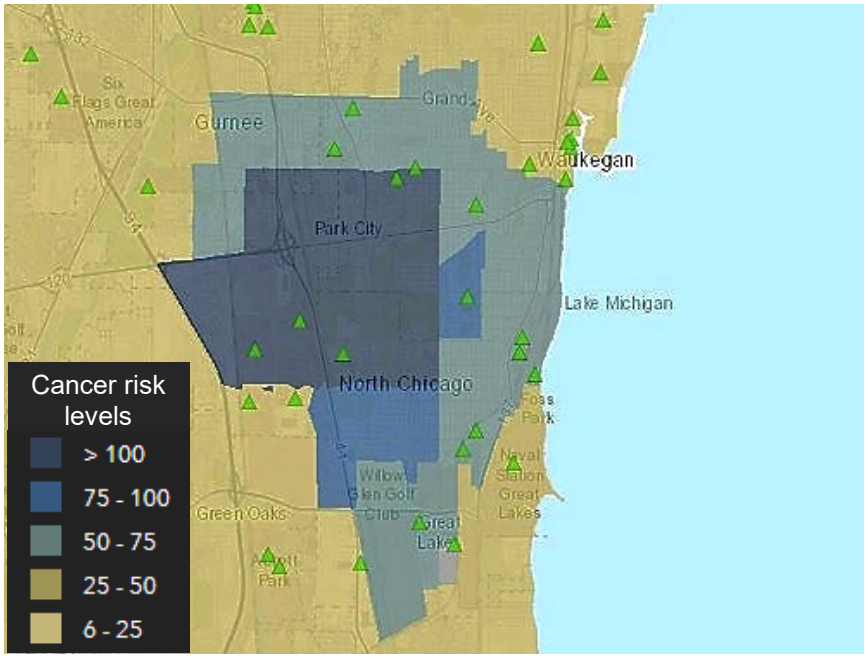
U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Congressionally Requested Report: Improving air quality

EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions

Report No. 21-P-0123 **April 15, 2021**



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Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CMS	Clean Air Act Stationary Source Compliance Monitoring Strategy
EPA	U.S. Environmental Protection Agency
FCE	Full Compliance Evaluation
NATA	National Air Toxics Assessment
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OIG	Office of Inspector General

Cover Image: A 2014 National Air Toxics Assessment map of part of Lake County, Illinois, that includes Gurnee and Waukegan. The colors on the map represent the different levels of cancer risk. For example, the dark blue color indicates that the cancer risk is greater than 100 in one million. (EPA image)

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U.S. Environmental Protection Agency
Office of Inspector General

21-P-0123
April 15, 2021

At a Glance

Why We Did This Audit

We received four congressional requests regarding actions by Regions 5 and 6 to address ethylene oxide emissions. In response, we conducted this audit to address:

- Whether the U.S. Environmental Protection Agency complied with all statutory, regulatory, and policy requirements and protocols in disclosing public health information about ethylene oxide emissions from three facilities in Illinois.
- Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at ethylene oxide-emitting facilities across Regions 5 and 6.
- Whether the EPA has conducted inspections at ethylene oxide-emitting facilities in Regions 5 and 6.

In December 2016, the EPA revised its characterization of ethylene oxide to "carcinogenic to humans."

This audit addresses the following:

- *Improving air quality.*

This audit addresses a top EPA management challenge:

- *Communicating risks.*

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EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions

What We Found

The EPA did not achieve its mission when senior leaders issued instructions to Region 5 that impacted the region's ability to address ethylene oxide emissions and when the EPA delayed communicating health risks regarding ethylene oxide.

The EPA delayed communicating health risks to community residents in Illinois, which is part of EPA Region 5, who lived near ethylene oxide-emitting facilities. Specifically, Office of Air and Radiation leadership delayed informing the Willowbrook, Illinois, community about the results of the EPA's May 2018 short-term monitoring around the Sterigenics facility and did not conduct public meetings with residents either near the Medline facility in Waukegan, Illinois, or the Vantage facility in Gurnee, Illinois. Outside of the residual risk review process, the Office of Inspector General did not identify any statutory, regulatory, or specific policy requirements or protocols to disclose public health information about ethylene oxide emissions. The EPA's mission statement and risk communication guidance state, however, that communities should have accurate information to participate in decision-making processes.

According to two Region 5 managers, a then-senior leader in the Office of Air and Radiation, who was a political appointee, instructed Region 5 to not conduct inspections at ethylene oxide-emitting facilities unless invited by the state to conduct a joint inspection. Region 6 managers and inspectors stated that they did not receive such policy instructions. Office of Air and Radiation senior leaders also issued additional instructions that hindered Region 5's ability to effectively address ethylene oxide emissions, according to Region 5 personnel.

The EPA delegates authority to state, local, and tribal agencies to implement federal environmental programs. The states in Regions 5 and 6 generally inspected major and synthetic minor facilities that emit ethylene oxide from fiscal years 2018 through 2020, according to the frequencies outlined in the EPA's 2016 *Clean Air Act Stationary Source Compliance Monitoring Strategy* or a state's alternative Clean Air Act CMS plan.

Recommendations and Planned Agency Corrective Actions

We recommend that the assistant administrator for Air and Radiation develop standard operating procedures describing the roles and responsibilities of the Office of Air and Radiation and EPA regional offices in assessing and addressing air toxics emissions and how the Office of Air and Radiation will work with regional offices to communicate preliminary air toxics risk information to the public. The Agency's response to the draft report stated that its air toxics strategy would address these recommendations. We reviewed the draft air toxics strategy, and it did not address our concerns. We consider the two recommendations unresolved.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

April 15, 2021

MEMORANDUM

SUBJECT: EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions
Report No. 21-P-0123

FROM: Sean W. O'Donnell

TO: Joseph Goffman, Acting Assistant Administrator
Office of Air and Radiation

This is our report on the subject audit conducted by the Office of Inspector General of the U.S. Environmental Protection Agency. The project number for this audit was OA&E-FY19-0091. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The Office of Air and Radiation is responsible for the issues discussed in the report.

Action Required

This report contains unresolved recommendations. The resolution process, as described in the EPA's Audit Management Procedures, begins immediately with the issuance of this report. Furthermore, we request a written response to the final report within 60 days of this memorandum. Your response will be posted on the OIG's website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

We will post this report to our website at www.epa.gov/oig.

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Chapter 1
Introduction

Purpose

The Office of Inspector General for the U.S. Environmental Protection Agency received four congressional requests (Appendix A) between November 2018 and January 2019 regarding the actions of EPA Regions 5 and 6 to address ethylene oxide emissions. In response to the congressional requests, we conducted this audit to determine:

Top Management Challenge

This audit addresses the following top management challenge for the Agency, as identified in OIG Report No. 20-N-0231, *EPA's FYs 2020–2021 Top Management Challenges*, issued July 21, 2020:

- Communicating risks.

- Whether the EPA complied with all statutory, regulatory, and policy requirements and protocols in disclosing public health information about ethylene oxide emissions from the Sterigenics facility in Willowbrook, Illinois (DuPage County); the Medline Industries facility in Waukegan, Illinois (Lake County); and the Vantage Specialty Chemicals facility in Gurnee, Illinois (Lake County).

- Whether EPA senior political appointees instructed EPA inspectors to avoid conducting inspections at ethylene oxide-emitting facilities across Regions 5 and 6.

- Whether the EPA has conducted inspections at ethylene oxide-emitting facilities in Regions 5 and 6.

