UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Public Health. Environmental and Environmental Justice Groups on EPA's Draft Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane under Section 6(b) of TSCA

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On November 20, 2020, the Environmental Protection Agency (EPA) announced the availability of a supplemental analysis to its draft risk evaluation for 1,4-dioxane under section 6(b) of the Toxic Substances Control Act (TSCA).[1] These comments on the risk evaluation supplement are being submitted by 10 public health, environmental and environmental justice organizations committed to assuring the safety of chemicals used in our homes, drinking water, workplaces, and the many products we use each day. The commenters include five groups who have advocated health protective and effective policies to implement 2016 TSCA amendments and five groups based in North Carolina who represent communities with drinking water contaminated by 1,4-dioxane. The commenters are as follows:

Safer Chemicals Healthy Families

Environmental Working Group

Natural Resources Defense Council

Earthjustice

Defend Our Health

Center for Environmental Health

Clean Cape Fear

Cape Fear River Watch

Haw River Assembly

Toxic Free NC

Executive Summary

1,4-dioxane is a chemical of high concern to which tens of millions of Americans are exposed. It causes cancer and other serious health effects and is pervasive in drinking water, surface water, ground water, air, workplaces and common household products. EPA's initial draft evaluation, published in July 2019,[2] ignored nearly all of these exposure pathways and focused primarily on risks to workers from the small universe of facilities that intentionally manufacture or process 1,4-dioxane. The initial draft thus failed to address risks to consumers who use numerous products in which 1,4-dioxane is present as a byproduct. It also failed to address the additional risks to consumers and workers from industrial discharges and "down the drain" releases of 1,4-dioxane that contaminate drinking water supplies across the US.

Our groups were extremely critical of these exclusions in our August 30, 2019 comments on the draft evaluation. In its peer review report of October 31, 2019,[3] EPA's independent Science Advisory Committee on Chemicals

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[1] 85 Federal Register 74341 (November 20, 2020). The supplemental analysis (supplement) is available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0067.

[2] 84 Federal Register 31315 (July 1, 2019).

[3] TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2019-02

(SACC) likewise faulted the narrow and limited draft evaluation for failing to present a comprehensive picture of all sources of 1,4-dioxane that contribute to general population exposure and risk. The SACC recommended extensive changes in the draft evaluation to address these concerns.

After ignoring these recommendations, EPA belatedly shifted course when industry groups pushed the Agency to make risk determinations for consumer products containing 1,4-dioxane as a byproduct. It appears that this industry lobbying was prompted by imminent regulation of these products by New York and California and a desire to preempt state regulation under section 18 of TSCA. In response, nearly four years after initiating the evaluation, EPA undertook an expedited analysis which concluded that consumer product exposures do not present an unreasonable risk of injury to health and that industrial surface water discharges of 1,4-dioxane likewise are not harmful to recreational users of impacted water bodies. This supplemental analysis continued to exclude all other environmental sources of exposure to 1,4-dioxane, including drinking water contaminated by 1,4-dioxane in surface water and groundwater, and failed to address risks to workers from the manufacture and use of the ethoxylation-based products EPA added to the evaluation.

As we show below, the supplement is incomplete and highly flawed, reflecting the rushed and superficial process by which it was developed. A more comprehensive analysis based on all available information and sound methodologies would demonstrate that consumer products and contaminated drinking water present unreasonable risks of cancer and non-cancer chronic effects and that surface water discharges of 1,4- dioxane also present unreasonable risks to human health because of their impacts on drinking water sources.

The principal points we make in these comments are as follows:

- ***EPA Has Short-Circuited Minimum Public Comment and Peer Review Requirements for TSCA Risk Evaluations (pp. 4-5)***

  - in order to complete the revised evaluation before the new Administration takes office on January 20, 2021, the Agency has allowed only 20 days for public comment and dispensed with peer review.
  - This truncated process is without precedent. It has curtailed the public's ability to provide informed feedback on the supplement and jettisoned the independent scientific review process which assures that EPA bases decisions under TSCA on the "best available science."
  - EPA must provide at least 60 days for public comments as required by its risk evaluation regulations and ask the SACC to peer review the supplement.

- ***EPA Should Determine that Consumer Products Containing 1,4-Dioxane as a Byproduct of Ethoxylation Present an Unreasonable Risk of Injury of Cancer (pp. 5-16)***

  - EPA's analysis of consumer product exposure significantly understates cancer risks.
    - The Agency fails to identify all consumer products in which 1,4-dioxane may be present
    - The supplement is based on assumed levels of 1,4-dioxane in consumer products that are significantly lower than previously reported levels for many products
    - EPA improperly makes risk determinations for individual products and routes of exposure rather than for cumulative product-related consumer exposures.

Peer Review for EPA Draft Risk Evaluations for 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD), October 31, 2019 (1,4-dioxane SACC report).

- Consistent with SACC recommendations, EPA must account for multiple routes and pathways of exposure, including by:
    - Combining inhalation and dermal exposures
    - Accounting for the use of multiple products simultaneously
    - Recognizing that some products are used multiple times a day
    - Developing chronic exposure scenarios for all 8 of the assessed consumer products based on their recurring and frequent use by some consumers
    - Factoring in background exposure to FDA-regulated personal care and cosmetic products
    - Estimating elevated exposure levels and risks for consumers who are also exposed to 1,4-dioxane in the workplace
- These adjustments in approach should result in risk determinations that exceed EPA's cancer benchmark of 1 X $10^{-6.}$

➢ ***Risk Estimates for Consumers Must Also Consider Drinking Water and Other Environmental Pathways of Exposure in Addition to Exposure from Products (pp. 16-25)***

- The exclusion of environmental releases from the 1.4-dioxane risk evaluation is contrary to TSCA and was categorically rejected by the SACC
- 1,4-dioxane is pervasive in indoor and outdoor air, adding to chronic exposure by consumers
- Groundwater contamination from 1,4-dioxane is also widespread as a result of waste disposal activities and releases at industrial sites.
- Contamination of drinking water at 1,4-dioxane levels that pose unacceptable cancer risks is well-documented in nearly all regions of the US and is attributable to both groundwater and surface water contamination.
- Areas with the highest 1,4-dioxane concentrations in drinking water are Southern California, Long Island and Eastern North Carolina.
- As a result, millions of consumers who use 1,4-dioxane-containing products also have chronic oral, inhalation and dermal exposure from contaminated drinking water.

➢ ***By Focusing only on Risks to Recreational Users and a Small Number of Dischargers, EPA Fails to Account for Known Impacts of Surface Water Discharges on Drinking Water Sources and Human Health (pp. 25-31)***

- EPA's basis for including surface water in the supplement conflicts with its exclusion of drinking water since neither are currently regulated under environmental laws
- By focusing only on occasional recreational exposure, EPA's analysis of surface water discharges fails to satisfy the source water protection goals of water quality criteria for human health under the Clean Water Act (CWA)
- It also fails to comply with TSCA because it ignores the contribution of surface water pollution to contaminated drinking water in North Carolina and other states
    - EPA's evaluation of surface water impacts of 1,4-dioxane discharges is based on only 24 sources – a sample that excludes over 1.6 million dischargers identified by EPA, many facilities that generate 1,4-dioxane as a byproduct, and "down the drain" household cleaning and personal care products.
    - Because of this grossly unrepresentative sample of dischargers, EPA only models surface water concentrations associated with individual facilities, not the aggregate pollutant loadings from numerous facilities discharging to the same water body.

    - In violation of SAAC's advice, EPA has relied on poorly designed modeling of ambient water discharges from industrial sources and deemphasized monitoring that captures 1,4-dioxane levels in surface water on a watershed basis.
- Monitoring of 1,4-dioxane throughout the North Carolina Cape Fear River Basin (CFRB) illustrates the significant surface and drinking water contamination caused by multiple discharge activities across a large watershed.
- A proper analysis of the impacts of surface water discharges on human health would demonstrate that these discharges present an unreasonable risk to drinking water users in the CFRB and elsewhere.

➢ ***The Supplement Fails to Address Non-Cancer Chronic Health Effects on Consumers Which Likely Present an Unreasonable Risk (pp. 31-33)***

- The supplement's evaluation of health risks to consumers is limited to acute toxicity and carcinogenicity; it does not include chronic non-cancer effects although the supplement elsewhere recognizes their importance.
- EPA's final evaluation must estimate chronic non-cancer risks to consumers, taking into account all pathways of exposure and subpopulations with elevated exposure levels.
- In addressing these risks, EPA must revise approaches that understate risk, including by:
    - Increasing Uncertainty Factors (UFs) to account for data-base uncertainty
    - Accounting for differences in susceptibility that increase risks to subpopulations
    - Combining exposure across oral, inhalation and dermal routes
- We expect that, properly conducted, EPA risk determinations will demonstrate unreasonable risks of non-cancer chronic effects to workers and consumers.

➢ ***EPA Must Expand its Evaluation of Worker Exposure to Include Manufacture, Processing and Commercial Use of Products in which 1,4-Dioxane is Present as a Byproduct of Ethoxylation (pp. 33-34)***

- EPA's initial risk evaluation did not address worker exposure during manufacture, processing and commercial use of household cleaning products, cosmetics and personal care products because byproducts were excluded from the evaluation.
- The supplement continues to exclude these worker exposure scenarios although it no longer excludes consumer exposures to the same products.
- Under TSCA, EPA cannot address some phases of chemical's life-cycle and ignore others.
- EPA must address the excluded worker populations in its final risk evaluation.
- It is particularly critical to account for the many workers who use cleaning products in industrial and commercial facilities, such as stores, offices, schools, public buildings, warehouses, and factories.

I. EPA Has Short-Circuited Minimum Public Comment and Peer Review Requirements for TSCA Risk Evaluations

EPA dragged its feet for months on including consumer product exposure in its draft risk evaluation, reversed course at the eleventh hour in response to industry pressure and finally issued a supplemental evaluation on November 20, 2020, five months after the statutory deadline to complete this evaluation. Now, in order to complete the evaluation before the new Administration takes office on January 20, 2021, the Agency has allowed only 20 days for public comment and dispensed with peer review. This rushed process is without precedent. It has curtailed the public's ability to provide informed feedback on the supplement and jettisoned the independent scientific review process contemplated by Congress when it established the SACC, which assures that EPA bases decisions under TSCA on the "best available science."

Our groups and other organizations requested that EPA extend the comment period by 40 days and asked for independent peer review of the supplement by the SACC but EPA denied these requests.

The supplement represents a major expansion in the scope of the 1,4-dioxane risk evaluation. EPA has added eight conditions of use involving consumer products in which 1,4-dioxane is present as a byproduct. EPA has also for the first time evaluated general population exposures to ambient water via recreational swimming and fish consumption. The analyses EPA has conducted on these pathways of human exposure are complex and based on extensive modeling. EPA's expanded evaluation will impact tens of millions of people for which 1,4-dioxane exposures and risks are being assessed for the first time. Because this assessment is incomplete and flawed, health protection will be denied if EPA makes determinations of no unreasonable risk that operate to preempt state regulation under section 18 of TSCA. For these reasons, probing, in-depth review of the supplement by the public and independent scientists is essential to assure that the final evaluation is credible and compliant with TSCA.

EPA's framework rules for TSCA risk evaluations require a comment period of at least 60 days. *See* 40 C.F.R. § 702.49(a). EPA's nearly 100-page "draft supplemental analysis" – along with more than 100 pages of new technical appendices -- is effectively a new risk evaluation for the consumer products and environmental release pathways it addresses and requires a 60-day comment period.

In addition, EPA must request that the SAAC peer review the supplement. All EPA risk evaluations of the initial 10 chemicals have undergone SAAC review. The earlier SACC report on the initial draft evaluation for 1,4-dioxane was highly detailed and made numerous recommendations for improvement. Now that EPA has broadened the scope of the evaluation to include ambient water contaminations and consumer product exposures affecting a broad segment of the US population, further peer review is essential to assure protection of public health. The prior work of the SACC puts it in a strong position to provide EPA with informed and knowledgeable feedback on the expanded evaluation. EPA should not finalize the evaluation until SACC review has been completed.

II. EPA Should Determine that Consumer Products Containing 1,4-Dioxane as a Byproduct of Ethoxylation Present an Unreasonable Risk of Injury of Cancer

EPA concludes that TSCA-regulated cleaning products containing 1,4-dioxane do not present an unreasonable risk to the health of consumers. This conclusion is based on an evaluation of eight product classes that EPA finds have consumer applications. For each of the eight uses, EPA evaluated non-cancer effects to consumers from acute inhalation and dermal exposures. In all cases, EPA found that margins of exposure (MOEs) for these effects were above its benchmark MOE. Recognizing that 1,4-dioxane is a probable carcinogen without a demonstrated threshold, EPA also evaluated cancer risks for four product classes that it found were used on a recurring basis. For this purpose, EPA constructed inhalation and dermal exposure scenarios that resulted in cancer risk estimates for each route that (with one exception) were below the Agency's cancer "benchmark" of 1×10^{-6}.

EPA's analysis of cancer risk was rushed, incomplete and flawed. A proper analysis that takes into account the best available information on the products containing 1,4-dioxane as a byproduct and the contaminant levels they contain and examines all sources of exposure by consumers would reach the opposite conclusion – that the cancer risk is likely above the EPA benchmark and is therefore unreasonable under TSCA.

