September 17, 2024
Dr. Meredith Williams, Director
Department of Toxic Substances Control
California Environmental Protection Agency
1001 "I" Street
P.O. Box 806 Sacramento, CA 95814

Re: Comments on Product-Chemical Profile for Personal Care and Cleaning Products Containing 1,4-Dioxane

Dear Director Williams,

As an ad hoc coalition comprised of the Household & Commercial Products Association (HCPA)[1], the American Cleaning Institute (ACI)[2], the Personal Care Products Council (PCPC)[3], the Independent Beauty Association (IBA)[4], the Consumer Brands Association (CBA)[5], the Worldwide Association for the Cleaning Industry (ISSA)[6], and their members, we want to convey our collective comments on the discussion draft Product-Chemical Profile for Personal Care and Cleaning Products Containing 1,4-Dioxane and potential Priority Product Designation of 1,4-dioxane in cleaning and personal care products. Collectively, these associations represent a significant portion of the companies this activity would impact were DTSC to designate personal care and cleaning products containing 1,4-dioxane as Priority Products. We appreciate the opportunity to provide comments to DTSC during the pre-regulatory

[1] https://www.thehcpa.org

[2] https://www.cleaninginstitute.org

[3] https://www.personalcarecouncil.org

[4] https://independentbeauty.org

[5] https://consumerbrandsassociation.org

[6] https://www.issa.com

period and urge DTSC to carefully evaluate these comments as the department considers taking formal regulatory action.

Our concerns include the following:

- Source Reductions Already Made through Efforts in New York
- Outdated and Incomplete Data Set for 1,4-Dioxane Concentrations and Product Use
- Significant Compliance and Administrative Burdens
- Reporting Requirement Issues - Confidential Business Information, Testing Challenges, Burdens on Testing Laboratories and Small Businesses
- Concentrated Products and Environmental Benefits
- DTSC's and EPA's Approaches to Toxicity
- Analytical Methods and Performance Criteria

For years, these associations have been leading advocates for companies, helping them demonstrate their unwavering commitment to transparency, product stewardship, and sustainability. This commitment is aimed at protecting consumers and workers. As the Priority Product Profile outlines, the California Cleaning Products Right to Know Act is a significant step towards transparency. It mandates the disclosure of intentionally added ingredients and certain non-functional constituents in formulations. Likewise, the California Safe Cosmetics Act of 2005 intended to address the regulation of cosmetics by government agencies and established the California Safe Cosmetics Program (CSCP) in the California Department of Public Health. For the Act, the term "cosmetics" includes a wide variety of personal care and cosmetic products. Cosmetics and personal care companies selling products in California must report to CSCP if they use ingredients identified on designated hazard lists. The Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2020 (CFFIRKA) expanded the hazard lists of reportable ingredients and focused on disclosure of unlabeled fragrance and flavor ingredients linked to adverse health effects. All this information is accessible to the public via an online searchable database. These efforts are particularly relevant to 1,4-dioxane, which has a disclosure requirement of 10 parts per million (ppm) if present in any formulation as a non-functional constituent (cleaning products) or as intentionally added (cosmetic and personal care products). It also covers the disclosure of any intentionally added ingredient, including those that could lead to 1,4-dioxane contamination.

Furthermore, cleaning product companies and trade associations have advocated third-party certifications that allow companies to showcase their leadership and commitment to producing safer products, such as the U.S. Environmental Protection Agency's Safer Choice program.[7] This not only instills confidence in consumers about the safety of the products but also promotes innovation and the production of safer products.

[7] https://www.epa.gov/saferchoice

For cosmetics (and, by definition, personal care products), the Modernization of Cosmetics Regulation Act of 2022[8] (MoCRA) makes safety substantiation mandatory for cosmetic companies. This means there is a requirement to "adequately substantiate" that a product is safe and maintain associated records to support such representations. This documentation has been available since July 1, 2024.

Source Reductions Already Made through Efforts in New York

The Product-Chemical Profile cites the recent New York law restricting 1,4-dioxane concentrations in household cleansing and personal care products at length. We want to draw your attention to the efforts undertaken per the requirements of the law. These efforts have been significant since even before New York State's Legislature enacted amendments to Environmental Conservation Law (ECL) Article 35[9] and Article 37[10] to establish a maximum allowable concentration of 1 part per million (ppm) for household cleansing and personal care products by December 31, 2023 (2 ppm since December 31, 2022). The implementation that limited the amount of 1,4-dioxane in cleansing and personal care products to one part per million was a monumental task. This required a significant undertaking by small and large companies to either reformulate products, ensure that their formulations fully comply with these requirements, or withdraw products from commerce.

