

March 24, 2022

Michael S. Regan, Administrator
U.S. Environmental Protection Agency
EPA Docket Center, Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Attention: Docket ID No. EPA-HQ-OAR-2018-0746

*Re: Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants:
Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review*

Dear Administrator Regan:

The Northeast States for Coordinated Air Use Management (NESCAUM) offer the following comments on the proposed “Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review” [87 Fed. Reg. 6466-6473 (February 4, 2022)] (hereinafter the “MON Reconsideration”).

NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont. Our member agencies have the primary responsibility in their states for implementing clean air programs that achieve the public health and environmental protection goals of the federal Clean Air Act.

In the MON Reconsideration, EPA is requesting comments on the cancer risk value used to assess ethylene oxide risk in the MON Residual Risk and Technology Review (RTR), which was conducted pursuant to §112(f)(2) of the Clean Air Act. Specifically, the MON Reconsideration requests comments on: (1) the continued use in the RTR of the cancer inhalation unit risk estimate (URE) for ethylene oxide derived by EPA’s Integrated Risk Information System (IRIS) and (2) the use of a risk value for ethylene oxide developed by the Texas Commission on Environmental Quality (TCEQ) as an alternative to EPA’s IRIS value.

NESCAUM strongly supports the continued use of the IRIS URE value for ethylene oxide in this and other §112(f)(2) risk evaluations. The preferential use of IRIS values was established in EPA’s 1999 “Residual Risk Report to Congress,” which stated the following:

Regardless of the endpoint of interest (acute, chronic non-cancer, or cancer effects), consensus toxicity criteria are preferred for conducting risk assessments. For chronic non-cancer and cancer criteria, the preferred source of data is EPA’s IRIS. This data base

provides toxicity criteria that have undergone internal peer review, and, for recent assessments, external peer review, and have been approved Agency-wide. The toxicological basis for the criterion is provided, as well as other supporting data and information regarding the uncertainty in the assessment.¹

The EPA has used toxicity values developed by other authoritative bodies when an IRIS value was not available for a pertinent contaminant. However, that is clearly not the case for ethylene oxide. Over an 18-year period, at least four drafts of the IRIS ethylene oxide cancer evaluation were reviewed by a wide range of “EPA scientists, interagency reviewers from other federal agencies and the Executive Office of the President, the public, and independent scientists external to the EPA,”² culminating in the adoption of the current IRIS URE in December 2016.

The issues considered in the TCEQ analysis, including the selection of a dose-response model, were carefully evaluated and documented in the development and review of the IRIS value. However, if the TCEQ or another party has evidence of new information that would merit a reconsideration of the IRIS derivation, that information should be submitted to IRIS for consideration and peer review. Reconsideration of the highly reviewed, recently finalized IRIS value for ethylene oxide in the context of a residual risk analysis is inappropriate.

Although not specifically a subject of this reconsideration, NESCAUM continues to be concerned that, in the MON RTR analysis, EPA altered the IRIS URE to justify the allowance of cancer risk levels higher than those generally considered to be acceptable by the Agency. The RTR states that, “(a)lthough the post-control risks are greater than 100-in-1 million (*i.e.*, 200 to 300-in-1 million), due to the inherent health protective nature of our risk assessment methods and the uncertainties in this assessment, we believe that this risk assessment is more likely to overestimate rather than underestimate the risks.” [84 Fed. Reg. 69217] The RTR then goes on to employ two alterations of the IRIS value that result in reduced risk estimates for this category: the use of a central estimate of ethylene oxide cancer risk rather than the upper bound confidence level and (2) the choice of an alternative dose-response model for calculating the risk of lymphoid cancer.

While NESCAUM acknowledges that risk assessment is not an exact science, we do not support EPA’s reinterpretation of IRIS cancer potencies to justify policy decisions. The use of conservative assumptions in cancer assessments is necessary and appropriate, due to the severity of the health impacts of that disease, particularly for known human carcinogens, like ethylene

¹ U.S. EPA, Residual Risk Report to Congress, pp. 56-57, March 1999, EPA-453/R-99-001. https://www.epa.gov/sites/production/files/2013-08/documents/risk_rep.pdf.

² U.S. EPA, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) in Support of Summary Information on the Integrated Risk Information System (IRIS), p. XV, December 2016. EPA/635/R–16/350Fa. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf.

oxide. As discussed above, the IRIS URE was developed after careful consideration of all available models and was subject to extensive internal and external scientific review. Therefore, NESCAUM is again urging EPA to not alter the IRIS URE for ethylene oxide when calculating risks in the RTR.

NESCAUM strongly recommends that EPA continue to use the IRIS URE for ethylene oxide to evaluate cancer risk in the MON RTR and in subsequent risk analyses. Reconsideration of the highly vetted IRIS ethylene oxide URE in the context of a residual risk analysis is inappropriate. Any party with scientific data on the toxicity of ethylene oxide not considered in the IRIS deliberative process should present those data to IRIS for evaluation and peer review. Further, the IRIS URE should not be altered to rationalize policy decisions, including determinations of the adequacy of proposed control requirements in RTRs.

Sincerely,



Paul J. Miller
Executive Director

cc: NESCAUM Directors
NESCAUM Air Toxics and Public Health Committee
Lynne Hamjian, Cynthia Greene, EPA R1
Rick Ruvo, Kirk Wieber, Matthew Laurita, EPA R2