



September 8, 2023

Cindy Wheeler
Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency

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

RE: EPA-HQ-OPPT-2016-0723: 1,4-Dioxane; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment

Dear Ms. Wheeler:

The American Cleaning Institute® (ACI)¹ is pleased to provide the following comments regarding the US Environmental Protection Agency's (EPA's) request for comments on the Draft Revision to the Toxic Substances Control Act (TSCA) Risk Determination for 1,4-Dioxane. Our position is predicated on our response to EPA's 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation which includes ACI's in-depth technical evaluation of the Supplement to the Risk Evaluation and is being submitted separately by ACI.

1,4-Dioxane is formed as a trace level impurity during ethoxylation, sulfonation, sulfation and esterification processes. The cleaning products industry is taking steps to decrease 1,4-dioxane levels to below 1 ppm in the finished product where the substance can remain present as an unintended byproduct. ACI members are actively engaged in concerted efforts to reduce the presence of 1,4-dioxane in their products.²

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.

² The state of New York has established specific concentration limits for the presence of 1,4-Dioxane in household cleansing and personal care products sold or offered for sale in the state. As of December 31, 2022 the maximum allowable concentration of 1,4-Dioxane that may remain present in such products is 2 ppm. By the end of 2023, that level may not exceed 1 ppm.

General Comments

ACI considers the use of untested methodologies to be inappropriate for risk evaluations.³ The outcome of this assessment and subsequent regulations will be based on methodologies that have not been previously peer reviewed and toxicological limits that are unfit for purpose. As these new methods have not been the subject of public comment or peer review in the application in TSCA risk evaluations, ACI recommends that these methods not be used to inform revised Risk Determinations until they are validated. This would be more consistent with EPA's commitment in Section 702.41 of its Risk Evaluation framework rule to ensure "all supporting analyses and components of the risk evaluation are suitable for their intended purpose."

With this in mind, ACI submits our concern with the use of the "Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0" in this evaluation. While this screening approach has been reviewed by the Science Advisory Committee on Chemicals (SACC), the SACC 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. 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 evaluated risks drove the unreasonable risk determination.

ACI is concerned that the draft Fenceline 1.0 approach was used 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 premature to apply the Fenceline 1.0 approach to revise and update a final risk evaluation; this current approach should be applied only as a screening tool and not for risk evaluation.

ACI is also 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 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. As noted in our comments on the Draft Supplement to the TSCA Risk Evaluation (and elaborated on in Appendix A of those comments), the potential risks identified are significantly changed when treated as a threshold carcinogen, adopted by other international regulators.

Further, ACI agrees with the SACC that EPA should prioritize the use of existing data from published risk evaluations rather than relying on modeling results. 1,4-Dioxane environmental monitoring is well documented.

³ The Agency itself has stated its updates to the 1,4-Dioxane Risk Evaluation (and by implications, the risk Determinations) to rely on "new methods and novel applications of existing methods" that have not been previously peer reviewed. EPA also reports it has applied for 1,4-Dioxane certain new methods for reviewing critical exposure pathways not previously assessed by EPA.

2023 Draft Unreasonable Risk Determinations

Processing (including repackaging, recycling, non-incorporative, as a reactant, and as a byproduct); Disposal

It is unclear how EPA derived an unreasonable risk determination for circumstances described by not evaluated in the 2020 Risk Evaluation or the 2023 Draft Supplement, such as when 1,4-dioxane is generated as a byproduct during sulfonation, sulfation and esterification processes. ACI recommends that EPA and the surfactant industry collaborate with regard to generating studies to support an evaluation and subsequent determination based on data for both worker risk and environmental exposure due to disposal from surfactant manufacturing facilities.

ACI agrees with EPA's finding that there is no unreasonable risk to the general population from exposures to drinking water contaminated with 1,4-dioxane from down-the-drain (DTD) releases of consumer and commercial products that contain 1,4-dioxane as a byproduct. Further, ACI estimates that the implementation of the New York Department of Environmental Conservation (DEC) limitations on 1,4-dioxane in consumer and commercial cleaning products will further reduce any potential risk associated with the DTD releases of these products.

Workers: Industrial/Commercial Use: Dish Soap and Dishwashing Detergent

ACI recommends that EPA revise the occupational and down the drain (DTD) assessments for dish soap and dishwashing detergent. The occupational use scenario for both these product categories is incorrect. EPA used data from what appears to be a formulating and packaging plant (indicating exposures from unloading and transferring detergent formulation, transport container cleaning and washing operations) and not that of a worker washing dishes (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. For example, 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 of date with current industry standards (see below). Additionally, the 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. In summary, the EPA derived LOD of 2.1 mg/m³ carries significant uncertainty with it 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 Limit of Detection (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).

For evaluating and modeling risk for workers washing various wares and DTD environmental risk, EPA should use concentration levels in line with current industry measured values. As noted above, the maximum permitted 1, 4-dioxane concentrations established by the NY Department of Environmental Conservation (DEC) is a maximum allowable concentration of 2 ppm of 1,4-dioxane on December 31, 2022, and 1 ppm on December 31, 2023. By using data

from the NYS DEC 1,4-dioxane approved waivers spreadsheet, the concentration range of 1,4-dioxane in dish products which do not meet the limit is 2.01-15 ppm with a median of 8.4 ppm. These concentrations are overly conservative as they do not include products that meet the established (permitted) maximum allowable concentration. Therefore, the concentration of 1,4-dioxane present in dish soap and dishwashing detergent should be known to EPA and should be used to properly assess the occupational exposure and DTD estimates of these products.

Closing

As an unintended consequence of EPA's risk evaluation, determination and risk management efforts, further 1,4-dioxane reductions may result in increases in greenhouse gas emissions due to: (A) compromising the sustainability/cost advantages of cold-water cleaning, and (B) requiring additional energy for 1,4-dioxane removal methods. ACI appreciates this opportunity to provide comments and would be glad to meet with EPA officials to discuss our comments. We look forward to further engagement with EPA.

Sincerely,

A handwritten signature in blue ink that reads "James Kim". The signature is fluid and cursive, with the first name "James" and last name "Kim" clearly distinguishable.

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