In many cases, this was a multi-year effort on behalf of manufacturers and suppliers and, by our estimate, impacted well over 42,000 cleaning and personal care products. Reformulation in and of itself is a challenging activity that requires extensive interplay between the manufacturer and supplier(s) and might result in switching ingredients or ingredient blends or adjusting the relative amounts of the ingredients in the product. In addition, an important consideration for many companies, especially those with products available in the consumer space, is that when their products are formulated for New York State and distributed through retail chains, they will be distributed nationwide. Correspondingly, efforts that fulfill the requirements within New York will also benefit products sold nationwide, including in California. Even companies that do not distribute products through retail chains have similarly complex supply chains, and it is unlikely they would have different products in California than in New York.

The state of New York allowed companies to apply for a time-limited waiver if they could not meet the regulatory requirements in the allotted time. Several companies used these time-limited waivers to provide additional time to reach the two or one ppm threshold as allowed by the statute. We also appreciate that DTSC has acknowledged these efforts in setting the Alternative Assessment Threshold (AAT) at one ppm.

Further, DTSC states that "[s]ource reduction, a potential outcome of listing a

[8] https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf

[9] https://www.nysenate.gov/legislation/laws/ENV/35-0105

[10] https://www.nysenate.gov/legislation/laws/ENV/37-0117

personal care or cleaning product containing 1,4-dioxane as a Priority Product, would be an effective way to reduce the presence of 1,4-dioxane in wastewater and therefore assist California in meeting policy goals for recycled water." It's important to note that almost every company that sells products in New York State has already met the proposed requirements in California as described by DTSC, demonstrating the industry's commitment to compliance and alignment with statutory standards. Significant source reduction has already occurred through product compliance with the New York State law, and with those products also being sold in California, the potential for adverse impacts in California has already been reduced. This is an important consideration before proceeding with regulatory activity.

Considering these points, we want to consider several additional concerns as DTSC embarks on the regulatory process.

Outdated and Incomplete Data Set for 1,4-Dioxane Concentrations and Product Use

Companies have made significant progress in reducing levels of 1,4-dioxane—generated as a trace-level impurity from the production of ethoxylated surfactants—below one ppm in household cleansing and personal care products to achieve compliance with this limit under New York State law.[11] We appreciate DTSC accounting for this in proposing an AAT of 1 ppm. However, because the Draft Profile contains information only up to June 2023, this cutoff introduces limitations that affect DTSC's assessment. 1,4-dioxane concentrations detected in personal care and cleaning products sold in the U.S. since 2009 are provided in Table 4, and manufacturer-reported 1,4-dioxane concentrations in relevant products are provided in Table 5; the latter of which was obtained from the New York State Department of Environmental Conservation (NYS DEC), at a time point and from a source where all products reported could have concentrations above one ppm. This data is limited and unverifiable, of unknown quality, and unlikely to reflect concentrations of 1,4-dioxane in household cleaning and personal care products currently available to consumers[12]. Regarding data quality, the reports cited in Table 4 only present results and do not provide information on the sample collection and analytical methods necessary to assess the data quality.

Correspondingly, these datasets need to account for the product landscape following the implementation of the NYS limit of 1 ppm on December 31, 2023, a compliance deadline likely known to DTSC. As a result, the Draft Profile assumes "there are products present in the New York market, and likely the California market, with relatively high concentrations of 1,4-dioxane," which does not reflect product concentrations when the Draft Profile was completed. Additionally, active waivers are decreasing in a number of cleaning and personal care products, with maximum concentrations well those in Table 5. More importantly, many products already had

[11] Available at: https://dec.ny.gov/environmental-protection/help-for-businesses/household-personal-cosmetic-dioxane-limits

[12] CCE Report link is broken - see here https://static1.squarespace.com/static/5b72eb5b8ab7222baffc8dbb/t/5c9a8745ee6eb01dd7c77d5e/1553631051532/FINAL319_+The+2019+Consumer+Shopping+Guide+.pdf.

levels of 1,4-dioxane at or below one ppm; therefore, they never required a time-limited waiver and would never be listed. For instance, Table 5 indicates that there were 415 shampoo product waivers with a mean of 5.6, but if you look at the waivers effective December 31, 2023, through December 30, 2024, indicate only 167 shampoo product waivers with a mean of 3.4 ppm. Notably, the products with waivers must meet the one ppm standard by December 31, 2024, or the products are not compliant with New York law. If the assumption is made that similar products are sold across the U.S., taken with the California Air Resources data (Table 6), that would indicate that over 95% of shampoo products would comply with the one ppm threshold. In addition, the use of European Chemicals Agency (ECHA) assumptions for both concentrations of manual dishwashing detergent (30 and 100 ppm) and shampoo (50 and 300 ppm)[13] are not representative of the current market for these products and therefore, these assumptions should be reevaluated in any assessment that informs the potential impacts to human and environmental exposure and risk.

