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

NOV 15 2019

OFFICE OF
THE ADMINISTRATOR

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

FROM: Douglas Benevento, Associate Deputy Administrator

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 recommendations 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's results, along with the Agency's position on the recommendations. 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. At the same time, it is an important chemical in our society as a building block for other chemicals and for sterilizing medical devices that cannot be sterilized with other methods. EPA continues to progress on a suite of actions to address ethylene oxide emissions while working closely with other federal partners and is glad for the opportunity to respond to the OIG's alert on this important topic. Because of its importance to public health and society, we take our work to protect those very seriously and gladly provide these responses for your consideration. We further wish to emphasize the complicated and interrelated environmental and public health concerns around the use of ethylene oxide and hope your office understands these concerns and the fact that there is much more to learn about this chemical.

Executive Summary

The Agency respectfully disagrees with the draft report, and it is our recommendation that the report be withdrawn so that it can be amended to more accurately reflect the work of the Agency and its state and local public health partners. The OIG should withdraw this management alert and work with the Agency to gain a better understanding of the complicated and interrelated environmental and public health concerns around the use of ethylene oxide, as well as the full range of risk communication efforts that have been undertaken by EPA and other public health agencies in addressing the most recent NATA results. The OIG should also work with the Agency to gain a better understanding of the risk communication tools used by the Agency, which include but are not limited to public meetings. The management alert takes a small slice of work that was done and then focuses in on one activity and attempts to draw global conclusions. It

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makes recommendations for specific risk communication tools which is outside the expertise of the Inspector General. The result is an inaccurate conclusion. The management alert is misleading because it excludes outreach by state and local public health officials that should be reflected in the management alert, and it does not take into account or summarily disregards other outreach conducted by EPA if it was not a "public meeting." Here are a few examples of that outreach:

Colorado: The Colorado Department of Public Health and the Environment (CDPHE) conducted air quality monitoring around Terumo BCT, which operates a medical equipment sterilizer in Lakewood, Colorado, before and after the installation of additional ethylene oxide emissions controls. CDPHE, in conjunction with EPA Region 8, the Jefferson County Public Health Department and the facility, then participated in an open house in December 2018 to answer questions from citizens, the media, and local officials. A summary of CDPHE's work, with links to the monitoring report and risk assessment, can be found at https://www.colorado.gov/cdphe/ethylene-oxide.

- Michigan: The Michigan Department of Environment, Great Lakes and Energy (EGLE) held an open house and community meeting March 6, 2019, to discuss results of, and answer the public's questions about, EGLE's air qualtiy monitoring and modeling work to assess risks from ethylene oxide emissions from Viant, a medical device manufacturer that uses ethylene oxide in Grand Rapids, Michigan.[1] EGLE held a second open house, informational session and public hearing on October 23, 2019, to address additional public questions and take comments on a draft administrative consent order, under which the company is to end sterilization of medical equipment using ethylene oxide by December 31, 2019, conduct monthly air sampling through February 2020, and pay a penalty of $110,000. EPA Region 5 attended the open house and information session for the October 2019 meeting.
- Illinois: The Illinois EPA (IEPA) has been working with two facilities in Lake County, Illinois (Medline, a commercial sterilizer and Vantage, a chemical manufacturer) to obtain ethylene oxide emissions reductions. IEPA gave a regulatory-focused presentation as part of a meeting initiated by a state legislator on October 2, 2019. EPA Region 5 attended the meeting to listen to concerns from the community.
- South Carolina: The South Carolina Department of Health and Environmental Control (DHEC) is planning community outreach and a public meeting near Lanxess, a chemical manufacturer that emits ethylene oxide. EPA Region 4 is communicating closely with the state about this meeting which will take place on December 2, 2019.

While some states are taking the lead in community outreach, EPA is also providing support to states and territories on outreach as requested. In Puerto Rico, for example, EPA Region 2 has been working with the Edwards Lifesciences plant in Anasco, Puerto Rico in coordination with the permitting authority, the Puerto Rico Department of Natural and Environmental Resources (PRDNER) to ensure that ethylene oxide emissions are properly calculated at the facility and to identify potential measures the facility can take to reduce emissions. In addition, before the end of the calendar year, EPA will be collecting data that will allow it to better assess fugitive emissions from the Edwards Lifesciences facility. EPA Region 2 has also communicated with the Mayor about the ethylene oxide issue and will soon begin discussions with PRDNER and the Mayor concerning public outreach. While details are still being worked out, it is likely that EPA, PRDNER and the Mayor will host a public session to give some general information about actions at the facility and to answer questions. This session will likely occur in January 2020. And in

[1] https://content.govdelivery.com/accounts/MIDEQ/bulletins/2615190

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Missouri, EPA Region 7 is working closely with officials in Jackson, Missouri to plan public outreach regarding a commercial sterilizer in that area and the steps that facility has taken to reduce emissions.

Additionally, the management alert fails to recognize the necessity of investigating and verifying the screening-level National Air Toxics Assessment (NATA) results. To this end, the report inappropriately recommends action at sites where the risk data have not been fully quality assured. This is troubling because the OIG is recommending that unverified data be used for risk communication purposes.

The report assumes that if only public meetings were held, that would be acceptable risk communication. To be certain, the Agency agrees with the importance of public outreach and that the Agency should constantly seek to improve its risk communication efforts. However, when conducting outreach to the public, it is critical that we work with our state and local partners so that we present a unified, consistent message to communities. This lesson was emphasized in Willowbrook, Illinois when the Agency for Toxics Substances and Disease Registry (ATSDR) released a report on the risks of ethylene oxide in that community without prior consultation with state and local officials. The result was that local public health officials were not prepared to answer questions on an ATSDR report they had not seen. This management alert commits the same error and will likely result in confusion rather than to accurately communicate risk.