Background

Ethylene oxide is a flammable and colorless gas used to make chemicals that are needed to manufacture a variety of products, including antifreeze, textiles, plastics, detergents, and adhesives. It is also used to sterilize medical equipment and other items that cannot be sterilized by methods such as steam. A variety of sources emit ethylene oxide, including chemical manufacturing facilities and medical equipment sterilization facilities. The Sterigenics facility and the Medline facility are medical equipment sterilization facilities. The Vantage facility is a chemical manufacturing facility that uses ethylene oxide to produce

The EPA classifies ethylene oxide as carcinogenic to humans, meaning it can cause cancer. Studies show that breathing air containing elevated ethylene oxide levels over many years increases the risk of developing lymphoid cancers in males and females and breast cancer in females.

ingredients for personal care, food, and consumer products, as well as other uses. Ethylene oxide is one of 187 hazardous air pollutants regulated by the EPA.[1] Also known as air toxics, hazardous air pollutants are known or suspected to cause cancer or other serious health effects.

The EPA increased the cancer risk value for ethylene oxide in December 2016 based on studies from the National Institute for Occupational Safety and Health. The EPA estimated the chemical to be 30 times more carcinogenic to adults than previously thought, and the Agency revised ethylene oxide's carcinogenic description from "probably carcinogenic to humans" to "carcinogenic to humans." Studies show that breathing air containing elevated ethylene oxide levels over many years increases the risk of developing lymphoid cancers in males and females and breast cancer in females. For a single year of exposure to ethylene oxide, the risk of developing cancer is greater for children than for adults. This is because ethylene oxide can damage deoxyribonucleic acid, which is hereditary material in humans.

Residual Risk Reviews

The 1990 amendments to the Clean Air Act require the EPA to establish technology-based standards for sources of air toxics and to, within eight years thereafter, review the remaining health risks to the public and establish additional standards to reduce the public's health risk to acceptable levels, if necessary. This regulatory review is known as the residual risk review. Through the residual risk review, the EPA can communicate risks to the public through its regulatory public notice and comment process.

Ethylene Oxide Identified as Significant Health Risk

The EPA periodically conducts the National Air Toxics Assessment, known as NATA, to assess the public health risk from exposure to air toxics. NATA is not required by regulation and is not part of the EPA's regulatory program that addresses air toxics emissions. NATA is a screening tool that can assist the EPA and state, local, and tribal air agencies in identifying geographic areas, pollutants, or emission sources for further examination. Based on the updated cancer risk value for ethylene oxide, the EPA's 2014 NATA identified ethylene oxide as a new and significant driver of cancer risk. The 2014 NATA was released on August 22, 2018, but is based on emission inventories reported for calendar year 2014. The EPA began working on the 2014 NATA in 2016 and used the most recent emission inventories at the time, which were for the calendar year 2014.

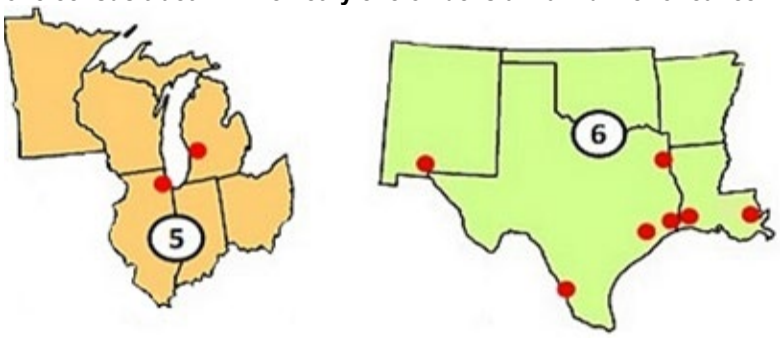
[1] On June 18, 2020, the EPA granted petitions to add 1-bromopropane to the list of air toxics contained in the Clean Air Act. The EPA stated in the petition grant that it will take a separate regulatory action to add 1-bromopropane to the list of air toxics under Clean Air Act Section 112(b)(1). Once this separate regulatory action is completed, the number of listed air toxics will be 188.

The EPA identified census tracts with elevated estimated cancer risks primarily driven by ethylene oxide emissions in 17 metropolitan areas. Census tracts are small, relatively permanent statistical subdivisions of a county with boundaries that normally follow visible features, such as roads and rivers. The U.S. Census Bureau designs census tracts with a goal that each tract contain about 4,000 people and 1,600 housing units.

NATA presents cancer risk estimates based on a cumulative 70-year lifetime exposure. For example, a cancer risk of one in one million implies that if one million people are exposed to the same concentration of a pollutant continuously for 70 years, one person would likely develop cancer from this exposure. This risk would be in addition to any baseline cancer risk of a person not exposed to these air toxics. The EPA generally considers a risk of 100 in one million, or one in 10,000, as not sufficiently protective of public health.

Of the 17 metropolitan areas containing census tracts with cancer risks equal to or greater than 100 in one million, two are in Region 5, while seven are in Region 6 (Figure 1).[2] The EPA identified three facilities that contributed to elevated estimated cancer risks in Illinois: Sterigenics, Medline, and Vantage.[3]

Figure 1: Metropolitan areas in Regions 5 and 6 where there is at least one census tract in which ethylene oxide is a main driver of cancer risk



Source: Developed by EPA OIG based on 2014 NATA and information from the EPA. (EPA OIG graphic)

Note: According to the EPA, a facility in New Mexico installed a control device that reduced ethylene oxide emissions prior to the 2014 NATA release.

Responsible Offices

The EPA's Office of Air Quality Planning and Standards, within the Office of Air and Radiation, conducts the NATA. OAQPS works with regional offices and states to ensure the accuracy of the emissions data used in conducting the NATA. EPA regional offices and delegated state and local agencies inspect ethylene oxide-emitting facilities.

[2] Region 5 states include Illinois, Indiana, Minnesota, Michigan, Ohio, and Wisconsin. Region 6 states include Arkansas, Louisiana, Oklahoma, New Mexico, and Texas.
[3] The Vantage facility was not modeled as part of the 2014 NATA because of an error in the National Emissions Inventory.

Scope and Methodology

We conducted our work from March 2019 to February 2021. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

To address congressional concerns related to risk communication and inspections of ethylene oxide-emitting facilities, we:

- Interviewed staff and managers in OAQPS; Regions 5 and 6, including Clean Air Act inspectors or their supervisors; and the Agency for Toxic Substances and Disease Registry, known as ATSDR.

- Interviewed staff in the Office of Enforcement and Compliance Assurance.

- Reviewed the EPA's *Clean Air Act Stationary Source Compliance Monitoring Strategy,* known as CMS, issued October 4, 2016.

- Reviewed the EPA's *FY2020 – FY2023 National Compliance Initiatives,* issued June 7, 2019.

- Searched the Toxics Release Inventory, Enforcement and Compliance History Online, and Integrated Compliance Information System databases to determine the universe of ethylene oxide-emitting facilities and confirmed the information with regional and state personnel.

- Obtained information from states in Regions 5 and 6 about the most recent full compliance evaluations, or FCEs, conducted at major and synthetic minor facilities when incomplete information was found in the Enforcement and Compliance History Online database.

- Reviewed the Clean Air Act, the EPA's mission statement, the Agency's guidance on risk communication, and regional communications plans.

- Reviewed news media reports related to public concerns about ethylene oxide emissions from the Sterigenics, Medline, and Vantage facilities in Illinois.

- Accessed and reviewed email accounts of key officials in OAR and Region 5 that were pertinent to our audit objectives. The email accounts that the OIG reviewed included content that was in the accounts at the

time the Office of Environmental Information, now the Office of Mission Support, received the OIG's email access request, including deleted and sent/received items from December 2017 to June 2019.