We are deeply concerned that DTSC cited cleaning product usage at the height of the global pandemic, which is not reflective of the current market or any other point in time. From page 40, "Historical market data for cleaning products may not reflect more recent trends. Notably, the COVID-19 pandemic may have led to an increase in the use of cleaning products and injuries and illnesses caused by exposure to these products. According to the Centers for Disease Control and Prevention (CDC), 45,550 cleaning- and disinfectant-related exposure calls were reported during January to March 2020, an increase of 20.4% from the same timeframe in 2019 (Chang et al. 2020). While the correlation may not be causal, increased media coverage of the pandemic, consumer product shortage, restricted retail purchasing rules, and workplace sanitizing efforts, along with stay-at-home orders, could account for the sharp increase in cleaning and disinfecting product purchase and use (NPR 2020)." While we agree that increased use of cleaning products should be evaluated, indications are that market sales have returned to pre-pandemic levels. While market data is not publicly available, poison center data often serves as a proxy for market sales. If one looks at the National Poison Data System reports, one will note that Cleaning Product cases are 184,402, 214,960, 188,868, and 181,572 for 2019 through 2022, respectively, likely mirroring product sales.[14]

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[13] European Union Risk Assessment Report 1,4-Dioxane, https://echa.europa.eu/documents/10162/a4e83a6a-c421-4243-a8df-3e84893082aa

[14] The National Poison Data System Annual Reports are available here - https://poisoncenters.org/annual-reports/. Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Brooks DE, Dibert KW, Rivers LJ, Pham NPT, Ryan ML. 2019 Annual Report of the America's Poison Centers' National Poison Data System (NPDS): 37th Annual Report. *Clinical Toxicology* (Phila). 2020 Dec; 58(12):1360-1541. PubMed PMID: 33305966.

Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the America's Poison Centers' National Poison Data System (NPDS): 38th Annual Report. *Clinical Toxicology* (Phila). 2021 Dec; 59(12):1282-1501. doi: 10.1080/15563650.2021.1989785. PMID: 34890263.

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The combination of outdated market analysis, lab studies, and manufacturer-reported waiver request 1,4-dioxane concentrations has likely resulted in a biased and skewed dataset that needs to reflect post-pandemic sales adjustments or the current pace of product innovation and reformulation. If DTSC proceeds with the designation of priority product(s), a much more comprehensive and robust dataset that reflects the current marketplace should be developed utilizing the more robust and reflective values based upon the legal requirements in New York. We urge DTSC to update the dataset and perform a longer-term market analysis before and after the pandemic to reflect the marketplace better.

Significant Compliance and Administrative Burdens

We are concerned that DTSC's proposed approach would impose a substantial regulatory burden upon both DTSC and those manufacturers with the product(s) fully compliant with both New York 1,4-dioxane limits and the proposed Alternatives Assessment Threshold of one part per million and at the same time fail to produce any incremental environmental benefits. As noted, when DTSC designates a Priority Product, it will encompass 1,4-dioxane as a contaminant or nonfunctional constituent, a product category, and an Alternatives Assessment Threshold. Correspondingly, manufacturers of Priority Products with 1,4-dioxane present at any level must submit a Priority Product Notification (PPN), and these manufacturers of Priority Products with 1,4-dioxane concentrations at or below the AAT value can choose to submit an AAT Notification (AATN) in place of conducting an Alternatives Analysis or other means of complying with the Safer Consumer Products Regulations. This approach would require a manufacturer with a product fully compliant with New York's requirements to submit a PPN and AATN, a costly and burdensome process that would serve no value in this context because there are no incremental environmental benefits to be had because of compliance with NYS requirements. We caution that DTSC may not have adequately described the number of possible products within the regulation due to the

