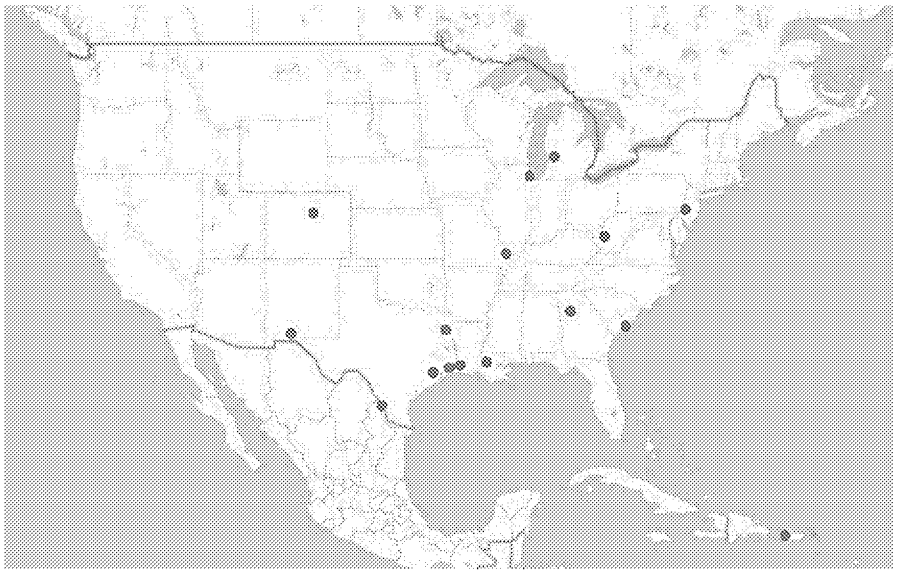
U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Improving air quality

Management Alert: Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns

Report No. 20-N-0128 **March 31, 2020**



Report Contributors:

Bao Chuong
Andrew Lavenburg
Gaida Mahgoub
Renee McGhee-Lenart
James Hatfield

Abbreviations

EPA	U.S. Environmental Protection Agency
NATA	National Air Toxics Assessment
OIG	Office of Inspector General

Cover Image: Metropolitan areas in the United States where there is at least one census tract in which ethylene oxide is a significant risk driver for cancer. (OIG-developed image based on the 2014 NATA and information from the EPA)

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U.S. Environmental Protection Agency
Office of Inspector General

20-N-0128
March 31, 2020

At a Glance

Why We Did This Project

While conducting an audit of the U.S. Environmental Protection Agency's actions to address air toxics emissions through its residual risk and technology review program, the EPA's Office of Inspector General identified an urgent matter related to whether the EPA had informed the public about health risks from exposure to ethylene oxide emissions. Therefore, we are issuing this management alert so that the EPA can address this matter while our overall audit work continues.

Ethylene oxide is a gas used to make other chemicals that are needed to manufacture a variety of products and to sterilize medical equipment. Studies show that breathing in elevated ethylene oxide levels over many years can lead to lymphoid cancers in males and females and breast cancer in females. In December 2016, the EPA revised its characterization of the chemical to "carcinogenic to humans."

This report addresses the following:

- *Improving air quality.*

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Management Alert: Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns

What We Found

The EPA needs to inform residents who live near facilities with significant ethylene oxide emissions about their elevated estimated cancer risks so they can manage their health risks.

Through its National Air Toxics Assessment, the EPA identified areas where exposure to ethylene oxide emissions could contribute to an elevated estimated lifetime cancer risk equal to or greater than 100 in one million, a risk level that the EPA generally considers not sufficiently protective of health. These emissions primarily come from chemical manufacturing plants and commercial sterilizers that sterilize medical equipment.

The EPA has prioritized activities to more fully assess ethylene oxide emissions and the associated health risks to the public near 25 high-priority facilities. These activities include communicating with facilities and states about gathering emissions information and communicating with elected officials about the National Air Toxics Assessment results. While the EPA or state personnel, or both, have met with residents living near nine of the 25 high-priority facilities, communities near 16 facilities have yet to be afforded public meetings or other direct outreach to learn about the health risks and actions being taken to address those risks.

The OIG did not identify any specific statutory, regulatory, or policy requirements for the EPA to provide the public additional information regarding its preliminary determination that certain ethylene oxide-emitting facilities may present health risks to surrounding communities. However, the EPA's mission statement includes working to ensure that "[a]ll parts of society … have access to accurate information sufficient to effectively participate in managing human health and environmental risks." Thus, the Agency should work to ensure that the health risks and actions that the EPA is taking to address those risks are directly and promptly communicated to residents living near all the high-priority facilities.

Recommendations and Planned Agency Corrective Actions

We recommend that the Agency provide residents in 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. In its response to our draft report, the Agency proposed an alternative recommendation with corrective actions that focused on completing more refined investigations of risk prior to conducting significant public outreach. We do not believe that the Agency should delay providing forums for interactive outreach with residents in these communities. Therefore, our recommendation is unresolved pending receipt of an acceptable corrective action plan with milestones from the EPA.

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

THE INSPECTOR GENERAL

March 31, 2020

MEMORANDUM

SUBJECT: Management Alert: Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns
Report No. 20-N-0128

FROM: Sean W. O'Donnell

TO: Doug Benevento, Associate Deputy Administrator

While conducting an audit of the U.S. Environmental Protection Agency's actions to address air toxics emissions through its residual risk and technology review program (Project No. OA&E-FY19-0091), the EPA's Office of Inspector General identified an urgent matter to report to the Agency. The OIG is alerting you to this matter because of the disparity in the extent and nature of communication between the EPA and impacted communities where the EPA has identified significant health risks to the public from ethylene oxide emissions. This report presents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The EPA's Office of Air Quality Planning and Standards, within the Office of Air and Radiation, and EPA Regions 2–8 are responsible for the issues discussed in this report. Due to the significance of the issues and the involvement of multiple offices, the report is addressed to the associate deputy administrator.

Action Required

This report contains an unresolved recommendation. In accordance with EPA Manual 2750, the resolution process begins immediately with the issuance of this report. We are requesting a meeting within 30 days between the associate deputy administrator and the OIG's assistant inspector general for Audit and Evaluation. If resolution is still not reached, the Office of the Administrator is required to complete and submit a dispute resolution request to the chief financial officer.