The OIG should withdraw this management alert and work with the Agency to gain a better understanding of the complicated and interrelated environmental and public health concerns around the use of ethylene oxide, as well as the full range of risk communication efforts that have been undertaken by EPA and other public health agencies in addressing the most recent NATA results. The OIG should also work with the Agency to gain a better understanding of the risk communication tools used by the Agency, which include but are not limited to public meetings. Finally, the management alert recommends public meetings at sites where the data have not yet been fully quality assured. We recommend the OIG delete those sites from the draft report. If the OIG will not withdraw the report pending these discussions, then it should, at a minimum, amend the report to recognize the important role that state and local governments play in communicating risk to the public and recognize that there are a full range of communication tools available to the Agency that are effective.

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

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

Since the 2014 National Air Toxics Assessment (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, EPA has been taking a two-pronged approach to address these emissions. First, 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. Second, 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 public health professionals as well as ensuring that elected leaders in impacted communities are informed. Because the OIG report only focuses on whether EPA held a community meeting, it either misses or ignores other public outreach and work done by state and local

officials. There are examples provided below of outreach done to communicate with the public that are not included in the report. By excluding this information, the OIG report is misleading and inaccurate in its analysis of our overall efforts to communicate risk.

Statutory Authority: EPA has existing rules for industries that emit ethylene oxide based on CAA Air Act requirements. On July 16, 1992 (57 FR 31576), EPA published a list of sources for which National Emission Standards for Hazardous Air Pollutants were to be promulgated (i.e., 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 includes ethylene oxide. Then, EPA evaluates 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 required periodic review of the technologies used by facilities in the source categories, it is commonly referred to as a "risk and technology review." As will be described further below rules for two of these listed source categories that emit ethylene oxide are 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) 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. On November 1, 2019, the Agency signed a proposed rulemaking for the MON (i.e., the risk and technology review). 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 has determined 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. The Agency will take public comment for 45 days after the proposal is published in the Federal Register and will hold two public hearings. EPA is under a court order to issue a final CAA-required risk and technology review of the MON rule by March 13, 2020.

For the Ethylene Oxide Commercial Sterilizers source category, the existing technology-based rule 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 action in the regulatory arena in the near future. Over the past year, EPA's Office of Air and Radiation has been gathering data to support its review of the NESHAP for commercial sterilizers. 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 may need to convene a Small Business Advocacy Review (SBAR) Panel before taking any significant regulatory action. EPA will soon request nominations to serve as small entity representatives as part of a possible SBAR Panel, in the event that is needed. Further, to

obtain additional data needed to support a formal notice-and-comment rulemaking, the Agency is close to taking two actions under the CAA. First, EPA will issue an Advance Notice of Proposed Rulemaking (ANPRM), which would provide an avenue for interested parties to give us additional data and information about commercial sterilizers. The ANPRM will highlight the Agency's efforts on addressing ethylene oxide emissions from commercial sterilizer facilities. It will not impose requirements on the regulated community. Primarily, it seeks to notify the public of our intent to analyze environmental and economic impacts associated with potential emission reduction strategies for this source category. It will also explain how a proposed rule would address CAA-required technology review for this source category and is expected to include an assessment of the impacts of identified control strategies and give the public an opportunity to provide comments and information for the Agency to consider in developing a rule and assessing impacts. Second, EPA will issue a request for information under CAA section 114 to several commercial sterilization companies, which will require these companies to provide certain information. 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 may be 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 improve 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 risk 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 in NATA based on census tract-level screening criteria.

Response to Results Highlighted in the Report

Informing communities of health risks. In its draft report, the OIG states that "communities should be informed of health risks according to EPA's mission statement and risk communication guidance." The draft report also notes that as part of the EPA's work to accomplish its mission of protecting public health and the environment, EPA works to ensure that "(a)ll parts of society — communities, individuals, businesses, and state, local and tribal governments — have access to *accurate* [emphasis added] information sufficient to effectively participate in managing human health and environmental risks." [2] EPA agrees that the public should have accurate information about health risks in their community, and we note that it can take time for the Agency and its state partners to conduct the follow-up investigations that NATA suggests are needed. Because NATA is a screening-level assessment, as discussed below, additional work always is necessary to determine whether risks in a particular area are higher or lower than the screening analysis estimated.

EPA and states work together in an effective partnership to manage air quality in the United States. EPA's role is largely one of setting national standards, conducting certain oversight, and providing support and assistance to states. The states' role, as clearly defined in the CAA, is to have primary responsibility for air pollution prevention and air pollution control at its source. This lead role for states is especially true in dealing with local air pollution issues, such as those associated with air toxics. Because states are also the permitting authorities in these areas, they often are better equipped and positioned to work with facilities to

[2] https://www.epa.gov/aboutepa/our-mission-and-what-we-do

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better characterize their air emissions and develop the most up-to-date assessment of emissions and possible risk. This approach, which is used across most of the country, allows state air agencies to effectively and expeditiously manage environmental issues in their states, with strong and appropriate support and assistance from the federal government. While we acknowledge that, for ethylene oxide, communicating our efforts is ongoing, we also note that, as discussed below, this state-led work has resulted in the installation of controls, or the commitment to install controls, at a number of facilities, which will reduce risk and improve public health protection more quickly than EPA can accomplish through its national regulatory processes. EPA remains committed to helping states better characterize risks and supporting state- and local-led outreach efforts for communities.

