



September 8, 2023

Alaa Kamel
Mission Support Division
Office of Program Support
Office of Chemical Safety and Pollution Prevention

(via Federal eRulemaking Portal: <http://www.regulations.gov>)

RE: EPA-HQ-OPPT-2022-0905: 1,4-Dioxane: Draft Supplement to the TSCA Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Meeting and Request for Comment

Dear Dr. Kamel:

The American Cleaning Institute® (ACI)¹ is pleased to provide comments on the U.S. Environmental Protection Agency (EPA) Office of Pollution Prevention and Toxics' (OPPT) 2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane (the "2023 Draft Supplement"). ACI commends OPPT with undertaking these additional evaluations as recommended by OPPT's Science Advisory Committee on Chemicals (SACC).

ACI members include many manufacturers and processors of ethoxylated surfactants. These surfactants have highly valuable uses that substantially benefit society as a whole, due to their highly adaptable/customizable properties. Depending on the chemistry, these surfactant products may contain certain trace levels of 1,4-dioxane as a technically unavoidable impurity/byproduct. Over the past decade, many ACI members have made substantial investments to reduce the 1,4-dioxane impurity content in various products. Our members are also developing new technologies to further reduce any (already very low levels) 1,4-dioxane releases from production sites.

ACI is concerned that scientific deficiencies in OPPT's 2020 Final Risk Evaluation for 1,4-Dioxane (the "2020 Final 1,4-DX RE") were carried through into the 2023 Draft Supplement without consideration of reasonably available information that informs the carcinogenic mode of action (MOA) for 1,4-dioxane and supports a threshold approach for evaluating potential

¹ACI represents the \$60 billion U.S. cleaning product supply chain. ACI members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors. ACI serves the growth and innovation of the U.S. cleaning products industry by advancing the health and quality of life of people and protecting our planet. ACI achieves this through a continuous commitment to sound science and being a credible voice for the cleaning products industry.

carcinogenic risks to workers and the general population. ACI notes that other authoritative regulatory agencies around the world have recently concluded that 1,4-dioxane is a threshold carcinogen. OPPT provides inadequate explanation why it departs from the best available science and the judgment of other authoritative bodies.

ACI is concerned that OPPT appears to be rushing the 2023 Draft Supplement through the public comment and peer-review process to meet a deadline, rather than ensuring that the new non-peer-reviewed methods used are fit-for-purpose for risk revaluations performed under the Toxic Substances Control Act (TSCA).

ACI further notes discrepancies with OPPT's reliance on reasonably available monitoring data, where in some instances (worker inhalation exposures), it relies on decades old, single site data, for quantifying potential risks, yet in others (*e.g.*, general population exposures *via* surface water), OPPT utilizes modeling estimates *in lieu* of the measurement data, despite having more robust data sets.

An overview of our comments is provided below. A more comprehensive document with full technical comments is attached in Appendix A.

ACI's Procedural Concerns

ACI is concerned that the Agency has not provided sufficient detail concerning the methods EPA has used to prepare the Draft Supplement and has only recently made certain background documents available to the public for examination. These process deficiencies are putting the regulated community at a disadvantage and make it challenging to engage meaningfully with EPA about very important factors that inform the draft final Risk Determinations for 1,4-Dioxane and ultimately will provide the bases for a proposed TSCA Section 6 Risk Mitigation Rule for 1,4-Dioxane.

1,4-Dioxane was one of the first 10 chemical substances to undergo the TSCA risk evaluation process after passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA in 2016. There are no direct consumer uses of 1,4-dioxane; however, it is present as a byproduct in consumer products, including products manufactured and distributed by ACI members.

EPA issued the final Risk Evaluation for 1,4-Dioxane in December 2020. After its release, EPA determined an additional supplement to the final Risk Evaluation for 1,4-Dioxane was needed to consider critical exposure pathways not previously assessed. Specifically, the 2023 Draft Supplement includes evaluation of additional conditions of use in which 1,4-dioxane is present as a byproduct in industrial processes and commercial products and evaluates risks from general population exposures to 1,4-dioxane released to ambient surface water and groundwater, ambient air, and land. To evaluate these additional exposure pathways, EPA has used new methods and novel applications of existing methods which have not been the subject of public comment or peer review for applications in TSCA Risk Evaluations.

