Tuesday, November 16, 2021 9:11 AM
To: White, Terri-A <White.Terri-A@epa.gov>; Delgrosso, Karen <Delgrosso.Karen@epa.gov>; Seneca, Roy <Seneca.Roy@epa.gov>
Cc: Landis, Jeffrey <Landis.Jeffrey@epa.gov>
Subject: FW: Please call me

Including the OPA EtO group for awareness.

Chad Nitsch
Director, Office of Public Affairs
US Environmental Protection Agency – Region 3 (Mid-Atlantic: WV, VA, PA, MD, DE, DC, and 7 federally recognized tribes)
215-814-5434
For Region 3 employees:

Want to know what is going on in Region 3?
Click on Ollie the Owl:

R3 IN THE KNOW

From: Scheifele, Hans <Scheifele.Hans@epa.gov>
Sent: Monday, November 15, 2021 7:41 PM
To: Beal, Madeline <Beal.Madeline@epa.gov>; Bremer, Kristen <Bremer.Kristen@epa.gov>; Landis, Jeffrey <Landis.Jeffrey@epa.gov>; Truesdell, Rod <Truesdell.Rod@epa.gov>; Nitsch, Chad <Nitsch.Chad@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Cc: Harwood, Jackie <Harwood.Jackie@epa.gov>; Noonan, Jenny <Noonan.Jenny@epa.gov>
Subject: RE: Please call me

Good Evening,

Attached are OCSPP's responses, approved by Michal, to the questions below which relate to our program:

Is Braun and the ETO sterilization sector covered under TRI?
IF so, where do we find those reports related to a specific facility?
According to the TRI map, BBraun released 10000-100000 lbs in 2019. What does that mean? Put that into perspective?

Thanks,
Hans

From: Beal, Madeline <Beal.Madeline@epa.gov>
Sent: Tuesday, November 9, 2021 2:56 PM
To: Bremer, Kristen <Bremer.Kristen@epa.gov>; Landis, Jeffrey <Landis.Jeffrey@epa.gov>; Truesdell, Rod <Truesdell.Rod@epa.gov>; Nitsch, Chad <Nitsch.Chad@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>
Cc: Harwood, Jackie <Harwood.Jackie@epa.gov>; Noonan, Jenny <Noonan.Jenny@epa.gov>
Subject: FW: Please call me

Hi all,
I am attaching some questions from a TV reporter at ABC. We have gone around with him a few times. We shared the explainers and indicated a willingness to do a background interview (I think, I was on leave and Jackie was managing but I believe the proposal was someone from R3 plus me, but it never materialized.) He is now back with additional questions. I have attempted to label them with who I think is on but there are a number of places where the questions cross lines, so please read through the whole list and make sure I have it right.

I think taking these one by one and/or doing a background interview is probably the best bet given that we already shared a lot of information with him previously and these questions are all pretty specific. That said much of this is available online and we may be able to share links in many places. Let me know your thoughts.

-mads

From: Pradelli, Chad <Chad.Pradelli@abc.com>
Sent: Tuesday, November 9, 2021 2:01 PM
To: Beal, Madeline <Beal.Madeline@epa.gov>
Cc: Harwood, Jackie <Harwood.Jackie@epa.gov>; EPA Press Office <Press@epa.gov>; Mettendorf, Cheryl <Cheryl.Mettendorf@abc.com>
Subject: Re: Please call me

Sorry, here are the questiosn.

What is the current regulation for the emissions of ETO with regard to sterilization facilities?
Proposed Rule changes for sterilizations facilities are currently under review? what are those possible changes? and what is the process of final approval and when may that happen?
Is it true with respect to sterilizers that the EPA did nothing new in terms of ETO regulation in 2006?
Should the emissions control of ETO be increased from 99% to 99.9 %?
Is Braun considered a small business? What is a small business in the eyes of the EPA?
What controls are currently in place for sterilizers?
What known controls are in use now? How much do these cost?
You mention state of the art controls in GA, Missouri, and Illinois? What are those controls specifically?
How does state law differ in those states compared to PA with regard to newest and best practices of control?
Does that include fence line monitoring? Why isn't that required? Is that a possible rule change?
For workers what does the interim decision entail for protective clothing?
How much ethylene Oxide is allowed to be emitted from a sterilization company? are there any proposed amounts? Do you foresee those amounts changing?
What are background ETO levels? Is that naturally occurring? What could that be from?
Is Braun and the ETO sterilization sector covered under TRI?
IF so, where do we find those reports related to a specific facility?
According to the TRI map, BBraun released 10000-100000 lbs in 2019. What does that mean? Put that into perspective?