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Feldman, Kaitlyn Brown, P. T. Pham Nathaniel, Alvin C. Bronstein & Julie A. Weber (2022) 2021 Annual Report of the National Poison Data System© (NPDS) from America's Poison Centers: 39th Annual Report, *Clinical Toxicology*, 60:12, 1381-1643, DOI: 10.1080/15563650.2022.2132768

David D. Gummin , James B. Mowry , Michael C. Beuhler , Daniel A. Spyker , Laura J. Rivers , Ryan Feldman , Kaitlyn Brown , Nathaniel P.T. Pham , Alvin C. Bronstein & Carol DesLauriers (2023) 2022 Annual Report of the National Poison Data System® (NPDS) from America's Poison Centers®: 40th Annual Report, *Clinical Toxicology*, 61:10, 717-939, DOI: 10.1080/15563650.2023.2268981.

differing scope of the CARB regulations,[15] New York's law,[16] and the Safer Consumer Products regulation.[17] As noted in the Product-Chemical Profile in Table 6, dish detergents represent nearly 900 products, shampoos over 6,600 products or 40,000 if all personal and cleaning products are included - the vast majority now below one ppm.[18] Correspondingly, the estimated total costs for this effort[19], the Priority Product

[15] "Consumer Product" means a chemically formulated product used by household and institutional consumers including, but not limited to, detergents; cleaning compounds; polishes; floor finishes; cosmetics; personal care products; home, lawn, and garden products; disinfectants; sanitizers; aerosol paints; and automotive specialty products; but does not include other paint products, furniture coatings, or architectural coatings. As used in this article, the term "consumer product" shall also refer to aerosol adhesives, including aerosol adhesives used for consumer, industrial, and commercial uses.

Cal. Code Regs. tit. 17 § 94508

[16] 108952 (f) "Designated product" means a finished product that is an air care product, automotive product, general cleaning product, or a polish or floor maintenance product used primarily for janitorial, domestic, or institutional cleaning purposes. "Designated product" shall not mean any of the following:

(1) Foods, drugs, and cosmetics, including personal care items such as toothpaste, shampoo, and hand soap.

(2) Industrial products specifically manufactured for, and exclusively used in the following:

(A) Oil and gas production.

(B) Steel production.

(C) Heavy industry manufacturing.

(D) Industrial water treatment.

(E) Industrial textile maintenance and processing other than industrial laundering.

(F) Food and beverage processing and packaging.

(G) Other industrial manufacturing processes.

https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB258

[17] (b) "Consumer product" means a product or part of the product that is used, brought, or leased for use by a person for any purposes. "Consumer product" does not include any of the following:

(1) A dangerous drug or dangerous device as defined in Section 4022 of the Business of Professions Code.

(2) Dental restorative materials as defined in subdivision (b) of Section 1648.20 of the Business and Professions Code.

(3) A device as defined in Section 4023 of the Business of Professions Code.

(4) A food as defined in subdivision (a) of Section 109935.

(5) The packaging associated with any of the items specified in paragraph (1), (2), or (3).

(6) A pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).

Cal. Health & Saf. Code § 25251

[18] There are 11 manual dishwashing products and 1052 total products have active waivers at https://www.dec.ny.gov/fs/projects/waivers/1-4DApprovedWaivers.xlsx

[19] Assumptions are 6600 shampoo products and 900 manual dishwashing products for a total of 7500 total products. Individual manufacturer cost range of $480-$960 per product Priority Product Notification from Table 1 and Estimated Fiscal Cost to DTSC per notification from Table 2 of Economic and Fiscal Impact

Notifications for the cleaning and personal care industry would range from $3.6M to $7.2M (which does not consider the efforts of also submitting an Alternative Assessment Threshold Notification), and the administrative burden on DTSC would be estimated to be between $18.4M and 42.8M. For a frame of reference, the Safer Consumer Products Program had a budget of $28.1M for the fiscal year 2023-2024.[20] As has been noted by DTSC, 1,4-dioxane is a contaminant found in groundwater, effluent, and drinking water. Water is an ingredient in each of the identified product categories. According to the California Code of Regulations (69505.3 – Alternatives Analysis Threshold Notification In Lieu of Alternatives Analysis), at any 1,4-dioxane concentration threshold, all products in each category will need to submit and continuously upkeep an AATN for each product. This will result in tens of thousands of products needing to be tracked by companies and DTSC.

Notwithstanding DTSC's proposal of an AAT of 1 ppm, consistent with New York State's limit for 1,4-dioxane as a byproduct contaminant in household cleansing and personal care products (as of December 31, 2023), we are deeply concerned that a Priority Product designation would result in a significant regulatory burden for products both above and below the AAT, such that no additional source reduction will be gained in California. We recommend that DTSC carefully consider the source reductions to minimize the regulatory burden on companies and the administrative burden on DTSC.