EPA recommends that the draft report be revised to provide a more accurate representation of the federal and state roles and responsibilities with respect to community engagement.

Timing of public outreach. As stated on EPA's website for NATA,"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." To be clear, NATA tells us where to look closer – it does *not* provide final, definitive risk information. As such, it is necessary to investigate and verify the NATA census-tract levels prior to conducting any public outreach.

One of the reasons additional work is necessary is because NATA relies on existing emissions inventory information and presents results at the census tract level. Specifically, EPA uses facility and emissions information from the 40,000 facilities included in the National Emissions Inventory, combined with census blocks as defined by the U.S. Census Bureau, to model ambient concentrations of pollutants at the block level. In the process of developing risk estimates by census tract, these block-level concentrations are aggregated by taking a population-weighted average resulting in a tract-level concentration, which is then adjusted for exposure (e.g., commuting patterns) and used to develop risk estimates by census tract.[3] While we acknowledge that certain census block-level information is generated as part of estimating census tract-level risks in our national assessment, we do not present block-level risks as part of NATA for several reasons.[4]

First, as described above, block-level concentrations are aggregated across a tract using population weighting. This can result in exposure and risk varying significantly across the tract and within larger geographic areas such as counties and states. Therefore, NATA results are shown at the census tract level – the smallest geographic area at which EPA is comfortable presenting screening-level estimates of risk. While even census tract-level information may be somewhat uncertain[5], we believe that this is most refined spatial information that our national assessment is capable of providing.

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[3] 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

[4] 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.

[5] 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

Second, some key inputs for calculating risks vary by spatial scale and are only reliable at the census tract level. For example, mobile source emissions are input to the model via gridded emissions, not a single point; so, it would not be precise to use a smaller geographic scale - such as census block - to present results.

The NATA website also clearly states 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." Furthermore, NATA has several important 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 actual real-world measurements. For all these reasons, one should keep in mind that NATA 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
- include risk estimates that are uncertain.

EPA recommends that the draft report be revised to reflect the need for investigation and verification prior to holding any public meetings or conducting public outreach. Accurate data matter when communicating risk; the management alert at a minimum should recognize the critical importance of communicating accurate information.

Regions' communications focus/summary of public meetings with residents near ethylene-oxide emitting facilities: We wish to respond to these two results in the draft report together, because they are intertwined. The draft report states that "Regions' focus has been on communicating with facilities, states and elected officials and not residents." We disagree with the implication that communicating with facilities, states, and elected officials is somehow improper or ineffective. Communicating with facilities is necessary both for verifying emissions and obtaining timely, voluntary reductions. Communicating with elected officials is prudent in areas where EPA actions may affect their constituencies. And communicating with states, who, as noted above, have primary responsibility for air pollution control in their jurisdictions, is a critical step toward both addressing ethylene oxide emissions and sharing information with residents. Indeed, EPA is not always the agency best positioned to communicate about risks after NATA is issued. In many cases, it is states that have been working to obtain updated emissions information and check the NATA results, and some have conducted more refined risk analyses for their areas. We can only guess at the disapprobation of the OIG had we not collaborated with local and state public health officials or ignored their guidance about how best to address the NATA results. As further outlined in other parts of this report, states and local public health professionals took the lead at multiple sites across the Country with EPA supporting their efforts. It is unclear why this outreach is unacceptable to the OIG, but the lack of acknowledgment of these efforts is unfortunate.

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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

EPA believes it is wholly appropriate for states to take the lead in the NATA follow-up work, including public outreach, and a number of states have done so. A summary of the outreach being done around the country is provided in Attachment A.

Despite this progress, EPA acknowledges that public outreach has occurred more slowly in some areas than others. However, we do not believe that public meetings are always the first, or best, step in sharing information with residents. In some communities, working closely with local officials is a better approach to ensure that outreach best fits the needs of local communities, such as the outreach approach outlined in EPA Region 7's communications plan. When meetings are planned, EPA encourages state air agencies to plan them with community participation when possible, such as the two meetings EPA planned in the Willowbrook, Illinois area in November 2018 and May 2019. This work takes time but ensures that the interests of community members are addressed. In addition, other methods of sharing information with the public can be valuable, for example the CDPHE website and report mentioned above.

As EPA has participated in these community meetings, we've gathered important information to share with others about how to go through this process effectively. For those areas where public meetings are a step used to share information with the community, we are developing a three-part series of webinars for EPA Regions and states on the lessons EPA has learned from our community outreach efforts. The first webinar will discuss the "business case" for the importance of early community engagement and why it is important. A month later, the second webinar will focus on planning for community engagement events and how to empower the community in the planning. Finally, the third webinar will describe different meeting format options to deliver effective community engagement.

EPA recommends that the draft report be revised to reflect the important and leading role of states in community outreach, and to clarify that such outreach does not need to be limited to public meetings and may take other forms.

Response to the report's recommendation: The draft report recommends that the Associate Deputy Administrator direct EPA Regional Offices to hold public meetings as soon as practicable in all areas where estimated cancer risks are equal to or greater than 100 in 1 million at the census block level. As discussed above, we strongly disagree with this recommendation on several points:

- Prior to any public outreach, it is necessary to investigate and verify the NATA census tract-level results.
- States, not EPA, are the appropriate lead agency for addressing local air toxics issues, such as ethylene oxide. EPA remains committed to helping states better characterize risks and supporting state- and local-led outreach efforts for communities as requested.
- Considerable public outreach has already occurred or will occur in the near future (see Attachment A).
- Effectively sharing information with the public occurs in many forms and public meetings may not be the best approach for initial public outreach in all areas.