This pretty much covers it from my perspective. Bear with me, this stuff is not easy to digest, and grasp. So some of these may be mundane. Thanks for help.

Chad Pradelli
Investigative Reporter
WPVI-TV
cell-215-908-2600
chad.pradelli@abc.com

From: Beal, Madeline <Beal.Madeline@epa.gov>
Sent: Tuesday, November 9, 2021 1:07 PM
To: Pradelli, Chad <Chad.Pradelli@abc.com>
Cc: Harwood, Jackie <Harwood.Jackie@epa.gov>; EPA Press Office <Press@epa.gov>
Subject: RE: Please call me

Mr. Pradelli,

My colleague Jackie shared your inquiry with me and I will work to get you a response. It looks like we didn't receive the questions though. Can you please reshare? Also can you verify which rule you have in mind in your question below? Finally, do you have a deadline?

-Madeline

Madeline Beal, MPH (she/her)

Senior Risk Communication Advisor
Office of the Administrator
Environmental Protection Agency
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(202)578-5640 (cell)
beal.madeline@epa.gov

From: Pradelli, Chad <Chad.Pradelli@abc.com>
Sent: Tuesday, November 9, 2021 10:30 AM
To: Harwood, Jackie <Harwood.Jackie@epa.gov>
Subject: Re: Please call me

One other questions....a proposed rule was scheduled for 2021 with regard to ETO. Has that done?

Chad Pradelli
Investigative Reporter
WPVI-TV
cell-215-908-2600
chad.pradelli@abc.com

From: Pradelli, Chad <Chad.Pradelli@abc.com>
Sent: Tuesday, November 9, 2021 10:24 AM
To: Harwood, Jackie <Harwood.Jackie@epa.gov>; Mettendorf, Cheryl <Cheryl.Mettendorf@abc.com>
Subject: Re: Please call me

Jackie,

I'd like to schedule a background conversation. Here are some of the questions I currenlty have. Let me know thanks.

Chad Pradelli
Investigative Reporter
WPVI-TV
cell-215-908-2600
chad.pradelli@abc.com

From: Harwood, Jackie <Harwood.Jackie@epa.gov>
Sent: Tuesday, September 21, 2021 2:58 PM
To: Pradelli, Chad <Chad.Pradelli@abc.com>
Cc: EPA Press Office <Press@epa.gov>; Mettendorf, Cheryl <Cheryl.Mettendorf@abc.com>
Subject: RE: Please call me

Hi again Chad,

Below is an EPA statement on EtO that you are welcome to use in your story, and some background information on EtO. Thanks for your patience.

Please let us know if you have any further questions.

Best,
Jackie

Jackie Harwood
Senior Advisor
Office of Public Affairs
U.S. Environmental Protection Agency
(202) 564-7578
Harwood.Jackie@epa.gov

EPA Statement on EtO:

> EPA is committed to addressing ethylene oxide from industrial sources. The Agency has set deadlines for completing a thorough review of its regulations that apply to industries that emit ethylene oxide, as required under the Clean Air Act. For each of these complex rules, the Agency will work to develop up-to-date, accurate information about emissions from the industries, share information with surrounding communities and seek public input during the rulemaking process.
>
> In addition, the Agency has made significant progress in addressing the concerns that EPA's Office of Inspector General raised in their 2020 "Management Alert – Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities…" Most importantly, Administrator Regan directed EPA Regions to provide a forum for an interactive exchange of information with EPA and~~/or~~ state agencies in communities near the 25 facilities that the OIG identified as priority. Recent accomplishments include work in Delaware, Puerto Rico, Texas, Louisiana, and Wisconsin.

