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February 6, 2020

U.S. Environmental Protection Agency
EPA Docket Center
Docket ID Number EPA-HQ-OAR-2018-0746
Mail-Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Sir/Madam:

On behalf of the National Association of Clean Air Agencies (NACAA), thank you for this opportunity to comment on the proposed National Emissions Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review (RTR), which were published in the *Federal Register* on December 17, 2019 (84 Fed. Reg. 69,182). NACAA is the national, non-partisan, non-profit association of air pollution control agencies in 41 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.

EPA is right to recognize the importance of reducing exposures to emissions of ethylene oxide (EtO), which is a substance that is carcinogenic to humans[1] including increasing the risk of "some types of cancers, including cancers of the white blood cells (such as non-Hodgkin lymphoma, myeloma and lymphocytic leukemia); and breast cancer in females."[2] In light of the adverse health implications related to EtO exposure, we are encouraged by the fact that EPA's proposal clearly states "that the risks for this source category under the current MACT provisions are unacceptable"[3] and calls for further action to reduce emissions. The agency should seek the best options for ameliorating these unacceptable risks and protect the public with an ample margin of safety, as the Clean Air Act intended. Accordingly, the following are comments and recommendations related to elements of the proposed rule, including provisions that are troubling.

[1] https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?&substance_nmbr=1025
[2] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/background-information-ethylene-oxide#what
[3] 84 Fed. Reg. 69,213

Use of IRIS for Risk Estimates

For this rulemaking, EPA rightfully begins its analysis using the Integrated Risk Information System (IRIS) estimates for EtO that were updated in 2016. NACAA strongly supports the use of IRIS information. Accordingly, we do not support the deviations from the IRIS estimates that EPA is considering. Our concerns are discussed in greater detail below.

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 MON proposal, EPA itself articulates the fact that IRIS is the first place from which the agency seeks UREs, only turning to other sources when IRIS does not contain the necessary data:

> For residual risk assessments, we generally use UREs from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using California EPA (CalEPA) UREs, where available.[4]

With respect to the IRIS EtO risk value specifically, it was updated in 2016 following an extremely thorough and comprehensive, peer-reviewed evaluation that took nearly two decades, beginning in December 1998, resulting in a cancer risk unit value of 3×10^{-3} per $\mu g/m^3$.[5] It included in-depth assessments on the part of EPA and multiple rounds of extensive internal and external review and public comment, all of which were well documented.

In light of the importance of using the best and most scientifically defensible resources, NACAA is very concerned that EPA is again soliciting public comment on the use of the updated IRIS risk value for regulatory purposes[6] as it did in the Hydrochloric Acid Production RTR proposal, signaling it would consider deviating from those numbers. NACAA's letter of March 28, 2019 includes comments on that proposal.[7]

Additionally, in the MON proposal, it is troubling that EPA discusses two possibilities for straying from and undermining the IRIS numbers. In the first, EPA discusses the uncertainty associated with the current URE for EtO, which the agency then used in the health risk assessment to justify reducing the risk to acceptable levels.[8] 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).[9]

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[4] 84 Fed. Reg. 69,191
[5] https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730
[6] 84 Fed. Reg. 69,218
[7] http://www.4cleanair.org/sites/default/files/Documents/hydrochloric_acid_RTR_comments.pdf
[8] 84 Fed. Reg. 69,217-69,219
[9] 84 Fed. Reg. 69,218

In the second instance, EPA solicits comments on the use of an alternative URE that the Texas Commission on Environmental Quality (TCEQ) recently proposed.[10] The TCEQ proposal differs from the IRIS estimates in a number of ways, resulting in a much less protective risk estimate than the IRIS URE. In particular, a key breast cancer study was not included in the Texas URE determination, however it was included in the IRIS determination.[11]. Additionally, the EtO cancer URE proposed by TCEQ does not reflect observed cancer incidence in occupationally exposed people. By ignoring breast cancer risk and using a poorly fitting model for lymphoid cancers, TCEQ's URE drastically underestimates risks. EPA has failed to adequately explain the differences in the IRIS and TCEQ URE values or why the agency would even consider deviating from the IRIS values in favor of the Texas estimates.

The TCEQ estimates have not been through a transparent, publicly available scientific peer review process commensurate with that of IRIS. The Texas public comment period for its EtO URE closed on September 26, 2019. As a result, the opportunity for the newly affected national stakeholders (outside of Texas) to comment on the Texas URE is no longer available. Further, when the Texas URE was proposed, its determination had no national impact.

NACAA does not support the use of an uncertainty assessment in the health risk assessment to justify reducing the estimated risk to acceptable levels, nor the use of the TCEQ alternative. It is important to note that during the IRIS process for developing the updated EtO URE, the information that EPA is now raising in its uncertainty discussion for this proposal, as well as the data TCEQ relied upon to develop its draft, were available and considered. Yet, with this information in hand, IRIS's thorough assessment and peer-review process ultimately resulted in the URE currently contained in IRIS. To raise this information anew in an effort to second-guess the IRIS results is highly inappropriate.

The uncertainties present in the toxicology determination should not be considered to be over predictions of estimates of risk. Instead 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, EPA should not claim that the IRIS URE is biased toward over-prediction. EPA has not proven why the protective estimates in IRIS should not continue to be considered.

If EPA believes the EtO URE is flawed in some way and needs to be updated again, it should be done through the robust IRIS process for scientific and public peer review. The agency should not use this rulemaking to circumvent, undermine or dilute the IRIS findings.

In summary, considering the scientifically defensible and comprehensive nature of the EtO review that led to the updated URE in 2016, there would be no justification for deviating from the updated IRIS EtO findings during the regulatory process, as EPA is suggesting in this proposal. EPA should not use this proposal (or any other rulemaking, for that matter) to second-guess IRIS to avoid difficult decisions that must be made about control options.

