HOUSEHOLD & COMMERCIAL PRODUCTS ASSOCIATION

Innovative Products For **Home. Work. Life.**

September 8, 2023
Alaa Kamel
Mission Support Division
Office of Program Support
Environmental Protection Agency
1200 Pennsylvania Ave. NW, Washington, DC 20460–0001

Re: 1,4-Dioxane: Draft Supplement to the TSCA Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Meeting (Docket No. EPA-HQ-OPPT-2022-0905).

Dear Dr. Kamel,

On behalf of the Household & Commercial Products Association[1] (HCPA) and its members, we want to convey our comments on 1,4-Dioxane: Draft Supplement to the TSCA Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Meeting (Docket No. EPA-HQ-OPPT-2022-0905). HCPA members manufacture, process and distribute a number of substances within the scope of the proposal that would be impacted by the proposed risk determination. With that in mind, we are providing these comments to assist the Agency in the development of the final rule.

1. Data gaps and outdated studies in occupational exposure assessments have led to unnecessary determinations of unreasonable risk.

HCPA would like to bring attention to EPA's preliminary determination of risk for several conditions of use (COUs) where the Agency has determined that 1,4 dioxane presents an unreasonable risk of injury to worker health and occupational non-users. These COUs were assessed on the basis of outdated information and limited datasets

[1] HCPA is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than $180 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. HCPA member companies employ hundreds of thousands of people globally. HCPA represents products including disinfectants that kill germs in homes, hospitals and restaurants; air fresheners, room deodorizers, and candles that eliminate odors; pest management products for pets, home, lawn, and garden; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day.

that do not accurately represent use conditions for present-day workers. In these scenarios, where there is not enough information to demonstrate a scientifically rigorous evaluation of risk available, HCPA suggests that the Agency utilize modelling capabilities and work with technical experts to develop new robust data.

Dish Detergent and Dish Soap

HCPA is concerned that EPA's proposed unreasonable risk determination for 1,4-dioxane for workers under the industrial/commercial use of dish soap and dish detergent is not accurate. This determination made under the COU for dish soap and dishwasher detergent is derived from information that is not representative of these product categories. The study that is cited for these assessments (Belanger 1980)[2] is outdated and contains a limited set of samples from one Colgate-Palmolive facility that were evaluated in 1979. The concentrations of 1,4 dioxane from the Belanger study range from 0.000 to 0.423 percent by weight in sample. These values have not been observed in modern products and would be considered out of compliance with New York State (NYS) law[3] as of December 1, 2022. In this study, 1,4-dioxane levels in dish products were measured to be up to two-thousand times higher than the levels that are generally allowed to be in products according to the NYS Department of Environmental Conservation (NYS DEC):

"No household cleansing product shall be distributed, sold, offered or exposed for sale in this state which contains 1,4-dioxane other than such trace concentrations; such trace concentrations shall not exceed two parts per million by December thirty-first, two thousand twenty-two; and further, shall not exceed one part per million by December thirty-first, two thousand twenty-three.[3.]"

The NYS law is considered the de facto national upper limit as most companies manufacture and distribute dish soap and detergent on a national basis. HCPA has worked with its member companies to ensure that they are in compliance with the 2 parts per million limit (ppm) and prepared to meet the 1 ppm limit at the end of this year. Companies that were unable to comply with this law were instructed to file one-year waivers with the NYS DEC and report their current levels of 1,4 dioxane in any applicable product(s).

After DEC reviews and issues an approval for a waiver application request, the name

[2] Belanger (1980). Health Hazard Evaluation Report No. HHE-80-21-721, Colgate-Palmolive Co., Berkeley, California (No. HHE-80-21-721)

[3] New York State Environmental Conservation Law § Chapter 43-B, Article 35

of the manufacturer, the product name, and the current amount of 1,4 dioxane present in each product is made publicly available and updated on a monthly basis[4]. This information may be viewed on the NYS DEC website and currently ranges from 2.01 - 15.0 ppm for reported dish soaps and detergents. Even if the Agency was using the most conservative estimate of 15 ppm (i.e., 0.0015% by weight) in products, the expected 1,4-dioxane concentration would be almost 300 times lower than the 0.423% concentration cited in the risk assessment.

HCPA agrees with the Agency's acknowledgement that this data has a high degree of uncertainty as to the representativeness of these estimates due to the age of the monitoring data, number of non-detect results, and the limited sample size. However, the Agency should not utilize any information from this study due to this high degree of uncertainty. To produce the values in Table_Appendix F-32 "Estimated Inhalation Exposure for Workers during Various Conditions of Use" for dish detergent and dish soap, the Agency used the Limit of Detection (LOD) and LOD/2 for the worker high-end and central tendency inhalation exposure estimates from the Belanger 1980 study. In addition to the overly conservative concentration levels, these calculations do not properly account for air flow rates or engineering controls present in occupational settings. This information is based on a decades-old LOD for an outdated analytical method rather than real-world exposure scenarios and therefore has a low confidence interval.