While interviewing staff and managers in Region 5, we learned that OAR senior leaders issued instructions that impacted the region's role in addressing ethylene oxide emissions. We reviewed documents provided to us by Region 5. We discussed these instructions with managers and staff in Region 6 and OAQPS to determine whether they also received these instructions.

Prior Report

EPA OIG Report No. 20-N-0128, *Management Alert: Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns,* issued March 31, 2020, found that while the EPA or state personnel, or both, met with residents living near nine of the 25 high-priority ethylene oxide-emitting facilities, communities near 16 facilities have yet to be afforded public meetings or other direct outreach to learn about the health risks of ethylene oxide and actions being taken to address those risks.

We recommended that the EPA promptly provide all communities near the 25 high-priority ethylene oxide-emitting facilities with a forum for an interactive exchange of information with EPA or state personnel regarding health concerns related to exposure to ethylene oxide. The EPA provided an alternative recommendation and corrective actions that did not meet the intent of the OIG recommendation. Subsequently, the recommendation went into audit dispute resolution, and then-EPA Administrator Andrew Wheeler sided with OAR's proposed corrective action plan, which committed the EPA to, among other things, conduct additional, more refined risk assessments and outreach to affected communities by May 31, 2021.

Chapter 2
EPA Delayed Risk Communication Concerning Health Risks from Ethylene Oxide-Emitting Facilities in Illinois

The EPA delayed communicating preliminary findings of health risks from ethylene oxide-emitting facilities to community residents in Illinois. Moreover, we did not identify any statutory, regulatory, or specific policy requirements or protocols for disclosing public health information related to health risks posed by ethylene oxide-emitting facilities outside of the residual risk review process.

The EPA's mission statement asserts that the Agency works to ensure that "[a]ll parts of society—communities, individuals, businesses, and state, local and tribal governments—have access to accurate information sufficient to effectively participate in managing human health and environmental risks." The EPA's risk communication guidance also states that communities have the right to participate in decision-making processes that affect their lives and livelihoods.[4]

The EPA's actions have not been consistent with its mission or guidance on risk communication. Data from the short-term monitoring that the EPA conducted in May 2018 around the Sterigenics facility indicated elevated risks to people exposed to ethylene oxide for a lifetime, which is assumed to be 70 years, but the Agency chose to delay informing the community. In addition, the Agency did not conduct public meetings with residents near the Medline and the Vantage facilities.

Communities Should Have Access to Information to Help Manage Health Risks

Outside of the residual risk review process, we did not identify any statutory, regulatory, or specific policy requirements or protocols for disclosing public health information related to health risks posed by ethylene oxide-emitting facilities. The EPA has a regulatory process in place to conduct residual risk reviews to assess the health and environmental risks that remain after the implementation of technology-based standards limiting air toxics emissions. Employing this regulatory process, the EPA can communicate risks to the public through its regulatory public notice and comment process.

Commercial sterilizers, such as the Sterigenics and Medline facilities, are among the 119 types of industrial sources, referred to as source categories, that require residual risk reviews. The EPA finalized its residual risk review of commercial

[4] EPA, *Risk Communication in Action–the Tools of Message Mapping*, EPA/625/R-06/012, August 2007.

sterilizers in April 2006. In 2016, the EPA's Office of Research and Development found that ethylene oxide was more toxic than previously known and determined it was carcinogenic to humans. An EPA manager stated that while the Agency is required to conduct a review of technology-based standards every eight years, it is not required to conduct additional residual risk reviews. Therefore, the public may not have updated risk information in cases where residual risk reviews for a source category were conducted before the EPA discovered that the risk level of a pollutant increased.

The EPA's mission is to protect human health and the environment. The EPA achieves its mission in part by ensuring that all parts of society, such as communities and individuals, have "access to accurate information sufficient to effectively participate in managing human health and environmental risks."[5] In our *EPA's FYs 2020–2021 Top Management Challenges* report, we noted that one of the EPA's management challenges is communicating risk to allow the public to make informed decisions about its health and environment. Then-Acting Administrator Wheeler identified risk communication as one of his top priorities in his July 2018 speech to EPA employees, stating:

> Risk communication goes to the heart of EPA's mission of protecting public health and the environment. ... We must be able to speak with one voice and clearly explain to the American people the relevant environmental and health risks that they face, that their families face and that their children face.

Further, the EPA's risk communication guidance states that one of the seven "cardinal rules" of risk communication is to accept and involve the public as a legitimate partner.[6] The guidance also states that communities have the right to participate in decision-making processes that affect their lives and livelihoods.

To adhere to its mission statement and risk communication principles, the EPA should assure that all impacted communities are provided an opportunity to engage in an interactive exchange of information with the EPA and state agencies to more fully understand the health concerns related to ethylene oxide exposure and the actions that the EPA is taking to address those concerns.

OAR Leadership Delayed Informing Willowbrook Community About Results from Short-Term Monitoring of Sterigenics

After learning about the elevated estimated cancer risks from ethylene oxide emissions from point sources, which are generally large stationary sources, in the draft 2014 NATA, Region 5 wanted to confirm the emissions data used in the

[5] EPA website, *Our Mission and What We Do*, last updated on February 7, 2018.
[6] EPA, *Risk Communication in Action–the Risk Communication Workbook*, EPA/625/R-05/003, August 2007; EPA, *Risk Communication in Action–the Tools of Message Mapping*, EPA/625/R-06/012, August 2007.

draft 2014 NATA. Because OAQPS did not allow regions to disclose the draft 2014 NATA data to external stakeholders except states, Region 5 conducted its own internal modeling of Sterigenics and Elé, a chemical plant in McCook, Illinois, in November 2017. According to Region 5 staff, these two facilities were chosen, in part, because they represent two types of ethylene oxide-emitting sources—commercial sterilizers and chemical plants. The internal modeling confirmed that the two facilities had the potential to contribute to elevated cancer risks.

In December 2017, Region 5 sent letters to Sterigenics and Elé requesting their review of the modeling results and their suggestions for improvements for modeling accuracy. The Illinois Environmental Protection Agency received copies of the letters. From January to March 2018, Region 5 communicated with Sterigenics until Sterigenics stopped communicating with the region. Region 5 also communicated with Elé during this time period, and it took Elé until June 2018 to provide corrections to the modeling parameters.

Without information from Sterigenics to verify that the inputs for the Region 5 internal modeling were accurate, Region 5, with funding assistance from OAQPS, conducted monitoring for ethylene oxide near the Sterigenics facility May 16–18, 2018. Region 5 chose to monitor around the Sterigenics facility because:

- Region 5 has a warehouse next to the facility and would not have any issues with access rights to the property. This allowed the region to install monitors around the warehouse and the meteorological station on the warehouse's rooftop.

- It would allow the region to determine whether ethylene oxide could be detected using an EPA monitoring method and identify the levels of ethylene oxide, if any, present in the outdoor air.

After the monitoring data were received and reviewed, Region 5 provided the monitoring and modeling data to the ATSDR, which is another federal agency, and requested that it review the data.

Table 1 is a timeline of key events regarding the short-term monitoring around the Sterigenics facility.