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

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Chapter 1
Introduction

Purpose

While conducting the audit of the U.S. Environmental Protection Agency's actions to address air toxics emissions through its residual risk and technology review program (Project No. OA&E-FY19-0091), the EPA's Office of Inspector General identified an urgent matter to report to the Agency. This matter involves the communication of the EPA's current assessment of health risks to the public from exposure to ethylene oxide air emissions.

Background

Ethylene oxide is a flammable and colorless gas used to make chemicals that are needed in the manufacturing of a variety of products including antifreeze, textiles, plastics, detergents, and adhesives. It is also used to sterilize medical equipment or other devices 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. Ethylene oxide is one of 187 hazardous air pollutants regulated by the EPA. 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 found 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, or DNA, which is hereditary material in humans.

EPA Identified Ethylene Oxide as Significant Health Risk

The EPA periodically conducts the National Air Toxics Assessment to assess the public health risk from exposure to air toxics. The EPA and state, local, and tribal air agencies use NATA as a screening tool to help them identify 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 in 2018 but is based on emission inventories reported for calendar

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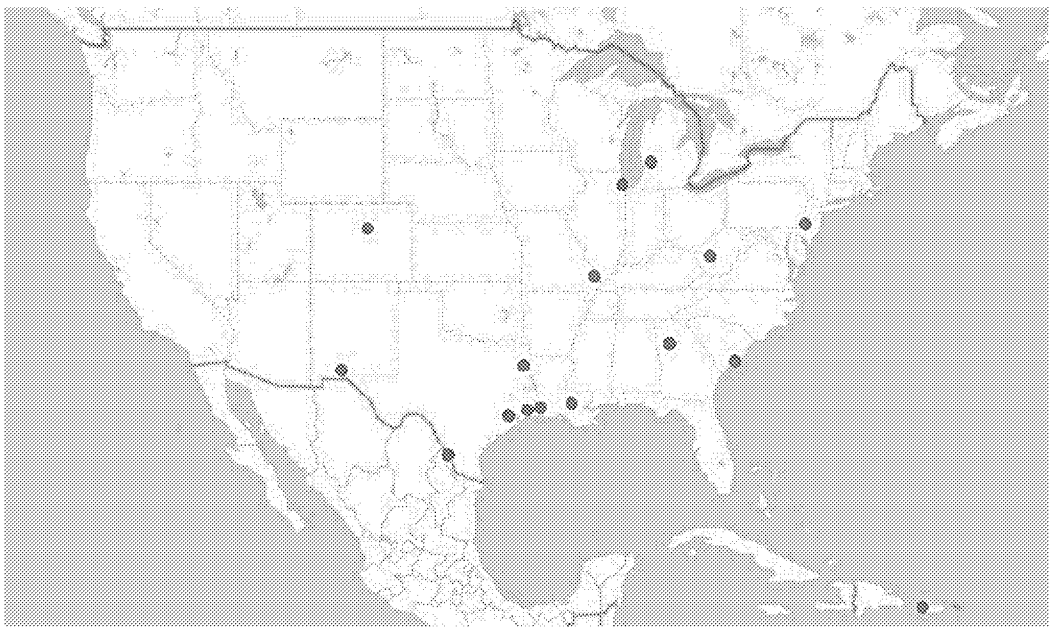
year 2014. The EPA identified census tracts with elevated estimated cancer risks primarily driven by ethylene oxide emissions in 17 metropolitan areas, as shown in Figure 1. Census tracts are small, relatively permanent statistical subdivisions of a county with boundaries that normally follow visible features, such as roads and streams. Census tracts ideally contain about 4,000 people and 1,600 housing units.

Figure 1: Metropolitan areas in the United States where there is at least one census tract in which ethylene oxide is the risk driver



Source: 2014 NATA and information from the EPA.

Note: Two of the metropolitan areas—Allentown-Bethlehem-Easton in Pennsylvania and Philadelphia-Camden-Wilmington in Pennsylvania, New Jersey, and Delaware—overlap, so only 16 areas are identifiable on the map.

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 over 70 years, one person would likely develop cancer from the exposure. This risk would be in addition to any baseline cancer risk of a person not exposed to these air toxics. According to the EPA's March 1999 *Residual Risk Report to Congress*, for establishing air toxics emissions standards, the EPA generally considers a risk of 100 in one million (or one in 10,000) as not sufficiently protective of public health and requires additional action to reduce that risk. Figure 2 illustrates the EPA decision-making process when addressing residual risk from air toxics emissions. Residual risk is the health and environmental risk that remains after implementation of technology-based control standards that have already been promulgated to address air toxics emissions. The Clean Air Act Amendments of 1990 required the EPA to establish technology-based standards for sources of air toxics and, within eight years thereafter, review

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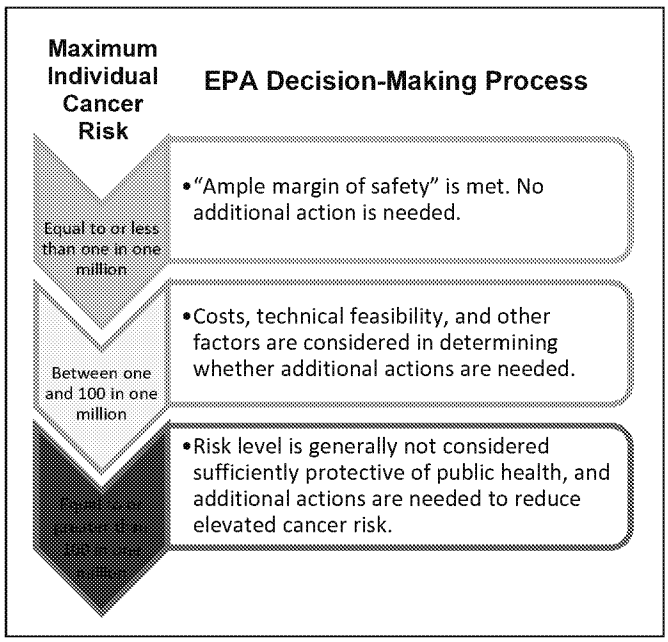
the remaining health risk to the public and establish additional standards to reduce the public's health risk to acceptable levels, if necessary.

