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

December 18, 2019

OFFICE OF
AIR AND RADIATION

Mr. William P. Gulledge
Senior Director
Chemical Products and Technology Division
American Chemistry Council
700 Second Street NE
Washington, DC 20002

Dear Mr. Gulledge:

This letter is in response to the September 20, 2018 Request for Correction (RFC) that you submitted, under section 515 of Public Law 106-554 (Information Quality Act, IQA), to the U.S. Environmental Protection Agency (EPA) on behalf of the Ethylene Oxide Panel of the American Chemistry Council (ACC). In the RFC, you request correction of the ethylene oxide (EtO) information in EPA's most recent update to the National Air Toxics Assessment (NATA) released on August 22, 2018.[1]

Summary of the Request

The NATA is EPA's periodic review of air toxics in the United States that is conducted approximately every three years as a screening tool for state, local, and tribal air agencies to help these agencies identify which pollutants, emission sources, and places they may wish to study further to better understand any possible risks to public health from air toxics. The most recent NATA was based on the 2014 emissions inventory (2014 NATA). The 2014 NATA relies upon the December 2016 *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)*,[2] referred to here as the "2016 EtO IRIS Assessment," to estimate potential health risks from EtO emissions from stationary sources.

The ACC argues that the 2014 NATA does not meet the IQA's criteria for quality, objectivity, utility, and integrity because it bases its evaluations of EtO risk on values reported in the 2016 EtO IRIS Assessment that the ACC asserts "is not the best available science." Instead, the ACC wants the 2014 NATA to base its evaluations of EtO risk on values in an ACC-sponsored 2010 journal article: *Valdez-Flores C, Sielken RL Jr, Teta MJ. 2010. Quantitative cancer risk assessment based on NIOSH and UCC epidemiological data for workers exposed to ethylene oxide. Regul Toxicol Pharmacol, 56(3): 312-20.*

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[1] The 2014 NATA is available at *https://www.epa.gov/national-air-toxics-assessment.*
[2] The 2016 EtO IRIS Assessment is available at:
https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?&substance_nmbr=1025.

EPA's Response to the ACC

As indicated in section 8.5 of EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (IQG),[3] if a group or an individual raises a question regarding information supporting a proposed rule, EPA generally expects to treat it procedurally like a comment to the rulemaking, addressing it in the response to comments rather than through a separate response mechanism. EPA believes that the thorough consideration provided by the public comment process serves the purposes of the IQG, provides an opportunity for correction of any information that is inconsistent with the IQG, and does not duplicate or interfere with the orderly conduct of the action. As such, when an information quality issue is raised on an EPA study, analysis or information that is disseminated with the draft or proposed action for public review and comment, EPA generally addresses it in the context of the final Agency action that relies on the information product.

In this regard, at the time the 2014 NATA was released, EPA had already initiated residual risk and technology reviews (RTR) for several National Emissions Standards for Hazardous Air Pollutants (NESHAP) source categories in which it was anticipated that information reported in the 2016 EtO IRIS Assessment would be at issue.

Specifically, information in the 2016 EtO IRIS Assessment is being used to support regulatory rulemakings under Section 112 of the Clean Air Act (CAA). These include the RTR review for the *NESHAP: Hydrochloric Acid Production*[4] proposed on February 4, 2019 and the RTR review for the *NESHAP: Miscellaneous Organic Chemical Manufacturing* (MON),[5] signed on November 1, 2019. Because EPA received comments from the ACC and others on the HCl proposed rule related to use of information in the 2016 EtO IRIS Assessment, and given that EPA anticipates receiving additional comments focused on the 2016 EtO IRIS Assessment in the MON RTR rulemaking, EPA believes it is appropriate to address this RFC as part of the MON RTR rulemaking.

The MON RTR rulemaking is the first RTR in which EtO is the regulated pollutant, and EPA thinks the way to ensure full consideration of all the comments it has received, and is expected to receive, from numerous entities on the 2016 EtO IRIS Assessment is to address them in that rulemaking.

In addition to the opportunities for public participation in the assessment of risks for EtO, the rulemaking process provides clear opportunities for public review and comment on the Agency's proposed risk reduction regulations under the CAA, including review and comment of the materials considered in the development of that action. The Agency reviews and considers all comments received related to each proposed rule, and, when the final rule is issued, provides

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[3] The IQG is available at *https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information*

[4] The Hydrochloric Acid (HCl) Production RTR is available at *https://www.epa.gov/stationary-sources-air-pollution/hydrochloric-acid-production-national-emission-standards-hazardous*

[5] The MON RTR is available at *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission*

the Agency responses to substantive comments.

Your Right to Appeal

If you are dissatisfied with this response, you may submit a Request for Reconsideration (RFR) to EPA. EPA requests that any such RFR be submitted within 90 days of the date of this response. If you choose to submit an RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 281 1R, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460); electronic mail (quality@epa.gov); or fax (202-565-2441). If you submit an RFR, please reference the request number assigned to the original Request for Correction (RFC #18003). Additional information about how to submit an RFR is listed on the EPA Information Quality Guidelines website at: *https://www.epa.gov/quality/frequent-questions-about-epas-quality-system#disagree-qg*.

Again, thank you for your letter. I appreciate the opportunity to be of service and trust the information provided is helpful.

Sincerely,

Anne L. Idsal
Acting Assistant Administrator

cc: David Harlow, OAR
David Dunlop, ORD
Peter Tsirigotis, OAR, OAQPS
Kevin Kirby, OMS