Table 1: Timeline of key events preceding and following the May 16–18, 2018 short-term monitoring around the Sterigenics facility

Date	Event
November 2017	Region 5 conducted internal modeling of the Sterigenics and Elé facilities.
12/22/17	Region 5 sent letters to Sterigenics and Elé requesting information and copied the Illinois Environmental Protection Agency on the letters.
January–March 2018	Region 5 communicated with the Sterigenics facility until the facility stopped communicating with the region.
February–March 2018	Region 5 and OAQPS jointly designed a monitoring plan.
5/16/18–5/18/18	Region 5 conducted monitoring around the Sterigenics facility.
5/30/18	Region 5 received preliminary monitoring data.
6/15/18	Region 5 completed quality assurance and quality control of the monitoring data.
6/20/18	The then-Region 5 regional administrator was briefed on the monitoring data and directed staff to prepare a website to post the monitoring data and a press release.
6/22/18	The then-assistant administrator for Air and Radiation directed the then-Region 5 regional administrator to not release monitoring results to the public. The then-regional administrator complied with this direction. The then-Region 5 acting deputy regional administrator sent an email regarding the monitoring results to staff working at the Region 5 Willowbrook site.
7/26/18	The ATSDR submitted a Letter Health Consultation of the Sterigenics facility's ethylene oxide emissions to a Region 5 manager, indicating that the facility would present a public health hazard to people living and working in Willowbrook "if measured and modeled data represent typical [ethylene oxide] ambient concentrations in ambient air."[a]
8/21/18	The ATSDR posted a Letter Health Consultation of Sterigenics facility's ethylene oxide emissions on its website.
8/22/18	The EPA released the 2014 NATA, posting the data on its website. The Region 5's webpage on Sterigenics facility monitoring was online for about an hour before the then-deputy assistant administrator for Air and Radiation directed Region 5 to take the webpage down.
8/29/18	The EPA, the Illinois Environmental Protection Agency, the ATSDR, and Sterigenics met with the Willowbrook community.
10/2/18	A revised webpage with less information on the Sterigenics facility was posted.

Source: Developed by EPA OIG based on information from the EPA and OIG analysis of EPA information. (EPA OIG table)

[a] An ATSDR Letter Health Consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material.

OAR Senior Leader Delayed Public Release of May 2018 Sterigenics Willowbrook Facility Monitoring Results

On June 20, 2018, the then-Region 5 regional administrator was briefed on the monitoring results. These monitoring results showed ambient ethylene oxide concentrations that would lead to increased cancer risk if people were exposed for a lifetime. According to a Region 5 manager who attended the briefing, the then-Region 5 regional administrator expressed concern about the monitoring results and wanted to immediately release them to the public to avoid another public health emergency like the Flint, Michigan drinking water crisis.

Region 5 staff were directed to prepare a public webpage to post the monitoring results and develop a press release. Region 5 planned to release the monitoring

results to the public on June 22, 2018. The then-assistant administrator for Air and Radiation delayed Region 5 from releasing the monitoring results because, according to Region 5 staff, the 2014 NATA had not been released, and the then-assistant administrator for Air and Radiation wanted to release both sets of data at the same time.

Despite not being allowed to release the monitoring results to the public, the then-acting deputy regional administrator for Region 5 informed staff working at its Willowbrook site of the monitoring results on June 22, 2018, stating that the measured ethylene oxide concentrations "do not pose an immediate health risk" and that the "EPA plans to conduct additional work to ensure that it understands the source and long-term exposure of [ethylene oxide] in the area, including any effects on indoor air quality." According to the ATSDR, if the measured ethylene oxide concentrations persisted long-term, then the ethylene oxide emissions from the Sterigenics facility would present a public health hazard to people living and working in Willowbrook.

OAR Senior Leader Directed Region 5 to Take Down Its Sterigenics Webpage, and Key Information Was Removed Before Webpage Was Reposted

OAR senior leaders wanted to release the 2014 NATA and the ATSDR's Sterigenics facility Letter Health Consultation around the same time because the Letter Health Consultation discussed the NATA data. The ATSDR released the Sterigenics facility Letter Health Consultation on August 21, 2018. The next day, the EPA released the 2014 NATA results to the public. At the same time, Region 5 posted the following information on its Sterigenics facility webpage:

- Background information on ethylene oxide, what the facility is, the facility's history, and why the EPA is involved.
- The May 2018 monitoring results showing high ethylene oxide concentrations and the health impacts from exposure to ethylene oxide.
- Details on how the EPA was responding, including efforts with the State of Illinois on working with the Sterigenics facility to reduce ethylene oxide emissions.
- Documents related to the Sterigenics facility, including a link to the ATSDR's Letter Health Consultation.

About an hour after the information was posted, the then-deputy assistant administrator for Air and Radiation directed Region 5 to take down the webpage because, according to an OAQPS manager, it was not similar to the Region 6 webpage on the Denka facility. The Denka facility is the only facility in the United States that produces a class of synthetic rubber called "neoprene," which is

made from chloroprene, a likely human carcinogen. Region 6 developed a webpage on the Denka facility to communicate elevated cancer risks from the facility found in the 2011 NATA. According to Region 5 staff, the Sterigenics webpage was modeled after the Denka facility webpage. We reviewed the webpage that was taken down and determined that it was similar to the current Denka facility webpage.

According to Region 5 staff, after the webpage was taken down, all that remained on the Region 5 website concerning the Sterigenics facility were the May 2018 monitoring results and the link to the ATSDR Letter Health Consultation. Without the background information on the Sterigenics facility, the public did not have any context regarding monitoring results or the ATSDR Letter Health Consultation. In September 2018, OAQPS took over communicating with the Sterigenics facility from Region 5. Region 5 revised the Sterigenics facility webpage based on input from OAR and posted it on October 2, 2018. We determined that the webpage as of January 15, 2021, did not include all the details that were in the original webpage, including the statement that the EPA has determined ethylene oxide to be carcinogenic to humans.

State and Local Agencies Communicated Risks to Residents Near Medline and Vantage Facilities

On August 29, 2018, the EPA, the Illinois Environmental Protection Agency, the ATSDR, and Sterigenics attended a public meeting with residents living near the Sterigenics facility in Willowbrook. The EPA, however, did not hold similar meetings in Lake County, which is the location of the Medline and Vantage facilities. The EPA's then-assistant administrator for Air and Radiation explained in a May 29, 2019 public meeting in Burr Ridge, Illinois, that Medline had taken concrete steps to address its ethylene oxide emissions, including agreeing to install additional controls. Questions regarding the Vantage facility were deferred to the state.

Although the EPA did not hold meetings with residents near the Medline or Vantage facilities, the following public meetings were held in Lake County:

- On May 23, 2019, the Illinois Environmental Protection Agency held a public meeting with residents living near the Medline facility. The meeting focused on the state's draft construction permit for Medline that required the facility to install controls and emissions monitors and limited total ethylene oxide emissions to 150 pounds annually.

- On October 2, 2019, Illinois State Senator Melinda Bush held a meeting with Lake County residents to discuss ethylene oxide emissions from the Vantage and Medline facilities. ATSDR staff also attended.

- On November 14, 2019, the Illinois Environmental Protection Agency held a public meeting with residents living near the Vantage facility. The meeting focused on the state's draft construction permit for Vantage that required enhanced leak detection and repair and limited total facility ethylene oxide emissions to 110 pounds annually.

Region 5 staff said that its Office of Regional Counsel and Office of External Communications staff attended these three meetings but did not participate or provide information. The 2019 fall meetings occurred more than a year after the NATA was released and the EPA first met with the residents near the Sterigenics facility. According to the news media, residents near the Medline and Vantage facilities were concerned that they first learned of their risks from ethylene oxide emissions six months after the August 29, 2018 public meeting for residents near the Sterigenics facility in Willowbrook. They were also concerned that they learned about the risks from news media and not from government officials.

Although the first public meetings with residents in Lake County did not occur until 2019, the EPA met with Lake County public officials on November 28, 2018. The EPA also met with the organization "Stop EtO in Lake County" on July 8, 2019, and April 2, 2020.

Conclusion

The EPA did not act consistently with its mission or guidance on risk communication because it delayed informing the Willowbrook community about the results from the May 2018 short-term monitoring around the Sterigenics facility. Further, the Agency did not actively conduct outreach with residents living near the Medline and Vantage facilities. Instead, state and local agencies communicated risks to these communities.