We, therefore, strongly recommend that the report's draft recommendation be reworded as follows (note, additions highlighted in yellow, deletions reflected by strikeouts):

> Direct Regional Offices to ~~promptly~~ continue working with state air agencies to investigate the NATA census-tract results for the higher risk areas to better understand and verify risks to public health and, where appropriate, work with and offer to lead or support state- or local-led ~~hold~~ public meetings ~~as soon as practicable~~ or other outreach efforts to inform

residents in communities that could face elevated estimated cancer risks from air exposure to ethylene oxide, ~~including all residents who live near facilities that contribute to estimated cancer risks of equal to or greater than 100 in 1 million at the census block level.~~ The residents should be provided with consistent and complete information regarding ethylene oxide emissions, including the elevated estimated cancer risks they face and how the state air agency and EPA are addressing these risks. EPA should continue to work as a partner with state and local public health officials to ensure that accurate, consistent and timely information is provided to the public.

In closing, 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 NATA identified potentially elevated risk from ethylene oxide. We will continue to provide both technical and outreach support where needed – e.g., 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 offer the Regions and states 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

For your consideration, we have included a detailed comments attachment to supplement this response (see Attachment B).

Attachments

Attachment A: Summary of State and EPA Outreach Efforts for NATA Higher Risk Areas

Attachment B: Suggested Technical Comments on Draft Report

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Attachment A: Summary of State and EPA Outreach Efforts for NATA Higher Risk Areas

Region 1

- Updated equipment, emissions data, and modeling for Covidien in North Haven, CT - Region 1 worked with CT DEEP and Covidien to revise the facility's 2017 Toxics Release Inventory (TRI) data from a reported range of EtO emissions to actual emissions. Covidien has installed new sterilizers controlling all vents with a LESNI balancer and catalytic oxidizer permitted to achieve 99.9% control efficiency or 1.0 ppm at the outlet. In 2016, Covidien permanently removed the older sterilizers. Emissions have been reduced from 207.1 lbs in 2014 to 134 pounds in 2017 and 126 pounds in 2018. EPA remodeled the Covidien North Haven, CT facility risk using 2017 emissions data, and the block level risks are estimated at below 100 in-1-million at the census block level.
- Regional Administrator Letter to Region 1 State Departments of Environment and Public Health, and Tribal Leaders - In August 2018, former-RA Alexandra Dunn sent letters to all New England state commissioners of departments of environmental protection and departments of public health, as well as all New England tribal leaders, announcing the 2014 NATA release. In this letter, former-RA Dunn included information on EtO and provided the Agency's EtO Fact Sheet.
- Health Care Industry Outreach – Region 1 regularly sends email outreach to over 1000 contacts in the health care industry, including hospitals, health care associations, environmental groups, as well as state and EPA contacts. Region 1 emailed this group information about EtO on December 21, 2017 (EPA Region 5 Fact Sheet 10/2017); August 2, 2018 (EPA Region 5 Fact Sheet and Case Study, July 2018); and October 16, 2019 (EPA's Ethylene Oxide regulatory update).
- Region 1 Presentations to States: Region 1 staff presented EtO and NATA updates to states at the following meetings: November 2017 NESCAUM Meeting (EtO Update by R1 & R2); October 25, 2018 NESCAUM Meeting (2014 NATA and EtO Update); November 15, 2018 EPA Region 1 Air Toxics Workshop (2014 NATA and EtO).

Region 2

- Puerto Rico - Edwards Lifesciencies in Anasco is a small facility that manufactures medical devices and uses EtO for sterilization. The Puerto Rico Department of Natural and Environmental Resources (PRDNER), with technical support from EPA, is working to identify how the facility can reduce emissions of EtO as part of the facility's permit. Region 2 is providing support to PRDNER and Edwards Lifesciences to conduct additional performance tests and additional risk modeling using more precise meteorological data to develop emission reduction requirements as part of the permit. Region 2 will continue to provide guidance and information to PRDNER.
- New Jersey - The BASF facility is not a concern as it stopped using EtO in its process after 2014.

Region 3

- West Virginia - Region 3 has met with the WV Department of Air Quality about three facilities: Union Carbide in Institute, Union Carbide in South Charleston, and Covestro in South Charleston. In July, Region 3 sent WVDAQ revised risk modeling using 2017 state emissions, updated maps of block level risks and EJ Screen Results. Further risk modeling is underway. Region 3 will continue to provide guidance and information to WV DAQ, including on state plans for outreach to local communities. Since late spring, Region 3 convened conference calls with community advocates and committed to hold quarterly calls.
- Delaware - Region 3 has met with the Delaware NREC about three facilities: Croda in New Castle, Christiana Hospital in New Castle, and Sunoco Logistics in Claymont.
  - Sunoco Logistics is closed.
  - Croda's EtO process unit is currently shut down but will restart in the fall. Croda will add a new scrubber with 99% control, will have a new permit with more LDAR considerations and DNREC held a public meeting on August 14.

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- Christiana Hospital sterilizes items for hospital use only. The permit allows 1 ton per year of EtO emissions, but usage is far below that. The hospital's permit is up for renewal soon and the emission limit will be reduced.

- Pennsylvania - Region 3 has met with PADEP about Braun in Allentown. Region 3 has sent PA DEP revised risk modeling using 2017 state emissions. PADEP reported that the last inspection conducted was March 14, 2018 which they were found to be in compliance. The results of the 2019 annual inspection for 2019 will be released soon. They plan to bring their TVA (VOC Leak Detection Equipment) to do Leak Detection and Repair. Region 3 air enforcement will coordinate with PADEP on inspection planning. The Title V permit is up for renewal August 2021. That would be another opportunity to revise any needed actions.

