

american cleaning institute®



July 12, 2024

Via E-Mail

Information Quality Guidelines Staff U.S. Environmental Protection Agency 1200 Pennsylvania Ave., N.W. (Mail Code 28221T) Washington, DC 20460 E-mail: <u>quality.guidelines@epa.gov</u>

> Re: Request for Reconsideration of EPA's Decision to Deny a Request for Correction of Information under the Information Quality Act: The Toxic Substances Control Act (TSCA) Risk Evaluation for 1,4-Dioxane

Dear Sir or Madam:

The American Cleaning Institute[®] (ACI) and the American Chemistry Council (ACC) (collectively, ACI/ACC) submit this Request for Reconsideration (RFR) of the U.S. Environmental Protection Agency's (EPA) decision to deny ACI/ACC's December 2023 Request for Correction of Information (RFC) under the Information Quality Act on the final "*Risk Evaluation for 1,4-Dioxane CASRN: 123-91-1*" (Final 1,4-DX RE) issued by EPA's Office of Pollution Prevention and Toxics (OPPT) in December 2020.¹ We believe that EPA's Information Quality Act (IQA) guidelines, discussed below, require EPA to reexamine its conclusion regarding the carcinogenicity of 1,4-dioxane (1,4-DX) based on a systematic review of literature published between issuance of the Final 1,4-DX RE in December 2020 and the "*Draft Supplement to the Risk Evaluation for 1,4-Dioxane CASRN 123-91-1*" (the 2023 Draft Supplement) in July 2023.²

¹ EPA (2020), *Final Risk Evaluation for 1,4-Dioxane CASRN: 123-91-1*, EPA Document EPA-740-R1-8007, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency (EPA), <u>https://www.epa.gov/sites/default/files/2020-12/documents/1._risk_evaluation_for_14-dioxane_casrn_123-91-1.pdf</u>.

² EPA (2023a), Draft Supplement to the Risk Evaluation for 1,4-Dioxane, CASRN 123-91-1, EPA Document # EPA-740-D-23-001, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency (EPA), <u>https://www.epa.gov/system/files/documents/2023-</u> 07/1.%20Draft%20Supplement%20to%20the%20Risk%20Evaluation%20for%2014-Dioxane%20-%20public%20release%20-%20hero%20-%20July%202023.pdf.

ACI/ACC submitted their RFC on December 14, 2023.³ EPA issued its decision to deny the RFC on April 16, 2024.⁴ ACI/ACC appreciate EPA's response to its RFC. However, EPA's response did not substantively address the content of the RFC or the underlying requirements of the IQA.

EPA stated in its denial that "[it] has concluded that the issues raised in this RFC are duplicative with comments and submissions received and addressed in the public comment opportunities associated with the development of the [Final 1,4-DX RE]."⁵ We respectfully disagree with these statements. EPA was repeatedly made aware of the deficiencies with its 2018 document titled "*Application of Systematic Review in TSCA Risk Evaluations*" (the "2018 SR Document"), as used in the Final 1,4-DX RE. In July 2019, a public commenter expressed concern over EPA's systematic review at the TSCA Science Advisory Committee on Chemicals (SACC) peer review meeting for the draft risk evaluation on 1,4-DX. The public commenter specifically stated the following: ⁶

The first critical piece of missing information is creating a protocol which is used to review all the evidence and outline the process for conducting the review. *This helps minimize bias and ensure transparency in the decision-making process*. It's also required by law to have a preestablished protocol, and there's not one for 1,4-Dioxane or the other TSCA chemicals. [emphasis added]

In February 2021, the National Academies of Science, Engineering, and Medicine (NASEM) issued a consensus report on the 2018 SR Document. NASEM concluded that the 2018 SR Document did not meet the criteria of "comprehensive, workable, objective, and transparent" and that "The OPPT approach to systematic review does not adequately meet the state-of-practice."⁷

³ ACC/ACI (2023), Request for Correction of Information under the Information Quality Act: The Toxic Substances Control Act (TSCA) Risk Evaluation for 1,4-Dioxane, American Cleaning Institute (ACI) and the American Chemistry Council (ACC), <u>https://www.epa.gov/system/files/documents/2023-12/aci-acc-rfc-for-14dx-dec-2023</u> final.pdf.

⁴ EPA (2024), Response to Request for Correction of Information under the Information Quality Act: The Toxic Substances Control Act (TSCA) Risk Evaluation for 1,4-Dioxane (RFC 23003), U.S. Environmental Protection Agency (EPA), <u>https://www.epa.gov/system/files/documents/2024-04/23002_rfc_14-dioxaneriskevaluation_epa_response_2024-04-16.pdf</u>.

⁵ *Id.* at 2.

⁶ EPA (2019) EPA Scientific Advisory Committee on Chemicals (SACC), Open Meeting, Toxic Substances Control Act, 1,4-Dioxane, Docket number: EPA-HQ-OPPT-2019-0238, Holiday Inn Rosslyn at Key Bridge, 1900 Fort Myer Drive, Arlington, VA 22209, July 29-30, 2019, 497 pp., <u>https://downloads.regulations.gov/EPA-HQ-OPPT-2019-0238-0064/content.pdf.</u>

⁷ NASEM (2021) The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, Consensus Study Report, Highlights, (Feb. 2021) at p. 4, <u>https://www.nap.edu/resource/25952/TSCA%204-pager%20final.pdf</u>.

In response to the NASEM review, EPA revised its systematic review method. On December 20, 2021, EPA released the 2021 "Draft Systematic Review Protocol Supporting TSCA Risk Evaluation for Chemical Substances Version 1.0" (the "2021 SR Protocol").⁸ EPA acknowledged in the 2021 Draft Protocol that:⁹

Previously [in the 2018 SR Document], EPA did not have a complete clear and documented TSCA systematic review (SR) protocol. EPA is addressing this lack of *a priori* protocol by releasing [the 2021 Draft Protocol].

