August 29, 2019

Meredith Williams
Acting Director
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: HCPA Comments on 1,4-Dioxane in Personal Care and Cleaning Products

Dear Mrs. Williams,

The Household & Commercial Products Association[1] (HCPA) appreciates the opportunity to provide comments on the Department of Toxic Substances Control (DTSC) on the potential listing of specific consumer products containing 1,4-dioxane as one or more Priority Products subject to the Safer Consumer Products regulations. Specifically, DTSC is seeking input on an Alternatives Analysis Threshold (AAT) of 1 ppm in personal care and cleaning products. HCPA appreciates that DTSC has an open and transparent process with multiple opportunities for stakeholder input, attempting to obtain the best available science to make their determinations.

Cleaning and personal care product manufacturers hold their products to the highest safety standards and ensure every ingredient's safety through rigorous science-based analysis and evaluation. Safety is always our first priority, which is why companies invest significant time and resources to make products that are better for human health and the environment. Formulators and manufacturers are continuously improving their products to account for new science and technology, everchanging regulations, consumer demand, sustainability goals or a host of other factors that change what's possible and the marketplace evolves.

1,4-Dioxane is a byproduct, of the manufacturing process of certain surfactants that and may appear in trace amounts in personal care and cleaning products. It is not an intentionally added ingredient in personal care and cleaning products and has no functional effect. Manufacturers and formulators continually work to ensure that the levels of any byproduct are kept well below any risk level. Industry has already dramatically lowered the levels of 1,4-dioxane in products and will continue to do so with new and emerging chemistries and technology.

[1] The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell $180 billion annually of products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ 200,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier and more productive lives.

There are no drop-in replacements that will retain both safety and performance while decreasing or removing 1,4-dioxane from a product. If there were, companies would have already switched to that technology. But reducing or eliminating chemicals of concern is no simple matter. Manufacturers continue to use surfactants that contain trace amount of 1,4-dioxane because they are the optimal choice in many product categories when assessing each benefit against any potential risk for all options.

HCPA does not believe that 1 ppm is an appropriate starting point for discussions regarding an AAT proposal. We believe that for the public to achieve maximum benefit, resources should be spent cleaning up legacy industrial uses of 1,4-dioxane that have been discharged into the environment rather than focusing on the infinitesimal amount from personal care and cleaning products. As DTSC itself says in their background document, the majority of 1,4-dioxane in drinking water is due to historical contamination of groundwater.

In these comments, we will discuss the deficiencies that HCPA believes needs to be considered before moving forward, provide information from sources that HCPA believes should be considered, and address the challenges that industry would face in meeting a 1 ppm threshold across categories. After reviewing HCPA's and other stakeholder comments, if DTSC still desires to proceed, HCPA recommends consideration of an AAT of 10 ppm for personal care and cleaning products.

The AAT proposal by DTSC has a number of deficiencies that should be addressed before DTSC can move forward.

There are a wide range of factors that have not been fully discussed or explored in either the background document or the AAT proposal document.

i) Scope of the covered products

DTSC has not yet proposed a Priority Product(s) but has instead released an ambiguous AAT proposal document that generically discussed all personal care and cleaning products. As stated in the AAT proposal document, DTSC is seeking input on a 1 ppm limit of 1,4-dioxane in personal care and cleaning products.

To better facilitate discussion and conversation, HCPA suggests DTSC better define the scope of products under consideration. For context, the recently completed California Air Resources Board (CARB) survey encompassed over 150 categories that could be considered cleaning products and the recently enacted Cleaning Product Right to Know Act defined numerous product categories within its scope. Thus, we encourage DTSC to better define and limit the scope or the department will become inundated with documentation from any manufacturer that has products that may contain trace amounts of 1,4-dioxane, even if the trace amount is below the threshold value.[2]

[2] Cal. Code Regs. Title 22 § 69505.3(a)(4)(B)

We do not believe DTSC carefully considered this requirement and is unlikely to have the resources to accommodate the volume of documentation that would be submitted if the specific product categories are not specified and further limited. Even if industry were able to either eliminate 1,4-dioxane completely from surfactants or products were reformulated to surfactants that are not known to contain 1,4-dioxane as a contaminant, the water source for the finished product may trigger the requirement for notification. Furthermore, if the scope is not limited to some degree, there could be considerable costs incurred by industry, without meaningful benefit, to test all products containing surfactants that may contain trace levels of 1,4-dioxane, as the AAT Notification in Lieu of an Alternatives Analysis requires a statement certifying that the 1,4-dioxane does or does not exceed the AAT.

