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

August 27, 2020

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Thomas R. Carper
Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Ranking Member Carper:

On behalf of the U.S. Environmental Protection Agency, I am writing in response to various inquiries from Members of Congress regarding ethylene oxide (EtO) emissions and EPA's response to a recent EPA Office of Inspector General (OIG) report on this matter. As EPA pursues its mission to protect public health and the environment, addressing ethylene oxide is a major priority for the Agency. While the EPA recognizes and values the important role of the OIG, in the case of this EtO report their recommendation regarding risk communication and outreach is based upon a flawed understanding of the facts, data, and the Clean Air Act. Attempts by the Agency to address OIG's concerns have been met with only a misunderstanding of the issues by OIG. At this point, the Agency cannot responsibly concur with OIG's demands.

Given the interest shown by Congress in this matter, the Agency is setting the record straight on our efforts to undertake an impactful response to EtO emissions, respond to OIG's report, and to provide meaningful and appropriate risk communication to the American people with regard to EtO. Quite simply, the OIG is recommending that the Agency provide risk communication outreach with regard to EtO emissions to certain communities where there is not the sufficient scientific data to support effective and accurate communication. Accepting the OIG recommendation would put the EPA at odds with its core mission of protecting human health and the environment and would risk undermining the Agency's current efforts to ensure meaningful and appropriate risk communication to the American people. Despite repeated conversations with the OIG, there remains a failure by the OIG to understand EPA's concerns with undertaking any such action in the arbitrary timelines and methods being recommended.

Risk communication is of critical importance to the work EPA does across our many regions, offices, and programs. This is because our mission is to protect public health and the environment, and it is impossible to effectively and efficiently pursue that mission without communicating about risk to the American people. Over the past year EPA has continued to build on our risk communication capabilities, and we will continue to support our state and local partners in their efforts to share information with the public. The Agency is committed to improving our long term ability on risk communication, but regardless of the outcome of the process with the OIG, we have plans to do direct outreach to communities in the coming months once we have better data to target appropriately.

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In order to provide meaningful and appropriate risk communication, it is important to understand why the OIG recommendations are based upon a flawed understanding of the facts, data, and the Clean Air Act. The Clean Air Act directs EPA to regulate air toxics, like EtO, by setting limits on the amount that industrial sources can *emit* to the air, rather than by setting *ambient standards*, which are limits on the amount of a pollutant that is allowed to be present in the outdoor air. After EPA sets emission standards, the Agency is then required to review them periodically, taking into consideration advancements in pollution control technology and evaluating the level of risk that may remain following the adoption of the initial emission standards. A risk level of 1-in-10,000 is one factor EPA uses in its risk reviews of air toxics to determine whether additional controls are necessary. However, this level is *not* a regulatory number or a bright line for determining whether a given level of risk is acceptable. Other health risk measures and information are also important when making a risk determination.

EPA considered this risk information in 2018 in the most recent update to the National Air Toxics Assessment (NATA). (Note, we refer to this version of NATA as the 2014 NATA because it uses emissions data for the year 2014, the most recent available at the time.) NATA is a non-regulatory preliminary screening tool that informs our local, state, and tribal partners of air toxics levels and potential risks in their jurisdictions. NATA only tells us where to look closer—it does not provide definitive, actionable risk information. The 2014 NATA used the EPA's Integrated Risk Information System (IRIS) cancer potency value updated in 2016 to make these estimates on air toxics levels and potential risks. When the results showed that EtO was more prevalent in communities than previously realized, EPA immediately began working with state and local jurisdictions to reduce emissions from EtO facilities through the following actions:

- EPA is conducting the required residual risk and technology review for a source category containing some chemical manufacturing facilities that emit EtO. The final revised emission standards imposed on these facilities will significantly lower the amount of EtO emitted by these facilities.
- EPA is undertaking a rulemaking to revise the emission standards for the commercial sterilizer source category that were first adopted in December 1994. For the approximately 100 commercial sterilizer facilities, work is currently underway on a new technology review. Approximately one-third of these facilities are small businesses, requiring the Agency to follow additional regulatory procedures such as consultation prior to issuing a proposed rule. Additionally, as part of this rulemaking, EPA is taking the unique step of evaluating the regulation of fugitive emissions, which we believe are a significant emission source. In order to do this, the Agency needed to collect information and establish a record that would support regulation. It is our goal to have a proposed regulation for interagency review in the fall.
- EPA is working with states to learn more about emissions from specific facilities, identify opportunities for early reduction, and further support and coordination on outreach to communities. When Congress promulgated the Clean Air Act, it found that "air pollution control at its source is the primary responsibility of States and local governments." States' efforts in this regard have already led to the installation of new pollution controls that will reduce EtO emissions in Colorado, Georgia, Illinois, and Missouri. EPA has supported states in this work, and we have worked closely with both state and local governments to ensure that communities for which we have reliable risk data are informed of that risk.

With these and other steps, and in partnership with state and local governments, we have moved responsibly in using our statutory authority and other tools to address the issues surrounding EtO emissions. It is a testament that EPA staff and our state and local partners could move so quickly to address EtO in a meaningful way.

The issues raised by the OIG in their March 31, 2020, Management Alert and subsequent report relate to whether outreach has been done in specific communities where we cannot yet reliably characterize the risk posed by EtO. By insisting that EPA must provide outreach in each of the communities based solely off of inaccurate and outdated data from a non-regulatory preliminary screening tool, the OIG has taken the position that appropriate risk communication need not include reliable data. The Agency fundamentally disagrees with that approach, and while we may agree that there is always a level of uncertainty around data, the level of uncertainty here is simply too high to allow for the responsible communication of risk. EPA cannot reliably communicate risk on the basis of raw data that may contain errors. Quality assurance of that data is imperative. The Agency's mission statement, as noted in the OIG report, states that the Agency work to ensure that "all parts of society . . . have access to ***accurate*** information sufficient to effectively participate in managing human health and environmental risks." The OIG is asking us to ignore the part of our mission statement that calls upon EPA to use reasonably accurate data in our decision making.