We have a few other considerations to highlight as well. Examples of how the compliance burden could increase include the need to test if a supplier's certification of analysis or other documentation could not be obtained to support an AATN or if resources are needed to perform supply chain inquiries as a toll manufacturer. If DTSC were to require manufacturers to submit AATNs, we recommend an approach similar to that of the California Department of Regulation's Registration Branch not to impede commerce for fully compliant products.

Reporting Requirement Issues - Confidential Business Information, Testing Challenges, Burdens on Testing Laboratories and Small Businesses

DTSC indicated two different ways of determining the levels of 1,4-dioxane: by testing or relying upon a supplier's certificate of analysis. This raises several concerns about protecting confidential information and whether sufficient protections exist. For example, certificates of analysis provided by suppliers to the manufacturers are often closely held business information. Suppliers may be hesitant to supply that type of information to the manufacturers or, more often, to allow that type of information to be publicly disclosed for a wide variety of business reasons. For example, suppliers or manufacturers may not want to disclose the degree or nature of business relationships.

Analysis Attachment to STD 399 for Listing Laundry Detergents Containing Nonylphenol Ethoxylates as a Priority Product.

https://dtsc.ca.gov/wp-content/uploads/sites/31/2024/07/11_Final-Std-399-Attachment.pdf

[20] https://bes.dtsc.ca.gov/wp-content/uploads/sites/42/2024/01/01162024-Item-6-Complete-DTSC-Budget-Update-January-2024-ADA.pdf

In addition, what happens if a company provides a certificate of analysis and changes suppliers? Would a manufacturer need to retest those products? In many cases, a company will identify a suite of suppliers for specific ingredient(s) that meet their internal criteria but may be required to switch from one supplier to another for various reasons, i.e., geographic locations, weather, or market considerations. This could place a considerable burden upon companies if they were required to perform this regulatory step each time they switched suppliers.

Additionally, many companies rely upon supplier information (e.g., certificates of analysis, questionnaires, specifications, or other means of demonstrating the contaminant levels in raw materials) rather than testing. When the supplier information cannot be disclosed, the manufacturer must test their products to meet the AAT requirements. Testing laboratories will be overwhelmed by the substantial increase in testing needs. Further, ingredient suppliers and manufacturers often report the maximum concentration of a contaminant to account for variations between batches and other factors, and the actual value may be much lower. The combination of these situations would incur a testing and reporting burden for companies on products already fully compliant in California and at or below the limit established in New York.

Collectively, we represent many small businesses, and DTSC should carefully consider the potential impact of disparate impacts on small businesses. These types of submissions are particularly difficult for smaller manufacturers to comply with. The costs for multiple and complicated analytical tests burden them disproportionately compared to large companies. Frequently, smaller producers fill 1,000 to 5,000 pieces per production. This means that any analytical costs are amortized across each piece per lot and would directly increase both cost and the retail price the company has to charge, effectively penalizing the small company.

Concentrated Products and Environmental Benefits

Given the environmental benefits of concentrated products, also recognized by DTSC, we encourage DTSC to provide a range of methods to demonstrate compliance with concentrated products in general. Reduced water content in a concentrated or refill concentrate product translates to reduced consumption of water and packaging and reduced transportation emissions; these benefits can be more significant for products sold in solid form. While concentrations of ingredients and byproducts in these formulas will be higher than their counterparts, those amounts are similar per use when concentrates or refills are diluted—that is, similar amounts go down the drain. This also doesn't consider *how* the concentrated product is delivered, which could be via metered dosing or dilution of the concentrate before use.

Concentrated and refill concentrate products should not be penalized through a uniform limit for 1,4-dioxane across all product forms, and dilution should not be inadvertently encouraged as a more straightforward means to achieve compliance. There are also considerable challenges with reformulating concentrated detergents and using different surfactant systems due to limits on the ingredients that can be solubilized with limited water content. Concentrated products are incentivized by

other policies in California, including packaging source reduction requirements in the Plastic Pollution Prevention and Packaging Producer Responsibility Act (SB 54) and the Rigid Plastic Packaging Container Law.[21, 22] Innovation and responsiveness to consumer demand for concentrated products should not be stifled. The environmental benefits of concentrated products are incentivized by other policies in California, including the reduction of packaging, as mentioned above.