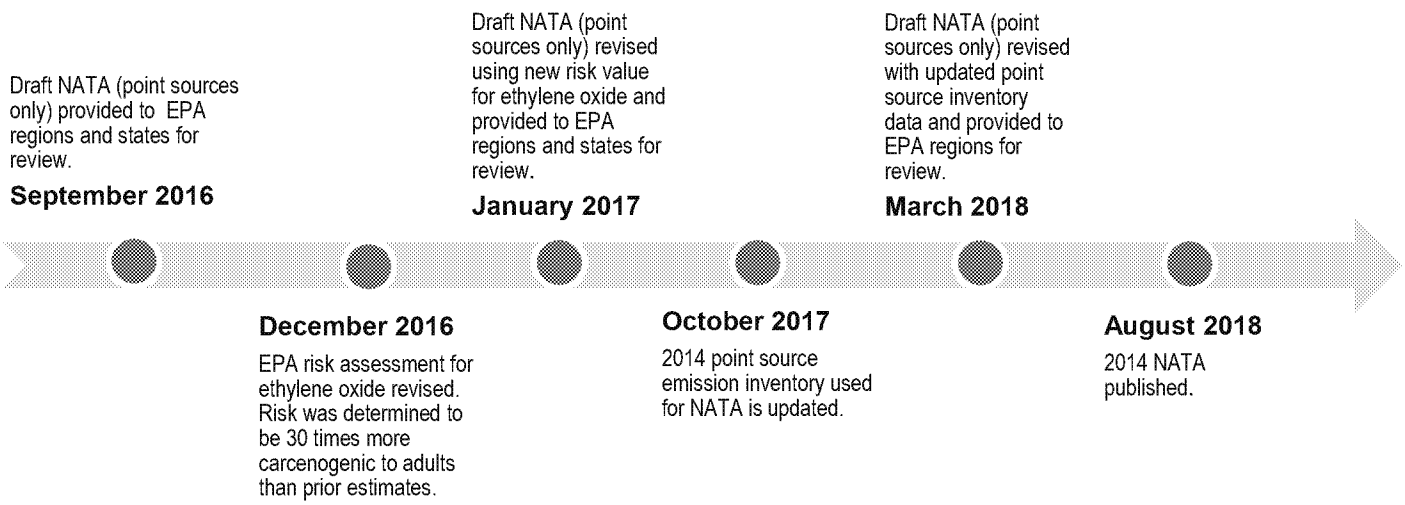
Figure 2: EPA decision-making process for addressing residual risk in the Agency's regulatory program



Source: OIG-developed based on information from the EPA.

The EPA released the 2014 NATA on August 22, 2018. Figure 3 provides a timeline of the development of the 2014 NATA.

Figure 3: Timeline for developing the 2014 NATA data



Source: OIG-developed based on information provided by the EPA.

Note: The first complete version of the 2014 NATA was provided to regions and states to review in June 2017, with a deadline of August 2017.

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On August 29, 2018, the mayor of Willowbrook, Illinois, one community impacted by ethylene oxide emissions, held a public meeting to provide information and answer the community's questions regarding ethylene oxide. The meeting included the EPA, the Illinois Environmental Protection Agency, and the Agency for Toxic Substances and Disease Registry. Since that meeting, residents in other communities, as well as members of Congress, have expressed concerns about the public health risk from exposure to ethylene oxide emissions and what actions the EPA is taking to address those concerns.

EPA's Approach for Addressing Risks from Ethylene Oxide

As the EPA was finalizing the 2014 NATA, the Agency identified 22 ethylene oxide-emitting facilities that contribute to elevated estimated cancer risks equal to or greater than 100 in one million at the census tract level. According to the EPA, the Agency has prioritized taking actions to assess and address the health risks from these 22 facilities as well as three additional facilities that were estimated to contribute to elevated estimated cancer risks equal to or greater than 1,000 in one million at the census block level. Census blocks represent smaller statistical areas bounded by visible features, such as roads and streams, and by nonvisible boundaries, such as property lines. A block is the smallest geographic unit for which the U.S. Census Bureau tabulates decennial census data.

Eleven of these 25 facilities are commercial sterilizers, which are facilities that sterilize medical equipment, and 14 are chemical plants. Throughout this report, we refer to these 25 facilities, which the EPA had previously designated as contributing to a high estimated cancer risk, as "high-priority" facilities. Each of the 17 metropolitan areas identified previously in Figure 1 contains at least one of the 25 high-priority facilities.

Since the release of the 2014 NATA, the EPA has developed a two-pronged approach to address ethylene oxide emissions that consists of (1) reviewing existing regulations and (2) gathering information to inform regulatory efforts and determine whether more immediate reduction steps are necessary in any particular location.

Regulatory review. The first prong of the EPA's approach is to review existing air emissions regulations pertaining to facilities that emit ethylene oxide. On December 17, 2019, the EPA proposed revised emissions standards for miscellaneous organic chemical manufacturing facilities, some of which emit ethylene oxide. A court order requires that the EPA issue the final rule by May 29, 2020.[1] On December 12, 2019, the EPA published an advance notice of proposed rulemaking in the Federal Register to solicit information from industry

[1] Pursuant to a court order issued on February 19, 2020, the deadline for the EPA to finalize revisions, if any, to the National Emission Standards for Hazardous Air Pollutants for the Miscellaneous Organic Chemical Manufacturing source category was modified from March 13, 2020, to May 29, 2020. See *California Communities Against Toxics, et al.* v. *Wheeler*, No. 1:15-cv-00512-TSC, order dated February 19, 2020.

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and the public regarding a potential future rulemaking to revise the current standards for commercial ethylene oxide sterilization facilities. The existing standards for these two source categories were developed prior to the EPA revising the unit risk estimate for ethylene oxide, which increased the EPA's estimate of cancer risk to adults. Thus, a facility could be complying with the existing standards, but exposure to the facility's emissions could create elevated and unacceptable public health risks.

In addition to the two source categories discussed above, ethylene oxide is emitted by facilities in other source categories, such as synthetic organic chemical manufacturing and polyether polyols production. Ethylene oxide is also emitted at area sources, which are smaller facilities. Of the 25 high-priority facilities:

- Four are in the synthetic organic chemical manufacturing industry source category.
- Two are in the polyether polyols production source category.
- Seven are chemical plants categorized as area sources.