Background Information on EtO:

Our Current Understanding of the Human Health and Environmental Risks of EtO

Ethylene oxide (EtO) is a gas

Ethylene oxide (EtO) is produced in large volumes at chemical manufacturing facilities. In the U.S., this gas is primarily used to make other chemicals that are used in making a range of products, including antifreeze, textiles, plastics, detergents, and adhesives. It is also used to sterilize devices that can't be sterilized using steam or radiation, such as some medical and dental equipment. EtO is also used to sterilize some food products such as spices, certain dried herbs, dried vegetables, sesame seeds and walnuts. Our bodies also produce EtO when metabolizing ethylene, which is produced naturally in the body Based on the information available to EPA, the percentage of ethylene converted to EtO in the body is expected to be low.

EtO is colorless and flammable

EtO is a flammable and colorless gas at room temperature. It dissolves in water and alcohol. EtO released into the air will break down within several months.

EtO primarily enters the environment in air

When EtO is produced or used, some of the gas may be released to the air and water. Release to the air is the primary way it enters the environment. When it is released in the water, EtO will either break down or be destroyed by bacteria. The time frame for the breakdown of EtO can vary depending on environmental conditions.

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. These workers potentially have higher-than-average exposure. The Occupational Safety and Health Administration (OSHA) regulates workers' exposure to EtO.
- *People who live near facilities* that release EtO to the outdoor air may be exposed to EtO, depending on how much EtO is released and how close they live to the facility.
- 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 evidence about whether EtO is commonly found in water.
- 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.

EtO in the air near facilities is unlikely to cause immediate health effects

Short-term inhalation exposure to high concentrations of EtO can cause headache, dizziness, nausea, fatigue, respiratory irritation (e.g., coughing, shortness of breath, wheezing) and, in some cases, vomiting and other types of gastrointestinal distress. Based on available data, however, EPA does not expect EtO levels in the outdoor air around facilities that release it to be high enough to cause immediate health effects (these are known as "acute" effects).

Long-term exposure to EtO may lead to harmful health effects

EtO is a human carcinogen. It causes cancer in humans. Scientific evidence in humans indicates that exposure to EtO for many years increases the risk of cancers of the white blood cells, including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia. Studies also show that long-term exposure to EtO increases the risk of breast cancer in women.

People who live near facilities that release EtO to the outdoor air may be exposed to EtO, depending on how much EtO is released and how close they live to the facility. Sometimes these people are called "bystanders." The greatest cancer risk is for people who have lived near a facility releasing EtO into the air for their entire lifetime.

Children may be more susceptible to the health effects of EtO exposure

Because children's bodies are growing, they are more susceptible to the effects of EtO. This is because EtO is *mutagenic*, meaning it can damage DNA. Children may be more susceptible to the harmful effects of mutagenic substances. For everyone, including children, risks would decrease with decreased exposure.

EtO may pose ecological risks to land animals

Land animals that live near facilities that release EtO to the outdoor air may be exposed to and affected by EtO. However, EtO has not been reported to *bioaccumulate* (increase over time) in organisms that live on land or in water.

EtO dissolves in water, and it can also evaporate from water back to the air. There is currently limited evidence that EtO is commonly found in water. Any release of EtO into water appears to be mostly from industrial sources. There is insufficient information on the movement of EtO in soil, although it is not considered a source of concern. There is also a lack of information on what happens to EtO in sediment. Because of its physical and chemical properties, EtO is not expected to be readily absorbed by sediment or soil. No data are available that indicate that EtO bioaccumulates in plants.

What EPA Is Doing to Address Ethylene Oxide and to Learn More About the Chemical

As EPA pursues its mission to protect human health and the environment, addressing ethylene oxide (EtO) is a major priority for the Agency. While EPA regulates EtO under a number of different environmental laws, the Agency's current efforts to reduce this chemical's impact falls into two main categories: air emissions of EtO and use of EtO as a pesticide. EPA is reviewing its current air regulations that limit the amount of EtO certain types of industries release into the outdoor air to determine whether EtO emissions to air can be further reduced, and is working with state, local and tribal air agency partners to identify opportunities for early air emission reductions. The Agency also is developing pesticide risk reduction requirements to protect workers who use EtO and people who live in surrounding communities. In addition, EPA regularly provides information to other agencies on measuring EtO in air. The Agency also is conducting and supporting research to improve our ability to measure EtO content in outdoor air.