EPA does not estimate the number of consumers exposed to 1,4-dioxane as a result of its presence as a contaminant in consumer products. However, each day, tens of millions of US residents use personal care, cosmetic and household products containing 1,4-dioxane and often multiple products are used simultaneously. The ongoing inhalation and dermal exposure resulting from daily intake of 1,4-dioxane in consumer products is augmented by its presence in drinking water, air emissions and the workplace. EPA is able to calculate a cancer risk that it deems "reasonable" only by artificially considering each 1,4-dioxane source in isolation from others. However, when all sources are combined to mirror actual real-world exposure, the cancer risk is clearly much larger than EPA has estimated.

A. EPA Has Failed to Identify All Consumer Products in which 1,4-Dioxane May be Present

As shown below, EPA identified 6 general categories of consumer products and then selected 8 specific products within these general categories for exposure and risk characterization:

Table 1-1 Additional Categories and Subcategories of Conditions of Use Included in the Supplemental Analysis to the Draft Risk Evaluation[4]

Life Cycle Stage	Category	Subcategory	References
Consumer uses	Paints and Coatings	1. Latex Wall Paint or Floor Lacquer	TSCA Work Plan Chemical Problem Formulation and Initial Assessment: 1,4-Dioxane (CASRN 123-91-1) (2015)
	Cleaning and Furniture Care Products	2. Surface Cleaner	
	Laundry and Dishwashing Products	3. Dish Soap 4. Dishwasher Detergent 5. Laundry Detergent	
	Arts, Crafts and Hobby Materials	6. Textile Dye	
	Automotive Care Products	7. Antifreeze	
	Other Consumer Uses	8. Spray Polyurethane Foam (SPF)	

According to the supplement, the basis for selecting these products was EPA's 2015 TSCA Work Plan Chemical Problem Formulation and Initial Assessment of 1,4-Dioxane (2015 problem formulation). This document, which preceded the 2016 TSCA amendments, contains limited information on the unintentional presence of 1,4-dioxane in consumer products. While EPA conducted an additional literature search for the supplement, there is no evidence that it contacted manufacturers to identify household products containing 1,4-dioxane or analyzed products for its presence. These steps were required to comply with EPA's obligation under section 26(k) of TSCA to obtain all "reasonably available" information on exposure. It is not clear why EPA did not request product composition data from manufacturers and analyze products, but presumably EPA's artificially compressed schedule for finalizing the supplement made that impossible.

In its November 18, 2020 presentation *1,4-Dioxane Limits for Household Cleansing, Personal Care, and Cosmetic Products,* the New York Department of Environmental Conservation (DEC) identified the following categories of household cleaning products:[5]

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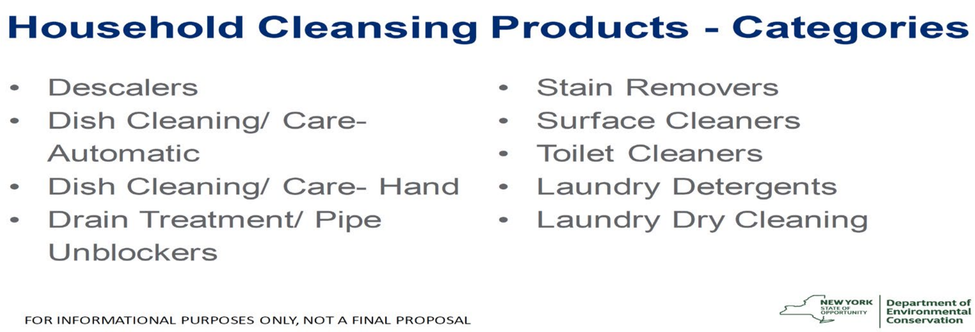
[4] Supplement at 9.

[5] https://www.dec.ny.gov/docs/materials_minerals_pdf/dioxaneslides.pdf (2020 DEC Presentation).



Several of these product types – descalers, drain treatment/product unblockers, stain removers and toilet cleaners -- are not addressed in the EPA supplement.

1,4-dioxane has also been identified as a contaminant in non-cleaning consumer products. ATSDR reports that:

> "1,4-dioxane was found to be an impurity at concentrations of 0.5 and 1–3% in two household adhesive products from the United States (NIH 2004). 1,4-Dioxane was detected in 2 of 62 samples of household adhesives at concentrations of 1.0 w/w% for boot cement and 2.8 w/w% for universal cement (EPA 1992)."[6]

Adhesives are also not addressed in the EPA supplement.

In 2015 comments on EPA's workplan problem formulation, the American Coatings Association (ACA) identified several products derived from ethoxylated raw materials contaminated with 1,4-dioxane. Products with consumer applications included automotive refinishing coatings, paints, caulks, sealants, and adhesives.[7] Although they fall within the general category of paints and coatings identified by EPA, the supplement does not discuss these specific products.

In short, consumers likely use a broader range of 1,4-dioxane-containing products than EPA has addressed. Accounting for these products would mean that consumer exposure to 1,4-dioxane is more frequent and larger in magnitude than the supplement indicates.

B. Reported Levels of 1,4-Dioxane in Consumer Products Are Higher Than the Supplement Assumes

EPA's exposure modeling for the 8 consumer products addressed in the supplement is based on assumptions about the range of 1,4-dioxane concentrations they contain. These assumptions are important drivers of exposure and risk; if 1,4-dioxane levels in a product are higher than EPA has estimated, exposure and risk will be correspondingly larger.

The concentrations incorporated in the supplement span a broad range of values and are derived from an extremely limited number of samples, creating a high degree of uncertainty. EPA could have reduced this uncertainty by seeking product monitoring data from manufacturers but did not take this step, apparently because of its compressed timetable, and thus likely failed to capture a substantial body of data on 1,4-dioxane

[6] ATSDR, Toxicological Profile For 1,4-Dioxane, April 2012, at 176 (ATSDR). https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=955&tid=199.

[7] Comment submitted by Javaneh Nekoomaram, Counsel, Government Affairs and Stephen Wieroniey, Director, Occupational Health and Product Safety, American Coatings Association (ACA), 2015, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0078-0007

levels in products. Moreover, EPA used central tendency weight fractions for chronic exposure scenarios for high- and moderate-intensity users, rather than the highest measured concentration for the product class. [8] Because of this approach, EPA's exposure and risk estimates would not capture products with the largest levels of 1,4-dioxane and thus would fail to estimate the use scenarios resulting in the highest risks to consumers, ignoring a potentially exposed or susceptible subpopulation (PESS) that EPA is required to consider under TSCA.

Equally important, EPA did not consider all publicly available concentration data and, as a result, failed to consider products with measured 1,4-dioxane levels above the upper end of the range on which it based its exposure estimates. For example, the 2015 problem formulation summarized data on 1,4-dioxane measured concentrations in products as follows:[9]

> "When used as a chemical intermediate, 1,4-dioxane concentrations are 100-380 ppm in pharmaceuticals and 1.0 to 2.8% w/w% in household adhesives (ATSDR, 2012). Unintentional contamination levels of 1,4- dioxane in products are . . . 6-160 ppm in household detergents (ATSDR, 2012) and 0.1 – 22 ppm in antifreeze and deicing products (European Chemicals Bureau, 2002. . . . In a study of household products (soaps, shampoos, cleaners and detergents) in Japan, 1,4-dioxane was detected in 40 out of 51 products at concentrations from 0.05 to 33 mg/kg with a mean of 2.7 mg/kg (Tanabe and Kawata, 2008)."

According to ATSDR:[10]

> "Other studies reported that household laundry detergents, shampoos, soaps, and skin cleansers were found to contain 1,4-dioxane at levels ranging from 6 to 160 ppm (Gelman Sciences 1989a, 1989b). In Denmark, cosmetic products and dishwashing detergent, which used polyethoxylated surfactants, contained 1,4-dioxane at levels ranging from 0.3 to 96 ppm and from 1.8 to 65 ppm, respectively (Rastogi 1990). "

The maximum levels reported for household detergents (160 ppm) are well above the maximum levels the supplement provides for dishwashing detergent (9.7 ppm) and laundry detergent (14 ppm). The higher levels would result in risks over 10 X greater than those calculated by EPA. Recent testing for New York DEC also reports higher levels for laundry detergent (21 ppm) and cleaning products (23.1 ppm), again resulting in higher estimates of exposure and risk.[11]

EPA provides little information with which to evaluate the few reported studies on which it relies and does not explain why it failed to include studies reporting higher levels that were cited in its 2015 problem formulation and the 2012 ATSDR ToxProfile. Moreover, EPA acknowledges that its understanding of the presence of 1,4-dioxane in consumer products and the resulting levels of exposure is extremely limited because of the lack of reliable information:[12]

> "Because 1,4-dioxane is present in consumer products as a byproduct and not as an ingredient, there is more uncertainty than typical when identifying and using concentration information. Unlike other chemicals that are ingredients in consumer products with readily available reported concentration

[8] Supplement, at 52-53.
[9] Workplan Problem Formulation at 27
[10] ATSDR at 176
[11] 2020 DEC Presentation.
[12] Supplement at 51 (emphasis added)

> ranges in SDSs for each product category, 1,4-dioxane concentrations have been sourced from a variety of primary and secondary sources such as governmental risk assessments, SDSs, literature reviews, emission studies, etc. *There are limited reasonably available data and they are not necessarily complete or consistently updated and general internet searches cannot guarantee entirely comprehensive product identification. Therefore, it is possible that the entire universe of products that contain 1,4- dioxane as a byproduct may not have been identified, or that certain changes in the universe of products may not have been captured, due to market changes or research limitations***.** Maximum identified weight fractions were used in acute high-intensity user scenarios and mean weight fractions were used in chronic high-intensity and moderate-intensity user scenarios, where possible. *While weight fractions are described as "maximum" in tables, these reflect only the maximum levels identified from available literature and other sources and may not capture the true maximum in specific products or batches.*

An obvious way to address these uncertainties would be to require manufacturers to submit analyses of 1,4-dioxane levels in their products and, if such data are limited, direct them to conduct product testing under section 4 of TSCA. However, EPA effectively ruled out this approach by, first, deciding not to include consumer product exposure in its draft risk evaluation and then, after belatedly reversing course, setting an unrealistic deadline for completing the revised evaluation driven by the political calendar and not its information needs. If EPA persists in issuing a final evaluation without obtaining adequate data from industry, it should at a minimum compensate for the inadequate information in its possession by making conservative, high-end assumptions about the size of the relevant product universe and the levels of 1,4-dioxane present in these products.

C. By Making Risk Determinations for Individual Products and Routes of Exposure, EPA Significantly Understates Overall Cancer Risk

As EPA acknowledges, "inhalation and dermal exposures were evaluated on a product-specific basis and are based on use of a single product type within a day, not multiple products. There was no aggregation of dermal and Inhalation exposure to single products either."[13] This approach violates TSCA because it results in a systematic understatement of real-world exposure and risk, which cannot be meaningfully determined without accounting for the combined contribution of the multiple sources of 1,4-dioxane to which the population is exposed.

1. Consistent with SACC Recommendations, EPA Must Account for Multiple Routes and Pathways of Exposure

Risk evaluations under TSCA section 6(b)(4)(A) must determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment." This requirement cannot be met without examining all sources of exposure that contribute to health and environmental risk. In addition, section 6(b)(4)(A) provides that a risk evaluation must determine the substance's risks under "the conditions of use." This broad term spans the entire life cycle of a chemical and is defined under section 3(4) to mean "the circumstances . . . under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." To focus on one source of exposure to the exclusion of others would fail to address the "circumstances" of a chemical's conditions of use throughout its life-cycle.

[13] Id. at 50.

EPA also has an obligation under section 6(b)(4) to address risks to "potentially exposed or susceptible subpopulations" – or PESSs. As defined in TSCA section 3(12), PESSs include groups that "may be at greater risk than the general population of adverse health effects . . .because of greater exposure." EPA cannot identify and evaluate the greater risk which highly exposed subpopulations face unless it accounts for the contribution of multiple routes and pathways of exposure, since the higher levels of exposure and risk experienced by specific groups is a function of the different sources by which they are exposed to 1,4-dioxane. For example, communities of color are more likely to be exposed to 1,4-dioxane through workplace exposure, by drinking water contaminated with 1,4-dioxane, and from use of consumer products containing the substance. EPA's failure to consider the greater risks to these highly exposed subpopulations raises serious environmental justice concerns.

In its review of EPA's initial draft evaluation for 1,4-dioxane, the SACC rejected the Agency's contention that, "[a]s a result of the limited nature of all routes of exposure to individuals resulting from the conditions of use of 1, 4-Dioxane, a consideration of aggregate exposures of 1, 4-Dioxane was deemed not to be applicable for this risk evaluation." SACC commented that "[t]his does not seem a strong justification for not considering aggregated exposure. If all routes of exposure are of limited nature, then would not a single route be of even more limited nature?"[14]

EPA's determinations of 1,4-dioxane exposure from consumer products continue to apply the flawed "single pathway" approach that the SACC previously rejected for 1-4-dioxane.