At the time we issued this report, the EPA had not yet scheduled regulatory reviews for these two source categories or the chemical plant area sources that emit ethylene oxide.

Information gathering. The second prong of the EPA's approach is to gather additional information about the facilities that emit ethylene oxide. This effort is intended to help inform the EPA's regulatory approach. It includes the EPA's efforts to work with states to identify opportunities for voluntary emission reductions in the near-term. The EPA is initially focusing its information gathering and voluntary reduction efforts on the 25 high-priority facilities.

Responsible Offices

The EPA's Office of Air Quality Planning and Standards, within the Office of Air and Radiation, and EPA Regions 2–8 are responsible for the issues discussed in this report. Due to the significance of these issues and the involvement of multiple offices, this report has been addressed to the associate deputy administrator, who manages the regions.

Scope and Methodology

We conducted our work related to this report from February 2019 to January 2020. While our overall audit, which is still ongoing, is being conducted in accordance with generally accepted government auditing standards, the work related to this report does not constitute an audit done in accordance with these standards.

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We reviewed the EPA's mission statement; its guidance on risk communication; the EPA communications strategy, as well as regional communications plans to address ethylene oxide emissions; the 2014 NATA; the EPA-generated lists of ethylene oxide-emitting facilities that contribute to an estimated increased lifetime cancer risk of at least 100 in one million based on the 2014 NATA; and lists of additional facilities based on preliminary information of the elevated estimated cancer risks at the census block level.

We contacted EPA regions that had at least one facility contributing to elevated health risks to determine what actions they have taken to communicate with the public regarding the EPA's assessment of the public health risk from ethylene oxide emissions. We also interviewed staff and managers from the EPA's Office of Air Quality Planning and Standards to identify the EPA's approach to addressing risk from ethylene oxide facilities.

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Chapter 2
EPA Should Inform Residents Living Near All High-Priority Ethylene Oxide-Emitting Facilities of Health Concerns

The EPA, state personnel, or both have met with residents living near nine of the 25 high-priority facilities where the EPA has estimated that ethylene oxide emissions significantly contribute to elevated estimated cancer risks. These meetings were held to inform the public and answer questions that residents had regarding ethylene oxide emission in their communities. In addition to public meetings, the EPA provided information on its website regarding activities to address ethylene oxide, and the seven EPA regions in which the high-priority facilities were located noted that they have informed states, elected officials, community advocates, or other interested parties about the ethylene oxide facilities contributing to elevated estimated cancer risks in their states.

Public meetings have not been conducted in communities near 16 facilities where the EPA estimated that ethylene oxide emissions contribute to elevated estimated cancer risks. These communities have not been given the same opportunity to interact with federal and state regulators to become informed on the issue. Some regions have taken action to correct this disparity. Region 2 plans to meet with residents living near one high-priority facility to inform them of health concerns. Additionally, Region 3 has a communications plan in place to work with state and local agencies on how they plan to inform communities near ethylene oxide-emitting facilities in that region, which includes four high-priority facilities. Similar plans to meet with communities near 11 high-priority facilities are not in place, most of which are in Texas and Louisiana in Region 6.

Appendix A lists the 25 high-priority facilities and whether EPA or state personnel have directly informed residents living near those facilities about their health risks.

Communities Should Have Access to Information to Help Manage Health Risks

The OIG did not identify any statutory, regulatory, or policy requirements for the EPA to provide the public additional information regarding its preliminary determination that certain ethylene oxide-emitting facilities may present health risks to surrounding communities. The EPA's mission statement, however, states 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."

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In addition, in our July 2019 report titled *FY 2019: EPA Management Challenges*, Report No. 19-N-0235, we noted that one of the EPA's management challenges is to improve risk communication by providing individuals and communities with sufficient information to make informed decisions to protect their health and the environment. EPA Administrator Andrew 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 a "cardinal rule" of risk communication is to accept and involve the public as a legitimate partner.[2] The guidance also states that communities have the right to participate in decision-making processes that affect their lives and livelihoods.

To fulfill 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.

EPA or State Agencies Have Held Public Meetings with Residents Living Near Nine High-Priority Facilities

The EPA, state agencies, or both have met with the residents near nine high-priority facilities located in four EPA regions to discuss health concerns related to ethylene oxide emissions:

- **Region 4**. The first two public meetings in Region 4 were held on August 19 and August 20, 2019, regarding cancer risks from ethylene oxide emissions from commercial sterilization facilities in Smyrna and Covington, Georgia. These meetings were held after residents learned about their cancer risks in July 2019 through the news media, almost a year after the 2014 NATA was released.

  On December 2, 2019, Region 4 attended a public meeting in Charleston, South Carolina, with residents living near another high-priority facility. At this meeting, the chief of the Bureau of Air Quality from the South

[2] EPA, *Risk Communication in Action–the Risk Communication Workbook*, EPA/625/R-05/003, August 2007; and EPA, *Risk Communication in Action–the Tools of Message Mapping*, EPA/625/R-06/012, August 2007.

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Carolina Department of Health and Environmental Control gave a presentation about NATA and ethylene oxide.

- **Region 5**. The first public meeting regarding ethylene oxide concerns was held on August 29, 2018, in Willowbrook, Illinois, a community near a commercial sterilization facility. As previously mentioned, this meeting was arranged by the mayor one week after the EPA released the 2014 NATA. The EPA and other agencies provided information and answered the community's questions. More than 400 people attended, according to a meeting summary. The EPA hosted a second public meeting, which consisted of an open house and a public forum, on November 29, 2018. The EPA also held a third public meeting on May 29, 2019, to discuss the EPA's risk assessment summary of the ethylene oxide emissions from the Willowbrook facility.

  State agency personnel held public meetings with residents living near ethylene oxide-emitting facilities in Grand Rapids, Michigan, and Lake County, Illinois.

- **Region 7.** Regional personnel held public meetings with residents living near two high-priority facilities in Verona, Missouri, and Jackson, Missouri. The last meeting was held on December 2, 2019.

- **Region 8**. Regional and state agency personnel met with residents near one high-priority facility in Lakewood, Colorado, on December 11, 2018.

