

FACT SHEET

Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP) Final Rule: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

ACTION

- On December 14, 2022, the U.S. Environmental Protection Agency (EPA) finalized a decision reaffirming its assessment of health risks associated with ethylene oxide, a harmful cancer-causing pollutant emitted by commercial sterilizers, chemical production facilities, and other industrial sources. This action will ensure that EPA's decisions relating to ethylene oxide are based on the best available science.
- This decision completes the Agency's reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Miscellaneous Organic Chemical Manufacturing source category ("2020 MON final rule"), and reflects careful consideration of public comments received on EPA's proposed reconsideration of the 2020 MON final rule earlier this year .
- This action addresses two issues: (1) the use of EPA's 2016 Integrated Risk Information System ("IRIS") value for ethylene oxide in assessing cancer risk for the source category; and (2) the use of the Texas Commission on Environmental Quality (TCEQ)'s less-protective risk value for ethylene oxide as an alternative to EPA's more protective 2016 IRIS value for purposes of evaluating risk under Clean Air Act section 112(f)(2).
- EPA has decided to retain its decision to use the 2016 IRIS value for ethylene oxide when assessing risk from Miscellaneous Organic Chemical Manufacturing facilities in the 2020 MON final rule. As described in detail in the decision, the 2016 IRIS value reflects the best available science on health impacts of ethylene oxide and was subject to rigorous internal review, interagency review, external peer review, and public comment. Commenters provided no information that called into question the science underpinning the 2016 IRIS value.
- Further, EPA has determined that TCEQ's risk value for ethylene oxide is unsuitable for use as an alternative to the 2016 IRIS value. EPA's assessment of TCEQ's risk value found that it excludes important scientific evidence on the health risks of ethylene oxide, and is based on a risk model that is inconsistent with the epidemiological data and resulted from a flawed analytical approach.
- As such, in this final action, EPA is making no changes to the risk assessment or emission standards for the miscellaneous organic chemical manufacturing source category.

BACKGROUND

- On August 12, 2020, the U.S. Environmental Protection Agency (EPA) published 2020 MON final rule, pursuant to Clean Air Act (CAA) sections 112(f)(2) and 112(d)(6).

- In the residual risk review, cancer risks were calculated using EPA's Integrated Risk Information System (IRIS) unit risk estimate (URE) for ethylene oxide and additional standards were imposed in the 2020 MON final rule because the risks were unacceptable based on that analysis.
- Language was also included in the 2020 MON final rule that indicated that "the EPA remains open to new and updated scientific information, as well as new dose response values such as the TCEQ value, as they become available" (85 FR 49098); however, by the close of the public comment period (March 19, 2020), the TCEQ dose-response value had not yet been finalized and could not be considered in the final action.
- Subsequently, EPA received and granted petitions for reconsideration of two issues, specifically, on (1) the use of EPA's IRIS value for ethylene oxide in assessing cancer risk for the source category, and (2) the use of the TCEQ risk value for ethylene oxide as an alternative risk value to EPA's IRIS value for purposes of evaluating risk under CAA section 112(f)(2).
- EPA responded to petitioners in June 2021 that reconsideration would be granted. On February 4, 2022, EPA published a proposed rule to reconsider the 2020 MON final rule and to request public comment on these issues. EPA held a public hearing on February 22, 2022 and took public comment through March 24, 2022.

FOR MORE INFORMATION

- Interested parties can download a copy of the proposed rule notice from EPA's website at <https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission>.
- Today's action and other background information are also available electronically at <https://www.regulations.gov/>, EPA's electronic public docket and comment system.
- For additional technical information about the rule, contact Susan Paret at the EPA's Office of Air Quality Planning and Standards, at (919) 541-5516 or at paret.susan@epa.gov