American Chemistry Council | Chlorine Chemistry Division

August 22, 2019

VIA ELECTRONIC MAIL (quality@epa.gov)
Information Quality Guidelines Processing Staff
Mail Code 2811R
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Request for Reconsideration of Agency denial of Information Quality Act Request for Correction of the TSCA Work Plan for Chemical Assessments: 2014 Update (October 2014) and TSCA Work Plan Chemicals: Methods Document (February 2012) regarding assessment of 1,2-dichloroethane (ethylene dichloride, CAS number 107-06-2); RFC #16002

Dear Sir or Madam:

The Chlorine Chemistry Division (CCD) 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 IQ Guidelines).[1] CCD's Request for Correction (RFC #16002) of numerous factual errors in documents developed for the Office of Pollution Prevention and Toxics (OPPT) TSCA Work Plan Chemicals Assessment Process related to potential exposure to, and environmental persistence of, 1,2-dichloroethane (ethylene dichloride or EDC) was submitted on December 15, 2015. The Request was denied in a letter from Assistant Administrator Alexandra Dapolito Dunn dated May 24, 2019. Both the original Request and the Agency's response are enclosed.

The information on EDC and the other chemicals presented in the 2012 Work Plan Chemicals Methods Document and the 2014 Update has the potential to result in major cross-Agency or cross-media policies.[2] Moreover, Congress amended TSCA in 2016 to accelerate review of existing chemicals – directing EPA to include at least 50 percent of the chemicals under review from the Work Plan. Earlier this year, EPA identified EDC and 19 other Work Plan chemicals as high-priority candidates for risk evaluation under TSCA over the next three years. Therefore, the Work Plan is "influential scientific, financial, or statistical information" since it "will have or does have a clear and substantial impact … on important public policies or private sector decisions."[3] As such, OPPT must ensure the quality,

[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] The 2012 Methods Document notes that OPPT considered presence in biota, drinking water, ambient and indoor air, and house dust as part of the Work Plan assessment.

[3] See EPA IQ Guidelines, at 19-20; see also OMB, Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies (OMB IQ Guidelines), 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002).

objectivity, and utility of the information and provide "sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public."[4]

EPA's denial does not respond to the significant factual issues raised by our Request. The letter asserts, rather, that

> As amended, TSCA specifically cites to the TSCA Work Plan Chemicals Methods Document of2012 and the 2014 update of the TSCA Work Plan for Chemical Assessments in the context of the mandates associated with the evaluation of existing chemicals (e.g., see TSCA section 6(b)). Having been specifically incorporated into TSCA, neither document (or the inclusion of ethylene dichloride in those documents) is subject to revision.

The letter concludes, "ACC's detailed comments that are provided in this RFC are best considered in the context of the public comment opportunities and review activities in the existing chemicals program under TSCA. As such, EPA will consider your comments when we conduct prioritization of ethylene dichloride."

While Congress referenced the Work Plan to aid the Agency in meeting the timelines laid out in the legislation,[5] it did not intend that the Work Plan serve as a mandate for prioritization. The Agency itself notes the need for flexibility in its prioritization guidance:

> TSCA requires EPA to evaluate the chemicals on the 2014 Work Plan as part of prioritization and risk evaluation; however, EPA is not bound by the findings of the 2014 Work Plan. EPA recognizes that science approaches have evolved and additional information has been developed for chemicals on the 2014 Work Plan. When a chemical is considered for prioritization, EPA will identify and review reasonably available information, including any new information.[6]

Therefore, EPA's response is not consistent with EPA or OMB IQ Guidelines, or recent IQA guidance provided by OMB.[7] The Agency fails to explain how OPPT met the essential requirements of the OMB guidelines to "make [the] methods transparent by providing documentation, ensure quality by reviewing the underlying methods used in developing the data and consulting (as appropriate) with experts and users, and keep users informed about corrections and revisions."[8]

OMB's recent IQA guidance clarifies that "agencies should not opine on the requestor's or the agency's policy position" and "[t]he agency response should contain a point-by-point response to any data quality

[4] OMB IQ Guidelines, at 8460.

[5] Senate Environment and Public Works Committee. Report – Frank R. Lautenberg Chemical Safety for the 21st Century Act. Report 114-7 (June 18, 2015), at 9.

[6] EPA. A working approach for identifying potential candidate chemicals for prioritization. Office of Chemical Safety and Pollution Prevention (Sept. 2018), at 7.

[7] OMB, Memorandum from Acting Director Russell T. Vought, Improving Implementation of the Information Quality Act (M19-15) (OMB Memorandum) (April 24, 2019).

[8] OMB IQ Guidelines, at 8453.

arguments contained in the RFC and should refer to a peer review that directly considered the issue being raised, if available."[9] The Agency has not addressed any of the specific issues raised by CCD related to potential exposure to, and persistence and bioaccumulation potential of, EDC. These issues include:

- the National Health and Nutrition Examination Survey (NHANES) data from the Center for Disease Control and Prevention indicating that EDC was not detected in the blood of at least 95 percent of the US residents sampled in 2003-2004 and 2005-2006,
- EPA's 2011 National Air Toxics Assessment (NATA) estimate that only 13 census tracts, representing 0.02% of the US population, may be exposed to concentrations of 0.01 microgram per cubic meter of EDC or higher, and
- EPA's National Contaminant Occurrence Database (NCOD) indicating that EDC was detected in less than 1 percent of the drinking water samples collected.

These data, readily available to EPA during preparation of the Work Plan, do not support an exposure score of 3 (high) as assigned in the Work Plan. Since submission of the 2015 RFC, moreover, all three of these data sources have been updated to provide further evidence for a low potential for exposure to EDC.

CCD requests that OPPT revise its conclusions about the potential exposure to EDC to accurately reflect the available information on uses, emissions, and environmental presence and persistence of the substance. Such revision will clearly indicate that the potential for exposure to the chemical is quite low and that review under the TSCA Work Plan Chemicals Assessment Process is not supported by the available information. Consequently, EDC should be removed from the TSCA Work Plan.

Please feel free to contact me at 202-249-6709 or judith_nordgren@americanchemistry.com if you have questions on the above information.

Sincerely,

Judith Nordgren

Judith Nordgren
Managing Director
Chlorine Chemistry Division

Enclosures

cc: Alexandra Dapolito Dunn, Assistant Administrator, Office of Chemical Safety and Pollution Prevention

[9] OMB Memorandum, at 10.