2. EPA Must Combine Dermal and Inhalation Exposures Since It Acknowledges that Consumers are Typically Exposed by Both Routes Simultaneously

As in previous evaluations, EPA does not aggregate the contribution of inhalation and dermal routes to consumer exposure to 1,4-dioxane even though it recognizes that these routes are concurrent for all 8 of the consumer products it evaluates. EPA's continued adherence to this approach is not defensible given its repeated rejection by the SACC.

In its report on the draft evaluation for 1-bromopropane (1-BP), the SACC recommended that EPA estimate "cumulative exposures, which involves both dermal and inhalation contact with 1-BP" because "dermal exposure to 1-BP would most likely correspond with simultaneous inhalation exposure" and "vapor and dermal exposures are not separable."[15]

Similarly, the SACC report on the draft evaluation for perchloroethylene (PCE) "recommend[s] estimating aggregate and cumulative exposures across inhalation and dermal routes of exposure"[16] and emphasizes that "consumer dermal and inhalation exposure estimates should be aggregated to obtain a more accurate estimate of the consumer's total exposure. "[17]

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[14] 1.4-Dioxane SACC Report at 75.

[15] TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2019-03, Peer Review for the United States Environmental Protection Agency (EPA) Draft Risk Evaluation for 1-Bromopropane (1-BP) (SACC Report on 1-BP), December 12, 2019, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0061, at 47, 73.

[16] TSCA Science Advisory Committee on Chemicals, Meeting Minutes and Final Report No. 2020-5 *Peer Review for EPA Draft Risk Evaluation of Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro),* August 18, 2020 (SACC Report on PCE) at 17

[17] Id. at 58-59.

Since EPA's exposure modeling shows that consumer exposure to 1,4-dioxane by both the dermal and inhalation routes is substantial, failure to combine these routes necessarily underestimates its cancer risks.

3. Consumers Use Multiple 1,4-Dioxane-containing Products, Resulting in Multiple Sources of Exposure and Risk

EPA's assumption that consumers do not use multiple products containing 1,4-dioxane and that the risk of each individual product can be determined in isolation from others is similarly flawed. 1,4-dioxane-containing household cleaning products are used pervasively by consumers and perform a wide range of essential functions in the home environment. Thus, a consumer who uses laundry detergent for clothes washing would also apply surface cleaners to kitchen counters, furniture, shower stalls and toilet bowls and similarly use dishwashing detergent or hand soap to clean dirty dishes. These activities would normally occur on the same day and each product used would contribute to consumer exposure, resulting in aggregate exposure significantly greater than the contribution of each product alone. EPA can readily account for multiple product use by combining estimated exposure levels for all cleaning products likely to be used on an ongoing basis. This would increase risk estimates significantly.

4. EPA Assumes a Single Use Event Per Day but Some Products Are Used Multiple Times

Also fallacious is EPA's assumption that household products are only used once a day and that exposure and risk are a function of that single use. It is common for large families to machine wash several loads of clothes a day, each requiring a separate application of laundry detergent. Similarly, dirty dishes are typically washed two or more times a day, resulting in two or more applications of dish soap or dishwashing detergent. Surface cleaners likewise may be used multiple times, as bathrooms, kitchens and other areas are cleaned in the course of the day. Frequent daily cleaning and laundering are most common in homes which have large families, provide childcare or babysitting, have residents who are immune-compromised, house people with allergies to dusts and mites, and have multiple pets. Moreover, in this year of the COVID pandemic, purchases of household cleaning products surged upwards by nearly 400 percent in the first week of March, 2020, reflecting greater usage as more people stayed in their homes rather than leaving for work or school.[18] For EPA to assume that cleaning products are used once per day is thus unsupportable and understates actual exposure and risk. As EPA admits, this approach "may not capture users that continuously use products throughout the day."[19]

In sum, EPA needs to recalculate its consumer risk estimates to reflect the combined effects of concurrent dermal and inhalation exposure, use of multiple 1,4-dioxane-containing cleaning products simultaneously and repeated applications of individual products in the course of a day.

5. EPA Erroneously Concludes that Four of the Consumer Products It Evaluates Lack Chronic Exposure

EPA explains in the supplement that "chronic inhalation exposures are only presented for conditions of use that are reasonably expected to involve daily use intervals (*i.e.,* surface cleaner, dish soap, dishwasher detergent, and laundry detergent) [and] that [o]ther conditions of use (*i.e.*, SPD, antifreeze, textile dye, and paint and floor lacquer) are not evaluated over durations based on expected infrequentand intermittent use frequencies."[20]

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[18] Cleaning product sales growth from the coronavirus in the U.S. in March 2020. Jan Conway, August 19, 2020. https://www.statista.com/statistics/1104333/cleaning-product-sales-growth-from-coronavirus-us/.
[19] Supplement at 52,
[20] Id. at 33.

This approach overlooks the use of these products on a frequent and recurring basis and ignores SACC's recommendation that similar uses of other risk evaluation chemicals should be evaluated for risks of chronic exposure.

For example, SPD, paints and floor lacquer are used regularly by consumers engaged in "do-it-yourself" home repair and renovation projects. Textile dye and other arts-and-crafts products are used regularly by home hobbyists and artists. Automotive maintenance products like anti-freeze, deicing fluids and body paint are used frequently by consumers who service their own and their friends' vehicles.

While EPA has consistently maintained that consumer products should not be evaluated for chronic health risks, it has conceded that intensive use of these products could result in chronic exposure. For example, EPA's draft 1-BP draft evaluation acknowledged that an assumption of infrequent consumer product use "may result in underestimating the exposure of certain consumer users, in particular those consumers who may be do-it-yourselfers who may use products more frequently or may use more than one product within a single day." [21] In its draft PCE evaluation, EPA similarly recognized that "there is uncertainty whether chronic risks may be of concern for consumers at the very high end of the range for frequency of use, especially if a product is used several days consecutively."[22] As EPA elaborated:[23]

> "[T]here is a growing consumer practice to complete projects or activities as do it yourselfers. Do it yourself activities could lead to an increased frequency of product use as well as using more than one product containing a chemical of concern within a given day. These and other factors associated with do it yourself activities could result in underestimating consumer exposure concentrations modeled in this evaluation for the do it yourself consumer."

Based on these considerations, SACC has recommended that EPA address chronic exposure scenarios for consumer products. Thus, in its report on the TCE evaluation, the SACC "disagreed with EPA's decision not to characterize chronic risks for consumers." As it explained:[24]

> "Several Committee members suggested that some consumers are likely to be exposed more frequently and more pervasively to emissions from these products than indicated by the Westat survey data (U.S. EPA, 1987). Firstly, certain high-exposed consumers (hobbyists, home businesses, etc.) are likely to use more than one trichloroethylene-containing product on the same day and/or multiple and consecutive days. Secondly, the Westat survey was unlikely to capture the true distribution of use frequency for high-end users (i.e., oversampling these subpopulations would have been required to obtain a reliable estimate of use patterns for these individuals). Thirdly, it is likely that contributions to indoor air concentrations (and, therefore, exposures) persist for longer periods of time than assumed by EPA from sources such as carpet spot cleaners and fabric sprays (see also, for example, Doucette et al., 2018; Gorder and Dettenmaier, 2011)"

The SACC report on the draft PCE evaluation likewise indicated that "[s]everal Committee members would also like to see chronic exposures to consumers by both dermal and inhalation routes estimated and included in

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[21] 1-BP Draft Evaluation at 130.

[22] Draft Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro), April 2020, at 402.

[23] Id at 245.

[24] TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2020-4 Peer Review for EPA Draft Risk Evaluation for Trichloroethylene (TCE), June 1, 2020, at 58.

the assessment."[25] Since "some consumer use scenarios are likely to be associated with chronic exposures because of high frequency of the activity or because of elevated indoor air levels from use and storage in the home," the report recommended that "[t]hese exposures should be evaluated for the chronic endpoints as well as acute endpoints."[26]

While the 4 non-cleaning products evaluated only for acute effects in the supplement might have some occasional users, the subset of consumers that use these products intensively would qualify as a PESS under TSCA because of their higher exposure to 1,4-dioxane. Thus, EPA must address whether these consumers are at risk of chronic health effects and evaluate whether these risks are unreasonable. Moreover, users of the four products likely overlap with users of four household cleaning products addressed by EPA and thus all eight products would contribute to chronic exposure by these consumers, resulting in a greater cumulative cancer risk.

D. In Determining Risks from TSCA-regulated Consumer Products, EPA Fails to Account for Background Exposure from FDA-regulated Personal Care and Cosmetic Products

In its consumer product exposure analysis, EPA assumes that "background concentrations" of 1,4-dioxane are "zero."[27] In fact, consumers who use the TSCA-regulated products evaluated by EPA also have significant exposure to numerous personal care and cosmetic products that similarly derive from ethoxylated raw materials and also contain 1,4-dioxane as a contaminant. Although beyond TSCA authority and regulated by the Food and Drug Administration (FDA), these products contribute to 1,4-dioxane exposure by consumers and represent a "background" level of cancer risk which must be considered in determining whether the additional risk from TSCA-regulated products is "unreasonable."

The SACC has consistently urged EPA to consider background exposure in TSCA risk evaluations. Thus, its report on the initial 1,4-dioxane draft evaluation underscored that "[t]he decision not to further analyze background levels of 1,4-Dioxane in any matrix . . . cannot be supported by any risk assessment principle. Any current use scenarios increase exposures over those currently being experienced."[28] The PCE report similarly emphasized that:[29]

> "[T]he exposures identified in most COUs underestimate risk if background and co-exposures are not considered cumulatively and in aggregate, including across chemicals with similar properties. This would be important to consider if EPA's intention is to keep worker, ONU, and consumer exposures below health-based benchmarks. For example, the MOE benchmarks . . . do not consider that these workers have other exposures from air, water, and consumer use. MOEs should be large enough to leave room in the "risk bucket" for these, and also for co-exposures to similar chemicals."

[25] SACC Report on PCE at 18.
[26] Id. at 91-92.
[27] EPA, Draft Risk Evaluation for 1,4-Dioxane Draft Supplemental File: Consumer Exposure Assessment Model Input Parameters, November 2020.
[28] 1,4-Dioxane SACC Report at 45.
[29] PCE SAAC Report at 104.

The report recommended that EPA address "whether exposures and associated risks are underestimated by not considering background exposures"[30] and faulted EPA for "not discussing all exposure pathways, even if not TSCA regulated, to get a complete exposure assessment."[31]

To determine the extent of 1,4-dioxane's presence in in personal care products and cosmetics, the Environmental Working Group (EWG) analyzed its Skin Deep® cosmetics database for ingredients produced through ethoxylation, such as polyethylene, polyethylene glycol (PEG) and ceteareth and found these ingredients in over 8,000 personal care products, including shampoos, soaps, lotions, sunscreens, toothpastes and cosmetics. According to EWG, 200+ of these products are marketed to children and infants.[32] These products are used by a large portion of the US population. EWG conducted an online survey in 2004 "of the cosmetics and personal care products used by 2,300 people" and found that 1 in 5 adults is potentially exposed every day to 1,4-dioxane.[33]

As described in EPA's 2015 problem formulation, "the Canadian risk assessment presented aggregate 1,4-dioxane exposure estimates for various age groups including infants, children and adults (Environment Canada and Health Canada, 2010). Adult women were considered the highest exposed demographic group due to the use of cosmetics as well as other consumer products" According to the problem formulation, "EPA/OPPT concludes that . . . Adult women who use multiple cosmetics and cleaning products are likely the most exposed population." [34]

FDA testing to determine the levels of 1,4-dioxane in ethoxylated raw materials and surfactants has been summarized by ATSDR as follows:[35]

> "Since 1979, FDA has conducted periodic surveys of levels of 1,4-dioxane in ethoxylated raw materials used in cosmetic products and finished cosmetic products (Black et al. 2001). In 1997, the average concentration of 1,4-dioxane in ethoxylated raw materials used in cosmetic products was 348 ppm (range, 45–1,102 ppm). In previous years, the average concentrations of 1,4-dioxane were 49 ppm (1979), 207 ppm (1980), 71 ppm (1993), and 180 ppm (1996). The average concentration of 1,4-dioxane in ethoxylated alkyl sulfate surfactants was reported to be 229 ppm (range, 71–580 ppm), 226 ppm (range, 6–1,410 ppm), 80 ppm (range, 16–243 ppm), 188 ppm (range, 20–653 ppm), and 48 ppm (range, 45–1,102 ppm) in the years 1979, 1980, 1983, 1993, 1996, and 1997, respectively (Black et al. 2001)."