Recommendation

We recommend that the assistant administrator for Air and Radiation:

1. Develop standard operating procedures describing how the Office of Air and Radiation will work with EPA regional offices to communicate preliminary air toxics risk information, including elevated risks found in the National Air Toxics Assessment, to the public so that communities are promptly informed of potential health concerns.

Agency Response and OIG Assessment

The Agency provided corrective actions and a milestone for Recommendation 1. OAQPS is establishing an air toxics strategy that will discuss how it will address emerging air toxics issues and how those issues will be elevated and handled within OAQPS, EPA regions, and external stakeholders. The strategy will also

include a framework to improve internal and external communication, coordination, and collaboration on air toxics. After reviewing and being briefed on the draft strategy, we determined that it does not address our concerns about how OAR will work with EPA regional offices to communicate preliminary air toxics risk information to the public so that communities are promptly informed of potential health concerns. The recommendation is unresolved.

Appendix B contains OAR's response to the draft report. OAR and Region 5 also submitted technical comments on the draft report. We have considered those comments and updated the report as appropriate.

Chapter 3
OAR Senior Management Hindered Region 5's Ability to Address Ethylene Oxide Emissions and Achieve EPA's Mission

An OAQPS manager relayed policy instructions from an OAR senior political appointee to Region 5 to not conduct inspections at ethylene oxide facilities unless invited by the state, according to two Region 5 managers. These policy instructions were relayed after one Region 5 manager asked whether the region could inspect or send out Clean Air Act Section 114 letters to ethylene oxide facilities.[7] According to one Region 5 manager, an OAR senior political appointee wanted the region to address ethylene oxide emissions through regulatory or voluntary control efforts and not enforcement tools, such as on-site inspections or Clean Air Act Section 114 letters.

While interviewing staff and managers in Region 5, we learned that OAR senior leaders issued other instructions that impacted Region 5's role in addressing ethylene oxide emissions. These oral instructions were for Region 5 to:

- Not send Clean Air Act Section 114 letters to facilities.
- Limit ambient air monitoring for ethylene oxide to the Sterigenics facility.
- Not seek the ATSDR's assistance for toxicological or health assessments and risk communication.
- Coordinate with OAQPS before starting any modeling of facility emissions.

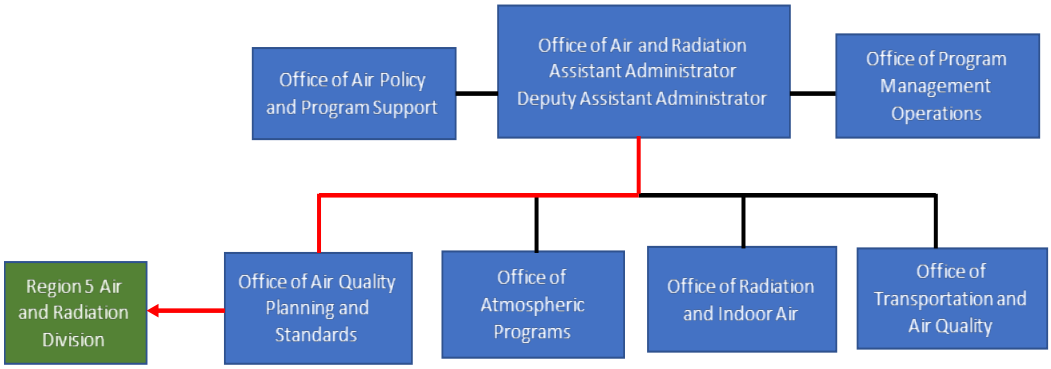
OAR Senior Political Leader Instructed Region 5 Not to Conduct Inspections Unless Invited by the State

After the then-assistant administrator for Air and Radiation delayed Region 5 from informing the Willowbrook community about the results of the May 2018 short-term monitoring around the Sterigenics facility and OAQPS took over communicating with the Sterigenics facility on ethylene oxide issues in September 2018, Region 5 staff started asking OAR headquarters for permission before conducting ethylene oxide-related activities. For example, in September 2018, a Region 5 manager asked an OAQPS manager whether the region could conduct inspections at ethylene oxide-emitting facilities. According to Region 5, the OAQPS manager asked the then-deputy assistant administrator for Air and Radiation and then orally relayed instructions to two Region 5 managers to not conduct any inspections at ethylene oxide-emitting facilities

[7] To inform the development of National Emission Standards for Hazardous Air Pollutants and for other Clean Air Act purposes, Section 114 of the Clean Air Act authorizes the EPA to require regulated entities to develop and submit a broad range of information, as well as to install monitoring equipment and sample emissions.

unless invited by the state. Figure 2 shows the dissemination of the inspection instruction from OAR to Region 5.

Figure 2: Dissemination of the inspection instruction from OAR to Region 5



Source: Developed by OIG based on information from the EPA. (EPA OIG image)

Note: Red line shows how the inspection instruction went from OAR to Region 5.

The Region 5 manager orally relayed this information to other Region 5 managers, who were responsible for relaying the information to the inspectors. According to Region 5 personnel, OAQPS personnel had directed Region 5 to not conduct inspections at ethylene oxide facilities because the region did not follow EPA headquarters two-pronged approach, which includes reviewing regulations pertaining to facilities that emit ethylene oxide and collecting information from facilities.

EPA's Two-Pronged Approach to Address Ethylene Oxide Emissions

Regulatory review. The first prong of the EPA's approach is to review existing air emissions regulations pertaining to facilities that emit ethylene oxide.

Information gathering. The second prong of the EPA's approach is to work closely with state and local air agencies to gather additional information on facility emissions to determine whether more immediate emission reduction steps are needed.

Region 5 personnel orally communicated to one state agency and one local agency that OAR headquarters directed Region 5 to not inspect ethylene oxide facilities unless invited by a state. Within one day, these agencies emailed Region 5 requesting the region's presence and assistance with on-site inspections at ethylene oxide-emitting facilities because of the region's expertise.

By contrast, Region 6 managers and inspectors stated that they did not receive instructions to not inspect ethylene oxide facilities unless invited by a state. While Region 6 had its states take the lead in assessing ethylene oxide emissions from facilities, Region 5 had conducted modeling of the Sterigenics and Elé facilities, communicated with the two facilities to ensure modeling accuracy, and conducted ambient monitoring at the Sterigenics facility. OAQPS personnel were aware of Region 5's actions, and Region 5 personnel believed that it was up to OAQPS personnel to decide which issues OAR senior political appointees were briefed on.

The instructions from OAR leadership prevented Region 5 personnel from initiating inspections at ethylene oxide facilities to address potential noncompliance with emission standards unless the state invited them. For example, Region 5 informed the Michigan Department of Environmental Quality—now the Michigan Department of Environment, Great Lakes, and Energy—about the instructions and was invited by the department to participate in an inspection at a Michigan facility. Region 5 participated in the inspection on October 12, 2018.

OAR Issued Additional Instructions that Restricted Region 5's Ability to Fulfill EPA's Mission

While collecting information to address our objective, we learned that OAR senior political appointees orally issued other instructions that impacted Region 5's role in addressing ethylene oxide emissions, some of which impacted other regions as well. We deemed this information relevant to the scope of our work and have included it in this report. These instructions included:

- Not to send Clean Air Act Section 114 letters to facilities.
- Limit ambient air monitoring for ethylene oxide to the Sterigenics facility.
- Not to seek the ATSDR's assistance for toxicological or health assessments and risk communication.
- Coordinate with OAQPS before starting any modeling of facility emissions.