ii) A practical quantitation limit (PQL) for 1,4-dioxane needs to be determined by first developing a validated analytical protocol

The AAT is based on a value set at five to ten times the detection limit, so at a minimum, analytic methods would need to be able to detect 1,4-dioxane at least 0.2 ppm in finished products to allow an AAT of 1 ppm. To the best of HCPA's knowledge, there is not a validated method that can accomplish this level in finished products. An AAT around 10 ppm is more likely achievable based on current methods, but that needs to be validated. HCPA suggests that DTSC and stakeholders work with third party analytical labs to determine what is currently possible for finished products before continuing discussion on a potential AAT.

In the Safer Consumer Products regulations, the AAT is the PQL for any chemical(s) of concern that is/are present in a priority product; however, there is no current validated analytical protocol for finished products. DTSC identified the Environmental Protection Agency (EPA) Method 522 as a method for quantifying 1,4-dioxane in water but noted its limitations in personal care and cleaning products. DTSC also identifies United States Pharmacopeia (USP) methods 228 and 467 and EPA Method 8260 and 8270 as methods that can determine 1,4-dioxane content but note that modifications would be necessary to accommodate the wide array of personal care and cleaning products. DTSC concludes that with modifications to EPA Method 8260 and 8270, they anticipate that laboratories would be capable of reaching a PQL of 1 ppm for all products. HCPA is not as optimistic until the proper validation steps are completed.

Method development and validation is critical to the scientific world. Reliable analytical data can only be achieved once a method has been developed **and** validated. Personal care and cleaning products range from simple to incredibly complex formulations. Manufacturers of the raw materials that go into these products must utilize different methods that have different levels of detection depending on the chemistry that is being tested. While some of these methods are able to detect 1 ppm of 1,4-dioxane in some of the raw materials before they are significantly diluted in final formulation that does not mean the 1,4-dioxane can be detected in this finished product using the same test method. Without the proper testing, we cannot take for granted that a single PQL will be sufficient. It is also possible that there will be differing PQL

value (or values) for each product category. Moreover, it is likely that differing formulations will have interferences from other constituents within the product that would significantly increase analytical complexity. HCPA recommends creating and validating a matrix that identifies the validated methodology for all products covered once the scope is determined.

Even if one method could be developed for all products under this scope, it is critical that it be validated across multiple laboratories to ensure consistent results against the theoretical value that can be determined by the manufacturer of the product by utilizing their supply chain. If multiple methods are developed due to the complexity of the various formulations that currently exist, in addition to ensuring that consistent results can be duplicated between various laboratories against the theoretical value, testing needs to occur between any overlapping product categories which exist to confirm that each method obtains similar results.

If a method or methods are developed and validated, only then can all stakeholders and DTSC properly move forward collaboratively in setting an AAT.

iii) HCPA recommends DTSC review standards and recommendations by independent, scientific organizations

HCPA appreciates DTSC seeking stakeholder input and believes that it would be beneficial for DTSC to review the following standards and recommendations by independent, scientific organizations.

The current USP/NF (United States Pharmacopeia (USP) and the National Formulary (NF)) monograph (USP 42-NF37, official May 1, 2019) includes a monograph[3] for polyethylene glycol with requirements for testing of and acceptable level of 1,4-dioxane. Polyethylene glycols produced to be used as excipients or active pharmaceutical ingredients into drugs need to meet the polyethylene glycol monograph requirements. The acceptance criteria for the limit of 1,4-dioxane is not more than 10 ppm.

The International Cooperation on Cosmetics Regulation (ICCR) is an international group of regulatory authorities for cosmetics from Brazil, Canada, the European Union, Japan and the United States. Their working group published their consideration on acceptable trace levels of 1,4-dioxane in cosmetic products[4] recommending setting a target level for 1,4-dioxane in finished cosmetic products in two phases, with the first level in finished product at 25 ppm with an eventual reduction to 10 ppm over a suitable transition period.