As described by ATSDR, FDA has also tested numerous personal care products and cosmetics:[36]

> "In an FDA survey of cosmetic finished products in the United States, the average concentrations of 1,4-dioxane were reported to be 50 ppm (range, 2–279 ppm), 19 ppm (range, 2–36 ppm), and 2 ppm (range, 1–8 ppm) for the years 1981, 1982, and 1983, respectively (Black et al. 2001). After a 10-year break, FDA resumed its surveys of cosmetic finished products in 1992. The number of products analyzed for 1,4-dioxane between 1992 and 1997 totaled 99. Since 1994, the focus was on children's shampoos and

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[30] Id at 105.
[31] Id at 45.
[32] EWG Surveys Personal Care Product Companies About 1,4-Dioxane, https://www.ewg.org/release/ewg-surveys-personal-care-product-companies-about-14-dioxane; Hundreds of Kids' Cosmetics Products May Contain Hidden Carcinogen, https://www.ewg.org/enviroblog/2017/07/hundreds-kids-cosmetics-products-may-contain-hidden-carcinogen.
[33] https://www.ewg.org/news/news-releases/2007/02/08/ewg-research-shows-22-percent-all-cosmetics-may-be-contaminated-cancer.
[34] 2015 Problem Formulation at 27-28
[35] ATSDR at 176.
[36] Id.

bubble baths, which are typically formulated with ethoxylated raw materials. FDA observed that the previous downward trend in the levels of 1,4-dioxane in products in the late 1980s was no longer evident in the 1990s. The average concentrations of 1,4-dioxane in cosmetic finished products were reported to be 41 ppm (range, 5–141 ppm), 79 ppm (range, 50–112 ppm), 45 ppm (range, 20–107 ppm), 74 ppm (range, 42–90 ppm), 14 ppm (range, 6–34 ppm), and 19 ppm (range, 6–34 ppm) in the years 1992, 1993, 1994, 1995, 1996, and 1997, respectively (Black et al. 2001)."

More recently, extensive testing of personal care products and cosmetics has been conducted by the Campaign for Safe Cosmetics (2007). According to ATSDR,[37] the Center reported --

> "that the levels of 1,4-dioxane in cosmetic products that were tested were slightly lower than in the survey conducted by the FDA in the 1990s. The levels of 1,4-dioxane in these products ranged from 1.5 to 12 ppm in baby and children's products and from 2 to 23 ppm in adult products. A second survey released in March of 2009 had similar results. Thirty-two out of 48 consumer products had detectable levels of 1,4-dioxane, with levels ranging from 0.27 to 35 ppm (Campaign for Safe Cosmetics 2009)."

In 2019, further testing was reported by the Citizens' Campaign for the Environment. In *Shopping Safe: the 2019 Consumer Shopping Guide,* the Campaign indicated that it had found 1,4-dioxane levels of 1 ppm or higher in a large number of baby products, body washes and gels, hand soap, men's personal care products and shampoos. Several products had levels of 1,4-dioxane above 10 ppm.[38] More recently, a high percentage of body products and shampoos was found to have 1,4-dioxane levels above 1 ppm in testing conducted by the New York State Pollution Prevention Institute.[39]

In sum, total intake of 1,4-dioxane from inhalation and dermal exposure to FDA-regulated cosmetics and personal care products is substantial and the many consumers who use these products are also users of TSCA-regulated household cleaning and other products. If EPA ignores the contribution of this background exposure and bases its risk determinations solely on exposure to TSCA-regulated products, it will underestimate the true cancer risk to consumers. In quantifying background exposure, EPA must factor in consumption levels for different subpopulations, particularly adult women, who are most highly exposed to 1,4-dioxane from personal care products and cosmetics. EPA must also factor in increased exposures by low wage workers and communities of color, who are most highly exposed through the use of cleaning other consumer products and the disposal of wastes containing 1,4-dioxane in or near their neighborhoods.

E. EPA Fails to Account for Elevated Cancer Risks to Consumers Who Are Also Exposed to 1,4-Dioxane in the Workplace

Consumers exposed to 1,4-dioxane in their places of employment are at greater risk than the general population because their exposure is from two different sources. The supplement makes no effort to evaluate the aggregate exposure – and elevated risk -- from concurrent workplace and consumer pathways. However, individuals who receive 1,4-dioxane from both sources are clearly PESSs under TSCA by virtue of their elevated exposure and, for this reason, the higher risks they face must be separately addressed in EPA's evaluation.

Thus, the SACC has strongly recommended that EPA combine consumer and workplace pathways so that risks to this highly exposed segment of the population are not underestimated. For example, the SACC report on the 1-BP draft evaluation states that:

[37] Id.
[38] https://static1.squarespace.com/static/5b72eb5b8ab7222baffc8dbb/t/5df157d77894063402af288c/1576097757857/FINAL319_+The+2019+Consumer+Shopping+Guide+.pdf.
[39] 2020 DEC Presentation.

"The Committee found that the draft risk evaluation failed to consider cumulative or aggregate exposures. It was pointed out that a worker who is occupationally exposed may also be exposed through other conditions of use in the home. Yet, these exposures are decoupled in the draft risk evaluation."[40]

Similarly, the SACC report on the PCE evaluation "recommended that the EPA consider aggregate and cumulative exposure across inhalation and dermal routes of exposure [and] in work and out of work exposures"[41] and faulted the Agency for failing to "consider that these workers have other exposures from air, water, and consumer use."[42]

The subpopulation with concurrent workplace and consumer exposure to 1,4-dioxane is a large one. It includes not only workers engaged in intentional production and processing activities but those who manufacture ethoxylated raw materials containing 1,4-dioxane byproducts[43] or use these raw materials to formulate household cleaning and personal care products and cosmetics. Moreover, many cleaning products containing 1,4-dioxane have commercial and industrial applications and are used by workers at a wide range of facilities, including offices, hotels, restaurants, laundromats, stores, warehouses, and factories. These groups of workers are highly likely to also use one or more products containing 1,4-dioxane in their homes, adding to exposure and risk from workplace activities.

The exclusion of consumers with concurrent workplace exposure is another example of EPA's flawed and unprotective risk determination for 1,4-dioxane-containing consumer products. EPA must expand its analysis to account for the higher levels of exposure and risk of this PESS.

In sum, if EPA corrects its analysis to properly account for total exposure to 1,4-dioxane in consumer products, consumers in general – and PESSs in particular – would likely have cancer risks in excess of the 1×10^{-6} EPA benchmark for unreasonable risk to the general population.[44]

III. Risks to Consumers Cannot be Adequately Addressed Without Considering Environmental Pathways of Exposure

EPA's evaluation of risks from 1,4-dioxane in household cleaning and other products is also incomplete because it continues to ignore the contribution of air pollution and contamination of drinking water and groundwater to total consumer exposure.

A. The Exclusion of Environmental Releases from the 1.4-dioxane Risk Evaluation is Contrary to TSCA and Has Been Strongly Criticized by the SACC

EPA excluded environmental sources of 1,4-dioxane from its initial draft evaluation on the rationale "that other environmental statutes administered by EPA adequately assess and effectively manage these exposures."[45] In

[40] SACC Report on 1-BP Evaluation at 16.
[41] PCE SACC Report at 54.
[42] Id. at 104.
[43] ATSDR notes that "Individuals involved in the manufacture of ethoxylated chemicals may be exposed to 1,4-dioxane from its occurrence as a by-product, and in particular during the stripping process, which is carried out to remove 1,4-dioxane from certain ethoxylated chemicals (mainly surfactants and emulsifiers) (EC 2002)." ATSDR at 179
[44] This benchmark should not be treated as a bright line for unreasonable risk in all cases. For 1,4-dioxane, a higher benchmark – 1×10^{-7} for example -- would be warranted because of the unusually large percentage of the US population exposed through consumer products and other pathways and the need to account for the higher susceptibility to 1,4-dioxane's carcinogenicity by certain subpopulations.
[45] Draft Risk Evaluation for 1,4-Dioxane, June 2019, at 156.

our comments on the draft evaluation, we demonstrated that this approach is legally flawed because TSCA was clearly intended to provide for a comprehensive examination of risks from all pathways, including those subject to media-specific environmental laws. We also emphasized that EPA's exclusion of environmental pathways of exposure ignored the significance of these pathways for 1,4-dioxane and resulted in significant understatement of its risks to health because of the failure to account for all sources of exposure.

In its report on the 1,4-dioxane draft evaluation, the SACC voiced similar concerns:[46]

> "Exposure scenarios that include consumers are important given the known presence of 1,4-Dioxane in plastics, other commercially available products, surface water, drinking water, groundwater, and in sediments. The Committee also had concerns that the omission of these multiple routes of exposure puts workers who inhale or ingest 1,4-Dioxane outside the workplace at even greater risk."

The SACC added that:[47]

> "The Committee discussed that if each program office of the EPA says others are assessing the risks and thus not including them in their assessment, the U.S. public will be left with no overall IRIS assessment of risks. If risks have been assessed by other program offices of EPA then the Agency should present them as part of the underlying data to support this TSCA Evaluation—if not, the Agency must gather the data for an assessment or include an assessment based on the assumption of near-worst-case exposures."

The SACC underscored that "[g]eneral human population and biota exposure must be assessed for inhalation, ingestion, and dermal routes [and that] [d]ifferent sub-populations may have different extents of exposure, but each route must be assessed."[48] EPA's narrower approach, it said, "strayed from basic risk assessment principles by omitting well known exposure routes such as water consumption by all occupationally and non-occupationally-exposed humans as well as similar exposures to other biological receptors."[49]

The SACC also emphasized that:[50]

> "Several Committee members noted a concern on the exclusion of the general population and susceptible populations from the Problem Formulation under the assumption that other regulations (e.g., Clean Water Act, Clean Air Act, Safe Drinking Water Act) cover the pathways and noted this is counter to the state-of-the-art practice for risk assessment. Several committee members also observed that failure to assess 1,4-Dioxane exposure in the general population may leave substantial portions of the population at risk. This is particularly concerning for drinking water."

The SACC review of the 1-BP draft risk evaluation similarly took EPA to task for failing to consider air emissions and other environmental releases: [51]

> "The lack of consideration for general population exposures excludes a vast extent of the US population (workers, consumers, school children, and other populations) who are exposed to 1-BP, perhaps on a daily basis. The lack of consideration of the general population exposure is concerning given the strong evidence of widespread exposure to a chemical that may be 1-BP based (from biomonitoring data)."

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[46] 1,4-Dioxane and HBCD SACC Report, at 18.
[47] Id.
[48] Id.
[49] Id.
[50] Id. at 72
[51] SACC 1-BP Report at 17.

The SACC report for the methylene chloride evaluation raised similar concerns:[52]

> "Several Committee members expressed concern that large quantities of methylene chloride are volatilized to ambient air from diverse and disperse uses and that there is no COU that provides a basis for setting any limit on these emissions. While EPA asserts that the Clean Air Act (CAA) can be used to control these emissions, Committee members thought the CAA would address only a fraction of total emissions, i.e. only from Major Sources as defined by the 1990 CAA Amendments."

The SACC expressed concern that "readers of this Evaluation receive a partial picture of risks, finding for example, that recycling and proper disposal present the only environmental hazards under TSCA" and that "this incomplete picture of risks may be used to promote improper releases and disposal of methylene chloride."[53]

The SACC report for PCE reiterated these concerns, emphasizing that

> "not considering all sources of PCE exposure results in an incomplete picture of exposures and subsequent underestimation of PCE exposures to occupational workers and consumers. Occupational workers, ONUs and consumers are exposed to the same population sources of PCE such as that in community drinking water and ambient air, in addition to their manufacturing, processing or product use exposures. The Committee continues to question the justification for this exclusion used by the Agency, namely that other statutes adequately assess and effectively manage these exposures, without further details or supporting information."[54]

The SACC specifically recommended that "PCE exposures that the general population experience, such as from drinking water, should be estimated and used to better estimate consumers' total exposure"[55]

However, in the face of strong and repeated SACC concerns, the supplement continues to ignore exposure to 1,4-dioxane from air emissions, drinking water and groundwater. As EPA admits, it "did not evaluate unreasonable risk to the general population from ambient air, drinking water, and sediment pathways for any conditions of use in this risk evaluation, and the draft unreasonable risk determinations do not account for exposures to the general population from ambient air, drinking water, and sediment pathways."[56]

As discussed below, EPA's failure to consider these significant contributors to exposure violates TSCA and results in an assessment of risks to consumers that is incomplete and under-protective.

B. 1,4-Dioxane Is Pervasive in Outdoor and Indoor Air

ATSDR identifies "inhalation of 1,4-dioxane in air" as among "[t]he primary routes of human exposure to 1,4-dioxane for the general population."[57] It summarizes measurements of 1,4-dioxane in ambient air as follows:[58]

> "In 1984, the concentration of 1,4-dioxane ranged from 0.1–0.4 μg/m^3 in ambient air sampled from the United States. No information was provided in this source on the locations where the air sampling occurred (EC 2002). In the early to mid 1980s, the mean ambient levels of 1,4-dioxane in outdoor air was measured as part of the VOC National Ambient Database in the United States (Shah and Singh 1988). The mean concentration of 1,4-dioxane was 0.107 ppbv or 0.385 μg/m^3 (n=617; median, 0.000 ppbv).

[52] SACC Methylene Chloride Report at 75.
[53] Id.
[54] PCE SACC Report, at 46.
[55] Id. at 58
[56] Supplement at 5.
[57] ATSDR at 177.
[58] Id. at 170.

1,4-Dioxane was detected in outdoor air samples from the United States between 1981 and 1984 (detection limit unspecified). In the winter of 1984, 1,4-dioxane was detected in 67% of outdoor air samples from Los Angeles communities (n=25) at a median concentration of 0.27 μg/m^3. In the summer of 1984, 1,4-dioxane was detected in 22% of outdoor air samples from Los Angeles communities (n=23) at a median concentration of 0.02 μg/m^3. In the summer of 1984, 1,4-dioxane was detected in 20% of outdoor air samples from Antioch/West Pittsburg, California (n=10) at a median concentration of 0.03 μg/m^3 (Pellizzari et al. 1986). Between 1979 and 1984, the mean concentration of 1,4-dioxane in ambient air was 0.44 μg/m^3 (range, 0–30 μg/m^3; detected in 187 of 533 samples) in samples collected from 12 unspecified urban/suburban locations in the United States (EPA 1993)."