EPA is reviewing Clean Air Act regulations for industries that emit EtO into the air

Since 2018, as part of a two-pronged approach to reduce EtO emissions, EPA has been reviewing its Clean Air Act regulations for facilities that release the chemical to the outdoor air. These types of regulations are known as National Emissions Standards for Hazardous Air Pollutants, or NESHAP. Hazardous air pollutants also are known as "air toxics." The Agency has started its review with two rules:

1) **The air toxics rule for Miscellaneous Organic Chemical Manufacturing, often called "the MON."** After conducting a "risk and technology review," EPA published a final rule in August 2020 that requires additional controls on covered equipment and processes that emit ethylene oxide to reduce risk to surrounding communities and protect public health.
   Many chemical plants are covered by multiple air toxics rules. The MON regulates air toxics emissions from certain types of processes and equipment; nine of the 201 facilities subject to the rule emit EtO from those processes and equipment. At another 22 of the 201 facilities, EtO emissions from other types of equipment or processes are covered by other rules.
   The MON is available at https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission
2) **The air toxics rule for Ethylene Oxide Commercial Sterilizers**. As directed by the Clean Air Act, EPA regulates emissions of EtO from many commercial sterilizers. The Agency is in the process of reviewing this rule, which was established in 1994 and last updated in 2006. A technology review of the rule, which is required by law, is now due. During a technology review, EPA will examine new developments in practices, processes and control technologies, considering cost and feasibility, as well as address any previously unregulated emission points. As part of the current review for this rule, EPA has taken a number of steps necessary to develop a proposal, including obtaining data and information on emissions of EtO, equipment configuration and processes, and possible control strategies.
   In addition, because nearly one-third of the sterilizers subject to the rule are small businesses, EPA was required by law to convene a Small Business Advocacy Review Panel, which includes conversations with small entity representatives to understand the potential impacts of the rule on small businesses. When EPA issues a proposed rule, the proposed rule is made available to the public, so that the public will have the opportunity to review it and submit comments. More information: https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities

EPA is working with state air agencies to reduce EtO emissions

The responsibility for managing air quality in the U.S. is shared by EPA and state, local and tribal air agencies. Several states are working to address EtO in their jurisdictions – often faster than what EPA's rulemaking process can accomplish. For example, in Georgia, the state worked with two commercial sterilizers in the Atlanta area, which have installed equipment to significantly reduce EtO emissions. In Illinois, a commercial sterilizer installed state-of-the art pollution controls as required by a new state law. And in Missouri, a commercial sterilizer is voluntarily installing pollution controls. EPA has provided technical support to air agencies as part of this work. In addition, EPA is coordinating with air agencies to share information with communities about the risks from long-term exposure to EtO in the outdoor air.

EPA is working toward mitigating EtO's impact on workers

While OSHA is the federal agency that protects workers from exposures to harmful substances in their workplace, EPA also is working to reduce the impact of EtO on workers by reevaluating the terms of the registration for use of EtO as a sterilant, which is considered a type of pesticide. Pesticide labels, which are part of a pesticide registration and are legally binding under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), carry directions and precautions that define who may use a pesticide, as well as where, how, how much, and how often it may be used. Failure to follow the label is a violation of federal law. EPA's Office of Pesticide Programs 2020 draft risk assessment for ethylene oxide concludes that EtO poses inhalation risks of concern and that additional mitigation measures are necessary to protect workers' health and surrounding communities.

EPA considers EtO critical for sterilizing medical equipment and necessary to protect public health. According to the Food and Drug Administration (FDA), EtO is the only sterilization method available for many medical devices. Approximately 50 percent of all medical devices are treated with EtO in the United States annually. EtO treatment is also a principal method used to sterilize herbs and spices. The spice industry estimated that approximately 32 percent of herbs and whole spices are treated with EtO annually.