Public meetings have been used to inform residents of ethylene oxide concerns at the nine high-priority facilities discussed above. However, EPA and state personnel could use other risk communication tools—such as webinars, workshops, and door-to-door communication—to discuss health concerns and take questions from the residents living near the remaining 16 high-priority facilities.

EPA Plans to Conduct Direct Outreach Efforts to Inform Residents Living Near Five High-Priority Facilities

The EPA has plans to conduct public outreach to residents near five high-priority facilities located in two EPA regions to discuss health concerns related to ethylene oxide emissions:

- **Region 2**. Regional personnel plans to meet with residents living near a high-priority facility in Puerto Rico in spring 2020.

- **Region 3**. The Region, which has four high-priority facilities that emit ethylene oxide, has developed a strategic risk communication plan to work with state and local agencies on how they will inform communities that may be in areas of concern. This plan consists of various proposed

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activities during the first half of 2020, such as meetings with city councils and door-to-door communication.

EPA Does Not Have Plans to Conduct Direct Outreach Efforts to Inform Residents Living Near 11 High-Priority Facilities

The EPA does not have plans to hold public meetings or otherwise directly inform residents living near 11 high-priority facilities of health risks. One of these facilities is in Region 5 and ten are in Region 6.

Region 6 provided us with a draft communication plan, which stated that it will collaborate with states on community meetings and further public outreach. The plan did not, however, include time frames for conducting public meetings or any other direct outreach by the EPA. Furthermore, Region 6 personnel told us that Texas and Louisiana state agency personnel would take the lead in informing the public about health risks from ethylene oxide emissions. Region 6 personnel stated that as of January 2020, regional, Louisiana, and Texas state agency personnel had not communicated with the communities near the high-priority facilities.

Conclusions

The EPA and state agencies have conducted a variety of outreach efforts to communicate health concerns associated with ethylene oxide emissions. The EPA or state agencies have held public meetings in communities near nine ethylene oxide emitting facilities to inform the public about ethylene oxide emissions in their communities. However, public meetings or other direct outreach efforts have not been afforded to residents living near 16 of the high-priority ethylene oxide-emitting facilities. Although Regions 2 and 3 have plans to work with states and one territory to communicate with residents living near the high-priority facilities in those respective regions, there are still communities around 11 high-priority facilities where the EPA has no plans for direct outreach with residents about health risks from ethylene oxide emissions.

While we recognize that state agency personnel can play a lead role in these meetings, the EPA's participation is important for two reasons:

- To provide a consistent message.
- To fulfill the EPA's critical leadership role in developing any future regulatory standards for ethylene oxide-emitting facilities under the Agency's two-pronged approach to address ethylene oxide emissions.

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Recommendation

We recommend that the associate deputy administrator:

1. Improve and continue to implement ongoing risk communication efforts by promptly providing residents in all communities near the 25 ethylene oxide-emitting facilities identified as high-priority by the EPA with a forum for an interactive exchange of information with the EPA or the states regarding health concerns related to exposure to ethylene oxide.

Agency Response and OIG Assessment

The EPA offered an alternative recommendation to the OIG's draft report recommendation. The alternative recommendation stated:

> Improve, as necessary, and continue to implement ongoing efforts to conduct additional, more refined investigation of risks in all high-risk areas. Based on this work, support state/territory-led efforts to communicate risk information to residents in all communities near ethylene oxide-emitting facilities in high priority areas.

The Agency's response also offered three corrective actions to implement its proposed recommendation, but these proposed actions did not provide a timeline for when the more refined investigation of risks would be completed and when the residents would be informed of the results. The Agency's response to our draft report is included in Appendix B.

In the absence of an acceptable corrective action plan, we continue to recommend that the Agency promptly provide residents with a forum for an interactive exchange of information on the risks of ethylene oxide to their communities. We agree that the Agency should continue its ongoing efforts to conduct additional, more refined investigations of risks for communities near the 25 high-priority facilities and the census block facilities. However, these efforts should not preclude the Agency and the respective states from promptly informing the communities near the high-priority facilities about the NATA results and the actions that the EPA and the states are taking to address public health concerns associated with ethylene oxide emissions. This will help assure that all residents near high-priority facilities have access to similar information and the opportunity to manage their personal health risk.

Our recommendation is considered unresolved. We are requesting a meeting within 30 days between the associate deputy administrator and the OIG's assistant inspector general for Audit and Evaluation.

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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	11	Improve and continue to implement ongoing risk communication efforts by promptly providing residents in all communities near the 25 ethylene oxide-emitting facilities identified as high-priority by the EPA with a forum for an interactive exchange of information with the EPA or the states regarding health concerns related to exposure to ethylene oxide.	U	Associate Deputy Administrator		

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

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Appendix A

EPA or State Actions to Directly Inform Residents Living Near 25 High-Priority Ethylene Oxide-Emitting Facilities of Health Risks

EPA region	Facility	Location	Type of facility	Date of first EPA or state action to directly inform residents living near facility
2	Edwards Lifesciences Corp.	Anasco, PR	Commercial sterilizer	Planned for spring 2020.
3	B Braun Medical Inc.	Allentown, PA	Commercial sterilizer	Communications plan identifies potential outreach activities for first half of calendar year 2020.
3	Union Carbide Corp. – Institute	Institute, WV	Chemical plant	Communications plan identifies potential outreach activities for first half of calendar year 2020.
3	Croda	New Castle, DE	Chemical plant	Communications plan identifies potential outreach activities for first half of calendar year 2020.
3	Union Carbide Corp. – South Charleston Facility	South Charleston, WV	Chemical plant	Communications plan identifies potential outreach activities for first half of calendar year 2020.
4	Solvay USA (Lanxess)	Charleston, SC	Chemical plant	December 2, 2019
4	C R Bard (Becton, Dickinson, and Co.)	Covington, GA	Commercial sterilizer	August 20, 2019
4	Griffith Micro Science Inc. (Sterigenics)	Smyrna, GA	Commercial sterilizer	August 19, 2019
5	Sterigenics US	Willowbrook, IL	Commercial sterilizer	August 29, 2018
5	Medline Industries, Northpoint Services Division	Waukegan, IL	Commercial sterilizer	May 23, 2019
5	Medtronic Sterile Systems Operation (Viant Medical)	Grand Rapids, MI	Commercial sterilizer	March 6, 2019
5	Air Products Performance Manufacturing (Evonik)	Milton, WI	Chemical plant	None
6	BCP Ingredients	St. Gabriel, LA	Chemical plant	None
6	Union Carbide Corp., St Charles Operations	Taft, LA	Chemical plant	None
6	Huntsman, Port Neches Operations	Port Neches, TX	Chemical plant	None
6	Eastman Chemical Texas Operations	Longview, TX	Chemical plant	None
6	Taminco US (Eastman Corp.)	St. Gabriel, LA	Chemical plant	None
6	Sasol Chemicals (USA) – Lake Charles Chemical Complex	Westlake, LA	Chemical plant	None

