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

December 13, 2021

OFFICE OF
AIR AND RADIATION

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

Via Electronic Mail: Bill_Gulledge@americanchemistry.com

Dear Mr. Gulledge:

Thank you for the Request for Correction (RFC) you submitted on September 20, 2018 under section 515 of Public Law 106-554, Consolidated Appropriations Act (2001; known as the 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). The RFC was assigned RFC# 18003 for tracking purposes. 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] As explained below and in the attached memorandum from EPA's Office of Research and Development (ORD), EPA concludes that the RFC has not identified a need for correction.

Summary of the Request

The NATA is EPA's periodic review of air toxics in the United States, which has been 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) and released in August 2018. 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.

[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.

The ACC claims 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 requests that the 2014 NATA 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.*

Background

EPA initially responded to this request in a letter dated December 18, 2019, to the ACC from then Acting Assistant Administrator Anne L. Idsal. The letter cited 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] stating that "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." 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.

Specifically, information in the 2016 EtO IRIS Assessment was 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] proposed 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 anticipated receiving additional comments focused on the 2016 EtO IRIS Assessment in the MON RTR rulemaking, EPA stated in the December 18, 2019, letter to the ACC that EPA would address this RFC as part of the MON RTR rulemaking, the first RTR in which EtO is the regulated pollutant and for which the inhalation URE from the 2016 EtO IRIS Assessment was used.

The ACC submitted comments on the MON RTR proposal, which EPA addressed in the final MON rule. However, because EPA was under a court ordered deadline to issue the final MON rule by May 29, 2020, EPA determined that it was appropriate to issue the final MON rule separately from the Agency response to the September 20, 2018, RFC to ensure that the ACC's request would be given the complete attention it warrants.

[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

EPA's Response to the ACC

Under section 515 of the Consolidated Appropriations Act (2001; known as the Information Quality Act), the purpose of an RFC is to allow "affected persons to seek and obtain correction of information maintained and disseminated by the agency…"

EPA has reviewed the ACC's September 20, 2018, RFC and finds this document has not identified a need for correction in the 2016 EtO IRIS Assessment. The attached memorandum, *ORD review of comments on the IRIS EtO assessment contained in the ACC Request for Correction submitted regarding EPA's National Air Toxics Assessment,* provides detailed responses to the comments presented in the RFC regarding the 2016 EtO IRIS Assessment's reliance on the NIOSH cohort studies, choice of dose-response models, and consideration of endogenous sources of EtO. EPA has determined that the inhalation unit risk estimate (URE) derived in the 2016 EtO IRIS Assessment was the appropriate human health value to use for EtO in the 2014 NATA.[6]

Your Right to Appeal

If you are dissatisfied with this response, you may submit a Request for Reconsideration (RFR). EPA requests that any such RFR be submitted within 90 days of the date of EPA's response. If you choose to submit an RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Enterprise Quality Management Division, Mail Code 2821T, USEPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460); or electronic mail (quality@epa.gov). If you submit an RFR, please reference the IQG identifier assigned to this original Request for Correction (RFC # 18003). Additional information about how to submit an RFR is listed on the EPA Information Quality Guidelines website at http://epa.gov/quality/informationguidelines/index.html.

Sincerely,

Joseph Goffman
Principal Deputy Assistant Administrator

cc: Peter Tsirigotis, EPA/OAR/OAQPS
Robert Tallent, EPA/OMS
Wayne Cascio, EPA/ORD

[6] EPA's use of the IRIS value in CAA rulemakings will be addressed in the reconsideration of the final rule, "National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing (MON) Residual Risk and Technology Review" (85 FR 49084, August 12, 2020). This review will include consideration of additional information presented in comments on the MON that were not included in the 2018 Request for Correction.