In such circumstances, additional time should be granted to permit review by the general public and the regulated community of such materials and for public comment thereon. However, one month following the July 10, 2023, Federal Register notice announcing the availability of the Draft Supplement, additional technical materials were still being added to the public docket for this action. *See*, e.g., August 8, 2023 Memorandum transmitting EPA’s calculations for an Existing Chemical Exposure Limit for work-place exposures to 1,4-Dioxane (<https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0039/content.pdf>) and August 9, 2023 Memorandum transmitting, among other things, revised charge questions for the Science Advisory Committee on Chemicals (SACC) (<https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0038/content.pdf>).

It is unreasonable for EPA to expect interested parties to review these recently released technical materials (thousands of pages of highly complex information) and to provide public comment by September 8, 2023. It also is inconsistent with the procedures established in EPA’s regulations for performing Risk Evaluation pursuant to Section 6 of TSCA, which call for EPA to provide no fewer than 60-days to comment on a Draft Risk Evaluation and to make public the information upon which the Agency has relied. *See* 40 CFR Part 702, Subpart B, and §702.51 in particular. It also is unfair to provide an insufficient amount of time for the careful review of such materials to members of the SACC who will be called upon to respond to charge questions concerning (as described by EPA) many “recently developed tools and approaches that have not been peer reviewed for use in TSCA risk evaluations.”

ACI Remains Concerned About Use of Novel and New Methods Prior to Peer Review

ACI is concerned by the Agency’s use of various new methodologies that are (without the benefit of Peer Review) inappropriate for use in the Draft Supplement to a Final Risk Evaluation or EPA’s Draft Revised Risk Determinations for this substance. The draft final documents are currently based, in significant part, on what the Agency itself describes as “new methods and novel applications of existing methods” that have not been previously peer reviewed and applied to critical exposure pathways not previously assessed by EPA. As these new methods have not been the subject of public comment or peer review for their application in TSCA risk evaluations, ACI recommends that these methods not be included or relied upon until they are validated. Furthermore, ACI requests the revised Risk Determinations be withdrawn pending SACC review and EPA’s response to the Committee’s findings.

Only after these new methods have been peer reviewed and refined following the peer review would it be appropriate for EPA to use them for risk evaluations. Doing so is also consistent with the requirements established at 40 CFR §702.45 which provide that the Agency’s own Peer Review Handbook as well as OMB’s Final Information Quality Bulletin for Peer Review will guide EPA efforts to ensure data quality. Given the nature of a risk evaluation undertaken pursuant to Section 6 of TSCA, a final risk evaluation would be considered a highly influential scientific assessment as that term has been defined in guidance issued by the Office of Management and Budget because the evaluation will have impacts on public policy beyond the evaluation itself. The final Risk Evaluation will be determinative of whether EPA must promulgate a risk mitigation rule. Such a rule will have a material impact on the makers of

products containing 1,4-dioxane, including on their manufacturing methods, the products they are able to offer, and the individuals they employ.

In fact, pausing (or withdrawing) the draft Supplemental Risk Evaluation (and the draft revised Risk Determination) pending the completion of the peer review, and EPA then implementing any required changes to its new methods, is what should be required in light of the Agency's procedural rules for Risk Evaluations which commit EPA to "ensuring that all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and well-tailored to the problem and decisions at hand...". 40 CFR §702.41(a). Moving forward on the draft Supplemental Risk Evaluation (and draft Risk Determinations) reflects EPA's haste, but not its attention to the procedures required in its own (and OMB's) guidance for conducting peer reviews. Such haste can affect data quality, which EPA's and OMB's Data Quality Guidelines are intended to prevent. Before making use of novel methods and new models, EPA is required to not only complete the peer review but then to "prepare a written response to the peer review report" and to "explain[] (a) the agency's agreement or disagreement with the views expressed in the report, (b) the actions the agency has undertaken or will undertake in response to the report, and (c) the reasons the agency believes those actions satisfy the key concerns stated in the report (if applicable). The agency shall disseminate its response to the peer review report on the agency's Web site with the related material..."²

Of particular concern to ACI is the use of the "Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0" which has been applied in this Supplement to the Risk Evaluation. While an initial version of this screening approach has been reviewed by the SACC, the Committee stated that it "had difficulty reproducing results that were relevant to understanding and reviewing the document and indicated multiple limitations and uncertainties," and made recommendations for improvement.³ Using methylene chloride as an example, even with the multi-year analysis (conducted in response to SACC feedback), EPA was unable to formally determine whether the risks evaluated drive the unreasonable risk determination.³

ACI is concerned by the fact that the draft Fenceline 1.0 approach was used for 1,4-dioxane to assess the ambient air pathway to determine exposures and associated risks to fenceline communities, and that surface water concentrations were modeled using the draft approach (including multi-year analysis). It is with some irony that EPA has advised the SACC in its revised charge questions that the Agency relied on "reasonably available information" to identify its model's input parameters, while simultaneously asking the peer reviewers to "provide additional sources of reasonably available data that may improve the parameter distributions".⁴ Until all reasonably available data and information have been identified and reviewed by EPA, and further improvements are made on that basis to the Agency's assessment approach, the

² Final Information Quality Bulletin for Peer Review (OMB); 70 Fed. Reg. 2664, at 2676.

³ Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-01, Docket ID Number EPA-HQ-OPPT-2021-0415.

⁴ See Revised Charge Questions for SACC. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2022-0905-0040>.

current methods must be considered unreliable and should be applied only as a screening tool (and should not provide the underlying basis for a revised risk evaluation).

Like the SACC, ACI recommends EPA should prioritize the use of existing data from published risk evaluations rather than relying on modeling results. This is especially true for 1,4-dioxane, for which environmental monitoring information is well documented.⁵

As discussed in greater detail in the enclosed appendix [Appendix A: Analysis of EPA's Draft Supplement to the Risk Evaluation of 1,4-Dioxane], ACI is very concerned about the conclusions EPA has reached with regard to potential carcinogenic effects of exposures to 1,4-dioxane. This is especially concerning where, as here, EPA has concluded that carcinogenicity should be the primary driver for the Agency's unreasonable risk determinations. The conclusions EPA has reached do not acknowledge certain uncertainties with regard to the mode of action, and EPA has given greater weight to certain information at the expense of other studies and without adequate explanation or justifications. This has resulted in the application of a linear approach to assessing risk associated with potential for carcinogenicity, where ample evidence exists to support use of a threshold mode of action. ACI recommends that EPA consider the recent publications challenging the notion of a non-threshold mode of action for 1,4-dioxane carcinogenicity which have resulted in the use of default assumptions and conservative unit risk and slope factors. ACI has explained these concerns in our enclosed analysis, including why use of a threshold mode of action approach may be both technically justified and would be sufficiently protective of human health for this endpoint. ACI also recommends the Agency carefully review further support for ACI's technical analysis as provided by information addressed in the American Chemistry Council 1,4-Dioxane Panel's comments which are being submitted separately by ACC.

Additional Substantive Comments

ACI recommends EPA update its assessment of exposures under certain conditions of use for which more reliable data should be available and used by EPA. These include:

Industrial/Commercial Use: Dish Soap and Dishwashing Detergent

ACI recommends that EPA revise both the occupational and down the drain (DTD) assessments for dish soap and dishwashing detergent.

The Agency's assessment of exposure during occupational use scenario for dish soap and dish washing detergents is incorrect: EPA used data from a formulating and packaging plant (indicating exposures from unloading and transferring detergent formulation, transport container cleaning and washing operations) and not estimates for a worker washing wares (Belanger, 1980). From the literature search, this study took place at a formulation plant (Colgate-Palmolive Company, Berkeley, California; since sold in 1982). If these scenarios were to be used for evaluating occupational exposure to 1,4-dioxane in a dish soap/dishwashing detergent formulation facility, EPA needs to update some of the assumptions. The use of 40+ year old data where some of the products have 1,4-dioxane level in excess of 0.4% (>4000 ppm) is grossly out

⁵ CA Water Board, 2022; NWQMC, 2022; NY DOH, 2022; Commonwealth of Massachusetts, 2018; U.S. EPA, 2017d

of date with current industry standards. Additionally, the Limit of Detection (LOD) reported was 0.01 mg/sample and the EPA estimated sampling flow rates based on the sample method to develop an LOD with mg/m³ units. The EPA derived LOD of 2.1 mg/m³ has significant uncertainty and given that all the air samples were non-detect, is a significant factor in the risk assessment. In the current scenarios, EPA used the estimated LOD and one-half the LOD (LOD/2) for the worker high-end and central-tendency exposure estimates. These values are two to four orders of magnitude (for dish soap and dishwasher detergent, respectively) greater than the risk evaluation consumer exposure inhalation estimate (though this is no longer a suitable comparison). Moreover, the figures being used by EPA do not represent the best information reasonably available to EPA, which is committed to do under its own requirements and is required to do under Section 26 of TSCA. *See also 40 CFR §702.41(b).*

Data reflecting current industry standards for 1,4-dioxane should be used by EPA.