The Scientific Committee on Consumer Safety (SCCS) is an independent scientific committee which provides the European Commission with scientific advice when preparing policy and

[3] *United States Pharmacopeia and National Formulary* (USP 42-NF 37). Rockville, MD: United States Pharmacopeial Convention; 2018.
[4] ICCR, Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products. Final Report Published Jan 2017. Retrieved from https://iccr-cosmetics.org/files/2414/8717/1555/ICCR_14-Dioxane_Final_2017.pdf

proposals relating to consumer safety, public health and the environment. The European Commission asked the SCCS to review the ICCR report and while the SCCS rejected the two phase approach, they did recommend that a trace level of 1,4-dioxane of under 10 ppm is safe in cosmetic products and should be phased in over a short transition period.[5]

It is from these sources that HCPA recommends consideration of an AAT at 10 ppm for personal care and cleaning products once a method or methods for determining the concentration of 1,4-dioxane in finished products are developed and validated.

iv) DTSC has not fully determined the contribution of 1,4-dioxane in water from down-the-drain activities of sample products in the AAT Proposal

DTSC relies upon publications[6,7] which were not published in scientific peer-review journals or independently reviewed (to the best our knowledge) as the basis for the down-the-drain estimations of a very limited number of product categories. The methodologies in these studies are either described insufficiently[6] or completely lacking[7] making it impossible to replicate the presented results or validate their testing. Given the limited sample size and the small number of product categories, HCPA recommends that more data is generated before basing an entire programmatic proposal upon their findings.

For instance, the data used for estimating the contribution of 1,4-dioxane in water from laundry detergent comes from testing 18 products. In 2015, there were 1,757 different laundry detergent products sold in the state of California which could be liquid, powder, concentrates or single-use packets[8]. Because of the differences in how these different product forms are formulated and how they are used, the expected resulting down-the-drain contribution will vary, and a single number cannot be used.

For laundry products, the details of the washing machine's operation also must be taken into account, which DTSC has not done in the AAT proposal. The amount of detergent and the volume of water used are significantly different when used in a standard washing machine compared to a high efficiency washing machine. So, between the product form, the concentration of the detergent, the type of washing machine, the volume of water used by the household, and the level of regional dilution post-consumer use, HCPA recommends further research before drawing any conclusions about the concentration of 1,4-dioxane in a broad product category such as laundry detergent. We need to ensure that the right detergent, at the

[5] SCCS, Opinion on the Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products. 2015 Dec 15. SCCS/1570/15. Retrieved from https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_194.pdf

[6] Sarantis, H., Malkan, S. & Archer, L. 2009. *No More Toxic Tub – Getting Contaminants Out of Children's Bath & Personal Care Products.* Campaign for Safer Cosmetics

[7] Citizens Campaign for the Environment. 2018 *Shopping Safe: The 2018 Consumer Shopping Guide Protecting Your Household From 1,4-Dioxane Exposure.*

[8] California Air Resources Board. Final 2015 Consumer & Commercial Product Survey Data Summary. 2019

right product usage, at the right water usage is utilized for estimating the influent 1,4-dioxane contribution from laundering clothes.

Other product categories that DTSC may consider could have similar challenges. As such, DTSC should rely on a comprehensive survey of the marketplace. In the proposal document, DTSC states that "Representative I&I samples will be collected as part of DTSC's independent product testing study." HCPA recommends extending this planned independent product testing study to include all products which DTSC is potentially considering designating as a Priority Product. The dataset that served as the basis for all the calculations used in the AAT proposal should not be used. Instead, an independent product testing study should be conducted. This would provide the necessary information to properly estimate contributions for personal care or cleaning products.

v) The main source of 1,4-dioxane contamination has not been adequately considered

The focus of the AAT proposal is on 1,4-dioxane in the water supply, which has occurred for a number of reasons. In DTSC's background document for 1,4-Dioxane in Personal Care and Cleaning Products (Page 3), DTSC states "Industrial discharge often represents the largest source of 1,4-dioxane in wastewater…" and "…the majority of 1,4-dioxane in drinking water is due to historical contamination of groundwater…" but has ignored any discussion of this impact. There are multiple studies that have been published looking at 1,4-dioxane in water, particularly in groundwater sites in California[9] and Wastewater Treatment Plants,[10] around military installations[11] or industrial sites. These studies focus on the major sources of 1,4-dioxane groundwater contamination, which is not from personal care and cleaning products.

