ASSISTANT ADMINISTRATOR FOR CHEMICAL SAFETY AND POLLUTION PREVENTION
WASHINGTON, D.C. 20460

April 16, 2024

Dr. James Kim
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Via Email: *jkim@cleaninginstitute.org*

Mr. Stephen Risotto
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Re: 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 23002).

Dear Dr. Kim and Mr. Risotto,

This letter is the response to the Request for Correction, dated December 14, 2023 and assigned **RFC # 23002** for tracking purposes,[1] 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 EPA (EPA IQG).[2] In the RFC, the ACI and ACC requested the correction of information in the following EPA document disseminated by the Office of Pollution Prevention and Toxics (OPPT) in December 2020:

> "Final Risk Evaluation for 1,4-Dioxane CASRN: 123-91-1" (EPA Document # EPA-740-R1-8007), issued pursuant to section 6 of the Toxic Substances Control Act in December 2020 (herein after referred to in this response as the "2020 Risk Evaluation for 1,4-Dioxane").[3]

In requesting that the 2020 Risk Evaluation for 1,4-Dioxane be corrected, ACI/ACC state that "OPPT's conclusion that data gaps in the carcinogenic MOA for 1,4-DX, led OPPT to apply a linear low-dose extrapolation, violates the scientific standards under TSCA." ACI/ACC ask the EPA to withdraw that risk evaluation, reexamine its conclusions and issue a corrected risk evaluation for 1,4-Dioxane.

The EPA IQG outlines administrative mechanisms for the EPA's pre-dissemination review of information products and describes mechanisms to enable affected persons to seek and obtain corrections from the EPA regarding disseminated information that they believe does not comply with

[1] A copy of the RFC is posted on the EPA IQG site at: *https://www.epa.gov/quality/requests-correction-and-reconsideration#23002*.
[2] *https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.*
[3] *https://www.epa.gov/sites/default/files/2020-12/documents/1._risk_evaluation_for_14-dioxane_casrn_123-91-1.pdf*.

the EPA IQG or Office of Management and Budget guidelines (i.e., OMB Information Quality Guidelines and Memorandum M-19-15).[4] The EPA is committed to applying the OMB guidelines, including each of the updates outlined in M-19-15, to the EPA IQG. The RFC process under the EPA IQG is intended to provide a mechanism to correct errors where the disseminated product does not meet information quality standards. As stated in Section 8.5, the EPA IQG are not intended to duplicate or interfere with the orderly conduct of a process involving public comment opportunities that allow for the correction of any information that does not comply with the Guidelines.

A key component of the TSCA Existing Chemical Risk Evaluation process is the reiterative public comment opportunities that are provided throughout each stage of the process, and the EPA has concluded that the public comment process is integrated throughout the 3-stages of the TSCA Existing Chemical Risk Evaluation process. Those public comment opportunities serve the purposes of the EPA IQG by providing opportunities for the correction of any information that does not comply with the Guidelines. Public comment data, including the EPA's responses, are made available through the web interface Regulations.gov, bulk comment data download feature, and Application Programming Interface.

After review of the RFC you submitted, the EPA 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 2020 Risk Evaluation for 1,4-Dioxane.[5] Comments by ACC were submitted on the EPA conclusion that there is insufficient evidence to determine the mechanism of action for carcinogenicity of 1,4-dioxane, and its decision to apply linear extrapolation (pp 102-111). EPA considered MOA evidence consistent with EPA cancer guidelines (EPA, 2005) and determined that there was not sufficient evidence to determine a threshold MOA for cancer. These duplicate comments were also addressed in the context of the TSCA Existing Chemical Risk Evaluation process for 1,4-Dioxane. In response to public and external peer review comments, EPA also addressed comments about OPPT's systematic review methodology, its weight-of-evidence approach, and data quality evaluation strategies that meet the TSCA science standards for various data/information streams.

The EPA has concluded that the issues raised in this RFC were appropriately addressed in the TSCA Existing Chemical Evaluation public comment process used in developing and finalizing the 2020 Risk Evaluation for 1,4-Dioxane. The EPA has also determined that the TSCA Existing Chemical Evaluation public process was a more appropriate mechanism for you to provide comments and receive a response from the EPA, rather than through a separate response mechanism under the RFC process of the EPA IQG. As such, the EPA is denying your RFC.

Thank you for your interest in the EPA's information quality. Should you have questions or need additional information about the EPA's IQG process, you may contact us via email to *quality@epa.gov*

[4] *https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information*.
[5] *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.*

(our preferred method), or via regular mail to the EPA Enterprise Quality Management Division , Mail Code 2821T, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

Sincerely,

MICHAL FREEDHOFF

Digitally signed by MICHAL FREEDHOFF
Date: 2024.04.16 09:26:47 -04'00'

Michal Freedhoff

cc: Vaughn Noga, Chief Information Officer, and Deputy Assistant Administrator for Information Technology/Information Management
Katherine Chalfant, Director of Enterprise Quality Management Division, Office of Mission Support