Additionally, HCPA would like to bring attention to the differences in worker exposure scenarios for back-of-house restaurant and commercial dishwashing workers. HCPA disagrees with the assertion that commercial exposure is reasonably two to four orders of magnitude greater than the 2020 risk assessment consumer exposure inhalation estimate. Production data cannot accurately capture on-site warewashing exposure scenarios. Industry has taken steps to ensure the safety of this type of worker such as those listed in the National Science Foundation (NSF) Standard 3[5], which establishes minimum public health requirements for commercial warewashing. Dispensing methods that reduce worker exposure, particularly to 1,4-dioxane in concentrated cleaning products prior to dilution, have been widely adopted including direct machine dispensing, closed loop-systems, and optimized wash/run cycle times. These controls significantly minimize workers potential exposure to 1,4 dioxane, particularly when also factoring in the appreciable dilution of cleaning products during

[4] 1,4 Dioxane Approved Waivers: https://www.dec.ny.gov/fs/projects/waivers/1-4DApprovedWaivers.xlsx
[5] NSF/ANSI Standard 3 Commercial Warewashing Equipment

use, resulting in 1,4-dioxane concentrations generally several orders of magnitude lower than those present in the cleaning products in a concentrated state prior to dilution. Also, the dermal exposure model used by the EPA does not factor in typical use parameters and practices. These considerations include hand dish soap product dilution, rinse off factors, transient exposure, exposure duration effects, and volatilization.

HCPA recommends that the Belanger 1980 study be removed from the risk assessment due to significant data gaps and a high degree of uncertainty. The Agency should instead utilize the Monte-Carlo modelling methodology that was applied to laundry products generated using generic release data. When the EPA identifies unreasonable risk with low tier exposure modeling, the Agency should refine the model with a higher tier exposure model before making a final risk determination. Additionally, the Agency should consider utilizing the NYS 1,4 dioxane limits and waiver data for this product category as it accurately represents products that are currently on the market and being sold nationwide. Further, HCPA suggests that the Agency work with industry stakeholders to generate new data for the dish soap and dish detergent COU subcategories as needed to appropriately refine risk estimates.

Ethoxylated Byproduct

The study that was used to generate worker inhalation exposures for the ethoxylation process byproduct based on monitoring is another example of limited sample size and outdated information (see Table_Apx F-27). The data consists of a single value from one person during one shift at one site in the year 2000[6]. The Agency cannot determine the statistical representativeness of the one monitoring data point (*e.g.*, high-end, central tendency) towards potential exposures. The worker activities covered by this monitoring data, foreseeable activities, corresponding exposures, and workplace operations cannot be reliably represented by this data. The uncertainty in the representativeness of this monitoring data for all sites and worker activities in current operations is not only due to the low number of data points and lack of variability, but also the age of the monitoring data.

The surfactants industry is currently applying state-of-the art technology to mitigate the formation of 1,4-dioxane and to remove it in post-processing. For example, during sulfonation reactions to create sodium lauryl ether sulfate (SLES), several engineering controls are being used to minimize the formation of 1,4-dioxane byproduct. These

[6] Occupational Health and Safety Administration's Chemical Exposure Health Data

controls for SLES production include balancing the alcohol to sulfur trioxide gas ratio and rapid neutralization of the sulfation product with sodium hydroxide to prevent 1,4-dioxane formation in the ethoxylation process.

Manufacturers routinely monitor these processes to ensure they meet strict 1,4-dioxane limits. However, the current methodology for monitoring in manufacturing and processing plants cannot measure to the low detection limits expressed by EPA's Exposure Concentration Equivalency Limit (ECEL). To further the understanding of occupational exposure for the EPA and industry stakeholders, HCPA suggests a request for information. Industry stakeholder knowledge can be utilized to implement high-quality occupational monitoring. Although this information may not be available prior to the finalization of the evaluation, it can be used to generate more informed risk management strategies.

2. The EPA's ECEL for 1,4-dioxane faces challenges in accurately measuring exposure limits and assessing threshold carcinogen risk.

Current Testing Capabilities

A significant challenge in providing EPA with exposure data for chemicals such as 1,4-dioxane is that companies do not have the in-house capabilities to analyze lower limits of certain Existing Chemical Exposure Limits (ECEL). The ECEL for 1,4-dioxane is 0.055 ppm which is several orders of magnitude below the existing occupational exposure limits (OELs) currently used by analytical labs. For example, the American Conference of Governmental Industrial Hygienists (ACGIH) have established a Threshold Limit Value (TLV) for 1,4-dioxane of 20 ppm[7] which approximately 360 times higher than the 0.055 ppm ECEL. Current practices for OSHA and NIOSH require laboratories to quantify results at least 10% of the exposure limit. For 1,4-dioxane, this quantification would be currently 2 ppm for labs relying on the ACGIH TLV;. If the practice of 10% of the exposure limit were applied to the Agency ECEL of 0.055 ppm for 1,4-dioxane, that results in a value of 0.0055 ppm, a level that is not currently achievable. As a result, current non-detect results above the ECEL create a challenge for analysts trying to select the best statistical approach to translate those non-detect values into usable values that can be compared against the ECEL, and ECEL Action Level.