ATSDR's summary highlights ambient air levels of 1,4-dioxane near industrial sources as follows:[59]

"In the summer of 1981 (July 6–August 16), the geometric mean concentrations of 1,4-dioxane in air near three industrialized urban areas (i.e., Newark, Elizabeth, and Camden, New Jersey) of the United States were 0.01 (21 of 38 samples positive), 0.02 (15 of 38 samples positive), and 0.005 μg/m^3 (21 of35 samples positive), respectively (Harkov et al. 1983). The three same sites were also sampled from January 18–February 26, 1982. The geometric means of these samples ranged from 0 to 0.01 μg/m^3; 20% of samples were positive, with a maximum value of 5.31 μg/m^3 EC 2002). In 1983, near the Kramer Landfill in New Jersey, sampled ambient air contained 1,4-dioxane at a geometric mean concentration of 0.01 ppbv or 0.4 μg/m^3 (maximum, 0.09 ppbv or 0.3 μg/m^3). In 1982, at an urban/industrial site in Newark, New Jersey, ambient air contained 1,4-dioxane at a geometric mean concentration of 0.01 ppbv, or 0.4 μg/m^3 (n=26; maximum, 1.45 ppbv or 5.22 μg/m^3). At various landfills in the United States, the concentration of 1,4-dioxane in landfill gas was reported to be 0.62 μg/m^3 and 0.33 g/m^3 2)."

For comparison, the IRIS IUR for 1,4-dioxane is 5.0×10^{-6}.[60] This translates into a $1 X 10^{-6}$ cancer risk at 0.2 μg/m^3-- an ambient air concentration in the range of many of the monitored levels reported by ATSDR.

1,4-dioxane has also been consistently found in indoor air, as summarized by ATSDR as follows:[61]

"In the early to mid 1980s, the mean ambient levels of 1,4-dioxane in indoor air was measured as part of the VOC National Ambient Database in the United States (Shah and Singh 1988). The mean concentration of 1,4-dioxane in indoor air was 1.029 ppbv, or 3.704 μg/m^3 (n=585; median, 0.000 ppbv). 1,4-Dioxane was detected in indoor air samples from the United States between 1981 and 1984 (detection limit unspecified). In the winter of 1984, 1,4-dioxane was detected in 64% of indoor air samples from Los Angeles communities (n=25) at a median concentration of 0.26 μg/m^3. In the summer of 1984,

1,4-dioxane was detected in 17% of indoor air samples from Los Angeles communities (n=23) at a median concentration of 0.02 μg/m^3. In the summer of 1984, 1,4-dioxane was detected in 10% of indoor air samples from Antioch/West Pittsburg, California (n=10) at a median concentration of 0.07 μg/m^3 (Pellizzari et al. 1986). In a multi-national survey taken between 1978 and 1990, mean 1,4-dioxane levels were 11 μg/m^3 in indoor air samples taken from buildings (i.e., schools and offices) with reported unspecified complaints among the occupants (Brown et al. 1994). In June of 1990, 125 households in Woodland, California were monitored for a variety of toxic air contaminants. Approximately 21% of the indoor samples collected contained measurable amounts of 1,4-dioxane. The average concentration of

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[59] Id. at 171.
[60] https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=326.
[61] ATSDR at 171.

1,4-dioxane was below the quantifiable limit of 0.11 µg/m^3, and the measurements ranged from below the quantifiable limit to 140 µg/m^3 1997)."

These findings demonstrate the prevalence of background concentrations of 1,4-dioxane in the indoor environment – in some cases at levels that exceed EPA's cancer risk benchmark. As with other volatile substances like TCE and PCE, 1,4-dioxane's widespread presence in indoor air is evidence of chronic exposure by consumers and adds to the dermal and inhalation exposures resulting from consumer product use.

C. Millions of Consumers Who Use 1,4-Dioxane-Containing Products Also Have Oral, Inhalation and Dermal Exposure from Contaminated Drinking Water

EPA's exclusion of drinking water pathways of exposure from its initial draft evaluation was poorly received by many stakeholders and the SACC because it ignored a major contributor to consumer exposure and risk. As several of our groups emphasized in their comments, 1,4-dioxane contamination of surface water and groundwater has resulted in elevated levels in drinking water in many regions of the US, drawing considerable attention from local communities and state regulators. By continuing to omit contaminated drinking water from the evaluation, the supplement fails to account for a source of exposure that contributes to total consumer intake of 1,4-dioxane and greatly adds to the cancer risk from use of consumer products. Including drinking water in the evaluation would require EPA to add ingestion to inhalation and dermal routes of exposure; the draft risk evaluation and supplement do not account for this exposure pathway.

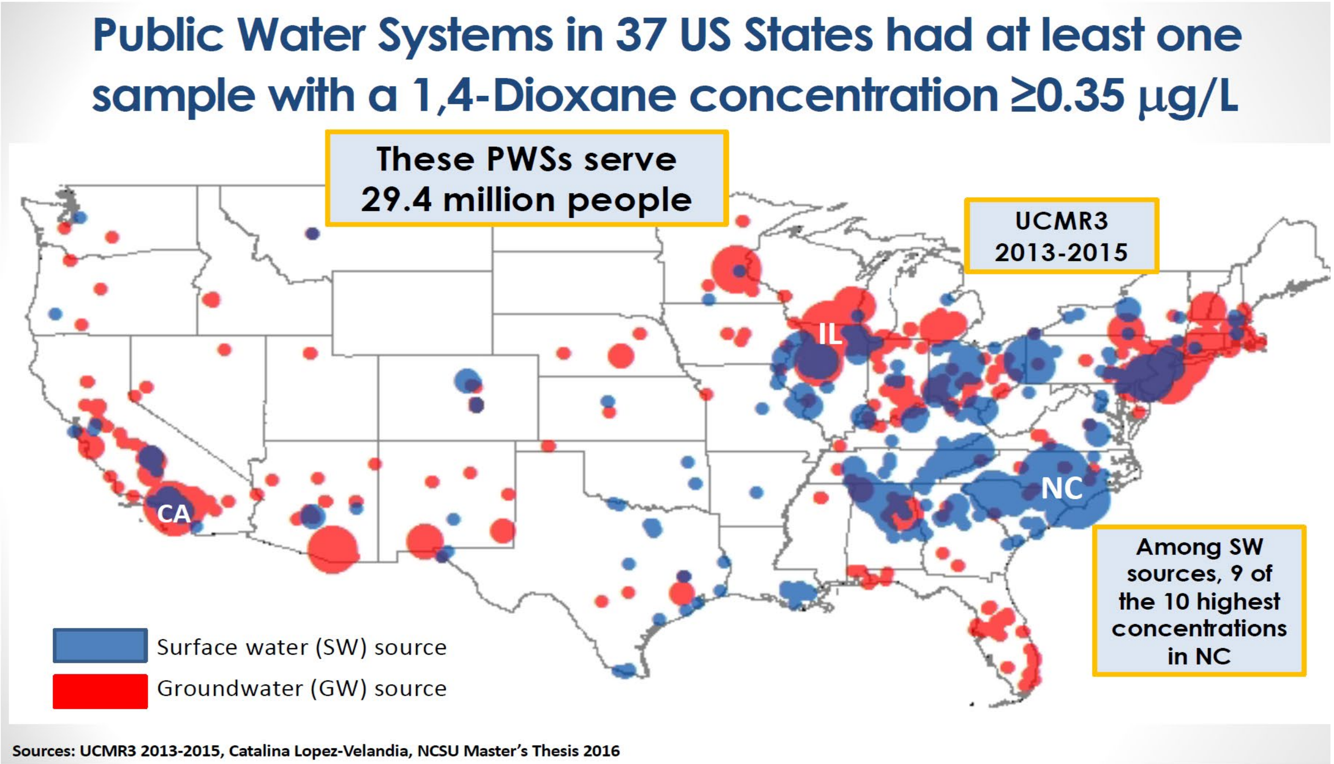
1. <u>1,4-Dioxane Contamination of Drinking Water Is a National Concern Affecting 90 Million Americans</u>

Concern about the presence of 1,4 dioxane in drinking water was sparked by the results of EPA's Third Unregulated Contaminant Monitoring Rule (UCMR3), which sampled almost 5000 US public water systems (PWSs), each serving more than 10,000 people, between 2013 and 2015.[62] 1,4-dioxane was detected above the reporting limit of 0.07 mg/L in 21 percent of PWSs. According to EWG, these PWSs provide "water supplies for nearly 90 million Americans in 45 states."[63] In addition, as the chart below shows,[64] 1,4-dioxane levels were above 0.35 mg/L in at least one sample from 6.9 percent of PWSs, serving a total of 29.4 million customers in 37 states. States with the most people exposed to 1,4-dioxane above 0.35 mg/L were California, with 2.5 million people exposed; North Carolina, with 1.2 million; and New York, with 700,000.

[62] Adamson DT, Piña EA, Cartwright AE, Rauch SR, Hunter, 1,4-Dioxane drinking water occurrence data from the third unregulated contaminant monitoring rule. *Sci Total Environ* 2017, 596 –597:236–245

[63] https://www.ewg.org/research/hidden-carcinogen-taints-tap-water-consumer-products-nationwide.

[64] Detlef Knappe, *Occurrence of 1,4-Dioxane in Drinking Water - National and North Carolina Perspectives,* Symposium on 1,4-Dioxane, Yale University, October 30, 2020 (Yale Presentation) at 4.



According to the EPA drinking water program, 1,4-dioxane levels of 0.35 mg/L (or 1 ppb) represent "the amount of 1,4-dioxane expected to cause no more than one additional case of cancer in 1 million people who drink and bathe with the water over a lifetime."[65] Several states have included this cancer risk threshold in their drinking water guidelines.

The UCMR3-based estimates understate the number of people consuming 1,4-dioxane in drinking water at levels of health concern because medium and small water systems may not test regularly for 1,4-dioxane and private wells are not required to test at all. As with other volatile compounds like TCE and PCE, water from municipal systems and private wells is not only ingested but used for bathing and showering, which result in inhalation and dermal exposure.

2. Elevated Levels of 1,4-Dioxane In Drinking Water Is a Serious Health Concern in Eastern North Carolina

Several of the signatories to these comments represent communities in North Carolina suffering from 1,4-dioxane drinking water contamination. According to EWG, 8 utilities from diverse locations in the state have reported 1,4-dioxane levels between 2.02 and 5.83 ppb.[66] In addition, 7 of the 20 highest 1,4-dioxane concentrations in the UCMR3 database were measured in drinking water sourced from the Cape Fear River and its tributaries (up to 13.3 µg/L). [67]

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[65] Id.

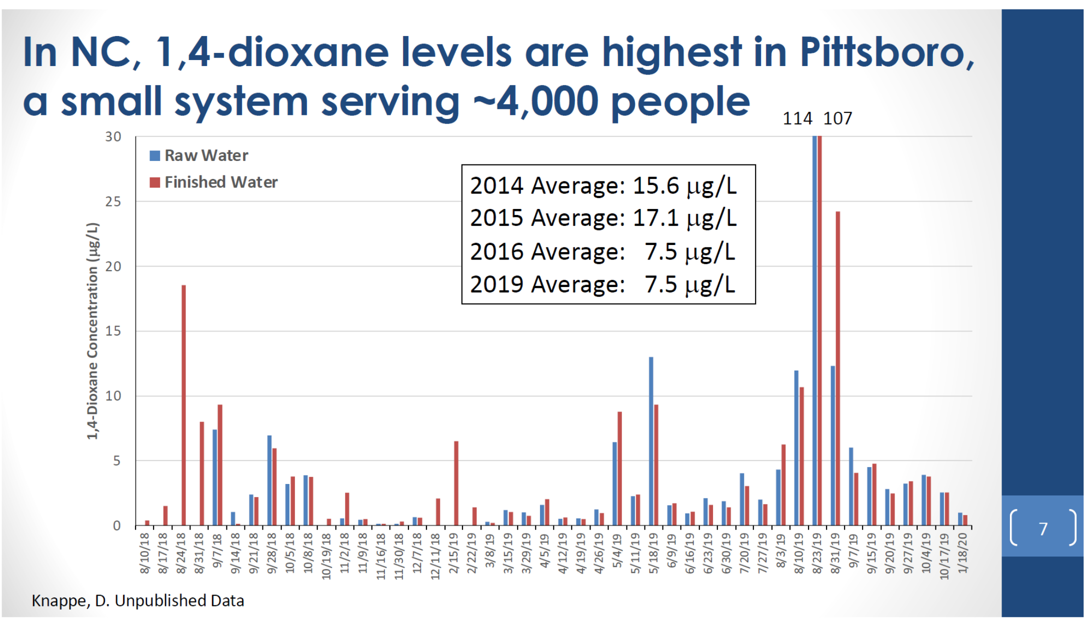
[66] https://cdn3.ewg.org/sites/default/files/u352/EWG_1%2C4-D_Table1_C03.pdf?_ga=2.82764254.910251039.1607558359-146002039.1582228418.