EPA also stated that the:¹⁰

[2021 Draft Protocol] is significantly different [from the 2018 SR Document] in that it includes descrition [*sic*] of the Evidence Integration process..., which was not previously included in the [2018 SR Document].

EPA relied upon the 2018 SR Document in the Final 1,4-DX RE. EPA did not address the public comments associated with the development of the Final 1,4-DX RE. This is so despite acknowledging the deficiencies with the 2018 SR Document, as identified by the public commenter at the TSCA SACC meeting on the draft risk evaluation for 1,4-DX and the later criticisms by NASEM.

The information provided in the RFC, discussed key scientific data and evaluations on the carcinogenic mode of action (MOA) for 1,4-DX that post-dated EPA's issuance of the Final 1,4-DX RE (*e.g.*, Health Canada, 2021; European Chemicals Agency (ECHA), 2022; and Lafranconi

⁸ EPA (2021) Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0, (Dec. 2021), <u>https://www.epa.gov/system/files/documents/2021-12/draft-systematic-review-protocol-supporting-tsca-risk-evaluations-for-chemical-substances_0.pdf</u>.

⁹ *Id.* at 144.

 $^{^{10}}$ Id. at 27.

et al., 2023).^{11,12,13} As such, we believe that EPA cannot simply reject the RFC on the basis that the issues raised in this RFC are duplicative with prior public comments and submissions received.

ACI/ACC recognizes that EPA may not be required to reevaluate its scientific support documents in each instance when new information is brought to light after completion of a risk evaluation. The information in the RFC, however, is not new. EPA has yet to address the scientific weakness described therein. In addition, EPA expanded the scope of the Final 1,4-DX RE when it issued the 2023 "*Draft Supplement to the Risk Evaluation for 1,4-Dioxane CASRN 123-91-1*" (the 2023 Draft Supplement)¹⁴. EPA stated in the 2023 Draft Supplement that "[t]he evaluation of...human health information did not differ from the respective information provided in the [Final 1,4-DX RE].... "¹⁵ It is unclear to us how EPA could reach this conclusion without an updated systematic review of the literature. EPA then limited the scope of the Pinal 1,4-DX RE.¹⁶

EPA's refusal to perform a systematic review of the literature on 1,4-DX that complies with the TSCA scientific standards, which would include assessing the dissenting reviews from competent authorities in Canada and Europe results in a risk evaluation that does not meet the scientific standards of TSCA or the Agency's IQA Guidelines for "Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the [EPA]."¹⁷

ACC/ACI (2023), supra n. 3, at 3, citing Health Canada (2021), Guidelines for Canadian Drinking Water Quality Guideline Technical Document 1,4-Dioxane, <u>https://www.canada.ca/content/dam/hc-</u> <u>sc/documents/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-1-4-</u> <u>dioxane/1-4-dioxane-pdf-eng.pdf</u>.

 ¹² Id., citing ECHA (2022), Committee for Risk Assessment, RAC, Opinion on Scientific Evaluation of Occupational Exposure Limits for 1,4-Dioxane, ECHA/RAC/OEL-O-0000007101-89- 01/F 18/03/2022, European Chemicals Agency (ECHA), https://echa.europa.eu/documents/10162/7937606/1 final opinion oel 1 4 dioxane en.pdf.

¹³ Id. at 12, citing Lafranconi et al. (2023), An Integrated Assessment of the 1,4-Dioxane Cancer Mode of Action and Threshold Response in Rodents, REGULATORY TOXICOLOGY AND PHARMACOLOGY, https://doi.org/10.1016/j.yrtph.2023.105428.

¹⁴ EPA (2023a), Draft Supplement to the Risk Evaluation for 1,4-Dioxane, CASRN 123-91-1, EPA Document # EPA-740-D-23-001, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency (EPA), <u>https://www.epa.gov/system/files/documents/2023-</u> 07/1.%20Draft%20Supplement%20to%20the%20Risk%20Evaluation%20for%2014-Dioxane%20-%20public%20release%20-%20hero%20-%20July%202023.pdf.

¹⁵ *Id.* at 188.

¹⁶ EPA (2023b), Draft Charge Questions, Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC) Peer Review of 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation, at 1, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0040/content.pdf.

¹⁷ EPA (2002), Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (October 2002), available at <u>https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf</u>.

ACI/ACC believe that an RFC is the appropriate mechanism for correcting the Final 1,4-DX RE. To address its scientific and legal obligations, EPA should update its framework analysis of the carcinogenic MOA for 1,4-DX after EPA completes a systematic review that complies with the quality standards in EPA's IQA guidelines and the TSCA scientific standards.

We appreciate the opportunity to provide this request for reconsideration of our original RFC. We remain committed to working with EPA on the issues outlined in the attached RFC and look forward to EPA's response.

Respectfully submitted,

Jomes Kin

James Kim Vice President, Science & Regulatory Affairs American Cleaning Institute (ACI) 1401 H Street, N.W., Suite 700 Washington, DC 20005 E-mail: jkim@cleaninginstitute.org

Robert Simon Vice President, Chemical Products and Technology American Chemistry Council (ACC) 700 Second Street, N.E. Washington, DC 20002 E-mail: <u>robert simon@americanchemistry.com</u>

Attachments:

Lafranconi-2023.pdf aci-acc-rfc-for-14-dx-dec-2023_final.pdf 23002 rfc 14-dioxane-riskevaluation epa response 2024-04-16.pdf