Mitigation is a focus of EPA's pesticide registration review of EtO. Currently, EtO labels require that workers wear protective clothing and respiratory protection. The proposed interim decision, which is the next step in the registration review process, will propose specific, detailed measures for reducing workers' and communities' exposure to EtO. The public will have an opportunity to comment on the proposed decision.

All documents related to EPA's assessment of EtO's use as a pesticide are available in docket EPA-HQ-OPP-2013-0244 on www.regulations.gov. For additional information, visit: https://www.epa.gov/ingredients-used-pesticide-products/ethylene-oxide-eto

Improving our understanding of EtO and the tools to help us learn more about it

Current air monitoring efforts

In recent years, several state air agencies have conducted air monitoring for EtO near known industrial sources that release EtO to the outdoor air. EPA has confidence in the results of EtO monitoring immediately downwind of these sources, where we find measured values well above the level of EtO that the current measurement method can detect. EPA and air agencies also are monitoring for EtO at a number of locations in two longstanding monitoring networks that are used to track trends in toxic air pollutants (these networks are not focused on particular industrial sources). Some results of this monitoring, however, have shown measured values closer to the method detection level, and EPA is less confident in these values. While these lower levels of EtO suggest there is a "background" level of EtO in the outdoor air, EPA is not yet certain about exact background EtO levels due to uncertainty with current measurement methods. Learn more at https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/epas-work-understand-background-levels-ethylene-oxide

Conducting research to better understand and measure EtO

EPA is researching ways to improve our ability to measure EtO in the outdoor air. This research will help improve measurement at the source of EtO emissions (such as industrial facilities) and measurement of EtO concentrations in the outdoor air. It also will help us determine potential origins of background EtO. The objectives for this research are:

- enable measurement of EtO at various levels, including at concentrations lower than what are currently possible to measure at the source of EtO emissions and in the outdoor air;
- provide real-time testing capability to measure EtO on a continuous or near continuous basis, compared to 12- and 24-hour testing capabilities with the current method;
- measure EtO in areas of interest to identify potential sources; and
- improve modeling capabilities to better understand how EtO interacts with other air pollutants in the atmosphere and estimate the movement and distribution of EtO in the environment.

Expanding reporting requirements for sterilization facilities

EPA is committing to broadening Toxics Release Inventory (TRI) reporting on EtO to include certain contract sterilization facilities that use EtO that are not currently required to report this information to EPA. TRI is a resource for learning about annual chemical releases, waste management, and pollution prevention activities reported by nearly 21,000 industrial and federal facilities.

Workers in contract sterilization facilities that use EtO and communities – including historically underserved communities – living near these facilities are potentially at the highest risks of being exposed to EtO. Making more information available about releases of EtO will inform the communities that live near these facilities and will assist the agency in identifying and responding to any human health and environmental threats such releases may cause.

Ethylene Oxide – Where to Learn More

EPA, state and local agencies, and the companies that use ethylene oxide (EtO) are responsible for reducing the amount of EtO people are exposed to at work and in their communities in two primary ways: by providing clear use the directions on pesticide labels include measure that protect workers' health; and limiting the amount of EtO that reaches the outdoor air.

If you have concerns about EtO exposure where you live, you should contact your local Department of Health, your state environmental authority, or the US EPA. You also can learn more about this pollutant in your community, and how you can participate in regulatory processes.

Take Care of Your Health

- **For adults:** – Taking care of your health is always important. If you think you are being exposed to ethylene oxide in the outdoor air or through pesticide use, be sure you keep up with routine health screenings and doctor's visits. If you have health concerns that you believe are related to EtO exposure, start by contacting your doctor. In addition, the Agency for Toxic Substances and Disease Registry (ATSDR) can tell you the location of occupational and environmental health clinics. These clinics specialize in recognizing, evaluating, and treating illnesses resulting from exposure to hazardous substances. You can reach ATSDR at Phone: 1-800-CDC-INFO · 888-232-6348 (TTY) or by email at Contact CDC-INFO
- **EtO and Your Child's Health:** If you are concerned about EtO and your child's health, contacting your doctor is a good place to start. If your doctor is not familiar with EtO, they can work with you to contact the Pediatric Environmental Health Specialty Unit (PEHSU) that serves your area. EPA and the ATSDR help fund the PEHSUs, which are a source of medical information and advice on environmental conditions that influence reproductive and children's health. If you don't have a doctor, you can contact the PEHSU for your area directly.
    - To find PEHSU experts for your area, visit https://www.pehsu.net/findhelp.html
    - More information about PEHSUs is available at https://www.pehsu.net/About_PEHSU.html

Want more details about EtO and health?