[67] Detlef R.U. Knappe, Catalina Lopez-Velandia, Zachary Hopkins, and Mei Sun, Water Resources Research Institute of The University of North Carolina, Report No. 478, *Occurrence Of 1,4-Dioxane In the Cape Fear River Watershed and Effectiveness of Water Treatment Options For 1,4-Dioxane Control,* 2016, at 5 (WRRI Report)

More recently, researchers at North Carolina State University conducted sampling for 1,4-dioxane at three drinking water treatment plants in the CFRB. Daily composite raw and finished water samples were analyzed and collected over a period of 2 months. Results were as follows:[68]

> "Raw and treated water 1,4-dioxane concentrations exceeded the NC stream water quality standard and the one in a million cancer risk level at all the three studied DWTPs (Figure 12). The average concentration for raw water in DWTP A (Figure 12a), treating Haw River water, was 8.8 µg/L (25 times the NC stream water quality standard and the 10^{-6} excess cancer risk level), whereas the maximum concentration was 36 µg/L. For the same DWTP the average finished water concentration was 8.7 µg/L (25 times the NC stream water quality standard and the 10^{-6} excess cancer risk level) and the maximum concentration was 31 µg/L.
>
> Results for the DWTP B (Figure 12b), located on the CFR further downstream, show an average 1,4-dioxane concentration for raw water of 2.8 µg/L (7 times the NC stream water quality standard and the 10^{-6} excess cancer risk level) and a maximum raw water concentration of 10.2 µg/L. In the finished water the average 1,4-dioxane concentration was 2.6 µg/L (7 times the NC stream water quality standard and the 10^{-6} excess cancer risk level) and the maximum concentration was 9.8 µg/L.
>
> Composite sampling results for DWTP C, located near the mouth of the CFR, are summarized in Figure 12c. This DWTP employs raw and settled water ozonation. The average raw water 1,4- dioxane concentration was 3.8 µg/L, and the maximum was 7.7 µg/L. The average 1,4-dioxane concentration in finished water was 1.2 µg/L and the maximum 2.1 µg/L."

Unpublished data from the same researchers report the highest 1,4-dioxane levels measured at a water utility in North Carolina: [69]



[68] Id. at 46-47.

[69] Yale Presentation at 7

The maximum concentrations reported – 114 and 107 ug/L – are nearly 300 times greater than EPA's one in a million cancer risk level, presenting a significant public health concern.

3. Users of Contaminated Drinking Water are PESSs that Must be Protected Under TSCA

The millions of users of contaminated drinking water in Eastern North Carolina and similar "hot spots" in other states comprise PESSs because their exposure is a function of both drinking water consumption and use of consumer products and therefore is greater than exposure by the general population. Moreover, individuals consuming contaminated water may be subject to other stressors or have conditions that increase their susceptibility to 1,4-dioxane's health effects. According to the California Department of Toxic Substances Control (DTSC),[70] "combined exposure from product use and drinking water . . . is of particular concern for children and those with liver disease, who may be more sensitive to exposure to 1,4-dioxane than the general population." In addition, "[e]nvironmental justice communities, which are already subject to socioeconomic and health stressors and other types of pollution may be particularly impacted by the additional exposure to 1,4-dioxane from consumer products." DTSC's mapping of the overlap between these communities and drinking water contamination also shows that 1,4-dioxane "in [drinking water] in some of these communities exceeds levels of concern." [71]

EPA is required under TSCA to make unreasonable risk determinations for these highly exposed and susceptible subpopulations. Since drinking water levels in many communities are well in excess of the concentrations deemed by EPA and state regulators to pose a 1 in 1 million cancer risk, the combined exposure from drinking water and consumer product pathways in these communities is likely well above EPA's unreasonable risk benchmark for carcinogenicity.

Despite the skepticism of SACC and many stakeholders, the supplement continues to assert that TSCA should not apply "when other EPA offices have expertise and experience to address specific environmental media" and that excluding drinking water from TSCA risk evaluations is necessary to "avoid duplicating efforts taken pursuant to other Agency programs."[72] In fact, as commenters earlier emphasized, 1,4-dioxane is NOT being "addressed" under the SDWA. EPA has not promulgated a National Primary Drinking Water regulation for 1,4-dioxane and has no plans to do so. Moreover, given the virtual absence of standard-setting activity in the national drinking water program, there is little prospect that 1,4-dioxane in drinking water will be regulated by EPA for the foreseeable future. Thus, if drinking water sources of exposure are not included in the ongoing TSCA risk evaluation, the risks they present will likely never be identified, evaluated, and reduced. In short, even if EPA is correct that TSCA is a "gap-filling" statute, addressing drinking water contamination in risk evaluations would in fact fill a serious "gap" in regulatory protection. To ignore this gap would violate the spirit and letter of TSCA.

D. Groundwater Contamination

Groundwater contamination from 1,4-dioxane is a longstanding concern and has resulted from a variety of sources, including waste disposal, leakage from septic tanks and underground storage tanks and releases from manufacturing and processing sites.

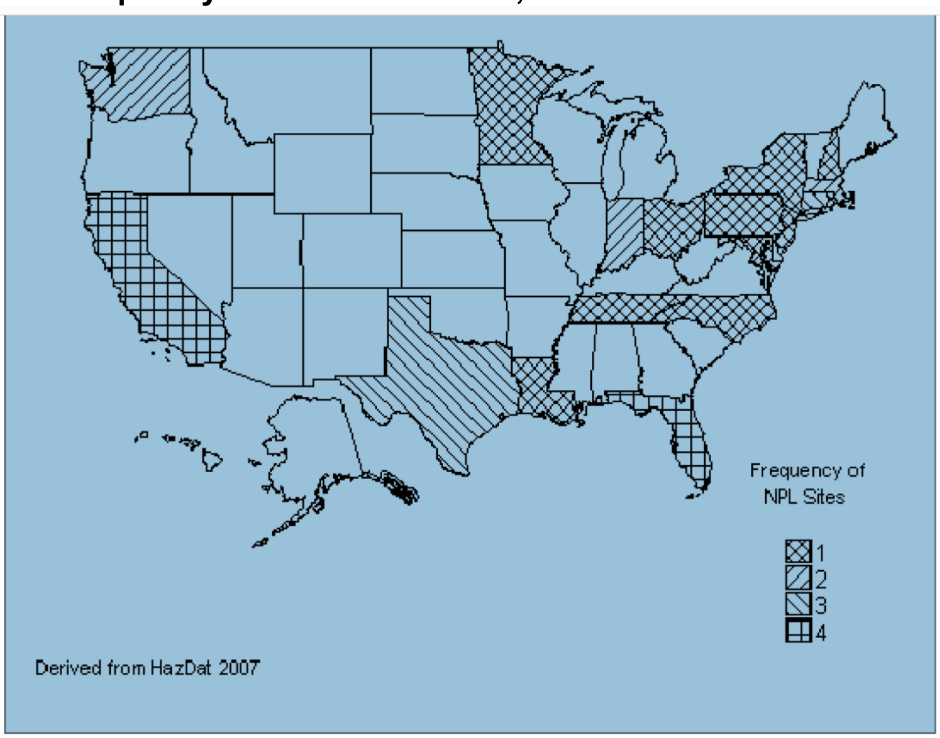
ATSDR has summarized groundwater monitoring results for 1,4-dioxane as follows:[73]

[70] Department of Toxic Substances Control, Safer Products and Workplaces Program, California Environmental Protection Agency, 1,4-Dioxane in Personal Care and Cleaning Products, May 23, 2019 at 3-4.
[71] Id.
[72] Supplement at 5.
[73] ATSDR at 172-173.

"1,4-Dioxane was determined at 1.1–109 µg/L in contaminated groundwater in California (Draper et al. 2000). Extensive groundwater contamination (<0.01–220 mg/L or <10–220,000 µg/L) with more limited surface water contamination (<0.01–0.29 mg/L or <10–290 µg/L) resulted from treatment of industrial waste water in an unlined oxidation lagoon in Ann Arbor, Michigan (DeRosa et al. 1996). Current levels of 1,4-dioxane were about 1 µg/L in eight groundwater wells located in the vicinity of this site. However, the number of non-detects was not provided in this source (Michigan DEQ 2004). 1,4-Dioxane was discovered in groundwater at more than 250 ppm (mg/L) at a San Jose, California solvent recycling facility in 1998. In a survey of TCA release sites in California, it was found that 1,4-dioxane was present in a majority of these sites (concentrations unspecified) (Mohr 2004). At the Stanford Linear Accelerator Center (SLAC) in Menlo Park, California, the occurrence of 1,4-dioxane in groundwater is closely associated with TCA and its abiotic degradation product, 1,1-dichloroethane. It was found at this location at a maximum concentration of 7,300 ppb (Mohr 2004). . . In groundwater beneath a landfill, the concentration of 1,4-dioxane was 500 µg/L at a site in Canada sampled in 1982 (EC 2002). Groundwater samples obtained from an abandoned waste-oil refinery near Westville, Indiana contained 1,4-dioxane at levels ranging from approximately 3 to 31,000 µg/L (USGS 2002)."

ATSDR also reports the presence of 1,4-dioxane in groundwater at numerous Superfund sites and in landfill leachate at numerous waste disposal facilities.[74] The distribution of 1,4-dioxane at Superfund sites nationally is as follows:[75]

Figure 6-1. Frequency of NPL Sites with 1,4-Dioxane Contamination



1,4-dioxane contamination of groundwater is considered a major source of drinking water contamination in "hot spots" such as Long Island, New York and Southern California and, according to UCMR3 data, "groundwater-

[74] Id at 173-74.
[75] Id. at 160.

derived drinking water is more likely to exceed the reference concentration of 0.35 mg/L than drinking water derived from surface water."[76] McElroy et al describe the sources of groundwater contamination as follows:[77]

> "In particular, 1,4-dioxane use was linked to the stabilization of the solvent TCA, an ozone-depleting substance when released to the atmo- sphere. Since the beginning of 1996, the use of TCA is banned by the Montreal Protocol [11] and 1,4-dioxane introduction into subsurface environments has decreased as a result [1]. Because of its use as a solvent stabilizer, 1,4-dioxane is commonly detected together with chlorinated solvents, such as TCA, TCE, and 1,1- DCE [17,21]. However, sources of 1,4-dioxane can be distinct from those of chlorinated solvents, as suggested by results of a recent groundwater survey along the mouth of the Llobregat River near Barcelona [20]. For example, landfill leachate [17], detergent manufacturing plants [17], and metal manufacturing/ chrome plating plants (with co-occurrence of Cr(VI) [23]) can be sources of 1,4-dioxane [17]. Thus, it is important to recognize that 1,4-dioxane contamination of groundwater can originate from a wide range of sources."

The Citizens Campaign for the Environment in Long Island, New York notes that:[78]

> "Groundwater plumes that contain the chemical Trichloroethane (TCA) are very likely to also contain 1,4-dioxane. According to Newsday's database of Long Island Superfund sites, there are at least 50 sites that are known to contain TCA, meaning there is a high probability they also contain 1,4-dioxane. 1,4-Dioxane does not easily degrade or break down in the environment and is highly mobile in soil and groundwater."

The Campaign explains that down the drain releases of consumer products "carry 1,4-dioxane directly into our groundwater through over 500,000 septic tanks and cesspools across Long Island. That groundwater eventually either flows outward into our surface waters or downward into our aquifers, which is the sole-source of Long Island's drinking water."

Although contaminated groundwater may be addressed at individual sites, EPA has no comprehensive program under the SDWA to evaluate and remediate the overall impact of 1,4-dioxane in groundwater on drinking water contamination. TSCA can thus play a critical role in understanding the contribution of groundwater pathways, along with products and surface water discharges, to total human exposure and risk.

IV. EPA's Evaluation of the Human Health Impacts of Surface Water Discharges Is Based on an Extremely Small Sample of Dischargers and Fails to Examine the Impacts of Discharges on Drinking Water

The supplement compiles data on source water discharges by several industrial facilities and uses these data to estimate surface water concentrations of 1,4-dioxane at the point of discharge to water bodies. It then evaluates the health effects of human exposures via oral and dermal routes from recreational swimming in ambient water. Based on the incidental nature of such exposures, EPA only focuses on only acute exposures and risks. The conclusion of its analysis is that there is "no unreasonable risk to the general population from all conditions of use."[79]

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[76] Amie C. McElroy, Michael R. Hyman and Detlef R. U. Knappe, *1,4-Dioxane in drinking water: emerging for 40 years and still unregulated* - ScienceDirect (doi.org), Current Opinion in Environmental Science & Health, Volume 7, February 2019, Pages 117-125 (McElroy et al.

[77] Id.

[78] https://www.citizenscampaign.org/14dioxane.

[79] Supplement at 6.

As discussed below, EPA's analysis is incomplete and flawed and ignores the most important aspect of surface water discharges of 1,4-dioxane -- their impact on human health due to their link to drinking water contamination.