To account for method sensitivity, methods need to be able to detect below the ECEL, not right at the ECEL. One strategy noted in the Draft ECEL for Occupational Use of 1,4-dioxane was to reduce method sensitivity by taking multiple samples and

[7] ACGIH 1,4-Dioxane: TLV(R) Chemical Substances 8th Edition Documentation

combining the results into one 8-hour time-weighted average (TWA). This strategy, however, will not reduce the sensitivity of the method. Labs have different levels of quantification; one approach to increase method sensitivity for labs that cannot currently detect below the ECEL is to switch the detector on a gas chromatograph-flame ionization detector (GC-FID) to a mass spectrometer (MS). With a GC-MS method samples results may be able to quantify below the ECEL.

HCPA suggests that the Agency work with industry laboratories to determine capabilities and method extension possibilities to meet any new proposed ECELs and ECEL Action Levels. This action would further the understanding exposure testing limits for both the EPA and industry stakeholders, allowing for the collection of high-quality exposure data.

Conservative Cancer Risk Studies

EPA's assessment of risk presented by exposure to 1,4-dioxane under the various scenarios in the Draft Supplement to the Risk Evaluation[8] relies on the incidence of tumors in laboratory animal studies.[9] These studies – two by inhalation and six by exposure in drinking water have generally reported an increase in liver and nasal tumors. Despite the available evidence, EPA's assessment defaults to a linear, non-threshold approach for estimating cancer risk. HCPA supports the comments made by the American Chemistry Council (ACC) and American Cleaning Institute (ACI) concluding that a threshold cancer mode of action (MOA) can be established for 1,4-dioxane based on the evidence for liver/nasal hyperplasia. There is sufficient evidence to calculate a cancer MOA threshold and the threshold for liver/nasal hyperplasia effects is equivalent to the cancer threshold because the cancer studies have all generally reported an increase in liver and nasal tumors. HCPA supports the ACC's comments suggesting that EPA use the threshold for liver/nasal effects to calculate cancer and non-cancer hazards.

3. Novel modelling techniques need to be based on robust data and the Agency should promote training on these techniques to ensure stakeholder understanding.

HCPA supports EPA's investment in Monte-Carlo Modelling methodology and the wealth of information that can be provided through the implementation of modelling techniques. The development and future use of modelling techniques offers a

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[8] USEPA. Draft Supplement to the Risk Evaluation for 1,4-Dioxane, CASRN 123-91-1. EPA-740-D-23-001. (2023). (Draft Supplement)

[9] USEPA. Final Risk Evaluation for 1,4-Dioxane, CASRN 123-91-1. EPA-740-R1-8007 (2020), at 211. (Final Risk Evaluation)

preferable alternative for scenarios with no comprehensive datasets available to ensure that risk assessments have a high degree of certainty. Reliance upon outdated data in risk assessments can have serious consequences, including inaccurate risk determination for certain Conditions of Use (COU), inadequate risk management plans, and inefficient resourcing. It is crucial to prioritize the use of up-to-date and reliable data to ensure that risk assessments are both scientifically sound and accurately representative of industry practices.

This is particularly important as the methods applied to this risk evaluation will influence their application to subsequent risk evaluations. The transparency and quality of data used in this specific modeling process are critical to ensuring that they will be effective in subsequent assessments. The Agency should ensure that its Monte Carlo modeling efforts adhere to best practices and guidelines for the risk assessment to maintain scientific rigor and credibility.

Training

The models included in the Supplemental Risk Assessment for 1,4-dioxane, such as the Monte-Carlo and SHEDS-HT models are not intuitive for users to navigate. Considering that these methodologies are novel and complex, it would be valuable to both the Agency and the regulated community to offer training on these methods. Previously, HCPA has submitted comments to the Agency encouraging EPA to bring back the Sustainable Futures program, which would benefit both the Agency and industry by training stakeholders on the assessment methods, computerized models, and tools that EPA uses to assess new chemicals. Sustainable Futures improves the regulated community's understanding of the EPA's review processes and expected concerns.

Offering training on this methodology during its early stages of implementation would allow companies to address any identified concerns proactively and create a more robust assessment. HCPA supports the Agency in its efforts to bring back the Sustainable Futures program and additionally encourages EPA to offer an incentive to companies who participate – for example, an expedited timeframe for reviews – in recognition of the multiple ways that Sustainable Futures furthers EPA's goals.

4. Procedural Concerns

HCPA would like to note the timeline constraints of the comment for the 2023 Draft

Supplement. This assessment includes evaluation of additional COUs in which 1,4-dioxane is present as a byproduct in industrial processes and commercial products using new methods and novel applications of existing methods. As these methodologies have not previously been used or evaluated, additional time is needed to allow the public and regulated community to fully understand these new approaches. The Federal Register notice announcing the availability of the Draft Supplement was released on July 10, 2023 and additional technical materials were being added to the supplemental risk assessment docket as late as August 10, 2023. HCPA requests that Agency take these considerations into account for future comment period timelines and ensure that stakeholders have sufficient time to evaluate the information provided.

5. Conclusion

We thank you for your careful consideration of our comments and would be happy to address any questions or clarifications.

Sincerely,

Carrie Brown
Senior Manager of Regulatory Affairs