Region 4

- Georgia – Region 4 has been working with Georgia Environmental Protection Division (EPD) to gather additional information on EtO emissions at these facilities:
  - Sterigenics Facility in Cobb County:
    - Between 2014 and 2017, the Sterigenics facility in Cobb County added controls that reduced EtO emissions by over 90 percent.
    - Sterigenics has submitted to EPD an application to modify the facility's permit that will allow the company to install additional controls to reduce emissions. The company has entered into a consent decree with the state to install these controls concurrent with the permit application.
    - In September 2019, the facility voluntarily shut down in order to install the new control equipment. The shutdown was estimated to last approximately one month.
    - During the week of September 23, Georgia EPD initiated a monitoring study around the Sterigenics facility (should last approximately six months).
    - The facility has not resumed operations to date due to permitting issues with the local government.
  - Becton Dickinson (BD) facility in Covington:
    - Current emissions are less than those used to develop the 2014 NATA
    - It has been reported that BD has pledged to spend $8M on emission control improvements at its Covington and Madison, Georgia facilities.
    - The city of Covington conducted a week-long monitoring exercise around the BD facility and reported high EtO emissions during this time frame.
    - Georgia EPD has begun their sampling regime around the facility and will begin releasing their results in the near future. The state has asked EPA to be available to help review/interpret various data sets.
    - In addition, the Region received the sampling data from Congressman Jody Hice's office and has been asked to review and provide the Congressman's office with a summary.
    - On October 28, 2019, BD Covington plant agreed through a consent order to move forward with the previously announced timelines for the $8 million in voluntary improvements the company committed to make in August 2019.
    - The Covington facility voluntarily suspended sterilization operations for a weeklong period from October 30 to November 6 to allow Georgia EPD to take ambient air monitoring samples in the area when the company's sterilization systems are not in operation. We expect to see the results of the monitoring later this week.
    - On October 31, 2019, BD submitted a SIP air permit application to Georgia EPD and it has been posted on the state's website.
    - Pursuant to the consent order, BD resumed sterilization operations at the site on November 7, 2019 and has agreed with the State to:
      - Operate at a reduced capacity at Covington,
      - Not expand production at its Madison, GA facility, and

- Implement certain operational modifications to further reduce emissions and protect product availability for patients.
  - EPA's evaluation of EPD's recent modeling analyses of emissions indicate that the lifetime cancer risk from EtO concentrations in residential areas around both facilities (Sterigenics and BD/Covington) does not exceed one hundred in one million.
  - EPA will continue to work with EPD to identify opportunities to further reduce EtO emissions from both facilities.
  - EPA, in coordination with GA EPD, held two community forums for residents surrounding the facilities: August 19, 2019 - Cobb Civic Center, Marietta, GA (for residents near the Cobb County Sterigenics Facility), and August 20, 2019 - Newton County Courthouse, Covington, GA (for residents near the BD/Covington Facility).
  - In weeks before the August 2019 meeting, EPA engaged community leaders on the upcoming meetings and incorporated roles for them in the meetings.
  - In weeks before and after the August 2019 meetings, R4 met with GA EPD and the Mayor of Covington, GA; Commissioners for Newton County, Cobb County, and Fulton county; Cobb County officials (health & safety, county department of public health, county attorney's office, and redevelopment office); staff for Congresswoman Lucy McBath's (D-GA 6th District), Representative Hank Johnson's (D-GA 4th District), and Governor Brian Kemp's offices; as well as Representative Jody Hice (R-GA 10th District).
  - Since the August 2019 meetings, EPA continues to provide updates to the community, upon request.
  - The City of Smyrna, Cobb County, and the City of Atlanta worked together to implement a sampling program around the Cobb County Sterigenics facility; as noted above, EPD has its own sampling program around this facility, BD/Covington, and at other locations in the state.
- South Carolina – Region 4 emailed an update to members of the South Carolina congressional delegation who represent the districts where the Lanxess facility is located (Charleston, SC).
  - Since August 2018, EPA, coordinating with the South Carolina Department of Health and Environmental Control (SC DHEC), has conducted leak detection sampling and inspections at the Lanxess facility.
  - SC DHEC has informed the Region that, working with the community closest to the Lanxess facility, they have scheduled a meeting for December 2, 2019. Six area communities will be invited. SC DHEC has asked EPA to attend and be available to answer questions, if needed.
  - In addition, the state plans to begin sampling for EtO near and away from the facility, partnering with the local communities to develop the Quality Assurance Action Plan. The facility also plans to conduct additional stack testing during the week of December 2, 2019.

Region 5

- Illinois – For the Sterigenics facility in Willowbrook, public meetings were held on August 29, 2018, November 29, 2018 and May 29, 2019. There has also been much interest from local officials, press and residents. The state held a formal public meeting on August 1, 2019.
  For the Medline facility in Waukegan, the state hosted a public information session about Medline construction permit on May 23, 2019. The state has also scheduled a public hearing for November 14, 2019 to accept comments on a draft construction permit that places a cap on EtO emissions from the Vantage facility in Gurnee. The Lake County Health Department conducted sampling near both Medline and Vantage in June and resumed sampling on October 26, 2019, to continue through January 21, 2020. In-person meetings were held with local officials on November 28, 2018 and May 20, 2019, and with a community group (Stop EtO in Lake County) on July 8, 2019. Illinois EPA and ATSDR attended an October 2, 2019 town hall meeting organized by Illinois State Senator Melinda Bush. There has been much interest from local officials, press and residents.
- Michigan – The Viant facility in Grand Rapids announced it will stop using EtO at the end of 2019. Michigan alleged violations at the Viant sterilizer in July 2018 and January 2019. Michigan conducted

ambient monitoring around the facility in November 2018 and March 2019. On July 24, 2019, Michigan's Department of Health and Human Services (MDHHS) released their cancer incidence data review for the area. Michigan Department of Environment, Great Lakes, and Energy held town hall meetings on March 6 and October 23, 2019.