A. EPA's Legal Justification for Including Surface Water Discharges in the Supplement Conflicts with Its Rationale for Excluding Drinking Water Contamination

EPA's initial draft evaluation did not examine the human health implications of surface water discharges. It has now reversed course and conducted this analysis because "1,4-Dioxane does not currently have established water quality criteria to protect human health under the CWA Section 304(a)."[80] This is a curious rationale because EPA has previously maintained that the potential application of another environmental law to an exposure pathway is sufficient to exclude it from evaluation under TSCA, regardless of whether it is actually being regulated under the other law. Indeed, EPA continues to exclude 1,4-dioxane in drinking water from its evaluation because it is theoretically subject to the SDWA even though it is not now regulated and there is little prospect of future regulation. How EPA can point to the absence of regulation under the CWA to justify addressing surface water under TSCA while excluding unregulated drinking water contamination is inexplicable.

B. EPA's Analysis of Surface Water Discharges Is Too Narrow to Satisfy the CWA and TSCA

Even accepting EPA's rationale, its analysis of surface water discharges is inadequate to achieve the purposes of water quality criteria under the CWA or to satisfy the requirements of TSCA.

EPA inaccurately describes water quality criteria as being designed to protect swimmers and eaters of fish.[81] In fact, EPA publishes separate recreational water quality criteria to protect swimmers. Its human health criteria under the CWA are designed to protect users of surface waters for drinking water consumption; the methodology they are based on embodies the source water protection principle that dischargers to surface water should pay for pollution control rather than downstream POTWs, water utilities or drinking water consumers. [82]

Surface water discharges of 1,4-dioxane impact human health because they are an important contributor to drinking water contamination. According to EWG, "1,4-Dioxane in drinking water sources can come from wastewater discharges, toxic waste and Superfund sites, as well as industrial facilities where plastics and solvents have been manufactured or used."[83] "Down the drain" discharges of personal care and cleaning products contaminated with 1,4-dioxane also contribute to groundwater and drinking water contamination because the chemical is not removed by most standard wastewater treatment systems and therefore is released to water bodies in their effluent.[84] For example, according to the Citizens Campaign for the Environment, "The elevated levels found in many laundry detergents make laundromats a potential point-source of contamination for 1,4-dioxane."[85]

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[80] Id at 26.

[81] Supplement at 26. While recognizing that human health risks due to catching contaminated fish are also within the ambit of water quality criteria, EPA concludes that "exposures to the general population via fish ingestion are not expected" because 1,4-dioxane is not accumulative. However, the supplement documents a bioconcentration factor (BCF) of 0.9, resulting in tissue levels nearly equivalent to the water concentration. Thus, even though 1,4-dioxane is not accumulative up the food chain, fish tissue concentrations may still pose a risk to consumers.

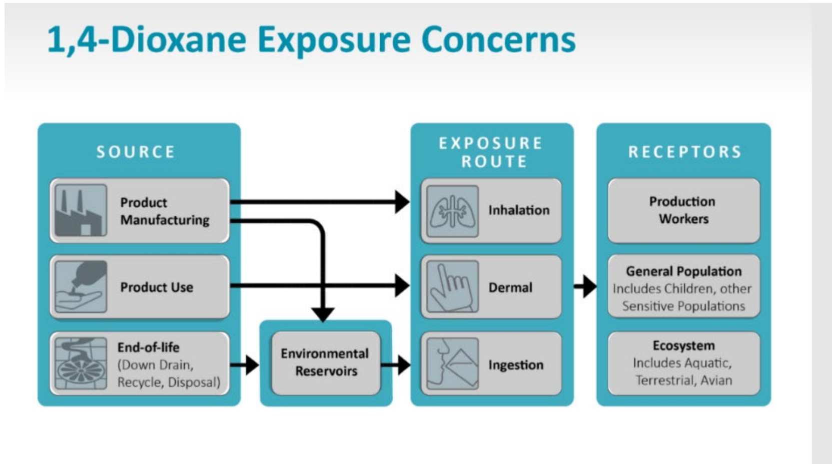
[82] www.epa.gov/wqc/methodology-deriving-ambient-water-quality-criteria-protection-human-health-2000-documents

[83] https://www.ewg.org/research/hidden-carcinogen-taints-tap-water-consumer-products-nationwide.

[84] DTSC, *1,4-Dioxane in Personal Care and Cleaning Products Public Meeting*, June 28, 2019. https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/07/DTSC-Presentation.pdf.

[85] https://www.citizenscampaign.org/14dioxane.

DTSC has depicted the different contributors to 1,4-dioxane exposure as follows:[86]



EPA's supplement presents an incomplete picture of 1,4-dioxane releases to surface water because it overlooks the many pathways by which it enters water bodies and the resulting contamination of drinking water sources.

C. EPA Ignores A Large Universe of Surface Water Discharges

EPA's evaluation of surface water impacts of 1,4-dioxane discharges is based on only 24 sources, comprising mainly chemical, pharmaceutical and pesticide manufacturers, that EPA admits are "likely not representative of all the releases in the U.S. for 2018."[87] The 24 sources do not include manufacturers of ethoxylated raw materials or finished cleaning products, personal care products or cosmetics formulated from these raw materials. Surface water discharges from these operations would likely include 1,4-dioxane since it is a byproduct of the production of ethoxylated substances.[88] According McElroy et al, "from a source water protection perspective, it is important, therefore, to identify not only facilities that manufacture, process, and/or use 1,4-dioxane but also those that generate 1,4-dioxane as a by-product."[89]

In addition, the supplement identifies several additional groups of 1,4-dioxane dischargers, representing over 1.6 million facilities:[90]

Discharge Category	Number of Facilities
Functional Fluids (Open-System)	89,000
Laboratory Chemicals	6,844
Film Cement	211
Spray Foam Application	1,553,559

[86] DTSC June 28. 2019 Presentation at 9.

[87] Supplement at 20. EPA also explains that the releases it modeled were based on engineering site-specific estimates from DMR and TRI reporting databases and "may not capture releases from certain facilities not meeting reporting thresholds." Id. at 30

[88] McElroy et al. As the authors note:

> "One important shortcoming of the Chemical Data Reporting and TRI databases consider the generation and release of 1,4-dioxane as a manufacturing by-product. 1,4-Dioxane is generated as a by-product in manufacturing processes involving ethylene oxide, such as the production of surfactants used in detergents and shampoos, and the production of polymers, such as polyester and polyethylene terephthalate."

[89] Id.

[90] Supplement at 19.

Printing Inks (3D)	10,767
Dry Film Lubricant	8
Disposal	14

EPA estimates the number of release days per year for these dischargers and calculates representative discharge levels but makes no attempt to estimate the resulting surface water concentrations attributable to each discharger. This is a significant limitation because the large universe of discharging facilities likely has significant cumulative water quality impacts that are broadly distributed geographically. Had EPA's analysis accounted for all of the numerous industrial point-sources of 1,4-dioxane, its modeling of ambient water levels would necessarily have reflected the impact of multiple discharges on specific water bodies. This would be a more realistic scenario than modeling the surface water impact of individual dischargers standing alone, the approach EPA uses in the supplement.

The supplement also ignores "down the drain" releases of 1,4-dioxane following the use of cleaning products, personal care products and cosmetics. These releases occur in tens of millions of homes on a daily basis as well as in numerous workplaces where industrial and commercial cleaning products are used. Along with other domestic waste, they are generally routed through sewage systems to POTWs. However, since 1,4-dioxane is difficult to treat and remove, it often passes through POTWs to surface waters, where it mixes with point-source discharges from industrial and commercial sites and contaminates drinking water sources.

D. Monitoring in North Carolina Demonstrates the Widespread Impact of 1,4-Dioxane Discharges on Drinking Water Quality

Monitoring of 1,4-dioxane throughout the North Carolina CFRB illustrates the significant surface water contamination caused by multiple discharge activities across a large watershed. Two studies report extensive monitoring results for the CFRB which demonstrate significant levels of 1,4-dioxane at several sampling locations.[91] These studies were part of a comprehensive effort to relate surface water discharges in the CFRB to elevated levels of 1,4-dioxane in drinking water sourced from the Cape Fear River and its tributaries. Referring to the extensive North Carolina monitoring of surface water, the SACC report on the initial draft evaluation emphasized that "[u]sing measured surface water concentrations is particularly important" and "recommended including these data in the estimates of chronic exposure and factoring these into the final risk."[92]

The first study by Sun et al, published in 2016,[93] sampled drinking water, groundwater, surface water, and wastewater treatment plant (WWTP) effluent at several locations within the CFRB. 1,4-dioxane concentrations

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[91] EPA discounts these studies on a variety of grounds, including that the "modeled surface water concentration ranges obtained from E-FAST 824 modeling (2.63E-03 - 5.09E+03 µg/L) encompass the full range of the surface water monitoring data." Supplement at 32. However, any suggestion that EPA's modeling estimates of 1,4-dioxane concentrations in surface water are consistent with the measured levels in North Carolina is extremely misleading. The EPA estimates are intended to represent ambient water levels from a single site at the point of discharge. They do not account for the impact of multiple sources discharging into the same water body and are not adjusted to reflect the potential for downstream transport and dilution. By contrast, the two North Carolina studies measured 1-4 dioxane levels at multiple locations downstream from discharging sites and necessarily accounted for all dischargers to the CFRB and for transport and dilution. That the monitored levels after dilution were within the range of EPA modeling estimates without dilution confirms that EPA's analysis failed to account for the numerous discharge sources impacting surface water quality for a large river system and provides no basis for determining surface water loadings on a river or basin-wide basis.

[92] SACC Report at 44.

[93] Mei Sun,, Catalina Lopez-Velandia, and Detlef R. U. Knappe, *Determination of 1,4-Dioxane in the Cape Fear River Watershed by Heated Purge-and-Trap Preconcentration and Gas Chromatography–Mass Spectrometry* Environ. Sci. Technol. 2016, 50, 2246−2254, https://pubs.acs.org/doi/10.1021/acs.est.5b05875

ranged from <0.15 µg/L in nonimpacted surface water to 436 µg/L downstream of a WWTP discharge. In WWTP effluent, 1,4-dioxane concentrations varied widely, with a range of 1.3-2.7 µg/L in one community and 105-1,405 µg/L in another. Discharges from three municipal WWTPs were primarily responsible for elevated 1,4-dioxane concentrations in the CFRB. The authors commented on the significance of the WWTP discharges as follows:

> "The impact of WWTP discharges 1−3 on downstream drinking water is substantial because all three discharges are located in the headwater region of the CFR basin. The CFR watershed provides water to more than 120 public water systems serving almost 1.5 million North Carolinians. Among them, over 1 million live downstream of WWTP discharges 1− 3 and receive drinking water impacted by elevated levels of 1,4- dioxane."

The authors noted that "[b]ecause of the widespread existence of 1,4-dioxane in consumer products, its occurrence in domestic wastewater is not surprising" but the high levels seen in WWTP effluent suggest that "one or more industrial sources overshadowed the 1,4-dioxane contribution that can be expected from the use of consumer products."

The second study was conducted by the North Carolina Department of Environmental Quality (DEQ). Monitoring results for 2015 and 2016 have been published; the results for 2017-18 have not yet been released.[94] As the DEQ report describes the key findings for 2015-16:

> "During the first year of the study, four areas of high 1,4-dioxane concentration were identified. Three of the four areas were located immediately downstream of domestic wastewater treatment facilities (WWTF), and one was further downstream of a WWTF, as well as downstream of an inactive textile manufacturing site and other possible legacy sources. In Year 1, these areas had maximum concentrations ranging from 171 to 1030 µg/L and mean concentrations from 43 to 351 µg/L. During Year 2, the same areas returned maximum values of 20 to 614 µg/L and means of 11 to 260 µg/L. Results in excess of the calculated criteria have been documented throughout the Haw, Deep, and Cape Fear Rivers, with the highest 1,4-dioxane values during both study years from the upper watersheds of the Haw and Deep Rivers."

The report presents 1,4-dioxane levels at different monitoring locations as follows:

[94] NC DEQ, *1,4-Dioxane Monitoring in the Cape Fear River Basin of North Carolina An Ongoing Screening, Source Identification, and Abatement Verification Study*, https://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/1-4-dioxane.