In addition to the information in this fact sheet, these federal resources may be helpful:

- EPA's Health Effects Notebook for Hazardous Air Pollutants includes a summary fact sheet on EtO, available at https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf
- Questions and answers related to health and ethylene oxide in the air are available at https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-health-information-about-ethylene-oxide
- Information about EPA's ongoing reevaluation of how EtO is used as a pesticide is available at https://www.epa.gov/ingredients-used-pesticide-products/ethylene-oxide-eto.
- EPA's 2016 updated final Integrated Risk Information System (IRIS) assessment concluded that EtO is carcinogenic to humans by the inhalation route of exposure. Because this assessment and the underlying science are sound, EPA stands behind this assessment. The technical document is available at https://go.usa.gov/xGFMm
- The National Cancer Institute has a summary of the health effects linked to ethylene oxide exposure here: https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/ethylene-oxide

Learn more about EtO in your community

- **EPA's Toxics Release Inventory (TRI)** provides information on the quantities of toxic chemicals that are released annually to air, water and land, or that otherwise are managed as waste by facilities throughout the United States. These facilities are mostly those involved in manufacturing, metal mining, electric power generation, chemical manufacturing and hazardous waste treatment, and include federal facilities. Ethylene oxide is a TRI-listed chemical, and facilities are required to report if they exceed the threshold amounts for activities such as manufacturing or processing. Note: Not all industry sectors are covered by the TRI Program, and not all facilities in covered sectors are required to report. For a summary of TRI information on EtO, see the 2019 TRI EtO Fact Sheet.

You also can use TRI Search Plus to find facilities that report ethylene oxide emissions near you. (https://edap.epa.gov/public/extensions/TRISearchPlus/TRISearchPlus.html)

- **EPA's National Emissions Inventory (NEI)** provides a detailed estimate of emissions of air pollutants, including hazardous air pollutants (EtO is a hazardous air pollutant). This inventory is released every three years, based primarily on data provided by state, local and tribal governments. Because hazardous air pollutant reporting is voluntary, the inventory may not include every chemical or facility in the country.
  To get EtO information from the inventory, go to https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data. You can use the facility mapping tab on the page to find facilities near you with EtO emissions that have been reported to the NEI. Click on the red dot on the map to find out how much EtO emissions were reported. You also can search for a list of EtO emitters using the data query tab on the page.
- **State or local air agencies may be a source of information, too**:
  Many facilities are required to have permits to emit pollution into the air. These permits limit the amount of pollutants that can be emitted. State and local air agencies generally have the responsibility for permitting, and some post permits to their website. Not sure of the state air agency in your area that issues such permits? Your state environmental agency is a good place to start. A list is available at https://www.epa.gov/home/health-and-environmental-agencies-us-states-and-territories.
  Some states have their own air regulations for EtO. Your individual state environmental agency or health department may also have resources available outlining local regulations and efforts they are taking to reduce emissions and inform communities.

Stay up to date on EPA's EtO work to know when there are opportunities for public input

- **Reviewing air regulations:** EPA is reviewing current regulations that limit industrial EtO emissions to the air, and it is providing state air agencies assistance as they work to learn more about EtO emissions from facilities in their jurisdictions and to identify opportunities for early reduction. A summary of this work is available at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/fact-sheet-epa-taking-steps-address-emissions-ethylene-oxide; EPA also provides updates on this work at https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-updates
- **Re-evaluating the pesticidal uses of EtO:** As it does for all pesticides, EPA re-evaluates the pesticidal uses of EtO every 15 years to ensure the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Documents related to this review are available at https://www.epa.gov/ingredents-used-pesticides-produts/ethylene-oxide-eto

Learn how to participate in the federal rulemaking process

When EPA publishes a proposed rule, it includes a comment period. During that time, any person can provide comments to the Agency about any aspect of the proposed regulation. For some rules, EPA holds a public hearing where you can provide comments in person. The Agency always accepts comments in writing. All comments – whether in person or written – get the same level of consideration.