- Region 5 has also reached out to additional facilities that we have identified as important EtO emissions sources but were not reported in the 2014 National Emissions Inventory, and therefore not in NATA—for instance Vantage Specialty Chemicals, in Gurnee, Illinois and American Contract Systems in Wisconsin and Ohio. In addition, Region 5 has reached out to some sources that were in NATA and had a census-block-level cancer risk greater than 100 in a million. For example, for Evonik in Milton, Wisconsin, the Region and the state conducted a joint inspection of the facility in June 2019 and are continuing to work with the facility to understand emissions and potential risk. The Region and the state also reached out to Cook in Elletsville, Indiana; as a result, the facility is implementing significant controls, including permanent total enclosure. The Region and/or the state has reached out to additional facilities in Illinois, Wisconsin, Michigan, Ohio and Minnesota.

Region 6

Region 6 is supporting state efforts to further examine/reduce EtO risks and emissions.

- Texas - TCEQ proposed a revised state health effects screening level (ESL) for EtO. On June 28, 2019, TCEQ released a draft ESL development decision document for public comment. The public comment period closed on September 26, 2019 and TCEQ is reviewing comments received. TCEQ may conduct a formal peer review which would push their final decision into early 2020. TCEQ communicated to Region 6 that the TCEQ is comfortable with its level of communication and interaction with the relevant offices at EPA regarding future decision making and Texas's efforts to revise the state EtO screening level.
- Louisiana - LDEQ sent letters to all permitted emitters of EtO requesting that they review their emissions data and explore proactive measures to reduce EtO emissions. LDEQ has had subsequent discussions with its facilities and has requested continued coordination with Region 6 on outreach and messaging.
- New Mexico Note that the 2014 NATA identified the Santa Teresa Facility in New Mexico as having elevated risk. NMED and Region 6 have since confirmed that the Santa Teresa Facility installed emissions controls in 2014, which reduced emissions.
- Oklahoma - Region 6 had discussions with ODEQ because they have their own state air toxics program and air monitoring network.

Region 7

- Missouri - Since fall 2018, Region 7 has partnered with the state of Missouri's Air Pollution Control Program in reaching out to two facilities identified in the 2014 NATA. These two facilities are located in Jackson and Verona, Missouri. Also, Region 7 developed a community engagement plan for these areas. The plan focused on building community partnerships to inform the areas about air toxics and ethylene oxide.
    - Midwest Sterilization in Jackson, which has been in operation since 1999, is a commercial sterilizer. Midwest has completed the installation of a new scrubber, conducted performance tests, and is continuing to discuss possible next steps for additional control. The installation of the scrubber reduces ethylene oxide emissions by 84%. Region 7 has engaged officials throughout the summer and is planning to present updated information to the City Council in December.
    - BCP Ingredients, in Verona, manufactures and markets choline chloride and repackages EtO for other users. Based on discussions with EPA, BCP evaluated 685 emissions points to better characterize their emissions and has voluntarily begun a leak detection program which resulted in a reduction of 96% of ethylene oxide emissions. BCP continues to work with EPA to evaluate other emission points. On October 11, 2019, EPA presented information on oversight of BCP and

ethylene oxide emissions at a city council meeting. A follow up presentation is scheduled for November 18, 2019.

Region 8

Colorado - The Terumo BCT facility has been emitting EtO for 20 years and is in compliance with its CAA permit issued by the Colorado Department of Public Health and Environment (CDPHE). NATA showed a modeled risk of 500 in one million over the census tract. From August 24-30, 2018 CDPHE collected air samples from four locations to characterize conditions before installation of upgraded control equipment. Between the NATA release on August 22nd and September 20th, Terumo BCT voluntarily rerouted previously uncontrolled emissions to an acid scrubber control device. This voluntary action resulted in, "the post-control sample concentrations [being] on average 50-75% lower than the pre-control sample concentrations." CDPHE repeated EtO monitoring from October 19-26, 2018 to verify that EtO emission reductions occurred compared to the earlier samples. On December 11, 2018, representatives from the EPA Region 8, CDPHE, Jefferson County Public Health and Terumo BCT participated in an open house to answer questions from interested community members, the media, and local officials about EtO emissions. The open house was publicized by Jefferson County Public Health, the announcement can be found at: https://www.jeffco.us/CivicAlerts.aspx?AID=674. Reports on CDPHE's monitoring and risk assessment continue to be publicly available at: https://www.colorado.gov/cdphe/ethylene-oxide.

Region 9

- No priority sources. Region 9 has done outreach to California, Arizona and Nevada about existing sterilizers, and to make them aware of emerging EtO and monitoring issues.

Region 10

- No priority sources.

