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

June 1, 2022

OFFICE OF
AIR AND RADIATION

MEMORANDUM

SUBJECT: EPA Response #3 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
Principal Deputy Assistant Administrator
Office of Air and Radiation

TO: Patrick Gilbride
Director, Implementation, Execution, and Enforcement
Office of Special Review and Evaluation
Office of the Inspector General

Thank you for the opportunity to respond further 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. On July 7, 2021, OAR provided additional information to supplement the March 5, 2021, response, and OAR is now providing additional details to 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 (NESHAP) 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. The Strategy will serve to help identify situations in which new risk information shows that an air pollutant is more toxic than previously determined. This happened most recently when the Agency issued in December 2016 an updated, more toxic inhalation unit risk estimate pursuant to its Integrated Risk Information System (IRIS) for ethylene oxide (EtO) (see EPA/635/R-16/350Fc, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Executive Summary, In Support of Summary Information on the Integrated Risk Information System (IRIS), December 2016).

We will commit to the following process to determine whether and when new public health risk analyses are needed in light of new information. First, we will ensure that we use the most up-to-date toxicity information available for all hazardous air pollutants (HAP) regulated under the Clean Air Act (CAA). One way to achieve this is to work closely with our Office of Research and Development (ORD) and the IRIS program. OAQPS and ORD coordination on IRIS and related toxicity assessments includes:

- Biweekly air toxics coordination meetings with OAQPS' Health and Environmental Impacts Division (HEID) management and ORD's Chemical and Pollutant Assessment Division (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's Center for Public Health and Environmental Assessment (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; and
- IRIS nominations by EPA HQ and Regional Offices, with ORD follow-up meetings.

Second, the basic trigger in our internal control process for determining whether and when to re-examine risk in further reviews of existing NESHAP is the issuance of an updated or new IRIS value that shows a pollutant to be more toxic than previously understood or provides a first-time health benchmark for assessing risk. As noted above, this occurred in 2016 for EtO and has been the driving factor in our current ongoing review of NESHAP for EtO. The issuance of an updated, more toxic IRIS value for other chemicals in the future would, as appropriate, produce a similar trigger for us to re-examine risk from exposure to these chemicals. Some of the factors we expect to consider in assessing the effect of an updated or new IRIS value (and the resultant risks) include EPA's new annual national screening analysis (AirToxScreen) and analyses of ambient air quality monitoring data, which may include case-specific studies.

Finally, in those situations where we are reviewing a NESHAP and there is new information on the toxicity of a given chemical of interest (and the statutorily-required residual risk review has already been completed for that source category), we will determine how to best consider the new risk information in the current review. As described in the roadmaps discussed in our response to Recommendation 2, we will evaluate the multiple tools available under the CAA for addressing

risk from emissions of air toxics. Those tools include conducting a discretionary residual risk assessment under CAA section 112(f)(2), conducting a review under CAA section 112(d)(6), and/or establishing new standards for unregulated pollutants if the original NESHAP did not regulate all HAP. We intend to use these tools to reduce risk – **consistent with the law and in a sequence that provides an ample margin of safety to protect public health.**

Planned Completion Dates: The draft completion date for revising the Strategy document (to reflect the above commitment) is Quarter 3, FY 2022.

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 NESHAP, as needed.

Response 2: OAR commits to conduct appropriate reviews to ensure that the standards for neoprene production, synthetic organic chemical manufacturing industry, polyether polyols production, and commercial sterilizers continue to provide an ample margin of safety to protect public health and that the standards for hospital sterilizers provide an ample margin of safety to protect public health. We note that this process would first involve an assessment of whether risks are acceptable followed by the ample margin of safety analysis, as outlined in the Benzene NESHAP. We created example roadmaps for two of the source categories at issue to illustrate the potential regulatory approaches for ensuring that the standards meet these commitments. Similar roadmaps will be followed for the other source categories.

Example: Commercial Sterilizers Roadmap

1. The required residual risk review and initial technology review for Commercial Sterilizers were finalized in 2006. The EPA has decided to conduct a second, discretionary public health risk assessment based on updated information regarding the toxicity of EtO.
2. We are conducting the second CAA section 112(d)(6) technology review, as required every 8 years, and we gathered data for reassessing the baseline risk from EtO emissions. Our assessment shows excess lifetime cancer risks significantly above 100-in-1 million level from multiple facilities based on the existing standards.
3. As part of the technology review, we identified previously unregulated emission points of EtO (as well as options for tightening some of the current standards), and we plan to propose new standards for the unregulated emission points. For the new standards for major sources, we plan to first identify under the authority of CAA section 112(d) the maximum achievable control technology (MACT) levels of control for the unregulated EtO emitted; if the Agency determines that it is not feasible to set numeric standards under CAA section 112(d)(2) and (3), it may set work practice standards pursuant to CAA section 112(h). Note that because a health threshold has not been established for EtO, a health-based emission limit under CAA section 112(d)(4) is not authorized. For unregulated EtO from area sources, the Agency may first identify levels that reflect generally available control technology (GACT) in lieu of MACT.

