

March 23, 2022

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U.S. Environmental Protection Agency
EPA Docket Center
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1200 Pennsylvania Avenue, NW
Washington, DC 20460

To Whom It May Concern:

On behalf of the National Association of Clean Air Agencies (NACAA), thank you for this opportunity to comment on the proposed Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing (MON) Residual Risk and Technology Review (RTR), which was published in the *Federal Register* on February 4, 2022 (87 Fed. Reg. 6,466)¹. NACAA is the national, non-partisan, non-profit association of air pollution control agencies in 40 states, including 115 local air agencies, the District of Columbia and four territories. The air quality professionals in our member agencies have vast experience dedicated to improving air quality in the United States. These comments are based upon that experience. The views expressed in these comments do not represent the positions of every state and local air pollution control agency in the country.

NACAA supports EPA's proposal to reaffirm the agency's reliance on the Integrated Risk Information System's (IRIS) toxicity value for ethylene oxide (EtO) when assessing risk in the MON RTR, rather than relying on a less-protective value recommended by the Texas Commission on Environmental Quality (TCEQ). NACAA has previously expressed strong support for EPA's use of the IRIS risk value for EtO in several letters, specifically in comments on the proposed Hydrochloric Acid Production RTR (March 28, 2019)², comments on the proposed MON RTR (February 6, 2020)³ and a letter to EPA outlining NACAA's air toxics priorities (May 25, 2021).⁴ In the letter commenting on the MON proposal, NACAA also articulated concerns with the TCEQ's proposed risk values for EtO. We urge EPA to consider the comments NACAA made in those earlier letters in its final reaffirmation of the use of the IRIS values for the MON.

¹ <https://www.govinfo.gov/content/pkg/FR-2022-02-04/pdf/2022-01923.pdf>

² https://www.4cleanair.org/wp-content/uploads/Documents/hydrochloric_acid_RTR_comments.pdf

³ https://www.4cleanair.org/wp-content/uploads/Documents/MON-NACAA_Comments_2-6-20.pdf

⁴ <https://www.4cleanair.org/wp-content/uploads/Documents/NACAAToxicsTransitionIssues-05252021.pdf>

In its proposal, EPA is seeking comment on two issues: 1) the use of the EPA 2016 Integrated Risk Information System (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 the EPA's IRIS value.

Use of the 2016 Integrated Risk Information System (IRIS) Value

NACAA agrees with EPA's decision to retain the use of the IRIS risk values for EtO in the MON and believes the agency has articulated a good case for doing so in its February 4, 2022 proposal. As we have stated in previous comments, IRIS has been and should continue to be EPA's primary source for Unit Risk Estimates (UREs); the purpose of the database is to foster consistency in the evaluation of chemical toxicity across EPA. IRIS produces high-quality, evidence-based assessments; its information and processes for evaluating substances have undergone extensive internal and external examination and peer review. In the case of the IRIS EtO risk value specifically, the 2016 update was the result of a very thorough and comprehensive peer-reviewed evaluation that took nearly two decades. It included well-documented in-depth assessments by EPA and multiple rounds of extensive internal and external review and public comment. Therefore, in light of the scientifically defensible and comprehensive nature of the EtO review that preceded the 2016 update to the URE, EPA would not be justified in deviating from the IRIS EtO findings.

It is due to NACAA's endorsement of the IRIS risk values that we opposed the use of an uncertainty assessment in the health risk assessment to justify EPA's claim that the estimated risks were "acceptable" in the proposed MON of December 17, 2019. That claim, based on the uncertainty discussion, was ultimately included in the final rule of August 12, 2020.⁵ Specifically, EPA quantified the uncertainty in the IRIS URE for EtO and reduced the risk about five times lower to determine that the regulation would reduce potential post-control risks to acceptable levels (i.e., 60- to 100-in-1 million, from the 200- to 300-in-1 million estimates without the application of the uncertainty estimates). During the process for updating the EtO URE in IRIS, the uncertainty information that EPA raised in the MON was considered. However, even considering this information, IRIS's thorough assessment and peer-review process ultimately resulted in the current IRIS values. Raising these uncertainty issues anew in the MON was inappropriately second-guessing the IRIS results.

As we stated in our earlier comments, the uncertainties in the toxicology determination are not over predictions of estimates of risk. They are a reasonable approach to protecting public health by considering all life stages (full lifetime) and sensitive populations. IRIS incorporated uncertainty factors in order to be adequately protective. Unless proven with scientific evidence, there should be no claims that the IRIS URE is biased toward over-prediction. EPA did not prove why the protective estimates in IRIS should not continue to be considered.

⁵ <https://www.govinfo.gov/content/pkg/FR-2020-08-12/pdf/2020-12776.pdf>

Use of the Texas Commission on Environmental Quality (TCEQ) Value

NACAA supports EPA's proposal to rely on the IRIS cancer risk value for EtO, rather than the value recommended by TCEQ. The TCEQ proposal differs from the IRIS estimates in several important ways, resulting in a much less protective risk estimate than the IRIS URE. EPA's proposal articulates well the reasons for using the IRIS numbers, rather than those of TCEQ, including raising some of the concerns NACAA expressed in previous comments. For example, TCEQ did not include key data related to breast cancer and it underestimated cancer in occupationally exposed people. By ignoring breast cancer risk and using a poorly fitting model for lymphoid cancers, TCEQ's estimate drastically underestimated risks, resulting in a value that is 2,000-times less protective than the IRIS value.

A key point in comparing the IRIS and TCEQ estimates is that during the comprehensive IRIS review that developed the updated EtO URE, the type of data TCEQ relied on to develop its estimate was already available and was evaluated as part of the IRIS process. Even considering this data, however, IRIS's thorough assessment and peer-review process ultimately resulted in the URE currently contained in IRIS, rather than something similar to the TCEQ estimate.

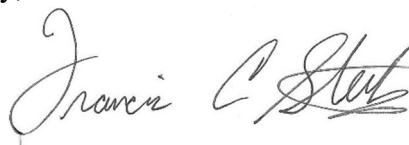
In summary, considering the scientifically defensible and comprehensive nature of the EtO review that led to the updated URE in 2016, there is no reason to deviate from the updated IRIS EtO findings during the regulatory process. Therefore, NACAA supports EPA's proposal to rely on the IRIS toxicity value for EtO, rather than the less-protective value recommended by TCEQ. Furthermore, if at some point in the future the EtO URE is in need of updating, it should be reexamined through the robust IRIS process for public and scientific peer review. EPA should not use the development of individual rules to circumvent, undermine or dilute the IRIS findings.

Thank you for this opportunity to comment on the proposal. Please contact us if we can provide additional information.

Sincerely,



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