



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

June 7, 2023

OFFICE OF MISSION SUPPORT

Ms. Judith Nordgren
Managing Director, Chlorine Chemistry Division
American Chemistry Council
700 Second Street, NE
Washington, D.C. 20002

Dear Ms. Nordgren:

This letter is in response to your Request for Reconsideration 16002A¹ dated August 22, 2019, that was submitted to the U.S. Environmental Protection Agency pursuant to EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency² (EPA IQG). These guidelines outline administrative mechanisms for EPA pre-dissemination review of information products and describe mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe does not comply with EPA or Office of Management and Budget Guidelines³ (i.e., OMB Information Quality Guidelines and Memorandum M-19-15).⁴ EPA is committed to applying these guidelines, including each of the updates outlined in M-19-15 to the EPA Information Quality Guidelines.

Your RFR asks the Agency to reconsider its response of May 24, 2019,⁵ which denied your Request for Correction 16002⁶ regarding the Agency's basis for conclusions about the potential exposure to 1,2-dichloroethane (ethylene dichloride or EDC (CASRN 107-06-2) and its planned review of this chemical as part of the Agency's chemical assessment efforts under the TSCA Work Plan. Specifically, you asked the Agency to revise its conclusions about the potential exposure to EDC as presented in the 2012 and 2014 TSCA Workplan documents, and that, as a result of those revisions, EDC should be removed from the TSCA Work Plan.

In accordance with EPA's IQG, a three-member executive panel met on May 30, 2023, to review your original RFC, the EPA response, and the RFR. The panel determined that the original reasoning behind EPA's denial of RFC 16002 was appropriate and consistent with the EPA IQG.

The Panel has determined that the documents entitled "TSCA Work Plan for Chemicals Assessments" (2014 Update) and the TSCA Work Plan Chemicals Methods Document (2012) are specifically incorporated into the language of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016 (Pub. L. 114-182),⁷ and that

¹ <https://www.epa.gov/quality/rfr-16002a-request-reconsideration-transmittal-letter-dated-082219-received-082219>

² <https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information>

³ https://www.epa.gov/sites/default/files/2021-03/documents/omb_iqgs.pdf

⁴ https://www.epa.gov/sites/default/files/2020-11/documents/omb-m-19-15_1.pdf

⁵ <https://www.epa.gov/quality/epa-response-rfc-16002-issued-05242019>

⁶ <https://www.epa.gov/quality/rfc-16002-tsca-work-plan-ethylene-dichloride>

⁷ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>

the documents and inclusion of EDC in those documents are not subject to revision. As such, the denial of your requests to make these revisions is appropriate as a legal matter.

In addition, we note that OMB encourages agencies to incorporate standards and procedures into existing information resources management practices rather than create new, potentially duplicative processes. As such, we outline the TSCA existing chemical evaluation process, which includes multiple opportunities for public participation throughout the 3 key steps, which consist of prioritization, risk evaluation and risk management. As you noted in your RFR, in describing its approach for prioritization, EPA stated that it will identify and review reasonably available information, including any new information.⁸ EPA further indicated that any conclusions in the 2014 TSCA Work Plan simply provides a starting point for prioritization under the TSCA existing chemical evaluation process and do not otherwise restrict the Agency's consideration of other relevant information, thereby providing another opportunity to correct or provide additional information for consideration.

In releasing the final designations in 2019,⁹ the Agency provided a detailed explanation of the process and its considerations, including its consideration of comments and additional information submitted during the two public comment periods, which was supplemented with additional details in the docket.¹⁰ EPA further explained that the designations are based on the conclusion that each chemical substance satisfies the definition of High-Priority Substance in TSCA section 6(b)(1)(B) and 40 CFR §702.3.¹¹ EPA also reiterated that a designation of a chemical substance as a high-priority substance is not a finding of unreasonable risk; rather, a final designation as a high-priority substance initiates the risk evaluation for the chemical substance. EPA developed a document for each substance to identify the information, analysis and basis used to support the designations. EPA also specifically explained that additional submitted information specific to high-priority substances (*e.g.*, relevant studies and assessments) will be considered in subsequent phases of risk evaluation and incorporated, as appropriate in draft scope documents and draft risk evaluation documents. These documents are subject to public comment opportunities.

EDC has progressed under the TSCA existing chemical evaluation process, completing the prioritization step in December 2019 after two opportunities for public comment on the Agency's considerations associated with its identification as a candidate for prioritization and its designation as a high priority substance for risk evaluation under TSCA.¹² In addition, EDC also completed the initial phase of the risk evaluation step under the TSCA existing chemical evaluation process, with the issuance (after undergoing public comment) of the final scope document in August 2020.¹³ The final scope document identifies the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations the EPA plans to consider in conducting the risk evaluation for EDC. EPA is currently conducting the risk evaluation for EDC and the risk evaluation process includes at least 2 more public comment opportunities, including an opportunity to present comments for external peer review and participation in a public meeting.

⁸ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation>

⁹ <https://www.federalregister.gov/documents/2019/12/30/2019-28225/high-priority-substance-designations-under-the-toxic-substances-control-act-tsca-and-initiation-of>

¹⁰ <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0131-0027>

¹¹ <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-702/subpart-A/section-702.3>

¹² <https://www.federalregister.gov/documents/2019/12/30/2019-28225/high-priority-substance-designations-under-the-toxic-substances-control-act-tsca-and-initiation-of>

¹³ <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0427-0048>

The Panel also determined that the issues you raised in your RFC and RFR are duplicative with comments raised during the ongoing public engagement process and reiterate that the ongoing public comment process for the existing chemical evaluation of EDC is the appropriate venue to submit comments and, hence, EPA is denying your RFR.

Thank you for your interest in EPA's information quality. Should you have questions or need additional information about the EPA's IQG process, you may contact us via email at quality@epa.gov (our preferred method), or via regular mail to the EPA Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460.

Sincerely,

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

cc: Michal Freedhoff, Assistant Administrator for Chemical Safety and Pollution Prevention