The Adamson article is particularly useful to this discussion, as it identified and evaluated more than 2,000 contaminated groundwater sites in California. Of these sites, 1,4-dioxane was detected at 194, with 95% also containing one or more chlorinated solvents. Historically, the main use of 1,4-dioxane was as a stabilizer in chlorinated solvents such as 1,1,1-trichloroethane[12] (TCA). Manufacture of 1,4-dioxane has decreased since it is no longer used as a stabilizer in chlorinated solvents[13] but it's obvious that legacy contamination from this use

[9] Adamson, D.T., Mahendra, S., Walker Jr., K.L., Rauch, S.R., Sengupta, S., and Newell, C.J. 2014. A Multisite Survey to Identify the Scale of the 1,4-Dioxane Problem at Contaminated Groundwater Sites. *Environmental Science & Technology*. 1, 254-258.

[10] Simonich, S.M. et al. 2013. Probabilistic Analysis of Risks to US Drinking Water Intakes from 1,4-Dioxane in Domestic Wastewater Treatment Plant Effluents. *Integrated Environmental Assessment and Management.* 9, 554-559.

[11] Anderson, R.H., Anderson, J.K. and Bower, P.A. 2012. Co-Occurrence of 1,4-Dioxane with Trichloroethylene in Chlorinated Solvent Groundwater Plumes at US Air Force Installations: Fact or Fiction. *Integrated Environmental Assessment and Management*. 8, 4, 731 – 737.

[12] Agency for Toxic Substances and Disease Registry. 2012. Toxicological profile for 1,4 dioxane. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. Retrieved from https://www.atsdr.cdc.gov/toxprofiles/tp187.pdf

[13] U.S. Environmental Protection Agency. 2016a. Public database 2016 chemical data reporting (May 2017 release). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from https://www.epa.gov/chemical-data-reporting

continues to impact California's water supply. We believe that DTSC and CalEPA should focus on remediation efforts as it would be a much more efficient utilization of resources.

Benefits of Ethoxylated Surfactants

A surface active agent, or surfactant for short, is a class of chemical that reduces surface tension and allows oil and water to mix.

The proper selection of surfactant(s) is critical to the overall efficacy of a cleaning product. Cleaning products are expected to clean a variety of soils, not all of which can be anticipated by the manufacturer. Manufacturers formulate their products to be robust and optimize the surfactant package to a critical micelle concentration, a concentration at which the surface tension no longer drops, even with additional surfactants. The types of soils that are expected to be cleaned, how much product will be used, and how the cleaning will take place all play a role in the process of selecting the right surfactant package. Further, the product form, concentration, solvent choice, viscosity, foam, presence of enzymes, chelating agents and other chemical additives all play a role in the selection of surfactant.

There are a number of reasons as to why manufacturers today choose to use various ethoxylated surfactants. These reasons are typically formulation/product category specific, but in general they offer good detergency/cleansing properties while also having a lower human health hazard profile (for example, most are known to be weak skin irritants). An example would be using ethoxylated surfactant in laundry detergents, a product category that has been reformulated multiple times as a result of environmental concerns not known at the time of their original formulation (phosphates, nonylphenol ethoxylates). Formulating laundry detergents with ethoxylated surfactants allows for use in machines at lower temperatures with less water and also allows for product compaction, all of which bring significant sustainability benefits in terms of energy consumption and transportation.

Manufacturers continue to use these surfactants in their products because they are the optimal choice in many product categories when assessing each benefit against any potential risk for all options. Ethoxylated surfactants, including both alkyl ethoxylates and alkyl ethoxysulfates, are not the only surfactants that will have trace amounts of 1,4-dioxane, but they are targeted in this discussion because the overall process to produce ethoxylated surfactants generates 1,4-dioxane as a byproduct.

Challenges to Controlling/Reducing the Amount of 1,4-Dioxane in Raw Chemicals

Chemical manufacturers have been working to reduce the 1,4-dioxane content in chemicals for decades. The U.S. Food and Drug Administration (FDA) has periodically monitored levels of 1,4-dioxane in cosmetic products since the late 1970s.[14] Through their studies, FDA has observed that the amount of 1,4-dioxane has been on the decline[15].

