March 14, 2022

**Via Email (quality@epa.gov)**
EPA Information Guidelines Processing Staff
Enterprise Quality Management Division
US Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code 2821T
Washington, DC 20460

Re: Request for Reconsideration of Agency Denial of Information Quality Act Request for Correction of 2014 National Air Toxics Assessment (NATA); RFC #18003

Dear Sir or Madam:

The Ethylene Oxide Panel of the American Chemistry Council (ACC) submits this Request for Reconsideration to EPA under the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA Guidelines).[1] ACC's Request for Correction (RFC #18003) of ethylene oxide (EO) information disseminated in the 2014 update to the National Air Toxics Assessment (NATA) was submitted on September 20, 2018. The Request was denied in a letter from Principal Deputy Assistant Administrator Joseph Goffman dated December 13, 2021. Both the original Request and the Agency's response are enclosed.

The 2014 NATA relies upon the "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] to determine the risk value for EO. As described in detail in ACC's Request, the 2014 NATA does not meet the Information Quality Act's (IQA) data quality requirements because EPA did not apply a transparent and systematic weight-of-evidence approach in assessing the cancer risks of EO exposures in the 2014 NATA and did not rely upon the best available science.

The 2014 NATA is influential scientific risk assessment information and must adhere to a rigorous standard of quality. The 2014 NATA is "influential" scientific risk assessment information as set forth in the EPA Guidelines because it "will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions" and involves "controversial scientific … issues."[3] Therefore, the 2014 NATA, and its underlying data, must adhere to a rigorous standard of quality, including meeting the higher standard of reproducibility. The EPA Guidelines require the use of the "best available science and supporting studies" and the collection of data using by

[1] EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (Oct. 2002).
[2] EPA/635/R-16/350Fa (December 2016) (EO IRIS Assessment).
[3] See EPA Guidelines, at 19-20 (internal citations omitted); 67 Fed. Reg. 8452, 8455 (Feb. 22, 2002) (OMB Guidelines).

"accepted methods or the best available methods" using "a 'weight-of-evidence' approach that considers all relevant information and its quality."[4]

EPA's response is not consistent with EPA or OMB Guidelines, or IQA guidance provided by OMB.[5] EPA's denial does not adequately respond to the significant factual issues raised by the Request. The letter simply asserts that "EPA concludes that the RFC has not identified a need for correction," citing to a memo issued by the EPA Office of Research and Development (ORD) in August 2021. The ORD memo relies almost entirely on statements from the Science Advisory Board review of the EO IRIS Assessment in 2015, without direct responding to the scientific arguments raised in the request. OMB's IQA guidance clarifies that "[t]he agency response should contain a point-by-point response to any data quality arguments contained in the RFC."[6]

The Agency has not addressed a number of the specific issues raised by ACC related to the use of the EO IRIS value in the NATA. These issues include:

- The implausibility of the supra-linear spline model based on the epidemiological and biological evidence;
- The deficiencies in the model due to statistical miscalculations and visual misrepresentations; and
- The failure to incorporate relevant findings from other high-quality epidemiology studies.

ACC intends to submit detailed comments on these issues in connection with its comments on the pending MON Reconsideration notice, which incorporates EPA's denial of this petition into EPA's basis for continuing to rely upon the IRIS value for regulatory purposes. ACC requests that EPA consider the information submitted to the docket for that rule in connection with its reconsideration of the denial at issue here. Upon completion of that review, ACC requests that the 2014 NATA risk estimates for EO be withdrawn and corrected to reflect scientifically-supportable risk values. Please feel free to contact me at 202-249-6714 or Bill_Gulledge@americanchemistry.com if you have questions on the above information.

Sincerely,

*William Gulledge*

William P. Gulledge

Senior Director, Chemical Products & Technology Division

[4] See EPA Guidelines, at 21-22.
[5] OMB, Memorandum from Acting Director Russell T. Vought, Improving Implementation of the Information Quality Act (M19-15) (OMB Memorandum) (April 24, 2019).
[6] Id. at 10.