APPENDIX B

NC DWR 1,4-Dioxane Monitoring Results

Station	Location	Stream Class	EL[1] (µg/L)	Year (n)[2]	1,4-Dioxane Concentration (µg/L)[3] Min	Median	Max	Mean
Haw River above Reedy Fork								
B4	Haw River at Troxler Mill Road near Reidsville	WS-IV NSW	0.35	1 (4)	35	169	1030	351
				2 (6)	<2	4	46	11
B1	Haw River at SR 1712 (Brooks Bridge Road)	WS-V NSW	80	1 (13)	<3	33	149	46
				2 (5)	<2	5	54	14
B0210000	Haw River at SR 1561 Hub Mill Road	WS-V NSW	80	1 (13)	<3	38	100	42
				2 (5)	<2	7	51	14
Buffalo Creek and Reedy Fork								
B0750000	South Buffalo Creek at SR 2821 Harvest Road at McLeansville	WS-V NSW	80	1 (15)	9	25	543	80
				2 (6)	7	12	86	28
B6	Reedy Fork at NC-61 near Ossipee	WS-V NSW	80	1 (4)	11	20	45	24
				2 (5)	9	9	62	20
B0840000	Reedy Fork at NC-87 at Ossipee	WS-V NSW	80	1 (13)	7	45	100	43
				2 (5)	7	10	20	12
Hasketts Creek								
NCSU24	Hasketts Creek at W.O.W. Road	C	80	1 (4)	147	269	478	291
				2 (5)	69	169	614	260
Haw River below Reedy Fork								
B2100000	Haw River at SR 1713 near Bynum (near Pittsboro intake)	WS-IV NSW	0.35	1 (13)	<3	13	66	18
				2 (5)	<2	8	14	8
Cape Fear River								
B8	Cape Fear River at Harnett County Public Utilities intake	WS-IV CA	0.35	1 (13)	<3	5	15	6
				2 (5)	<2	<2	<2	<2
B6370000	Cape Fear River at US-401 at Lillington	WS-IV	0.35	1 (15)	<3	4	15	6
				2 (5)	<2	2	3	2
B7480000	Cape Fear River at Hoffer WTP intake at Fayetteville	WS-IV CA	0.35	1 (12)	<3	3	11	4
				2 (5)	<2	<2	<3	<2
B8350000	Cape Fear River at Lock 1 near Kelly	WS-IV Sw	0.35	1 (12)	<3	3	11	4
				2 (5)	<2	2	3	2

Notably, like those reported by Sun et al, most of these measured levels in surface water were above the EPA and North Carolina recommended limit of 0.35 ppb for drinking water based on 1,4-dioxane's carcinogenicity. As discussed above, monitoring of drinking water sources in the CFRB in fact confirms a relationship between these surface water concentrations and elevated levels of 1,4-dioxane in drinking water.

In its report, DEQ notes that "municipal water and wastewater treatment facilities are generally not equipped to remove 1,4-dioxane through their treatment processes."[95] Since "certain industrial processes are more likely to utilize 1,4-dioxane or to create it as a by-product," DEQ commented that "WWTFs with such industries discharging to their collection system may expect to see greater loading of this contaminant in both their influent and effluent streams." It emphasized that since "1,4-dioxane is not used in or created by wastewater treatment processes, . . . the most significant contributions were constituents of industrial waste streams that were passing through WWTF treatment processes with varying levels of removal efficiency prior to entering surface waters." The report underscores that "the most prudent approaches to reducing 1,4-dioxane concentrations in surface water and drinking water are likely to be reduction, elimination, and/or capture and treatment at industrial sources using or generating the compound."[96]

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[95] Id. at 5.

[96] Id.

As these studies demonstrate, a proper analysis of the impacts of surface water discharges on human health should do what EPA's supplement fails to do -- account for all discharges (industrial and domestic) from upstream sources and examine the role of these sources in causing downstream drinking water contamination. This analysis would provide a basis for defining the contribution of manufacturing and processing sites and down-the-drain releases of consumer products to 1,4-dioxane levels in drinking water and enable EPA to determine whether these surface water discharges present an unreasonable risk to the health of drinking water users. Because it does not attempt this essential analysis, the supplement is fatally flawed under TSCA.

V. The Supplement Fails to Address Non-Cancer Chronic Health Risks to Consumers

Consistent with the initial draft evaluation, the supplement recognizes that 1,4-dioxane's human health hazards include serious non-cancer chronic effects demonstrated in studies of rats -- specifically systemic effects in the nasal cavity (respiratory metaplasia of the olfactory epithelium) and hepatocellular and renal toxicity (degeneration and necrosis of renal tubular cells and hepatocytes; hepatocellular mixed cell foci).[97] However, the supplement's evaluation of health risks to users of consumer products is limited to acute toxicity and carcinogenicity; it does not include chronic non-cancer effects.[98]

This is a significant omission. For several worker categories, the initial draft risk evaluation estimated margins of exposure (MOE) for non-cancer effects below the "benchmark" MOE of 30 by both inhalation and dermal routes of exposure.[99] It is likely that MOEs for consumers would similarly be unprotective, particularly if EPA fully accounts for all sources of consumer exposure as recommended above and addresses consumer subpopulations with elevated exposure (*i.e*. users of contaminated drinking water and individuals exposed at work and at home) that require specific protection as PESSs under TSCA. Thus, EPA's final evaluation must estimate chronic non-cancer risks to consumers, taking into all pathways of exposure and subpopulations with elevated exposure levels.

Moreover, when finalizing its evaluation, EPA must correct elements of its methodology that understate risks to both workers and consumers. These adjustments are as follows:

1. Increasing Uncertainty Factors to Account for Data-base Uncertainty

EPA's benchmark MOE for chronic effects is based on an uncertainty factor (UF) of 30. However, it does not reflect the lack of data on 1,4-dioxane for critical endpoints. EPA guidance calls for application of a UF where the absence of adequate data creates uncertainty in determining a chemical's health effects:[100]

> "The database UF is intended to account for the potential for deriving an underprotective RfD/RfC as a result of an incomplete characterization of the chemical's toxicity. In addition to identifying toxicity information that is lacking, review of existing data may also suggest that a lower reference value might result if additional data were available. Consequently, in deciding to apply this factor to account for deficiencies in the available data set and in identifying its magnitude, the assessor should consider both the data lacking and the data available for particular organ systems as well as life stages."

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[97] Supplement at 58.
[98] Id., at 62-65.
[99] Initial risk evaluation for 1,4-dioxane at 137-138.
[100] EPA-630-P02-002F, A Review of the Reference Dose and Reference Concentration Processes, at 4-44 (Dec. 2002) https://www.epa.gov/risk/review-reference-dose-and-reference-concentration-processes-document. (RD and RC Review).

The hazard database for 1,4-dioxane lacks studies that assess the potential for reproductive and developmental effects and developmental neurotoxicity (in light of its known neurotoxic effects in adults). A 10X UF should be added to reflect these data gaps. Increasing the benchmark MOE to 300.

2. Recognizing Differences in Susceptibility

As defined in section 3(12) of TSCA, PESS include groups within the general population who are at greater risk because of greater susceptibility as well as higher exposure. In its draft initial evaluation, EPA identified several groups that are more susceptible to 1,4-dioxane's health effects than the general population:[101]

> "Certain human subpopulations may be more susceptible to exposure to 1,4-dioxane than others. . . .In the workplace, some individuals may be more biologically susceptible to the effects of 1,4-dioxane due to genetic variability or pre-existing health conditions that increase variability in human response to chemical exposures. Variations in CYP enzyme expression may contribute to susceptibility because multiple CYP enzymes are involved in metabolism of 1,4-dioxane, including CYP2E1. There are large variations in CYP2E1 expression and functionality in humans (Ligocka et al., 2003) and similar variation in other CYPs involved in 1,4-dioxane metabolism are possible. Pre-existing conditions affecting the liver may also impair metabolism in some individuals. For example, fatty liver disease has been associated with reduced CYP function. Other pre-existing conditions affecting the kidneys, upper respiratory system, and other organs targeted by 1,4- dioxane could make some individuals more susceptible to workplace exposures.

EPA acknowledges that, because its initial evaluation was "limited to workplace exposures, . . . [it] does not address factors that may make children or other non-workers more susceptible to 1,4-dioxane" and that, "[d]ue to database deficiencies for potential reproductive and developmental toxicity of 1,4-dioxane, it is not known whether or not pregnant women in the workplace may be at greater risk from exposure."

The initial evaluation asserts that "[t]he variability in human susceptibility to 1,4-dioxane, including variability in CYPs, is reflected in the selection of the uncertainty factor for human variability included in the benchmark margin of exposure (MOE)." However, this UF is customarily used by EPA to account for normal expected variations in sensitivity within the healthy population.[102] Thus, EPA guidance provides that "a 10-fold factor may sometimes be too small because of factors that can influence large differences in susceptibility, such as genetic polymorphisms."[103] Since EPA has not analyzed how much more susceptible PESSs might be to 1,4-dioxane, it has no basis to conclude that a 10X UF will be adequately protective. Moreover, as EPA discussed in its draft evaluation for PCE, "variability in CYP metabolic capacity" – a factor highlighted in the 1,4-dioxane initial evaluation as enhancing its liver toxicity -- "is generally believed to vary by approximately 10-fold among all humans" and "individual variations in in vitro CYP2E1 activity as high as 20-50 fold have also been reported."[104]

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[101] Initial Risk Evaluation, at 108. Remarkably, the supplement ignores the statements in the initial draft evaluation and claims that " health data for all routes of exposure evaluated (i.e., dermal and inhalation) indicate that there is no increased susceptibility for any single group relative to the general population." Supplement at 5.

[102] For instance, in its draft Pigment Violet 29 risk evaluation EPA used an intraspecies UF of 10 despite finding "no evidence of increased susceptibility for any single group relative to the general population." Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline- 1,3,8,10(2H,9H)-tetrone) (Nov. 2018), found at https://www.epa.gov/sites/production/files/2018-11/documents/draft_pv29_risk_evaluation_public.pdf.

[103] RD and RC Review at 4-44.

[104] Draft PCE Evaluation at 300. In that evaluation, EPA admitted that it "was unable to directly account for all possible PESS considerations and subpopulations in the risk estimates." As a result, it "is unknown whether the 10x UF to account for human variability will cover the full breadth of human responses, and subpopulations with particular disease states or genetic predispositions may fall outside of the range covered by this UF." Id at 402.

Accordingly, the standard 10X UF for intraspecies variability would be inadequate to account for this genetic risk factor, which is only one of the sources of increased susceptibility that EPA has identified for 1,4-dioxane. Indeed, the 1,4-dioxane initial draft itself admits that "Information on induction of liver enzymes, genetic polymorphisms and gender differences was inadequate to quantitatively assess toxicokinetic or toxicodynamic differences in 1,4-Dioxane hazard between animals and humans and the potential variability in human susceptibility."[105]

In recognition of the TSCA mandate to determine risks to PESSs, a UF beyond the default intraspecies 10X factor should be applied, as EPA has previously done for other susceptible groups such as infants and children.[106] We recommend an additional 10X UF for workers and consumers in recognition of the uncertain range of genetic variability, the very large worker and consumer populations exposed to 1,4-dioxane, and EPA's inability to determine the susceptibility to the substance of children and pregnant women. This would increase the benchmark MOE for non-cancer chronic health effects to 1000X.

3. Combining Exposure Across Oral, Inhalation and Dermal Routes

As discussed above, both the initial draft evaluation and supplement fail to aggregate exposure and risk across dermal and inhalation routes of exposure, which occur simultaneously for workers and consumers. EPA must correct this omission in its final risk evaluation for both cancer and non-cancer effects. For the millions of consumers who have higher exposure because they ingest contaminated drinking water, EPA's risk determinations must also address the oral route of exposure in conjunction with dermal and inhalation contributions to total 1,4-dioxane intake.

We expect that, properly conducted, EPA risk determinations for 1,4-dioxane will demonstrate unreasonable risks of cancer and non-cancer chronic effects to workers and consumers.

VI. EPA Must Expand its Evaluation of Worker Exposure to Include Manufacture, Processing and Commercial Use of Products in which 1,4-Dioxane is Present as a Byproduct of Ethoxylation

EPA's initial risk evaluation did not address worker exposure to 1,4-dioxane during manufacture, processing and commercial use of household cleaning products, cosmetics and personal care products produced from ethoxylated raw materials containing 1,4-dioxane as a byproduct. As EPA indicated at the time, it excluded the presence of 1,4-dioxane in these products from its risk evaluation because it believed that exposure to the substance would be addressed in a future risk evaluation for ethoxylated chemicals. We opposed this exclusion because TSCA requires a comprehensive evaluation of all sources of exposure to 1,4-dioxane and because it is highly uncertain whether and when EPA might address the risks of ethoxylated chemicals.

EPA has now partially reversed its earlier approach and addressed consumer exposure to 1,4-dioxane-containing products in its supplement. However, it continues to exclude workplace risks relating to these conditions of use. This is unjustified under TSCA. EPA cannot address some phases of chemical's life-cycle and ignore others.

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[105] Initial Risk Evaluation at 151.

[106] EPA, Consideration of the FQPA Safety Factor and Other Uncertainty Factors In Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity, February 28, 2002, available at https://www.epa.gov/sites/production/files/2015-07/documents/apps-10x-sf-for-cra.pdf; Assessing susceptibility from early-life exposure to carcinogens. Environ Health Perspect. 2005;113(9):1125-33. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1280390/

Having designated consumer use of these products as TSCA conditions of use, it cannot fail to evaluate other "circumstances" of their manufacture, processing and use, including worker exposure that occurs during these activities.

Thus, EPA's final risk evaluation must include risks to workers from exposure that occurs during manufacture, processing and commercial use of products containing 1,4 dioxane as a byproduct. It is particularly critical for EPA to examine risks to the large population of workers who use cleaning products in industrial and commercial facilities, such as stores, offices, schools, public buildings, warehouses and factories.

Conclusion

EPA's rushed, incomplete and flawed supplement to its initial risk evaluation for 1,4-dioxane fails to adequately address public health risks to consumers and workers and would violate TSCA if finalized in its current form. EPA must significantly overhaul the supplement and underlying risk evaluation in accordance with the recommendations in these comments, provide 60 days for comment and request review by the SACC.

Please contact Bob Sussman at bobsussman1@comcast net with any questions about these comments.

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