- To read tips for providing effective comments, visit https://www.epa.gov/dockets/commenting-epa-dockets
- EPA also has held webinars on Techniques and Skills for Providing Effective Input in the EPA Rulemaking Process. You can watch a recording here: https://www.youtube.com/watch?v=jvWjA_3oUmw&feature=youtu.be
- Or view the slides here: https://www.epa.gov/sites/production/files/2019-04/documents/caa101_module_4_providing_effective_input.4.24.19.pdf

Learn what EPA is learning about EtO

- **Monitoring for background EtO:** EPA and a number of states are using existing, longstanding monitoring sites to learn how much EtO is present in the air that is not associated with a particular facility. This fact sheet provides a summary of this work. https://www.epa.gov/sites/production/files/2020-09/documents/background_eto_monitoring.september_2020.pdf
- **Conducting research:** EPA also is conducting research to learn more about how EtO moves through the environment and to develop methods for more accurately measuring it in the outdoor air. The Agency provides

updates on that work as it has more information to share at https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide

Learn about ongoing work and requirements at other federal agencies

- **Centers for Disease Control**
  - The Agency for Toxic Substances and Disease Registry (ATSDR) provides scientific and health effects information on EtO. One resource is ATSDR's Toxicological Profile for Ethylene Oxide and accompanying information sheet ToxFAQs™, which are available from 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 healthy working conditions. NIOSH resources on EtO are available at 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. FDA also inspects industrial facilities that sterilize medical devices and medical device manufacturing facilities to make sure that they have validated sterilization processes that meet FDA-recognized standards. FDA has conducted innovation challenges to identify new sterilization methods and technologies and to reduce ethylene oxide emissions. 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

-----Original Message-----
From: Pradelli, Chad <Chad.Pradelli@abc.com>
Sent: Monday, September 20, 2021 6:59 PM
To: Harwood, Jackie <Harwood.Jackie@epa.gov>
Subject: Re: Please call me

Ok. Ty

Chad Pradelli
Investigator Reporter
WPVI-TV
215-908-2600
@chadpradelli

> On Sep 20, 2021, at 6:58 PM, Harwood, Jackie <Harwood.Jackie@epa.gov> wrote:
>
> Hi Chad,
>
> Just wanted to let you know that it's taking us a little longer than expected to pull the information together. Hope to have it to you soon.
>
> Thanks,
> Jackie
>

>
> -----Original Message-----
> From: Pradelli, Chad <Chad.Pradelli@abc.com>
> Sent: Wednesday, September 15, 2021 10:44 AM
> To: Harwood, Jackie <Harwood.Jackie@epa.gov>
> Cc: EPA Press Office <Press@epa.gov>
> Subject: Re: Please call me
>
> Ty
>
> Chad Pradelli
> Investigator Reporter
> WPVI-TV
> 215-908-2600
> @chadpradelli
>
>> On Sep 15, 2021, at 10:43 AM, Harwood, Jackie <Harwood.Jackie@epa.gov> wrote:
>>
>> Hi Chad,
>>
>> Good to talk to you yesterday. As I mentioned, we are working to get you some background information on EtO and how EPA is working to address it. Hope to have this to you by Friday. Once you look that information over, we're happy to answer any questions you have.
>>
>> Best,
>> Jackie
>>
>> _____
>> Jackie Harwood
>> Senior Advisor
>> Office of Public Affairs
>> U.S. Environmental Protection Agency
>> (202) 564-7578
>> Harwood.Jackie@epa.gov
>>
>>
>>
>>
>> -----Original Message-----
>> From: Pradelli, Chad <Chad.Pradelli@abc.com>
>> Sent: Tuesday, September 14, 2021 10:31 AM
>> To: Harwood, Jackie <Harwood.Jackie@epa.gov>
>> Subject: Please call me
>>
>>
>> Thanks.
>>
>> Chad Pradelli
>> Investigator Reporter
>> WPVI-TV
>> 215-908-2600
>> @chadpradelli