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EPA region	Facility	Location	Type of facility	Date of first EPA or state action to directly inform residents living near facility
6	Air Products Performance Manufacturing Inc. – Reserve Plant (Evonik Materials Corp.)	Reserve, LA	Chemical plant	None
6	Midwest Sterilization Corp.	Laredo, TX	Commercial sterilizer	None
6	Shell Technology Center Houston	Houston, TX	Chemical plant	None
6	Sterigenics Santa Teresa Facility	Santa Teresa, NM	Commercial sterilizer	None
7	Midwest Sterilization Corp.	Jackson, MO	Commercial sterilizer	December 2, 2019
7	BCP Ingredients – Verona Plant	Verona, MO	Chemical plant	October 11, 2019
8	Terumo BCT Sterilization Services	Lakewood, CO	Commercial sterilizer	December 11, 2018

Source: The OIG developed the table using data from EPA-generated lists of facilities contributing to elevated estimated cancer risks at the census tract level in the 2014 NATA and the census block level and information from regions.

Note: The EPA prioritized 25 facilities: 22 that contribute to elevated estimated cancer risk equal to or greater than 100 in one million at the census tract level and three that contribute to elevated estimated cancer risks equal to or greater than 1,000 in one million at the census block level. The three facilities prioritized at the census block level are Union Carbide–South Charleston Facility in Region 3, Air Products Performance Manufacturing (Evonik) in Wisconsin in Region 5, and BCP Ingredients Verona Plant in Region 7.

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Agency Comments on Draft Report

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

January 31, 2020

MEMORANDUM

SUBJECT: Response to Office of Inspector General Management Alert

"Prompt Action Needed to Communicate Risks to Residents Living Near Facilities with Significant Ethylene Oxide Emissions," Project No. OA&E-FY19-0091 (January 24, 2020)

FROM: Douglas Benevento, Associate Deputy Administrator (/s/ January 31, 2020)

TO: James L. Hatfield, Director, Air Directorate
Office of Audit and Evaluation
Office of Inspector General

Thank you for the opportunity to respond to the issues and recommendation identified in the subject draft report from EPA's Office of Inspector General (OIG). Following is a summary of EPA's overall response to the draft report, along with its position on the recommendation. For those aspects of the report with which the Agency does not agree, we have explained our position.

Ethylene oxide is one of the 187 hazardous air pollutants that EPA regulates under the Clean Air Act (CAA), and it has been determined to be carcinogenic to humans. It also is a chemical that is important both to society and public health, as a building block for making other chemicals and in its use for sterilizing medical devices that cannot be sterilized using other methods. According to the Food and Drug Administration (FDA), nearly 20 billion medical devices are sterilized with ethylene oxide every year.[3]

[3] *Statement on concerns with medical device ability due to certain sterilization facility closures, October 25, 2019, available* at https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures

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EPA continues to make progress on a suite of actions to address ethylene oxide emissions while working closely with other federal partners and appreciates the opportunity to respond to the draft report on this important topic. As EPA pursues its mission to protect public health and the environment, we take our work very seriously and provide these responses for your consideration.

Consistent with the Agency's two-pronged approach for addressing air emissions of ethylene oxide, EPA will continue to work with affected state and local air agencies to look more closely at emissions from facilities and to emphasize the need for public outreach with respect to census tracts where the Agency's National Air Toxics Assessment (NATA) identified potentially elevated risk from ethylene oxide. We also wish to emphasize the complex, interrelated environmental and public health concerns around the use of ethylene oxide and hope your office understands both these concerns and that there is much more to learn about this chemical.

Executive Summary

In general, we find that much of the draft report is factually correct but wish to provide several line edits in the interest of improving its accuracy (see Attachment A). We do wish to highlight two important issues that have not received sufficient attention in the draft report: (1) the importance of conducting additional, more refined investigation of risks based on NATA results prior to conducting significant direct outreach with the public; and (2) recognition of the role that other government agencies should play in public outreach. Finally, we acknowledge the disparity in the extent and nature of communication between EPA and affected communities, and we offer several corrective actions for your consideration.

Background: Status of EPA's Efforts to Address Ethylene Oxide

In this section, we review EPA's statutory authority to regulate ethylene oxide, two existing CAA regulations covering ethylene oxide, and the status of our efforts to review those regulations. In addition, we provide an update on area-specific outreach activities.

The 2014 NATA, released in August 2018, identified potentially elevated health risks from ethylene oxide exposure in the air in a number of census tracts across the country. Since NATA's release, EPA has been taking a two-pronged approach to address emissions. In the first prong, the Agency is reviewing its CAA regulations for industrial facilities that emit ethylene oxide. An update on the status of our work on two CAA National Emission Standards for Hazardous Air Pollutants (NESHAP) addressing ethylene oxide is provided below. In the second prong, we have been working closely with state and local air agencies as they work to get additional information on facility emissions to determine whether more immediate emission reduction steps are necessary or possible in higher risk areas. This work is ongoing, and there have already been significant emission reductions in several areas. Also, as part of the second prong, we have been working with local and state environmental and public health professionals, as well as ensuring that elected leadership in affected communities are informed. The draft report summarizes some, but not all, of the work being done to communicate with the public.

Statutory Authority: EPA has existing CAA rules for industries that emit ethylene oxide. On July 16, 1992 (57 FR 31576), EPA published a list of sources for which NESHAP were to be

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promulgated (referred to as the "source category list"). Under Section 112 of the CAA, EPA first promulgates technology-based standards for categories of sources identified as emitting one or more of the hazardous air pollutants listed in CAA section 112(b), which include ethylene oxide. Then, the law requires that EPA evaluate those technology-based standards to determine whether additional standards are needed to address any remaining risk associated with emissions of hazardous air pollutants. This second step is commonly referred to as the "residual risk review." When combined with the CAA-required periodic review of the technologies used by facilities in the source categories, this review is commonly referred to as a "risk and technology review." As described further below, rules for facilities in two of these listed source categories are currently being reviewed.