4. EPA gathered a significant amount of new data and is currently assessing the emissions and associated risks that will remain after identification of the MACT and/or GACT levels of control pursuant to 112(d)(2) and (3) and (h) or (d)(5) for currently unregulated emissions sources. If in the rulemaking EPA finds that additional control is necessary to further reduce the remaining risk after identifying the MACT and/or GACT levels of control, OAQPS will provide regulatory options to the OAR Assistant Administrator for a decision on the approach for addressing the remaining risk. One of the following two approaches is anticipated:

   a. Establish standards under the combined authorities of CAA sections 112(d)(2) and (3), 112(d)(5), 112(h), and 112(d)(6) (as applicable) that consider the cost-effectiveness for controlling EtO and ensuring that such standards are sufficiently stringent to address the severity of risk attendant to exposure to EtO. Decisions under this technology review regarding what represents a cost-effective control of EtO 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. Concurrently with the technology review, we would conduct a risk assessment and take appropriate action to ensure that the standards continue to provide an ample margin of safety to protect public health. This could be an iterative process where we would have to assess more stringent options until we conclude that the standards are sufficiently protective; or,

   b. Conduct a review under CAA 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 to protect public health (considering all risk information, feasibility, cost, and other relevant factors), with standards issued under the combined authorities of CAA sections 112(d)(2) and (3), 112(d)(5), 112(h), 112(d)(6) and 112(f)(2) (as applicable).

Example: Hazardous Organic NESHAP (HON) Roadmap

1. The required residual risk review and initial technology review for the HON was finalized in 2006. The second CAA section 112(d)(6) technology review is overdue, and we were sued to complete that review and to redo the CAA section 112(f)(2) risk review. The claim that we must redo a CAA 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 also requested that EPA conduct a discretionary second residual risk review. By letter dated September 15, 2021, OAR partially granted the administrative petition and stated our intent to conduct a risk review (without specifying under what CAA authority) concurrently with the section 112(d)(6) technology review and to revise the HON as needed to continue to provide an ample margin of safety to protect public health. On February 24, 2022, the U.S. District Court for the District of Columbia entered a consent decree (CD) and court order establishing deadlines for EPA's overdue action under section 112(d)(6)

(as well as that under section 111(b)(1)(B)). The CD refers to OAR's September 15, 2021, letter.

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 CAA mandatory section 112(d)(6) technology review and/or the discretionary second 112(f)(2) residual risk review. Separately, we will evaluate the existing standards to ensure they were set correctly and to ensure that all start-up, shutdown and malfunction exemptions are removed.

3. We expect to find that excess lifetime cancer risks due to EtO are significantly above 100-in-1 million from multiple facilities, and we will develop options for addressing the remaining risk in our rulemaking. We are beginning the data-gathering phase of the project. When we have sufficient information, OAQPS will provide regulatory options to the OAR Assistant Administrator for a decision on the approach for addressing the remaining risk. One of the following two approaches is anticipated:

   a. Conduct 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. To the extent that cost-effectiveness of EtO control is addressed in the Commercial Sterilizers rulemaking, such a determination would significantly influence our consideration of what may be cost effective in this rulemaking, although industry-specific factors also would be considered. Concurrently with the technology review, we would conduct a risk assessment and take appropriate action to ensure that the standards continue to provide an ample margin of safety to protect public health. This could be an iterative process where we would have to assess more stringent options until we conclude that the standards are sufficiently protective; or,

   b. Conduct a review under CAA 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 to protect public health (considering all risk information, feasibility, and cost).

Planned Completion Dates: The draft dates for completing the review of each NESHAP are as follows:

Commercial Sterilizers: Quarter 3, FY 2023
Hospital Sterilizers: Quarter 4, FY 2024
Group 1 Polymers and Resins (Neoprene): Quarter 2, FY 2024
Synthetic Organic Chemical Manufacturing Industry: Quarter 2, FY 2024
Polyether Polyols Production: Quarter 4, FY 2024

Recommendation 3: Revise NESHAP for chemical manufacturing area sources (CMAS) to regulate ethylene oxide and conduct a residual risk review to ensure that the public is not exposed to unacceptable risks.

Response 3: As noted in our July 7, 2021, response, technology-based standards for EtO have not yet been established for the CMAS source category. Therefore, we plan to first evaluate EtO emissions from the source category, and if EtO emissions present a public health concern (i.e., by considering risk information), we will regulate EtO in the CMAS rule. Regulation would involve the establishment of technology-based EtO standards pursuant to either CAA section 112(d)(5) – so called "GACT" standards – or, perhaps, CAA sections 112(d)(2) and 112(d)(3) – so called "MACT" standards. While these standards must be set based on the criteria in the Act, we will consider other information, including risks, in examining this source category and in assessing the appropriate statutory authority. Provided we meet our goal to set initial EtO standards for CMAS by the end of FY 2024, the CAA would require us to complete a section 112(d)(6) technology review and/or section 112(f)(2) residual risk review, as applicable, no later than the end of 2032. However, within four years of promulgation (enough time to understand the level of emissions remaining after implementation of new standards) of any initial EtO standards for CMAS, EPA would assess the risks from EtO emissions from CMAS sources to inform us on whether an earlier review date is appropriate.

Planned Completion Dates: The draft date for completing the evaluation of this NESHAP and, if appropriate, the establishment of EtO emission standards is Quarter 4, FY 2024. The draft date for the determination of whether the remaining risks support an earlier review date for the next scheduled review is Quarter 4, FY 2028.

Thank you again for this opportunity to supplement our prior responses. If you have any questions regarding this response, please contact Tiffany Purifoy, OAQPS/OAR Audit Liaison, at (919) 541-0878.

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