



OFFICE OF THE ADMINISTRATOR

WASHINGTON, D.C. 20460

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Dear Dr. Kim and Mr. Simon,

This letter is in response to your Request for Reconsideration (RFR),¹ received by the U.S. Environmental Protection Agency on July 16, 2024, which was assigned RFR #23002A for tracking purposes. Your RFR requests that the Agency reconsider its denial of your Request for Correction (RFC) 23002,² in which you requested that EPA reexamine its conclusion regarding the carcinogenicity of 1,4-Dioxane based on a systematic review (SR) of literature published between issuance of the Final 1,4-Dioxane Risk Evaluation in December 2020³ and the “Draft Supplement to the Risk Evaluation for 1,4-Dioxane CASRN 123-91-1” (the 2023 Draft Supplement) in July 2023.⁴

In accordance with EPA’s Information Quality Guidelines, a three-member executive panel met on September 30, 2024, to review your request and the information you provided. The executive panel was comprised of the Science Advisor/Assistant Administrator (AA) for the Office of Research and Development (ORD), Chief Information Officer/AA for OMS, and the Economics Advisor/AA for the Office of Policy (OPI). The 3-member executive panel was chaired by the Chief Information Officer. The panel determined that EPA’s denial of the RFC 23002 was based on sound reasoning.

As noted in EPA’s denial of RFC 23002, the RFC process is intended to provide a mechanism to correct errors where the disseminated product does not meet information quality guidelines. The Draft Supplemental Risk Evaluation for 1,4-Dioxane (2023) was subject to rigorous independent peer review and public comment in 2023. Consistent with EPA’s Information Quality Guidelines, this peer review was presumptive of objectivity and “best available” science and supporting studies were conducted in accordance with sound and objective scientific practices at the time it was developed. The Information

¹ https://www.epa.gov/system/files/documents/2024-07/aci-acc-rfr-of-usepa-denial-of-rfc-12july2024_signed.pdf

² https://www.epa.gov/system/files/documents/2024-04/23002_rfc_14-dioxane-riskevaluation_epa_response_2024-04-16.pdf

³ https://www.epa.gov/sites/default/files/2020-12/documents/1._risk_evaluation_for_14-dioxane_casrn_123-91-1.pdf

⁴ <https://www.epa.gov/system/files/documents/2023-07/1.+Draft+Supplement+to+the+Risk+Evaluation+for+14-Dioxane+-+public+release+-+hero+-+July+2023.pdf>

Quality Guidelines commit EPA to ensure, “to the extent practicable,” that: “[t]he substance of the information is accurate, reliable, and unbiased. This involves the use of: (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer-reviewed science and supporting studies”.... “In applying these principles, “best available” usually refers to the availability at the time an assessment is made.” EPA is denying the RFR because it is duplicative with prior comments that EPA appropriately responded to in Response to Comments for the Final 1,4-Dioxane Risk Evaluation in 2020⁵ and the issues raised in the RFR were addressed by updates made in the Final supplemental 1,4-Dioxane assessment⁶ and in the updated final document responding to peer review and public comment.⁷

- The ACI/ACC request asserts that the Agency did not consider in its mode of action (MOA) analysis and cancer assessment certain information on the carcinogenic MOA for 1,4-Dioxane that post-dated EPA’s issuance of the Final 1,4-Dioxane risk evaluation – specifically, information referred to as Health Canada, 2021; European Chemicals Agency (ECHA), 2022; and Lafranconi et al., 2023. Contrary to this assertion, the data presented in Health Canada, 2021 and European Chemicals Agency (ECHA), 2022 are not new primary data and EPA considered the underlying data that was submitted by ACC in the MOA analysis and cancer assessment as shown in the 2020 response to comments. Lafranconi et al., 2023 is a final publication of primary data that was submitted during previous public comment and EPA updated the supplemental assessment and the response to comments to include consideration of published studies after the EPA 2020 1,4-Dioxane assessment.
- In response to ACC/ACI, EPA has addressed the weakness that NASEM identified in their 2020 report on TSCA systematic review approach with the publication of the revised *TSCA draft Systematic Review protocol (2021)*. This SR protocol publication also included updates with appendices specific to 1,4-Dioxane. The original *2020 1,4 Dioxane assessment*, the *TSCA draft Systematic Review protocol (2021)* and the supplemental SR files describe the SR approach and its implementation. The supplemental risk evaluation also utilized considerations that were outlined in the *TSCA draft Systematic Review protocol (2021)*. The Supplemental Risk Evaluation incorporated SACC recommendations on SR approach in the overall supplemental assessment (Appendix C). The SR appendices were published as supporting information of the supplemental risk evaluation. In addition, the SR approach for 1, 4-Dioxane considered prior assessments of Canada and Europe as well as EPA’s 2013 IRIS Toxicological Review of 1,4-Dioxane (with inhalation update; see <https://iris.epa.gov/document/&deid=247852>). Additionally, risk assessments may also include more limited data sets such as monitoring data used to support the exposure element of a risk assessment. In cases where these data may not themselves have been peer reviewed their quality and appropriate use would be addressed as part of the peer review of the overall risk assessment as called for under the Agency's peer review handbook.⁸

TSCA statutorily requires, among other things, that EPA: “use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner

⁵ <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0723-0125>

⁶ <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0723-0122>

⁷ [https://www.epa.gov/sites/default/files/2020-](https://www.epa.gov/sites/default/files/2020-12/documents/2._summary_of_external_peer_review_and_public_comments_and_disposition_for_14-dioxane.pdf)

[12/documents/2._summary_of_external_peer_review_and_public_comments_and_disposition_for_14-dioxane.pdf](https://www.epa.gov/sites/default/files/2020-12/documents/2._summary_of_external_peer_review_and_public_comments_and_disposition_for_14-dioxane.pdf)

⁸ https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf

consistent with the best available science;" "make decisions... based on the weight of the scientific evidence;" and "take into consideration information... that is reasonably available." While the prior TSCA Risk Evaluation Framework Rule defined weight of the scientific evidence in a way that invoked systematic review and a pre-established protocol, the revised Framework Rule does not. The revised Framework Rule explains that "EPA will apply systematic review methods to assess reasonably available information... in a manner that is objective, unbiased, and transparent." EPA's relevant actions under TSCA are consistent with the Agency's Information Quality Guidelines⁹ and Scientific Integrity policies and procedures.

The panel determined that the reasoning behind EPA's denial of the RFC 23002 remains sound and leverages the best scientific judgment of the scientific community. The panel found that the RFR was addressed through the prior and most recent peer review and public comment process of [supplemental risk evaluation for 1,4-Dioxane](#). Therefore, the panel determined that the comments in RFR are duplicative with prior comments and are responded to in Response to Comments for [Final Supplemental 1,4-Dioxane risk evaluation](#)¹⁰ posting.

As a result, EPA is denying your RFR.

EPA remains committed to the Information Quality Guidelines 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,

**JON
FARMER**

Digitally signed by JON
FARMER
Date: 2025.05.29
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Carter Farmer
Chief Information Officer
Office of the Administrator

⁹ https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf

¹⁰ <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0723-0122>