Once EPA sets or revises a national standard, facilities must get (or update) CAA Operating Permits from the state where the source is located or, in a few cases, from EPA. These permits list requirements to control air pollution that apply to the source. Facilities must comply with these permits or face penalties.

Rulemaking Actions: To ensure that its rules are defensible and sustainable, the Agency needs to build a solid, data-based record for its decisions. For the reviews of the NESHAP for Miscellaneous Organic Chemical Manufacturing (MON) facilities and the NESHAP for Ethylene Oxide Commercial Sterilizers, EPA is responsible for compiling information on emissions, potential control technology options, and costs for the many potentially affected facilities in these source categories.

For the MON source category, the existing technology-based rule was promulgated in November 2001 (68 FR 63852). There were several amendments after that date. EPA is under a court order to issue a final CAA-required risk and technology review of the MON rule by March 13, 2020. On November 1, 2019, the Agency signed a proposed rulemaking for the MON. This proposed rule was published in the Federal Register on December 17, 2019[4], and EPA held two public hearings in January 2020. The public comment period on this proposed rule closes on February 18, 2020. In this action, EPA is proposing significant emission reductions of ethylene oxide from covered facilities in order to reduce risks. EPA evaluated the risks posed by air toxics, including ethylene oxide, from this source category and proposed that cancer risks for this source category are unacceptable. To reduce risks to an acceptable level, EPA is proposing additional requirements for process vents, storage tanks, and equipment in ethylene oxide service.

For the Ethylene Oxide Commercial Sterilizers source category, the existing technology-based NESHAP was first promulgated in December 1994 (59 FR 62585). There were several amendments regarding control requirements after that date. A residual risk and technology review was completed in April 2006 (67 FR 17712).

EPA is in the process of soliciting and collecting information about commercial sterilizers, and we expect to take rulemaking action in mid-2020. Over the past year, EPA's Office of Air and Radiation has been gathering data to support its review of the Ethylene Oxide Commercial

[4] See https://www.federalregister.gov/documents/2019/12/17/2019-24573/national-emission-standards-for-hazardous-air-pollutants-miscellaneous-organic-chemical

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Sterilizers NESHAP. One challenge that we have identified for this source category is that about one-third of the more than 100 potentially affected facilities are small businesses. Given the potential impact of certain emission reduction strategies on these small businesses, the Agency has requested nominations for representatives of potentially affected small entities to advise a Small Business Advocacy Review (SBAR) Panel before the Agency takes any significant regulatory action. Further, to obtain additional data needed to support a formal notice-and-comment rulemaking, the Agency has recently taken two actions under the CAA. First, on December 5, 2019, EPA signed an Advance Notice of Proposed Rulemaking (published in the Federal Register on December 12, 2019[5]), which provides an avenue for interested parties to give us additional data and information about commercial sterilizers to inform a proposed rulemaking. Second, also in December 2019, EPA issued a request for information under CAA section 114 to several commercial sterilization companies, which requires these companies to provide information about their operations and control systems for each ethylene oxide sterilization facility that they own. In the months ahead, we plan to issue a proposed rule informed by the data collected via the ANPRM and section 114 requests, and, if necessary, by the SBAR Panel process. The proposal will solicit public comment on potential regulatory approaches and emission controls, and EPA will provide the opportunity for a public hearing. Once EPA has considered public input, EPA would then issue a final rule.

Area-Specific Activities: Because our rulemaking process takes time, we decided that more immediate action is necessary in higher risk areas identified by NATA. Our Regional offices have been working with affected state and local air agencies to look more closely at emissions from facilities in these areas. The purposes of this work are: to provide information to refine risk estimates; to help us as we review our regulations; and to identify whether it is possible to achieve early emission reductions, thereby reducing potential health risks to the public. Please note that in some Regions this work has included not only facilities in the higher risk areas identified by NATA, but also other facilities that emit ethylene oxide. Also, some Regions did not have higher-risk areas identified by NATA based on census tract-level screening criteria.

Response to Results Highlighted in the Report

Importance of conducting additional, more refined investigation of risks based on NATA results: NATA tells us where to look closer at potential risks in certain communities – it does *not* provide final, definitive risk information. EPA notes this on the NATA website: "EPA developed NATA as a screening tool for state, local and tribal air agencies. NATA's results help these agencies identify which pollutants, emission sources and places they may wish to study further to better understand any possible risks to public health from air toxics."[6]

Because NATA is a screen, additional work often is necessary to more fully understand the risks that NATA identifies as being potentially elevated. This step should be conducted prior to significant public outreach to community residents for two key reasons:

[5] See https://www.federalregister.gov/documents/2019/12/12/2019-26804/national-emission-standards-for-hazardous-air-pollutants-ethylene-oxide-commercial-sterilization-and
[6] See https://www.epa.gov/national-air-toxics-assessment/nata-overview

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1. NATA relies on existing emissions inventory information, which is several years old by the time the assessment is released. Specifically, EPA uses facility and emissions information from the 40,000 facilities included in the National Emissions Inventory (NEI), combined with census blocks as defined by the U.S. Census Bureau, to model ambient concentrations of pollutants at the block level. To develop risk estimates by census tract, these block-level concentrations are aggregated by taking a population-weighted average that results in a tract-level concentration. This concentration is then adjusted for exposure (e.g., commuting patterns) and used to develop risk estimates by census tract.[7, 8] The NATA released in August 2018 relied on the 2014 NEI, which was the most recent available. While attempts to verify emissions information are made during NATA's development, additional verification is necessary to determine whether the emissions estimates in the NEI are correct.
2. NATA presents results at the census tract level, which is the smallest geographic area at which it is appropriate to present NATA screening-level estimates of risk given inputs such as mobile source emissions, which are input to the model via gridded emissions rather than a single point. However, even census tract-level information may be somewhat uncertain.[9]