Additionally, California's consumer product regulations for volatile organic compound regulations provide support for concentrated products and language that we propose DTSC incorporate here.[23] This would allow manufacturers to use a dilution calculation akin to those utilized by the California Air Resources Board's Consumer VOC rules to demonstrate compliance in a finished product for concentrated products and adopt language from California Code of Regulations Title 17 § 94509 (b), e.g., "For consumer products for which the label, packaging, or accompanying literature specifically states that the product should be diluted with water before use, the limit[AAT] shall apply to the product only after the minimum recommended dilution has taken place."

We appreciate that DTSC recognizes the sustainability benefits of concentrated products and that they may be considered differently than in New York State. We want to note that many concentrated products sold in the industrial and institutional (I&I) markets are dispensed via automatic dispensers, which carefully regulate the dilution of the cleaning product to ensure proper dosage. These systems manage the concentrated product so that the user's exposure to the concentrate is limited, and we encourage careful consideration of this type of scenario.

DTSC's and EPA's Approaches to Toxicity

Among toxicological hazards, DTSC focuses primarily on carcinogenicity and refers to EPA's mode of action (MOA) approach and findings for 1,4-dioxane. We ask DTSC to review and consider an analysis submitted to EPA on the Agency's *1,4-Dioxane: Draft Supplement to the TSCA Risk Evaluation*, which addresses concerns with EPA's approach in detail, references an updated analysis, and strengthens support of a threshold approach.[24] Relevant for DTSC's Draft Profile, this analysis points to the misapplication of the agency's 2005 Guidelines for Carcinogenic Risk Assessment[25] by failing to acknowledge the allowance for uncertainty in a proposed MOA, not updating the MOA framework analysis to reflect the best available science applied in a manner consistent

[21] Cal. Pub. Res. Code § 42057

[22] 14 Cal. Code Regs. § 17945.3(d)(3) and (4)

[23] August 2022, available at: https://ww2.arb.ca.gov/sites/default/files/2022-10/Consumer%20Products%20Final%20Reg%20Order_10-21-2022.pdf

[24] See Appendix A Analysis at https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0723-0119 and https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0066

[25] U.S. EPA. (2005) Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F. Available at: https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment

with the weight of scientific evidence, reliance on a study with significant deficiencies (i.e., Kano et al., 2009—which does not represent the best available science but was cited in the Draft Profile)[26], and not acknowledging the presence of a threshold for genotoxicity (as evidenced in Gi et al., 2018—a study that was cited in the Draft Profile, but not on this point). The Draft Profile recognizes a potential correlation between the saturation of the metabolic pathways and genotoxicity at (and only at) high doses, but there is more to be considered.

Reasonably available information has been used by other regulatory agencies worldwide to reach conclusions on the carcinogenicity MOA that differ from EPA. For example, the European Chemicals Agency's (ECHA) Committee for Risk Assessment (RAC) concluded in 2022 that "the carcinogenicity of 1,4-dioxane is considered to be related to a non-genotoxic mechanism, involving saturation of metabolic capacity, irritation at high exposure levels and formation of liver tumours by regenerative proliferation." Acknowledging some uncertainty with residual risk, "a mode of action-based threshold is assumed for carcinogenic effects.[27] One outcome of the RAC's evaluation was an occupational exposure limit for 1,4-dioxane that is significantly higher than the EPA's existing chemical exposure limit in the EPA's proposed draft.[28] The RAC evaluation is in line with the Scientific Committee on Consumer Safety (SCCS) Scientific Opinion on The Report of the ICCR Working Group: Consideration on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products (2015)[29] that a trace level of 1,4-dioxane in cosmetic products of less than or equal to 10 ppm is safe. Additionally. the Commonwealth of Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) concluded that "[o]verall, indications are that the primary mechanism(s) of tumourigenicity for 1,4-dioxane in animals is non-genotoxic" and that "Evidence from animal studies indicates the existence of a threshold dose for toxicity and carcinogenicity at doses where 1,4-dioxane metabolism becomes saturated."[30] The European Chemicals Bureau (ECB) reached the same conclusion, which stated that "1,4-Dioxane is considered to be a carcinogen acting by a non-genotoxic mode of action. Therefore, a threshold approach is appropriate."[31]

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[26] Kano H et al. (2009). Carcinogenicity studies of 1,4-dioxane administered in drinking-water to rats and mice for 2 years. *Food and Chemical Toxicology*. 47(11):2776–2784. doi: 10.1016/j.fct.2009.08.012.