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Attachment B: Suggested Technical Comments on Draft Report

Page number	OIG statement	Agency response or clarification
Page 1 (Purpose), first paragraph, second sentence and last sentence	"Through its national air toxics assessment screening process, the EPA has identified areas near 56 facilities where exposure to ethylene oxide emissions contributes to an elevated estimated lifetime cancer risk."	This statement is incorrect. NATA identifies risk by census tract, not at the facility level. Based on the NATA results, EPA has identified census tracts for further examination. As discussed in our response, NATA does not present block-level risk, because of the uncertainties that information would contain. Block-level data should not be included in this report.
Page 1, first paragraph, third sentence	"Our audit work determined that the EPA has not met with residents living near 52 of the 56 facilities to inform them of the unacceptable health risks they may face from exposure to ethylene oxide emissions."	See note above. Also, as we note in our response, public meetings are not the only approach for community outreach and may not be the best approach in all communities.
Page 2, Figure 1	"EPA decision-making process for addressing residual risk"	Please clarify the title of this figure. These are general guidelines EPA uses in its regulatory work. Also, it should be understood that the assessment of factors identified for the yellow section are discretionary.
Page 3 (The 2014 NATA), first sentence	"The EPA periodically conducts a National Air Toxics Assessment (NATA) to evaluate the public health risk from exposure to air toxics from stationary and other sources."	NATA helps 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. See "What is NATA" at https://www.epa.gov/national-air-toxics-assessment/nata-overview
Page 4, first sentence	"The 2014 NATA identified ethylene oxide as a new and significant driver of cancer risk and as well as 22 ethylene oxide-emitting facilities that contribute to estimated cancer risks of equal to or greater than 100 in 1 million at the census tract level."	Please note that NATA identifies census tract areas, not facilities.
Page 4, third sentence	"Further, the EPA identified an additional 34 ethylene oxide-emitting facilities contributing to estimated cancer risks of equal to or greater than 100 in 1 million at the census block level."	This statement is incorrect. EPA has not identified an additional 34 facilities. (See discussion above for Page 1 (Purpose))

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Page 4, fourth, fifth and sixth sentences	"Although the EPA published the census tract risk levels in the NATA, it does not make the census block results publicly available. The estimated risks calculated for a census block can be higher than the overall risk for the census tract. When risk is considered at both the census tract and block levels, there are a total of 56 ethylene oxide-emitting facilities contributing to elevated estimated cancer risks."	Block level data should not be included in this report, and these sentences should be removed. As EPA notes in its response, census tracts are the smallest geographic area at which EPA is comfortable presenting screening-level estimates of risk. While even census tract-level information may be somewhat uncertain, we believe that this is most refined spatial information that our national assessment is capable of providing.
Page 4, footnotes 6	"Since these 34 facilities at the census block were identified in 2018, there is a possibility that some of them have changed their operating processes or no longer emit ethylene oxide. "	As discussed above, block-level data should not be included in this report. We also note that this statement is incorrect. It has been verified that some facilities have changed processes or no longer use ethylene oxide.
Page 5, first sentence	"The EPA's Office of Air and Radiation identified 25 facilities for the EPA regions to work with to achieve voluntary emissions reductions and thus limit the public's health risk from exposure to ethylene oxide emissions."	This sentence omits an important step. EPA identified facilities in the 22 higher risk census tracts, plus a few other facilities, for EPA regions and states for <u>further investigation</u> to determine whether emissions reductions were necessary. It is only after emissions information is verified and updated that EPA and the states are able to determine whether those reductions are needed.
Page 5, third sentence	"The EPA's current approach is to obtain voluntary emissions reductions from these facilities since existing regulatory requirements for these facilities were based on health studies that showed a lower potency for ethylene oxide than the current studies used in the 2014 NATA."	This statement is not correct. Several clarifications and corrections are needed here. • The existing regulations for both commercial sterilizers and miscellaneous organic chemical manufacturing were issued prior to the update of EPA's **<u>unit risk estimate</u>** (not health studies). • This sentence omits the fact that EPA is reviewing both of the above-referenced rules. • The statement omits the fact that EPA's approach also includes verifying emissions information in partnership with state and local air agencies. This step is critical to determining whether additional emissions reductions are necessary. • The Agency is seeking early voluntary reductions because we recognize such steps may achieve emission reductions more quickly than can be achieved EPA's through regulatory process.

		• Voluntary reductions are not the only step EPA is taking to address ethylene emissions (see note about reviewing regulations above).
Page 5 (Results), last paragraph	"The EPA has not held public meetings with communities near 52 of the 56 facilities that the agency has identified as contributing to elevated estimated cancer risks from exposure to ethylene oxide"	As noted above, EPA did not identify 56 facilities as potentially contributing to elevated cancer risks. Public meetings are not the only method for community outreach and may not be the best approach in all areas
Page 5, last full sentence	"The EPA has met with the residents living near three of the five facilities listed on the website"	This sentence omits meetings hosted or attended by state or local air agencies. These include open houses and meetings in: Lakewood, Colorado; Lake County, Illinois; and Grand Rapids, Michigan. It also does not note ongoing work to plan and schedule public meetings, such as Region 7's work in Jackson, Missouri, and Region 4's coordination with the South Carolina Department of Health and Environmental Control, which is planning a public meeting near the Lanxess chemical facility.
Page 6, first paragraph, first sentence	"Although there are no statutory, regulatory or policy requirements to disclose public health information about air toxics emissions, the EPA's mission statement states that the agency works to ensure that "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."	As noted in our response, while EPA agrees that the public should have accurate information about health risks in their community, we note that it can take time for the Agency and its state regulatory partners to conduct the follow-up investigations that NATA suggests are needed to ensure that we and our state partners are sharing accurate information with communities.
Page 6, subhead	"Regions' Focus Has Been on Communicating with Facilities, States, and Elected Officials and Not Residents"	As noted in our response, we disagree with the implication that communicating with facilities, states, and elected officials is somehow improper. Communicating with facilities is necessary both for verifying emissions and obtaining timely, voluntary reductions. Communicating with elected officials is prudent in areas where EPA actions may affect their constituencies. And communicating with states, who have primary responsibility for air pollution control actions in their jurisdictions, is a critical step toward both addressing ethylene oxide emissions and sharing information with residents. Indeed, EPA is not always the agency best positioned to communicate about risks after