EPA cautions NATA users that more investigation may be necessary, noting on the NATA website that "(w)e suggest you use NATA results cautiously. The uncertainty – and thus the accuracy – of the results varies by place and by pollutant. Often, more localized studies are needed to better characterize local-level risk. These studies often include air monitoring and more detailed modeling." The website also describes several important NATA limitations that need to be considered when looking at the results, including use of default assumptions and pollutant concentrations based on computer model simulations, not real-world measurements. EPA also reminds NATA users to keep in mind that the assessment's results:

- apply best to larger areas, not specific places;
- apply to groups, not to specific people;
- assume a person breathes the air toxics emitted in the analysis every day for 70 years;
- reflect just some of the variation in background pollutant concentrations;
- may give concentrations that are too high or too low for some air toxics and in some places;
- make some assumptions when data are missing or in error;
- may not accurately capture sources that emit only at certain times; and

[7] Technical Support Document for the 2014 National Air Toxics Assessment, 6.4.1. Model Results for Point Sources: Aggregation to Tract-level Results, p. 135, available at https://www.epa.gov/sites/production/files/2018-09/documents/2014_nata_technical_support_document.pdf

[8] While the screening-level NATA does not provide block level information, EPA does generate and consider block-level risk information for major sources of air toxics emissions in its regulatory program. Specifically, EPA generally conducts risk assessments at the block level when setting and reviewing a NESHAP. In these risk assessments, block-level risk information, including risk results, undergoes intensive quality assurance reviews.

[9] See, for example, EPA's Technical Support Document for the 2014 NATA, which notes that "(a)lthough results are reported at the census tract level, average risk estimates are far more uncertain at this level of spatial resolution than at the county or state level." Technical Support Document for the 2014 National Air Toxics Assessment, 7.2.2. Quantifying Variability, p. 141, available at https://www.epa.gov/sites/production/files/2018-09/documents/2014_nata_technical_support_document.pdf

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- include risk estimates that are uncertain.[10]

EPA recommends that the draft management alert be revised to reflect the need for additional, more refined investigation of risks prior to holding public meetings or conducting significant public outreach in communities where NATA identifies potentially elevated risk. The OIG's report should recognize the critical importance of providing information that is as detailed and up-to-date as possible when communicating risk.

Role of other government agencies in public outreach: The draft report fails to recognize the important role that other federal government agencies play in addressing ethylene oxide. The Food and Drug Administration is involved given the importance of ethylene oxide in sterilizing medical devices. Because half of the medical devices in the U.S. that require sterilization are sterilized with ethylene oxide[11], FDA is monitoring supplies in light of the permanent closure of one sterilizer in Willowbrook, Illinois, and the temporary closure of others. In addition, in the fall of 2019, FDA issued two public innovation challenges to encourage the development of new approaches for sterilizing medical devices.

The Agency for Toxics Substances and Disease Registry (ATSDR) is involved given the potential public health issues related to ethylene oxide emissions. In Illinois, ATSDR has conducted a risk assessment for people living in the areas of the commercial sterilizer in Willowbrook, Illinois, and also is working on a health consultation related to ethylene oxide emissions from two facilities in Lake County, Illinois.

A consistent, coordinated government-wide response is appropriate when communicating with the public about ethylene oxide. EPA recommends that the draft report be revised to reflect the role that other federal government agencies play in addressing ethylene oxide.

Response to the report's recommendation: The draft report recommends that the Associate Deputy Administrator improve and continue to implement ongoing risk communication efforts by promptly providing residents in all communities near the 25 ethylene oxide-emitting facilities that EPA identified as high-priority with a forum for and interactive exchange of information with the EPA and/or states regarding health concerns related to exposure to ethylene oxide. We offer edits to the recommendation in Attachment A. In response to the recommendation, we offer three corrective actions:

1. EPA will continue to implement ongoing efforts to conduct additional, more refined investigation of risks based on NATA screening-level results in all high-risk areas and will improve those efforts as necessary. Based on this work, EPA will also continue to support state/territory-led efforts to communicate risk information to residents in communities near industrial sources of interest.

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[10] NATA Limitations, available at: https://www.epa.gov/national-air-toxics-assessment/nata-limitations

[11] *Reduction of Ethylene Oxide Sterilization Emissions for Medical Devices and Potential for Utilizing Other Sterilization Modalities*, FDA, page 3. Available at https://www.fda.gov/media/132186/download

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2. The Wisconsin Department of Natural Resources (WDNR) is coordinating efforts to respond to potential ethylene oxide risks to the community near Evonik Industries in Milton, Wisconsin. EPA Region 5 is supporting WDNR efforts. This facility is regulated under Wisconsin's state air toxics rule (NR445), and the state has worked with the company for many years to reduce emissions. On June 24-25, 2019, WDNR and Region 5 conducted a joint inspection of the facility, which included leak detection and repair monitoring, and the state found no evidence of noncompliance. Since then, Region 5 has provided technical assistance to WDNR to help verify Evonik's emissions. The state has raised significant questions regarding the NATA screening-level results and is refining the analysis for the facility. Once we have a more complete assessment risk from the facility, EPA will support, as requested, state-led efforts to communicate risk information to residents in the community.

3. For the 10 high-priority industrial facilities in Region 6, EPA will continue its dialogue with the states of Louisiana and Texas to offer technical support and assistance to conduct additional, more refined investigation of risks based on updated NATA screening-level results. In addition, EPA will support, as requested, state-led efforts to communicate risk information to residents in communities near these facilities.

In closing, as we noted in the opening of this letter, EPA will continue to work with affected state and local air agencies to look more closely at emissions from facilities and to emphasize the need for public outreach with respect to census tracts where NATA identified potentially elevated risk from ethylene oxide. We will continue to provide both technical and outreach support where needed – e.g., reviewing monitoring plans or assisting with the development or review of outreach materials, as requested. In addition, the Agency is continuing to move ahead with planned public meetings where states or territories have requested our assistance. Finally, please note that EPA's Office of Air and Radiation will provide training on the importance of community engagement, best practices on planning for community engagement, and options for conducting meetings.

If you have any questions concerning our response, please contact Michael Koerber, Deputy Director, Office of Air Quality Planning & Standards, (919) 541-5557.

Attachment

In consideration of the Agency's technical comments to the draft management alert, the OIG made several revisions to the final report to incorporate additional information where appropriate. These technical comments have not been included in this Appendix.

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Appendix C

Distribution

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