The Agency has explained to the OIG that using the uncertain and preliminary screening data as the basis for public outreach would be irresponsible. Not only is the data incomplete, but the OIG is recommending the Agency use it as the basis to identify the communities requiring outreach. Acting on this basis is concerning since some of the data does not include correct source information and there may not be reliable information regarding receptor sites. Instead of immediately conducting outreach, the Agency maintains it is necessary to take meaningful and appropriate actions based on the important analysis and understanding of the data. By quality checking the data, the Agency will be able to appropriately determine what is missing and fill in data gaps to better understand where outreach is necessary. For example, for many of the areas estimated to have elevated risk by the previous 2014 NATA, EPA was able to gather sufficient additional information to develop a more accurate estimate of risk and then use that information to communicate with surrounding communities. In other areas, gathering this additional information has taken longer, but the Agency has made progress and expects to be able to communicate where appropriate with surrounding communities in the months ahead.

Risk communication should reflect the most *current available* information. This is a point that EPA has continued to emphasize during our discussions with the OIG and we have noted that the previous 2014 NATA relies on emissions data that are now six years old. Emblematic of this issue is the identification by the OIG of both the Sterigenics facility in Santa Teresa, New Mexico and the Air Products Performance Manufacturing (Evonik) facility in Milton, Wisconsin as "high-priority" ethylene oxide-emitting facilities. EPA has repeatedly pointed out to the OIG that current emissions at both facilities are now about *six times lower* than in 2014, well below the 1-in-10,000 risk level. The OIG continues to insist that the Agency go to these communities with inaccurate and outdated data and use that as the basis for public outreach, which is a poor reflection either on the attention the OIG is paying to the actual facts in this matter or on their judgment.

Perhaps most importantly, the OIG has continued to ignore the role of state and local governments, many of which properly insist upon taking the lead when communicating with the public on this issue and want information to be accurate before presenting it to communities. Under the strong federal-state partnerships that have been developed through implementation of the Clean Air Act, states have primary

responsibility for air pollution control with federal assistance. Most of the states with the high-risk areas identified by the 2014 NATA have expressed to EPA their desire to lead the EtO outreach efforts. As requested, EPA is playing a necessary support role by helping with data collection and analysis, providing financial assistance, and participating in state-led public meetings.

EPA has gone to great lengths to address all issues raised by the OIG, but the OIG has instead engaged in an erratic, goal post-moving endeavor that has been unproductive, unpredictable, and frustrating. At different times during the process EPA offered solutions to resolve all outstanding issues that were seemingly accepted only to have additional, unexpected issues raised by OIG.

For example, in attempts to submit and finalize the Agency's May 15 revised corrective action plan, EPA received conflicting input and feedback from OIG staff, resulting in unnecessary delays in finalization of the corrective actions for several months. This pattern continued in subsequent discussions with the Inspector General and EPA senior officials, and in follow up issues raised by OIG staff, causing continued frustration. Significant issues were not raised during a meeting when decisionmakers on both sides were present and ready to work through the issues. Instead, one outstanding issue was raised at the meeting which EPA committed to resolve but the very next day in a phone call OIG staff raised five new issues. In good faith, the Agency provided a new revised corrective action plan to the OIG on August 7, 2020, in which we proposed to reduce the timeframe for our work by about one third, and separately provided responses to the additional issues. On August 20, 2020, the OIG informed us that all this was still not good enough.

EPA's goal has been to work with the OIG to explain the intricacies of this matter and outline why some community outreach solely based upon the 2014 NATA is inappropriate given the uncertainty of the data. We will continue to work with the OIG and continue to provide them with accurate information so they are able to understand the EPA's processes and incorporate that appropriately in their recommendations for the Agency. The Administrator has made meaningful and appropriate risk communication to the American public a top priority for the Agency, and we take that responsibility seriously. We remain concerned with the OIG's desire to present data to communities that has not been verified for accuracy and has been associated with a corrective action process seemingly designed to elide pertinent facts and to keep the matter in controversy.

Finally, we have and will continue to offer support to our state and local partners on their community outreach efforts. With respect to the Croda facility, as a delegated state, the Delaware Department of Natural Resources and Environmental Control (DNREC) conducted two public meetings led by DNREC officials. While we did offer of assistance to DNREC, they did not tell us about or invite us to their public meetings. However, we confirmed that DNREC provided information to residents regarding the risk to public health as well as an explanation of ethylene oxide as cancer-causing, the very information the OIG is suggesting hasn't been provided to residents. Specifically, regarding their accidental release, DNREC and Croda have reached a settlement on the company's air and water violations. DNREC approved Croda's resumption of operations after numerous requirements were met. In addition, after coordination with DNREC and the New Castle County Office of Emergency Management, Croda also installed an emergency siren system to be used in conjunction with several other notification systems for alerting the public in the event of an accidental release by the facility.

EPA is continuing its regulatory work while doing everything we can to help address environmental and public health issues surrounding ethylene oxide. As demonstrated above, the actions this Administration has made and will continue to make are expected to result in meaningful reductions of air pollution in

the United States, as the EPA continues its mission to protect human health and the environment. If you have further questions, you may contact me, or your staff may contact Garrett Kral in the Office of Congressional and Intergovernmental Relations at Kral.Garrett@epa.gov or (202) 564-9114.

Sincerely,

Joseph A. Brazauskas, Jr.
Associate Administrator

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