		NATA is issued. In many cases, it is states that have been working to obtain updated emissions information and check the NATA results, and some have conducted more refined risk analyses for their areas.
Page 6, last paragraph	"In addition, EPA Regions 3, 4, 6 and 7 have developed communication/outreach plans."	Region 5 also developed a communications/outreach plan, which it provided to the OIG.
Page 7, first full paragraph	"The agency has not held public meetings with residents who live near 52 of 56 ethylene oxide-emitting facilities regarding the health risks they face. We note that since the EPA provided its preliminary NATA point source modeling for review in September 2016, regions and states had nearly 2 years to verify emissions data with all stationary sources, including ethylene oxide-emitting facilities, before the EPA published the 2014 NATA in August 2018 as shown in Figure 3."	As discussed above, block-level data should not be included in this report. Also, we do not agree with the contention that EPA and states had enough time to verify emissions data for all 40,000 point sources included in NATA.
Page 7, second full paragraph	"The mayor of Willowbrook arranged the meeting to occur 1 week after the 2014 NATA was released and invited the EPA to attend to provide information and answer the community's questions"	Additional context is needed for this statement and the comparison to the timing of the Georgia meetings. The first Willowbrook meeting was not called solely in response to NATA. In this instance, Region 5 had conducted preliminary air qualtiy monitoring and modeling, and the Agency for Toxic Substances and Disease Registry had issued a "letter health consultation" addressing potential risks in the Willowbrook area. This same level of refined information was not available in Georgia at the time of the NATA release.
Page 7, second full paragraph, last sentence	"In another instance, the EPA headquarters declined a request from Lake County, Illinois, public officials to hold a public meeting."	We note that in November 2018, EPA offered to Lake County elected officials to attend any public meeting which they convened in that county.
Page 7, last paragraph	"Appendix B lists the 34 facilities identified as contributing to elevated estimated cancer risks at the census block level. According to an internal document, the EPA prioritized working with three of these 34 facilities. As shown in	As discussed above, block-level data should not be included in this report. Our understanding is that Appendix B will be removed from the report. Also, the OIG's report fails to recognize all the outreach conducted by state air agencies.

	Appendices A and B, the EPA has not directly communicated health risks by meeting with residents near 18 of the 22 facilities identified in the 2014 NATA and residents near all 34 facilities identified at the census block level, respectively."	
Page 8 (The EPA Has Not Held Public Meetings with Residents Living Near 52 of 56 Ethylene Oxide-Emitting Facilities to Communicate Health Risks)	"It has been more than 1 year since the EPA published the 2014 NATA, but the agency has not held public meetings with residents who live near 52 of 56 ethylene oxide-emitting facilities regarding the health risks they face. We note that since the EPA provided its preliminary NATA point source modeling for review in September 2016, regions and states had nearly 2 years to verify emissions data with all stationary sources, including ethylene oxide-emitting facilities, before the EPA published the 2014 NATA in August 2018 as shown in Figure 3."	As discussed above, block-level data should not be included in this report. In addition, we ask whether the OIG believes public meetings should be conducted in situations where updated emissions information indicates that risk is below 100 in 1 million, or that a facility is no longer using ethylene oxide. We also note that public meetings are not the only avenue for public outreach and may not be the best approach in all areas. Finally, as EPA notes in its response letter, the OIG has omitted public outreach and meetings conducted by state air agencies, which may be better-positioned to know the communications needs and preferences of their communities.
Page 8, conclusion	"It has been over 1 year since the EPA published the 2014 NATA, but the agency has not held public meetings with residents who live near 52 of 56 ethylene oxide-emitting facilities regarding the health risks they face. Residents living in most of these areas have not received the same type of information to manage health risks related to exposure to ethylene oxide as residents living near the four facilities where the EPA has held public meetings. Consistent with its mission statement and key aspects of its risk communication guidance, the EPA should take prompt action to meet with these communities."	As discussed above, block-level data should not be included in this report. The numbers in this statement reflect the OIG's improper inclusion of block-level data and should be revised to reflect the priority areas identified by NATA (at the census tract). We also ask that the OIG clarify whether it is asking that public meetings be held in areas where updated emissions information and risk modeling show that risks are below 100 in 1 million. Further, the statement should be revised to reflect all public outreach and meetings conducted at the state and local level, including in Colorado, Michigan, Illinois and Delaware.
Page 8, Recommendations	"…Direct Regional Offices to promptly hold public meetings as soon as practicable to inform residents in communities that could face elevated estimated cancer risks from exposure to ethylene oxide,	Please see recommended revised language in EPA's response.

	including all residents who live near facilities that contribute to estimated cancer risks of equal to or greater than 100 in 1 million at the census block level. The residents should be provided with consistent and complete information regarding ethylene oxide emissions, including the elevated estimated cancer risks they face and how the EPA is addressing these risks. '	
Page 11, footnote d	Re. Medline	The meeting was to discuss a draft construction permit (not changes to the draft).
Page 11, Column 6	As footnote applies to Viant, and to Medline	Michigan Department of Environment, Great Lakes and Energy held a second open house and information session in conjunction with a public hearing on October 23, 2019. EPA Region 5 attended the open house/information session. For Medline, as noted in our response, the Illinois EPA appropriately participated as a panelist at a public meeting in Lake County. EPA Region 5 attended the meeting to listen to and understand concerns from the public.
Pages 12 and 13	Appendix B	Block-level data should not be included in this report. Our understanding is that Appendix B will be removed from the report.