[14] Food & Drug Administration. 2019. 1,4-Dioxane in Cosmetics: A Manufacturing Byproduct. Retrieved from: https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

[15] Food and Drug Administration. 1,4-Dioxane in Cosmetics: A Manufacturing Byproduct. Last updated 2019 Jan 29. Retrieved from: https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct

But the ability to control 1,4-dioxane formation during the production of surfactants is very limited as it is a competing side reaction of all ethoxylations and cannot be stopped. The primary means of removal is vacuum stripping at elevated temperatures. Because the ethoxylation reaction is different to manufacture various surfactants, a minimum amount of 1,4-dioxane cannot be determined as it would be different for each chemistry.

Reformulation Challenges in Cleaning Products

Safety is always our first priority, which is why companies invest significant time and resources to make products that are better for human health and the environment. Formulators and manufacturers are continuously improving their products to account for new science and technology, everchanging regulations, consumer demand, sustainability goals or a host of other factors that change what's possible and the marketplace evolves.

Industry has already dramatically lowered the levels of 1,4-dioxane in products, and continues to do so as new technology allows, in many cases reducing the level of 1,4-dioxane that may be present to the point where it is no longer detectable.[16]

Any time a formulator considers changing an ingredient in a product, avoiding a "regrettable substitution" that can have unintended consequences is a major consideration. Moving away from ethoxylated surfactants is a dramatic change, and what may appear to be easy can be incredibly complex and take years to resolve.[17] It is critical though for manufacturers to look holistically at each reformulation effort, otherwise regrettable substitutions may occur.

There are no drop-in replacements that will retain both safety and performance while decreasing or removing 1,4-dioxane from a product. If there were, companies would have already switched to that technology. But reducing or eliminating chemicals of concern is no simple matter. While a potential reformulation could lead toward a reduced 1,4-dioxane amount, utilizing the alternatives may sacrifice performance, increase potential irritancy, or make the product commercially unviable.

Furthermore, a chemistry that will reduce or eliminate 1,4-dioxane in one product will not necessarily work for another, much less across an entire category. What may be suitable for a dish soap may not be feasible for a laundry detergent. As such, it would be difficult and inappropriate to address generical reformulation questions across all cleaning products.

Recommendations and Conclusions

DTSC has not yet proposed a Priority Product(s) and HCPA recommends not moving forward with a proposal until there is a validated methodology to determine the 1,4-dioxane content in the Priority

[16] Seventh Generation LLC. Seventh Generation LLC Case Study Summary. Retrieved from http://business.edf.org/files/2015/05/7thGenCaseStudy.pdf

[17] Thomas, Katie. The 'No More Tears' Shampoo, Now With No Formaldehyde. The New York Times. 2014 Jan. 17. Retrieved from https://www.nytimes.com/2014/01/18/business/johnson-johnson-takes-first-step-in-removal-of-questionable-chemicals-from-products.html

Product(s) and an analysis is conducted on the impact of 1,4-dioxane in personal care and cleaning products on those that live in California.

In the AAT proposal, DTSC stated they planned on augmenting the dataset with their own study of 1,4-dioxane in personal care and cleaning products as well as institutional and industrial (I&I) products. HCPA recommends that DTSC identify representative samples for every product category that they may be considering designating as a Priority Product. By doing so, DTSC would have up to date information on the products being sold in the state of California to provide the basis for any action.

HCPA believes that with a validated methodology, an analysis on the products currently sold in the state of California, review the work of independent, scientific organizations and not relying on legislative activities in New York as justification to discuss an AAT, DTSC and stakeholders will be able to have meaningful conversations within the Safer Consumer Products Program regarding potential 1,4-dioxane contamination in personal care and cleaning products.

With the information presented in these comments and our other recommendations completed, HCPA recommends examination of an AAT at 10 ppm for personal care and cleaning products.

HCPA appreciates the opportunity to comment on DTSC's potential listing of specific consumer products containing 1,4-dioxane as one or more Priority Products subject to the requirements of the Safer Consumer Products regulations. If you have any questions about our comments, please do not hesitate to contact me at either ngeorges@thehcpa.org or 202-833-7304.

Respectfully submitted,

Nicholas Georges

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cc: HCPA Cleaning Products Division
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