The EPA's mission is "to protect human health and the environment." The Agency achieves its mission by ensuring, among other things, that:

- "Americans have clean air, land and water."
- "All parts of society--communities, individuals, businesses, and state, local and tribal governments--have access to accurate information sufficient to effectively participate in managing human health and environmental risks."

These instructions hindered Region 5's ability to effectively address ethylene oxide emissions in a timely manner.

OAR Senior Leaders Prevented OAQPS and Region 5 from Sending Clean Air Act Section 114 Letters to Facilities

OAR senior political appointees did not allow OAQPS and Region 5 to obtain information from ethylene oxide-emitting facilities through Clean Air Act Section 114 letters. Instead, those senior political appointees instructed Region 5 to obtain information voluntarily from ethylene oxide-emitting facilities through phone calls, emails, and letters delivered through the postal service or another delivery service. The Sterigenics and Elé facilities were unresponsive to these informal information

OAR's denial of Region 5's request to send Clean Air Act Section 114 letters to ethylene oxide-emitting facilities led to delays in the EPA obtaining critical information to further evaluate the cancer risks attributed to ethylene oxide emissions from these facilities.

requests, so Region 5 asked OAR headquarters whether the region could send out Clean Air Act Section 114 letters requiring the information. OAR headquarters did not approve the request.

OAQPS staff told us that they asked the then-assistant administrator for Air and Radiation for permission to send Clean Air Act Section 114 letters to multiple miscellaneous organic chemical manufacturing facilities with ethylene oxide emissions to obtain information for the miscellaneous organic chemical manufacturing risk and technology review proposed rule, which was in development. According to OAQPS staff, the then-assistant administrator for Air and Radiation allowed OAQPS to send one Clean Air Act Section 114 letter in November 2018 to the Lanxess facility in South Carolina that had one of the highest source category risk driven by ethylene oxide emissions. This Clean Air Act Section 114 letter included requirements for stack testing to quantify ethylene oxide emissions from certain emission points but did not include an OAQPS-requested requirement to monitor for fugitive emissions.

Region 5 Instructed to Not Conduct Monitoring for Ethylene Oxide

With the exception of the Sterigenics facility, where Region 5 conducted monitoring from November 2018 to March 2019, OAR instructed Region 5 not to conduct any new air monitoring for ethylene oxide. According to notes from a March 13, 2019 meeting, OAQPS managers and staff told a Region 5 manager that the then-assistant administrator for Air and Radiation said that:

- Modeling is a better tool for assessing risk.
- Monitoring would slow down the regulatory process.

According to Agency personnel, modeling is preferred over monitoring because of the detection limits associated with ethylene oxide monitoring. The detection limit of the EPA's contract laboratory performing this method, during the time of the Sterigenics monitoring, would have equated to a cancer risk well in excess of 100 in one million. According to an OAQPS manager, the EPA is working to improve the method detection limit because a non-detect does not mean that the risk is equal to or lower than 100 in one million. In the meantime, modeling would provide a more complete spatial and temporal assessment compared to monitoring, according to Agency personnel.

According to Region 5 staff, in August 2018, the EPA committed to conducting ambient monitoring around the Sterigenics facility. The EPA conducted monitoring from November 2018 through March 2019 despite the detection limitations. The monitoring results demonstrated that the facility's emissions were above the detection limit and higher than expected based on the September 2018 stack test data.

The Illinois Environmental Protection Agency found that the measured ambient ethylene oxide levels at the Sterigenics facility were an imminent and substantial endangerment to public health or welfare and issued a "seal order" in February 2019, which "sealed" the facility's ethylene oxide storage containers, restricting access to them. This access restriction prevented facility personnel from introducing ethylene oxide into the sterilization process.

The monitoring results suggested that fugitive emissions were likely the source of the high ambient concentrations given that the September 2018 stack test had shown that chamber back vent emissions had been controlled after being routed to existing control equipment. According to the EPA, the likely source of the majority of fugitive emissions at the Sterigenics facility was the off-gassing of sterilized products in uncontrolled areas of the facility. Fugitive emissions are generally not captured by emission control equipment or detected through normal equipment monitoring processes. Leaks are one source of fugitive emissions and are most often associated with equipment used for the movement of fluids and gases, such as pumps, valves, and connectors.

OAR Instructed Region 5 to Not Seek ATSDR's Assistance

Region 5 commonly sought the ATSDR's assistance for various risk assessment needs. Among a number of statutory mandates, the ATSDR also has responsibilities in the areas of public health assessments, the establishment and maintenance of toxicologic databases, and information dissemination. According to Region 5 personnel, an OAR senior leader instructed Region 5's Air and Radiation Division to no longer consult with the ATSDR and said that OAQPS would handle risk communication because the office is fully staffed with toxicologists. An OAQPS manager was not aware of who gave those instructions and stated that federal agencies should not be "providing different voices to the public."

Region 5 Was Instructed to Coordinate with OAQPS Before Starting Any Modeling of Facility Emissions

According to Region 5 personnel, an OAQPS manager told Region 5 to coordinate with OAQPS before conducting any modeling of ethylene oxide emissions.

Impact of OAR's Instructions on Region 5 and Public Health

The instructions from OAR ultimately hindered Region 5's ability to protect human health from ethylene oxide emissions in a timely manner. Region 5 could not assess potential noncompliance of emission standards with inspections. Furthermore, Region 5's inability to send Clean Air Act Section 114 letters to facilities allowed Sterigenics and Elé to delay providing critical information to the EPA that was needed to assess their ethylene oxide emissions and determine the

current cancer risk attributed to these emissions. While the Sterigenics facility is no longer in operation as of November 2020, the EPA was still assessing Elé's emissions nearly three years after Region 5 first communicated with Elé about the internal modeling results. According to Region 5, Region 5 and the Illinois Environmental Protection Agency will continue to investigate Elé, and additional follow-up is planned for 2021.

According to a Region 5 manager, the OAR instructions impacted Region 5's relationship with the Illinois Environmental Protection Agency, companies, and the ATSDR. For example, Region 5 personnel did not know that Illinois planned to issue a seal order to the Sterigenics facility until the order was reported by the news. The relationship with companies was likely impacted because companies understood that the EPA would not require them to provide additional information about their emissions since OAR would not allow Region 5 to issue Clean Air Act Section 114 letters. Further engagement, however, with companies and the state was necessary to fully address risks. Without effective relationships with companies or the state, the EPA lacked timely, accurate information about these facilities.

Conclusion

OAR senior leaders issued instructions that hindered Region 5's efforts to address ethylene oxide in a timely manner. OAR senior leaders' intervention to prevent Region 5 from gathering information and communicating with ethylene oxide-emitting facilities delayed the public from receiving timely, accurate information about health risks from ethylene oxide emissions.

Recommendation

We recommend that the assistant administrator for Air and Radiation:

2. Develop standard operating procedures describing the roles and responsibilities of the Office of Air and Radiation and regional offices in assessing and addressing air toxics emissions contributing to health risks, as found in the National Air Toxics Assessment or other studies.

Agency Response and OIG Assessment

The Agency provided corrective actions and a milestone to address Recommendation 2. As part of its air toxics strategy, OAQPS has already established three teams and an Air Toxics Council to improve its methods of communication, coordination, and collaboration around air toxics issues, both within OAQPS and with regional offices. One team under the strategy includes regional representatives, but the others only include cross-divisional OAQPS staff. After reviewing and being briefed on the draft strategy, we determined that the draft strategy does not provide specific information about roles and responsibilities, and the recommendation remains unresolved.

The Agency's response to our draft report is in Appendix B. The Agency also provided specific technical suggestions for our consideration, and we revised the report as appropriate.