[27] ECHA (2022a) Committee for Risk Assessment, RAC, Opinion on Scientific Evaluation of Occupational Exposure Limits for 1,4-Dioxane, ECHA/RAC/OEL-O-0000007101-89- 01/F 18/03/2022, European Chemicals Agency (ECHA), available at: https://echa.europa.eu/documents/10162/7937606/1_final_opinion_oel_1_4_dioxane_en.pdf/686365df-9485-c2ac-b342-289ec306d188?t=1656313877233

[28] U.S. EPA. (2023). Draft Existing Chemical Exposure Limit (ECEL) for Occupational Use of 1,4-Dioxane. Available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0905-0039.

[29] Available at https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_194.pdf

[30] NICNAS (1998) 1,4-Dioxane Priority Existing Chemical No. 7, Full Public Report, National Industrial Chemicals Notification and Assessment Scheme (NICNAS), 129 pp., at p. 61 (PDF p. 75), available at: https://www.industrialchemicals.gov.au/sites/default/files/PEC7-1-4-Dioxane.pdf

[31] ECB (2002) European Union Risk Assessment Report, 1,4-Dioxane, CAS No. 123-91-1, EINECS No. 204-

Additionally, Health Canada concluded that "[s]ince 1,4-dioxane acts through a non-genotoxic MOA and demonstrates dose-related non-linear kinetics, a non-linear (threshold) risk assessment approach is considered appropriate."[32] Health Canada also concluded, along with the World Health Organization, that a drinking water level of 50 ug/L is protective of public health.[33,34]

We strongly encourage DTSC to utilize the best available science and align with respected global authorities' conclusions that 1,4-dioxane is a threshold carcinogen.

Analytical Methods and Performance Criteria

We recommend that the proposed unit of measure for the one ppm AAT be based on a weight/weight measurement, not volume/volume as it is currently defined. Using volumetric sample preparation is appropriate for environmental/wastewater measurements, but the varying product densities and handling can significantly affect results, especially at low limits. Industry stakeholders expended considerable effort in conducting peer-reviewed research on methods to measure 1,4-dioxane at minuscule concentrations, which we appreciate DTSC including in the Draft Profile. We recommend that DTSC also include "Precise measurement of 1,4-dioxane concentration in cleaning products: A review of the current state-of-the-art"[35,36]

We fully support DTSC's proposal to allow the use of different but appropriate and validated test methodologies to determine the presence or levels of 1,4-dioxane in Priority Products. This enables those testing a product to choose the most suitable approach, considering sample preparation, product form, variable matrices, potential interferences, available instrumentation, etc. Regardless of the approach, it must be technically sound and scientifically valid.

We agree with the recommendation of a gas chromatograph/mass spectrometer (GC/MS) method to provide the best sensitivity and selectivity as trace levels while allowing other techniques that meet the performance criteria. Flame ionization

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661-8, Institute for Health and Consumer Protection, European Chemicals Bureau (ECB), 2nd Priority List, Vol. 21, 142 pp., at p. 91 (PDF p. 101), available at: https://echa.europa.eu/documents/10162/a4e83a6a-c421-4243-a8df-3e84893082aa

[32] Health Canada (2021) Guidelines for Canadian Drinking Water Quality Guideline Technical Document 1,4-Dioxane, 63 pp., at pp. 39-40 (PDF pp. 44-45), available at: https://www.canada.ca/content/dam/hc-sc/documents/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-1-4-dioxane/1-4-dioxane-pdf-eng.pdf

[33] Ibid.

[34] World Health Organization. (2005). 1,4-Dioxane in Drinking-water: Background document for development of WHO Guidelines for Drinking-water Quality. WHO/SDE/WSH/05.08/120. Available at: https://cdn.who.int/media/docs/default-source/wash-documents/wash-chemicals/dioxane-bd.pdf?sfvrsn=1910104c_4

[35] Palumbo B et al. (2023). A novel protocol for quantitative determination of 1,4-dioxane in finished cleaning products. *J Surfact Deterg*. 26(4): 565–576. doi: 10.1002/jsde.12674.

