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

July 7, 2021

OFFICE OF
AIR AND RADIATION

MEMORANDUM

SUBJECT: EPA Response #2 to Final Report: "EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health" - Report No. 21-P-0129, May 6, 2021

FROM: Joseph Goffman
Acting Assistant Administrator

TO: Renee McGhee-Lenart
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Office of Audit and Evaluation Programs, Offices, and Centers Oversight
Office of the Inspector General

Thank you for the opportunity to respond to your May 6, 2021, response to the Office of Air and Radiation (OAR) regarding the Office of the Inspector General's (OIG) January 14, 2021, draft report titled *EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health* (hereinafter "Report"). On March 5, 2021, OAR provided a response to OIG and proposed corrective actions to address Report Recommendations 1 through 4. On May 6, 2021, OIG replied, stating that the planned corrective action for Recommendation 4 was acceptable. However, OIG expressed concern with OAR's proposed corrective actions for Recommendations 1, 2, and 3. OAR and OIG discussed these concerns in a conference call on June 7, 2021, and several follow-up exchanges. OAR is providing the following information to supplement the March 5, 2021, response with details that address OIG's outstanding concerns.

Recommendation 1: Develop and implement an internal control process with specific criteria to determine whether and when new residual risk reviews of existing National Emission Standards for Hazardous Air Pollutants and uncontrolled emission sources are needed to incorporate new risk information that demonstrates that an air pollutant is more toxic than previously determined.

Response 1: The Office of Air Quality, Planning and Standards (OAQPS) has developed and is implementing its *Strategy for the Air Toxics Program*, which provides a process to identify and efficiently address new and emerging air toxics issues (described in detail in Appendix A of the document).

The process includes five key steps, the first of which is strategic engagement. Strategic engagement includes: 1) strategic engagement of staff and management with each other, EPA offices (e.g., Regional Offices, Office of Transportation and Air Quality, Office of Research and Development (ORD), and Office of Chemical Safety and Pollution Prevention (OCSPP)), EPA regulatory partners, and stakeholders to understand, obtain, and coordinate the development of information, and 2) strategic engagement of staff and management with regard to other sources of information, such as current scientific literature, routine and novel assessments, regular work activities, and policy and political interests. These types of engagement activities provide the foundation for early identification of potential new and emerging issues. With this engagement, the Agency is better able to identify new information about risk from air toxics and consider adjustments to regulatory programs.

In part from implementing the strategy, which began in Fall 2020, OAQPS' connections with ORD and the Integrated Risk and Information (IRIS) program have improved. OAQPS and ORD coordination on IRIS and related toxicity assessments includes:

- Biweekly air toxics coordination meetings with OAQPS/HEID management and ORD/CPAD management.
- IRIS quarterly Agency-wide updates, with meetings between HEID and CPAD on the status of specific chemicals, as requested.,
- OAQPS/HEID and ORD/CPHEA issue-specific meetings (e.g., evaluation of toxicity values issued by other entities, such as California EPA).
- Working meetings on specific issues related to individual chemicals and/or rulemakings.
- IRIS nominations by EPA HQ and Regional Offices, with ORD follow-up meetings.

Through communication, coordination, and collaboration with others at EPA and outside of EPA, members of the Air Toxics Evaluation and Screening Team (ATEST) actively monitor for new and emerging issues. Team members have responsibilities that include:

- Staying generally aware of emerging issues in their offices, regions, and/or divisions.
- Staying actively involved in and/or aware of relevant information from existing avenues, such as ORD meetings, and regular meetings with Office of Enforcement and Compliance Assurance and OCSPP.
- Engaging strategically with other EPA offices (e.g., ORD, OCSPP) to stay apprised of chemical and other assessments and activities and potential issues being addressed.

ATEST members routinely track various types of information, including:

- Air toxics health effects and risk information.[1]
- Air toxics emissions, modeling, and monitoring data.
- Emerging air toxics information of local or community concern.
- Emerging or growing industries (including changes in processes, changes in chemical use).

[1] ATEST tracks changes in health effects information, primarily in the form of new and revised dose-response values for hazardous air pollutants, including values issued by EPA's IRIS, the Agency for Toxic Substances and Disease Registry (ATSDR), California EPA, and EPA OCSPP's Toxic Substance and Control Act (TSCA) program.

These programs and systems support and enhance the Agency's understanding of emerging information about risk from air toxics. With this information, EPA is better able to identify and consider adjustments to its regulatory programs.

In addition, directly related to Clean Air Act (CAA) section 112 reviews of National Emission Standards for Hazardous Air Pollutants, EPA will incorporate into our internal control process the development of a regulatory roadmap, similar to those shown in our revised response to Recommendation 2, for categories where the Air Toxics Strategy identifies an emerging issue.

Recommendation 2: Conduct new residual risk reviews for Group I polymers and resins that cover neoprene production, synthetic organic chemical manufacturing industry, polyether polyols production, commercial sterilizers, and hospital sterilizers using the new risk values for chloroprene and ethylene oxide and revise the corresponding National Emission Standards for Hazardous Air Pollutants, as needed.

Response 2: As a supplement to our March 5, 2021, response, we note that the CAA provides more than one authority that EPA can use to reduce risks to public health by establishing emission standards for hazardous air pollutants. We understand OIG's request that OAQPS undertake risk reviews of these source categories under CAA section 112(f)(2), and in light of the CAA's multiple options to review risk, we are expeditiously evaluating the benefits and contraindications for each of these options to reduce risk from these source categories, with the aim of making an informed decision of the holistically best regulatory option to use. We have created roadmaps for several of the categories being reviewed to show regulatory approaches and potential outcomes based on the approaches. Similar roadmaps are planned for the other source categories.