Chapter 4
States in Regions 5 and 6 Have Generally Conducted Inspections of Ethylene Oxide-Emitting Facilities as Specified in Their CMS

The states in Regions 5 and 6 generally inspected major and synthetic minor facilities that emit ethylene oxide from fiscal years 2018 through 2020, according to the frequencies outlined in the EPA's CMS or a state's alternative Clean Air Act CMS plan. The states in Regions 5 and 6 conducted FCEs at 75 ethylene oxide-emitting facilities from fiscal years 2018 through 2020. The EPA conducted 12 on-site partial compliance evaluations of ethylene oxide-emitting facilities in Region 5 and 6 states during the same time period. Partial compliance evaluations are more targeted evaluations and generally less time-consuming and resource-intensive than FCEs.

An FCE is a comprehensive evaluation that assesses facility compliance as a whole, resulting in a compliance determination. An FCE addresses all regulated pollutants at all regulated emission units.

Title V of the Clean Air Act requires all major sources and a limited number of minor sources to have approved operating permits that outline what facilities must do to control air pollution. States delegated with implementing and enforcing the Title V operating permit program, which include all Region 5 and 6 states, are responsible for issuing permits and enforcing their requirements.

FCE Frequencies for Stationary Sources Are Outlined in CMS

The EPA's CMS focuses on federally enforceable requirements for Title V major sources and synthetic minor sources that emit or have the potential to emit at or above 80 percent of the Title V major source threshold. Major source thresholds for air toxics are emissions of ten tons per year for a single hazardous air pollutant or 25 tons per year of any combination of hazardous air pollutants.

According to the EPA's CMS guidance, states and local agencies should conduct an FCE, at a minimum:

- Once every two fiscal years at all Title V major sources, except those classified as mega-sites.
- Once every three fiscal years for mega-sites.
- Once every five fiscal years at synthetic minor sources, which are sources that emit or have the potential to emit at or above 80 percent of the Title V major source threshold.

These recommended FCE frequencies apply to EPA regions that directly implement the Clean Air Act in Indian Country or U.S. territories. The CMS only recommends FCE frequencies for major and synthetic minor facilities and not for minor facilities. Some ethylene oxide-emitting facilities are minor facilities, including Sterigenics, Vantage, Medline, and Elé.

According to the EPA's CMS guidance, each state submits a plan, known as a CMS plan, every two years at a minimum to implement its CMS. States may request and receive approval from their respective EPA region for alternative time frames to conduct FCEs for their major and synthetic minor facilities, which are incorporated into a state's CMS plan.

States in Regions 5 and 6 Have Generally Conducted FCEs for Major and Synthetic Minor Ethylene Oxide-Emitting Facilities

The states in Regions 5 and 6 generally conducted FCEs of ethylene oxide-emitting facilities according to the frequencies outlined in the EPA's CMS or alternative monitoring strategies approved by the regions from fiscal years 2018 to 2020. These states conducted FCEs at 75 ethylene oxide-emitting facilities from fiscal years 2018 to 2020. The EPA conducted 12 on-site partial compliance evaluations at ethylene-oxide emitting facilities during that same time period.

Conclusion

States in Regions 5 and 6 conducted FCEs of major and synthetic minor ethylene oxide-emitting facilities according to the frequencies outlined in the EPA's CMS or states' alternative Clean Air Act CMS from fiscal years 2018 through 2020.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	12	Develop standard operating procedures describing how the Office of Air and Radiation will work with EPA regional offices to communicate preliminary air toxics risk information, including elevated risks found in the National Air Toxics Assessment, to the public so that communities are promptly informed of potential health concerns.	U	Assistant Administrator for Air and Radiation		
2	19	Develop standard operating procedures describing the roles and responsibilities of the Office of Air and Radiation and regional offices in assessing and addressing air toxics emissions contributing to health risks, as found in the National Air Toxics Assessment, other studies, or public complaints.	U	Assistant Administrator for Air and Radiation		

[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

Congressional Requests to the OIG

November 1, 2018 Request from Senators Durbin and Duckworth and Congressman Foster

Congress of the United States
Washington, DC 20510

November 1, 2018

The Honorable Charles Sheehan
Acting Inspector General
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Acting Inspector General Sheehan,

We officially request the Office of the Inspector General of the U.S. Environmental Protection Agency (EPA) investigate if EPA complied with all statutory, regulatory, and policy requirements and protocols when it intentionally withheld critical health information from the public about carcinogenic air pollution from the Sterigenics facility in DuPage County, Illinois. We are concerned that the agency failed to take swift action to protect the health of a community that suffers from some of the highest cancer risks in the nation.

The 2016 Integrated Risk Information System report found ethylene oxide (EtO) to be much more carcinogenic at lower concentrations than previously thought. As a result, the 2014 National Air Toxics Assessment showed that DuPage County residents have an increased cancer risk from EtO exposure. In December 2017, EPA sent a letter to Sterigenics linking high cancer risks in the area to EtO emissions from the facility. However, EPA decided to withhold this vital information from the public for eight months.

An investigation is necessary to determine whether proper measures were taken to protect the lives of those affected by EtO emissions from the facility, to hold officials accountable, and to assure that proper protocol is followed in the future if any similar situation arises.

The EPA is responsible for protecting human health with safeguards to assure our nation has clean and safe air, water, and environment for all Americans. Making certain that proper action is taken when it is discovered that a community is facing a public health risk, is essential for the public to have confidence that the EPA is doing its job.

We look forward to your prompt response to this urgent request for a comprehensive investigation.

Sincerely,

RICHARD J. DURBIN
United States Senator

TAMMY DUCKWORTH
United States Senator

BILL FOSTER
United States Representative

November 7, 2018 Request from Senator Durbin

RICHARD J. DURBIN
ILLINOIS
DEMOCRATIC WHIP

COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

United States Senate
Washington, DC 20510–1304

November 7, 2018

The Honorable Charles Sheehan
Acting Inspector General
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Acting Inspector General Sheehan,

I write to follow up on a request from November 1 and ask the Office of the Inspector General of the U.S. Environmental Protection Agency (EPA) to investigate if statutory authority and proper protocols were followed when critical health information about carcinogenic ethylene oxide pollution from two additional facilities—Medline Industries, Inc. in Waukegan and Vantage Specialty Chemicals, Inc. in Gurnee—was intentionally withheld from residents in Lake County, Illinois.

After the findings of the 2016 Integrated Risk Information System report that indicated ethylene oxide (EtO) is much more carcinogenic at lower concentrations than previously thought, EPA acknowledged the increased risks but did not inform residents in DuPage and Lake counties of facilities near them that use and emit EtO and how those emission could cause long-term health concerns. This news is especially concerning as Vantage Specialty Chemicals has not reported its most recent EtO emissions, as it is required to do, and previous reports show that Vantage released more EtO than both Sterigenics and Medline.

Withholding this vital public health information from the communities with potentially high EtO exposure is unacceptable. The residents need reassurance that the EPA has their best interests in mind and is taking the proper steps to ensure the air they breathe is clean.

For this reason, I ask you expand the scope of my previously requested investigation to include the facilities in Lake County. I look forward to your prompt response.

Sincerely,

Dick Durbin

RICHARD J. DURBIN
United States Senator

January 17, 2019 Request from Senators Duckworth, Carper, and Durbin

United States Senate
WASHINGTON, DC 20510

January 17, 2019

VIA ELECTRONIC DELIVERY

Mr. Charles J. Sheehan
Acting Inspector General
Office of the Inspector General
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Acting Inspector General Sheehan:

We write to request that the U.S. Environmental Protection Agency (EPA) Office of Inspector General (OIG) immediately initiate an independent investigation into a serious allegation of misconduct involving failure to protect public health. Senator Duckworth's staff recently received information alleging that EPA senior political appointees instructed career civil servants to avoid conducting inspections in Region 5 of facilities that emit Ethylene Oxide (EtO), a known carcinogen.