[36] Hayes DG et al. (2022). Precise measurement of 1,4-dioxane concentration in cleaning products: A review of the current state-of-the-art. *J Surfact Deterg*. 25(6): 729-741. doi: 10.1002/jsde.12633.

detection has also achieved adequate selectivity and sensitivity across ethoxylated raw materials. To improve Appendix D, we ask that DTSC:

- Revise the proposed requirement for isotope dilution using 1,4-dioxane-d^8 as the internal standard, as Hayes et al. (2022) demonstrated that bromofluorobenzene and tetrahydrofuran are suitable and less expensive alternative internal standards. Stable isotope-labeled internal standards are best practices for gas or liquid chromatography paired with MS detection but are not recommended for non-MS-based techniques. DTSC should allow manufacturers to demonstrate appropriate method validation for different product analyses.

- Change the requirement for the initial calibration to use at least four different non-zero calibration concentrations instead of five; this is sufficient for process control strategies.

- Match the initial calibration verification with the continuing calibration verification, such that the calculated concentration of 1,4 dioxane and the surrogate in the initial calibration verification standard solution should both be within 20% of their actual concentration values.

- Change the range of the extraction recovery percentages for the expected analyte concentrations to 90-110 percent, which is both achievable and desirable for enforcement and verification purposes.

- Include "surrogate standard solution" in the "Definitions" section.

- Clarify the spiking level and consider different ranges for extraction recovery percentages for spiking (limit of detection or limit of quantitation level).

- Update the methods and criteria as new methods are developed.

Additional Recommendations for DTSC Consideration

DTSC has the opportunity now to continue stakeholder engagement and update information in the Draft Profile to provide a more current assessment of exposure and risk—e.g., more recent market trends and analytical data from additional products—which would help DTSC focus resources on higher-priority products.

While one or more of the ad hoc coalition members raised this concern in recent comments on the Safer Consumer Product 2024-2026 Work Plan, we want to reiterate that the definition of a "manufacturer" for the SCP program is broad and may include the entity that owns the brand the product is sold under, as well as contract manufacturing companies that develop the product but have no control over sales and distribution. As such, "manufacturers" may have vastly different types of information. For example, a contract manufacturer may know a product's formula and manufacturing process but not the product's intended market, distribution channels, or end-use conditions. Generic data call-ins or requests to all those who meet the SCP definition of a "manufacturer" for a particular product are likely to be overly broad and result in confusion, delays, and unnecessary burden. Considering the broad definition of "manufacturer" under the SCP Program and often complex supply chains, DTSC

should address the implications for different companies with roles in producing a product, having either direct compliance obligations or information that would support the obligations of others. A hierarchical element may be helpful. We recommend that the department tailor information requests to particular companies or types of companies, including ensuring that specific information is being requested from companies likely to have that information.

We also ask that DTSC communicate any changes in "definitions of the Chemical of Concern and the product categories… as well as any method performance criteria" as soon as possible during public engagement and rulemaking. These definitions should not conflict with definitions under other applicable statutes.

Consistent with DTSC's approach in this discussion draft Product-Chemical Profile, and as in the final Product-Chemical Profile for Toluene in Nail Products and final regulatory text, compliance testing should be performed at the point of manufacture.[37,38]

Should DTSC proceed with rulemaking, webinars on the proposed and final rules and compliance assistance tools (e.g., as additions to DTSC's Training Series on Complying with Priority Product Regulations) specific to the Priority Products would also be appreciated.[39]

During the August 20th DTSC webinar, there was a discussion about the scope of products under the potential regulation. Specifically, DTSC identified manual/hand dishwashing detergents and shampoo. Taken together, these two product categories represent no less than 7,500 products, according to CARB's 2015 report. As noted above, an estimated 95% of shampoo products would meet the one ppm AAT threshold and still need to submit an AATN. We urge DTSC to carefully consider the significant reduction in 1,4-dioxane concentrations in personal care and cleaning products that have already occurred through compliance efforts to meet the New York requirements before proceeding with regulatory activity.

We want to thank DTSC for the opportunity to detail the significant efforts undertaken by our industry to minimize the presence of 1,4-dioxane in cleaning and personal care products, as well as the numerous important questions DTSC should address before proceeding with regulatory activity under the Safer Consumer Products regulation. We encourage you to reach out with any questions or considerations we can address as you consider regulatory action.

Sincerely,

[37] Available at: https://dtsc.ca.gov/wp-content/uploads/sites/31/2023/06/Profile_Toluene-in-Nail-Products_FINAL.pdf

[38] Cal. Code Regs., tit. 22, § 69511.6(h). Available at: https://dtsc.ca.gov/wp-content/uploads/sites/31/2023/08/Final-Regulation-Text-with-OAL-Comments_FINAL_Final-Accessible.pdf.

[39] Available at: https://dtsc.ca.gov/scp/training-materials/

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