Commercial Sterilizers Roadmap

1. The required residual risk review and initial technology review for commercial sterilizers were finalized in 2006. The question of whether to conduct a discretionary second residual risk review based on updated information regarding the toxicity of ethylene oxide is being considered by EPA.

2. When conducting the second section 112(d)(6) technology review, as required every 8 years, we gathered data for reassessing the baseline risk from ethylene oxide emissions. Our assessment shows cancer risks significantly above 100-in-1 million for multiple facilities based on the existing standards.

3. As part of the technology review, we identified previously unregulated emission points of ethylene oxide (as well as options for tightening some of the current standards), and we plan to propose new MACT standards for the unregulated emission points. The new standards will be established under the authority of CAA section 112(d), which requires EPA to establish numeric MACT standards or health-based emissions limits for all hazardous air pollutants emitted from the source category, unless the Agency determines a work practice standard is appropriate. Note that because ethylene oxide is a carcinogen, a health-based emission limit under section 112(d)(4) is not authorized. Accordingly, EPA must establish numeric MACT standards under section 112(d)(2) and (3) or work practice standards under section 112(h) for all unregulated emissions of ethylene oxide.

4. EPA is currently assessing the emissions and associated risks that will remain after adoption of new standards (pursuant to section 112(d)(2) and (3)) for currently unregulated emissions sources, while concurrently gathering more data. If additional action is necessary to further reduce the remaining risk after establishing those standards, OAQPS will provide regulatory options to OAR,

and the Assistant Administrator (or Administrator, if the project is a Tier 1 rulemaking) will choose the approach for addressing the remaining risk. We anticipate pursuing one of the following two approaches:

a. Establish a cost effectiveness benchmark for ethylene oxide that ensures standards established pursuant to the technology review of existing standards is sufficiently stringent to address the severity of risk attendant to exposure to ethylene oxide. Currently, there is no cost-effectiveness benchmark established for ethylene oxide, and decisions under this technology review regarding what represents a cost-effective value for ethylene oxide will establish precedent for other upcoming rules. EPA would consider risk acceptability criteria in establishing the cost-effectiveness value with the expectation that such an approach would allow us to achieve the necessary risk reductions. After completing the technology review, we would recalculate risks considering these measures to ensure that risks are appropriately addressed.

b. Conduct a review under section 112(f)(2), which would require that risks be reduced to an acceptable level considering risk information only (no consideration of cost or technological feasibility), followed by further evaluation of measures to provide an ample margin of safety (considering all risk information, feasibility, cost, and other relevant factors).

Hazardous Organic NESHAP (HON) Roadmap

1. The required residual risk review and initial technology review for the HON was finalized in 2006. The second section 112(d)(6) technology review is overdue, and we have been sued to complete that review and to redo the section 112(f)(2) risk review. The claim that we must redo a section 112(f)(2) risk review has been litigated in a different district court for a different source category, and that court ruled that the CAA does not require a second residual risk review. *Citizens for Pennsylvania's Future, et al. v. Wheeler*, 469 F.Supp.3d 920 (N.D. Cal. 2020). In a separate administrative petition, the litigants in the current suit are also requesting that EPA conduct a discretionary second residual risk review.

2. We are undertaking a rulemaking for the HON. It appears that "gaps" are not an issue for the source category, and, therefore, the likely authorities for amending standards are the section 112(d)(6) technology review and/or the section 112(f)(2) residual risk review. Separately, we will evaluate the existing standards to ensure that all SSM exemptions are removed.

3. We expect to find that risks due to ethylene oxide are significantly above 100-in-1 million for multiple facilities, and we are beginning the data-gathering phase of the project. When we have sufficient information, OAQPS will provide regulatory options to OAR. The Assistant Administrator (or Administrator, if the project is a Tier 1 rulemaking) will choose the approach for addressing the remaining risk. We anticipate pursuing one of the following two approaches:

a. A technology review of the previously established standards, which would require cost-effective measures to reduce emissions. EPA would consider risk acceptability criteria in establishing the cost-effectiveness value with the expectation that such an approach would allow us to achieve the necessary risk reductions. The cost-effectiveness value established in the commercial sterilizer rulemaking would significantly influence the determination of what is considered cost effective in this rulemaking. As necessary, we would recalculate risks considering these measures to ensure that risks are appropriately addressed.

b. A review under section 112(f)(2), which would require that risks be reduced to an acceptable level considering risk information only (no consideration of cost), followed by further evaluation of measures to provide an ample margin of safety (considering all risk information, feasibility, and cost).

Recommendation 3: Revise National Emission Standards for Hazardous Air Pollutants for chemical manufacturing area sources to regulate ethylene oxide and conduct a residual risk review to ensure that the public is not exposed to unacceptable risks.

Response 3: As a supplement to our March 5, 2021, response, EPA notes that the CAA does not direct EPA to conduct a residual risk assessment for generally available control technology (GACT) standards. More importantly, because technology-based standards for ethylene oxide have not yet been established for the source category, it is premature to determine that a risk review is warranted. EPA must first evaluate ethylene oxide emissions from the source category, then determine whether it is necessary to regulate ethylene oxide in the Chemical Manufacturing Area Source rule, and complete the necessary revisions based on that analysis. Such revisions would involve the establishment of technology-based ethylene oxide standards; within 8 years of promulgation of those standards, EPA would consider the appropriate review authority through a process similar to those presented in the roadmaps above. Risk is not considered in establishing the initial section 112(d) standards, but given the significance of ethylene oxide, EPA will determine whether to conduct a discretionary risk review when we conduct the second technology review, consistent with the approaches set forth above for commercial sterilizers and the HON.

Thank you again for this opportunity to supplement our prior response. If you have any questions regarding this response, please contact JoLynn Colins, OAQPS/OAR Audit Liaison, at (919) 541-5671.

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