A review of public source reporting from EPA's official website appears to confirm EPA has failed to conduct inspections of EtO emitting facilities over the past six months across Region 5 and the Country, despite recent incidents involving dangerous exposure to this carcinogenic chemical. This fact pattern is concerning in and of itself. However, if the lax inspection and enforcement activity is a result of politically-motivated interference overriding recommendations of career staff, that would elevate our concerns from simple poor performance to potential outright misconduct by political appointees.

Accordingly, we urge the EPA OIG to swiftly begin a thorough independent investigation into allegations that senior EPA political appointees instructed or impeded investigations of facilities that emit EtO. Americans rely on EPA to protect them from public threats posed by contaminated air and water. The allegation that EPA may be preventing its personnel from carrying out this critical mission is disturbing and must be investigated to determine the truth, and if necessary, identify corrective actions.

Sincerely,

Tammy Duckworth
Ranking Member
U.S. Senate Subcommittee on
Fisheries, Water and Wildlife

Tom Carper
Ranking Member
U.S. Senate Committee on
Environment and Public Works

Richard J. Durbin
Democratic Whip
United States Senate

January 31, 2019 Request from Congressman Richmond

CEDRIC L. RICHMOND
2ND DISTRICT, LOUISIANA

506 CANNON HOUSE OFFICE BUILDING
(202) 225-6636

Congress of the United States
House of Representatives
Washington, DC 20515–1802

January 31, 2019

Mr. Charles J. Sheehan
Acting Inspector General
Office of the Inspector General
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, D.C. 20460

Dear Acting Inspector General Sheehan:

It has come to my attention that Senators Duckworth, Carper, and Durbin recently sent you a letter requesting an investigation into whether senior political appointees at the Environmental Protection Agency (EPA) instructed career civil servants to avoid inspecting facilities that emit Ethylene Oxide (EtO). While their letter concerned inspections in Region 5, these reports are disturbing to all of us who represent areas with facilities that emit EtO. I am requesting that you extend any investigation related to this issue to actions in Region 6, as well.

Acting EPA Secretary Andrew Wheeler was questioned by Senator Duckworth on the lack of inspection of EtO at his confirmation hearing where he stated, "We are monitoring a number of facilities that release ethylene oxide," but failed to mention any specifics surrounding that issue, such as where, how often, and the type of inspections being conducted.

In light of recent reports on this issue, my office examined information on the EPA's website and found no inspections of EtO facilities in Region 6 within the last six months. This has prompted me to write to you today. I ask that you conduct a thorough investigation to determine the truth. Have inspections by the EPA been conducted on these facilities in Region 6? If not, why? Have political appointees inappropriately interfered with the work of career civil servants on this matter?

I hope that you take action quickly to investigate this matter. The people of Louisiana's 2nd Congressional District and the nation deserve the truth and assurance that the EPA is transparently and effectively conducting its critical missions.

Sincerely,

Cedric L. Richmond

Agency Response to Draft Report

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 5, 2021

OFFICE OF
AIR AND RADIATION

MEMORANDUM

SUBJECT: EPA Response to OIG Draft Reports titled: "EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health" - Project No. OA&E-FY19-0091, January 14, 2021; and "EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions" - Project No. OA&E-FY19-0091, February 4, 2021

FROM: Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation

TO: Renee McGhee-Lenart
Acting Air Director
Office of the Inspector General

The Office of Air and Radiation (OAR) welcomes the opportunity to provide comment on the following two draft reports and their recommendations: *EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health* and *EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions*. We have provided our comments in the attachments to this memorandum and provide our initial thoughts on the recommendations in each of the two reports below, along with other information requested in the reports.

OIG Comment: For the purpose of this appendix, we only included the Agency's response to this report. We will include the section removed herein in the relevant report.

Section 2: EPA Response to Draft Report "EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions"

OIG Recommendation 1: Develop standard operating procedures describing how the Office of Air and Radiation will work with EPA regional offices to communicate preliminary air toxics risk information, including elevated risks found in the National Air Toxics Assessment, to the public so that communities are promptly informed of potential health concerns.

Response 1: We recognize the public as key users of the air toxics analyses done by OAQPS. As noted above, OAQPS is establishing a strategy to improve internal and external communication, coordination, and collaboration around air toxics. The Air Toxics Strategy establishes a standard operating procedure that realigns OAQPS to address air toxic issues more effectively and proactively. The strategy positions OAQPS to apply a systematic approach to air toxics management and mitigation, data and analytics, and new and emerging issues. Further, an outreach and implementation component embedded throughout the strategy ensures the office is focused not only on how to address air toxics issues, but how to more effectively understand the concerns of coregulators and the public, and to improve the ways in which findings are shared. Consistent with the Agency's mission statement, it is fundamental that we provide *accurate* information in communicating risks. As such, any preliminary air toxics risk information needs to be verified and quality assured prior to communicating with the public to avoid confusion and to build trust. Finally, we have collected a lot of information regarding regional needs and uses for NATA over time and look forward to continued engagement as new products/tools are developed.

Planned Completion Date: Quarter 4, FY 2021

OIG Recommendation 2: Develop standard operating procedures describing the roles and responsibilities of the Office of Air and Radiation and regional offices in assessing and addressing air toxics emissions contributing to potential health risks as found in the National Air Toxics Assessment, other studies, or public complaints.

Response 2: As part of the Air Toxics Strategy, OAQPS has established three teams and an Air Toxics Council to improve our methods of communication, coordination, and collaboration around air toxics issues – both within our office and with our Regional offices. The Air Toxics Evaluation and Screening Team, specifically, comprises a diverse group of OAQPS staff and includes regional participants. This group screens new and emerging air toxics issues that come to OAQPS through our interactions with a diverse set of internal and external stakeholders. Once preliminary assessments are conducted this team engages a newly formed Air Toxics Council, which includes OAQPS senior managers, to determine if further evaluation is needed, whether project teams need to be established for more substantive work, whether or not issues are national in scope, or whether issues are for OAQPS awareness and should be transferred to another office or EPA region for further action. The Management and Mitigation Team primarily includes OAQPS first-line managers; the team will recommend priorities and steer efforts to address management and mitigation of air toxics through collaborative regulatory and non-regulatory efforts and streamlined approaches. The Data and Analytics Team will recommend priorities and steer efforts to ensure that the range of air toxics data collection, infrastructure, and analysis efforts across OAQPS support short-term and long-term air toxics program priorities. The Management and Mitigation

and Data and Analytics Teams also brief the Air Toxics Council to engage in a substantive discourse about their short- and long-term assessments and recommendations. Outreach and implementation are key components of the strategy. As such, each team under the strategy includes OAQPS staff that specialize in outreach to states, locals, communities, and tribes.

Planned Completion Date: Quarter 4, FY 2021

If you have any questions regarding this response, please contact JoLynn Collins, OAQPS/OAR Audit Liaison, at (919) 541-0528.

cc: James Hatfield
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Peter Tsirigotis
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Appendix C

Distribution

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Associate Deputy Administrator
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Deputy Chief of Staff
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Agency Follow-Up Coordinator
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Regional Deputy Administrator for Region 5
Regional Deputy Administrator for Region 6
Assistant Administrator for Air and Radiation
Principal Deputy Assistant Administrator for Air and Radiation
Deputy Assistant Administrators for Air and Radiation
Director, Office of Air Quality Planning and Standards, Office of Air and Radiation
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