For evaluating and modeling risk for workers washing dishes and DTD environmental risk, EPA should use concentrations of 1,4-dioxane that may be present under current industry standards. New York State (NYS) Department of Environmental Conservation (DEC) established maximum allowable concentration limits on the amount of 1,4-dioxane that can be present in household cleansing and personal care products sold or offered for sale in New York. The maximum allowable concentration of 2 ppm of 1,4-dioxane was required to be met by December 31, 2022, and 1 ppm must be achieved by December 31, 2023. By using data from the NYS DEC 1,4-dioxane approved waivers spreadsheet, the Agency can assume the concentration range of 1,4-dioxane in dish products will range from 2.01 - 15 ppm with a median of 8.4 ppm. These numbers are highly conservative as they do not include products that meet the established maximum allowable concentration.

Ethoxylation Processes

While ACI acknowledges that EPA has limited data regarding the 1,4-dioxane formation during ethoxylation, sulfonation, sulfation, phosphation and esterification processes, ACI encourages EPA to seek out and make use of additional information that is available on these processes. The concentration of 1,4-dioxane formed through these processes depends on several factors including starting material, catalysts, target final product, extent of reaction, other reagents, reaction vessel type, etc.^{6,7} Optimizing these processes combined with post-reaction treatment processes are already used to minimize 1,4-dioxane in the final product.

ACI understands that the worker exposure models for ethoxylation byproduct rely on a workplace monitoring study from a single US production site conducted in 2000. Based on internal monitoring measurements conducted at US sites during the past 15 years under OSHA, we believe the 2000 exposure values used for the risk assessments are higher than can be expected of many typical production sites. Therefore, we believe that the risk derived in the new draft assessment will overestimate risk for the worker inhalation end point, and the derived

⁶ National Industrial Chemicals Notification and Assessment Scheme. 1998. Full Public Report: 1,4-Dioxane Priority Existing Chemical No. 7. Available online at <https://www.industrialchemicals.gov.au/sites/default/files/PEC7-1-4-Dioxane.pdf>.

⁷ Karsa, D.R. Design and Selection of Performance Surfactants, Annual Surfactants Review, vol. 2. 1999. (ISBN-13: 978-0849397424).

dermal endpoint. Before concluding that there is an unreasonable risk to workers at these sites, we would recommend that the agency take the time to work with the industry to collect more accurate and current information from a greater number of US sites. This could be timely achieved through a collaborative effort in which ACI members would be willing to engage, as discussed further below.

ACI also recognizes that there are numerous uncertainties regarding worker exposure due to limited monitoring data. The current methodology for monitoring in manufacturing and processing plants cannot measure to the low detection limits expressed by EPA. To further both our members' and EPA's understanding of occupational exposure, and the specific data EPA would like to collect, ACI suggests a collaboration to develop a harmonized survey form to for occupational exposure data. While ACI understands data from this collaboration may not be available prior to the finalization of the risk evaluation, we know it can be used to better inform potential risk management recommendations.

Further, the emissions models for ethoxylation byproduct production sites are derived from TRI emission reports published from 6 US based sites meeting the TRI reporting thresholds. As TRI regulations have a reporting threshold, these reports focus on larger production sites with higher (or highest) emissions, and products with higher trace dioxane content. Therefore, the modeled values are likely to be worst case, highly conservative, and significantly over-estimate the actual local risks from most typical US production sites.

Conclusion

ACI reiterates its request that EPA provide greater access to all technical materials relied on by EPA to prepare the Supplement to the Risk Evaluation and permit review by the general public and a more reasonable review and comment period to do so. Moreover, ACI encourages EPA to make better use of publicly available information concerning 1,4-dioxane content in cleaning products and to incorporate them into improved materials being provided to the SACC.

ACI requests the Agency carefully consider the technical comments and information we have provided in Appendix A and take this into account in accordance with the requirements of Section 26 of TSCA prior to issuing a final Risk Evaluation.

While we recognize the agency is compelled under TSCA to complete the risk assessments to congressional deadlines, this should not mean using outdated, very limited data, to rapidly conclude there are "unreasonable risks" from 1,4-dioxane as a byproduct. Given the importance of surfactant and other technologies that contain trace 1,4-dioxane as a byproduct, it is critical that the Agency work with industry to build more reliable risk assessment with more accurate and current data from a wider range of real-world sites.

ACI appreciates the opportunity to provide comments on the materials previously made available by EPA and looks forward to further engagement with EPA and a more reasonable period of time to review and comment on additional materials to be made available.

Sincerely,

A handwritten signature in blue ink that reads "James Kim". The signature is written in a cursive style with a prominent initial "J" and a long, sweeping underline.

James Kim, Ph.D., DABT
American Cleaning Institute