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

July 22, 2022

OFFICE OF MISSION SUPPORT

William P. Gulledge
American Chemistry Council
700 Second St., NE
Washington, DC 20002

Dear Mr. Gulledge,

This letter is in response to your Request for Reconsideration (RFR), received by the U.S. Environmental Protection Agency on March 14, 2022, which was assigned RFR number 18003A for tracking purposes. Your RFR requests that the Agency reconsider its denial of your Request for Correction (RFC) 18003, in which you requested that EPA should not use the ethylene oxide (EtO) IRIS Assessment's inhalation unit risk estimate (URE) to calculate cancer risk in the 2014 NATA or ongoing Clean Air Act (CAA) rulemakings. Your RFR highlights three issues which you assert were not addressed in our response to your RFC.

In accordance with EPA's Information Quality Guidelines, a three-member executive panel met on May 18, 2022 to review your request and the information you provided. The panel determined that the original reasoning behind EPA's denial of the RFC# 18003 remains sound. The panel found that the RFR did not identify errors related to EPA's use of the 2016 EtO IRIS assessment's inhalation cancer risk value.

We emphasize that the points raised in the RFC and restated in the RFR were previously addressed during the extensive public comment and peer review process that was completed prior to publication of the 2016 EtO IRIS assessment. In the process, ACC submitted extensive comment expressing its view that a model predicting less risk should be chosen, and EPA addressed these public comments. Because the RFC primarily raised scientific issues to which EPA had already responded during the IRIS peer review process, EPA's detailed response to the RFC referenced existing analysis and Science Advisory Board (SAB) advice that can be found in the appendices of the 2016 EtO IRIS assessment. EPA's response to the RFC included an attached memo from the Office of Research and Development to the Office of Air and Radiation, which specifically addressed the three issues highlighted in the RFR.

The first issue is a claim regarding "the implausibility of the supra-linear spline model based on the epidemiological and biological evidence." We responded to this point in section 2a of the memo where we explain that statistical model selection was based on model fit with the observed results in the NIOSH study, and was consistent with peer review advice received from the SAB. In the terminology of cancer risk assessment and EPA's Carcinogen Guidelines, the EPA two-piece linear spline model predicts a linear association between environmentally relevant EtO exposures and cancer risk.

The second issue is a claim that there are "deficiencies in the model due to statistical miscalculations and visual misrepresentations." We responded to this point in sections 2b and 2c of the memo. In section 2b, we affirmed that the statistical approach is reasonable and that the spline model represents data in the low exposure region of interest. We also noted that the statistical model preferred by ACC was previously evaluated by EPA and found to be a poor fit of the data in the low exposure region. In section 2c, we directed the reader to the SAB (2015) peer review, which noted consistency in model fit and categorical results.

The third issue is a claim that there was a "failure to incorporate relevant findings from other high-quality epidemiology studies." We responded to this point in section 1 of the memo where we noted that the extensive SAB peer review process resulted in the selection of the NIOSH epidemiological study as the basis of the EtO IRIS assessment. In addition, the IRIS assessment contains a very extensive analysis of the findings, strengths, and limitations of the number of studies that comprise the EtO cancer epidemiology database. The integrated analysis of this database, together with evaluation of experimental animal and mechanistic information, supported EPA's conclusions about the carcinogenicity and target organs of EtO. ACC comments on EtO epidemiology studies, including a view that another study should be used in quantitation, was carefully considered prior to the completion of the IRIS assessment.

EPA declines to include in this RFR any information that may be submitted by the petitioner in the forthcoming MON Reconsideration Notice because it is outside the scope of the RFR process. The intent of the RFR process is to evaluate the agency's decision on the petitioner's RFC (RFC 18003) and determine if corrective action is appropriate (EPA's Information Quality Guidelines).

Therefore, the executive panel determined that the Agency's use of the 2016 EtO IRIS Assessment's inhalation URE in the 2014 NATA is an appropriate use of best available science to inform decision making, and that assessment was developed according to our scientific integrity policy, peer review handbook, and information quality guidelines. As a result, EPA is denying your RFR. Your comments on the use of the IRIS value in the Miscellaneous Organic Chemical (MON) National Emissions Standards for Hazardous Air Pollutants (NESHAP) under the CAA are deferred to the MON reconsideration comment process.

EPA remains committed to the guidelines established by the Office of Management and Budget for maximizing the quality, integrity, objectivity, and reproducibility of information we disseminate to the public.

Thank you for your interest in EPA's information quality.

Sincerely,

VAUGHN NOGA Digitally signed by VAUGHN NOGA
Date: 2022.07.22 12:56:35 -04'00'

Vaughn Noga, Chief Information Officer and
Deputy Assistant Administrator for Environmental Information