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[10] 84 Fed. Reg. 69,218

[11] https://www.tceq.texas.gov/toxicology/ethylene-oxide

Control Options

It is essential that EPA ensure that its regulations provide the full protections required by the Clean Air Act. Accordingly, we recommend that the controls EPA mandate be those that flow logically from and are based upon the use of the best risk information, which in this case is from IRIS (without amending it through the application of uncertainty estimates), as well as the latest advancements in control technology. EPA should not raise uncertainty in the IRIS URE or fugitive emission estimates as an excuse to not require the emissions reductions that are proposed in this rule.

NACAA commends EPA for recognizing the need for more protective standards and for calling for additional control measures in the proposal. The following improvements, at the very least, should be contained in the final regulations:

- improvements to the leak detection and repair program, including lowering the definition of a leak, increasing the leak-inspection frequency, requiring leaks to be fixed within 15 days and removing the current the leak repair exemption for all pumps in EtO service;[12]

- enhancement of flare destruction efficiencies that go beyond the current general provision flare requirements;[13] and

- inclusion of the work practice provisions designed to prevent releases from pressure relief devices that directly vent to the atmosphere.[14]

EPA should, as appropriate, ensure that compliance with the MON National Emission Standards for Hazardous Air Pollutants (NESHAP) is also considered to be compliance with the New Source Performance Standards (NSPS) for this source category as well by adding reference to NSPS Subpart VVa to the existing reference to Subpart VV. Typically, NESHAPs are more stringent than NSPSs for a particular source category, so it makes sense that compliance with the MON would also be considered compliance with an analogous NSPS (in this case, Subparts VV and VVa), as long as the more stringent standard is the one that the source must meet (in this case, the MON). The concurrent coverage streamlines recordkeeping and reporting and eliminates unnecessary duplication.

Concentrations at Census Tract Centroids

In assessing the cancer risks related to the source category, EPA used long-term concentrations affecting the census blocks within 50 kilometers of each facility.[15] This analysis dilutes the effect of sources' emissions by estimating the impact at the centroid of the census block instead of at the property line or wherever the maximum exposed individual is. Census blocks can be large geographically, depending on the population density, so the maximum point of impact can be far from the centroid. It could be elsewhere in the census block, including at or near the

[12] 84 Fed. Reg. 69,214, 69,215 and 69,223
[13] 84 Fed. Reg. 69,199
[14] 84 Fed. Reg. 69,208
[15] 84 Fed. Reg. 69,191

property line where people may live or work. EPA itself alludes to this problem in the proposal.[16] Further, even if the area near the property line is not developed, over time homes and businesses could locate closer to the facility. While it is possible that population distribution is homogenous over a census block, this assumption is not necessarily accurate in considering the predicted impacts from the location of a source. NACAA recommends EPA identify and use the truly maximum individual risk, irrespective of its location in the census block, rather than using the predicted chronic exposures at the census block centroid as surrogates for the exposure concentrations for all people living in that block.

Facility-Wide and Cumulative Risks

EPA has rightly recognized the importance of considering the impact of emissions from all hazardous air pollutant (HAP) emitting operations in a facility to determine the facility-wide risks, rather than focusing solely on the source category that is the subject of the regulation.[17] This should continue to be standard practice when developing RTR regulations.

Acute Exposure

NACAA's past comments have raised concerns with EPA's use of Acute Exposure Guideline Levels (AEGLs) or Emergency Response Planning Guidelines (ERPGs) values to address acute exposures in the residual risk assessments. It appears EPA is still using them for those purposes in this proposal.[18] These limits were developed for accident release emergency planning and are not appropriate for assessing daily human exposure scenarios. In the December 2002 EPA document, "A Review of the Reference Dose and Reference Concentration Processes," the agency stated that the primary purpose of the AEGL program is to develop guidelines for once-in-a-lifetime short-term exposures to airborne concentrations of acutely toxic chemicals. They are not meant to evaluate the acute impacts from routine emissions that occur over the life of a facility. Unlike the reference concentrations (RfCs) for chronic exposures, the AEGLs and ERPGs do not include adequate safety and uncertainty factors and cannot be relied upon to protect the public from the adverse effects of exposure to toxic air pollutants. The use of AEGLs or ERPGs in residual risk assessments is not appropriate and does not ensure that public health is adequately protected from the acute impacts of HAP exposure. EPA has included the use of the California Reference Exposure Levels (RELs) to address acute exposures in the residual risk assessments[19] and EPA should use the RELs for these assessments.

Allowable Emissions

EPA should consider potential or allowable emissions, rather than actual emissions, as much as possible in evaluating residual risk. Since facility emissions could increase over time for a variety of reasons, and with them the associated impacts, the use of potential or allowable emissions is more appropriate. An analysis based on actual emissions from a single point in time could underestimate the residual risk from a source category. Further, the major source HAP

[16] 84 Fed. Reg. 69,196
[17] 84 Fed. Reg. 69,195
[18] 84 Fed. Reg. 69,192
[19] 84 Fed. Reg. 69,192

thresholds are based on maximum potential-to-emit, as opposed to actual emissions, and air agencies issue permits based on potential emissions. Limiting the scope of a risk evaluation to actual emissions would be inconsistent with the applicability section of Part 63 rules, so we were pleased to see references to the use of allowable emissions.[20] The agency should use allowable emissions as much as possible in the future, including in assessing acute health risks.

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

Sincerely,

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New Jersey
Co-Chair
NACAA Air Toxics Committee

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Co-Chair
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[20] 84 Fed. Reg. 69,190