Environmental Defense Fund

Comments on 1,4-Dioxane; Supplemental Analysis to the Draft Toxic Substances Control Act (TSCA) Risk Evaluation

Docket ID: EPA-HQ-OPPT-2019-0238

Submitted December 10, 2020

Summary

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on its draft Supplemental Analysis (hereafter "Supplement") to the draft risk evaluation for 1,4-dioxane being prepared under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.[1]

EDF has previously submitted extensive comments on EPA's draft risk evaluation for 1,4-dioxane, nearly all of which remain germane in the context of the Supplement. These prior comments are incorporated in full herein by reference.[2]

While EPA's Supplement represents an expansion in the scope of the risk evaluation – to now include certain ambient water exposures and certain consumer product exposures – those additions are so narrowly constructed as to omit major, and potentially the largest, sources of exposure and risk people face from the presence of 1,4-dioxane in water and products.

[1] U.S. EPA, *Draft Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane, CASRN: 123-91-1* (November 2020), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0067. All further citations to the Draft Supplemental Analysis consist of a page number in parentheses.

[2] Environmental Defense Fund, Comments on the Draft Risk Evaluation of 1,4-Dioxane, submitted August 30, 2019, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0058.

Omissions of key water-related exposures:
EPA's expansion of its analysis of water-related exposures includes only direct exposures from swimming and indirect exposures from fish consumption. EPA's rationale for now including these – its belated acknowledgment that 1,4-dioxane lacks a water quality criterion for human health under the Clean Water Act – applies equally to drinking water, as 1,4-dioxane lacks any national standard under the Safe Drinking Water Act. Yet EPA perpetuates this blatant contradiction by continuing to exclude drinking water exposures, which are chronic in nature, from its risk evaluation.

EPA's selective analysis of water-related exposures also excludes other obvious sources and routes of exposure, many of which are continuous or chronic in nature. Most notably, EPA ignores:

- dermal and inhalation exposures associated with bathing, showering and cooking in water (hot or warm) containing 1,4-dioxane;
- releases in wastewater (whether direct or indirect via wastewater treatment facilities) from residential or commercial activities entailing use of products containing 1,4-dioxane;
- contamination of groundwater, of which there is extensive and widespread evidence; and
- releases associated with oil and gas production (e.g., use in hydraulic fracturing and presence in produced waters).

Omissions of key product-related exposures:
EPA's expansion to include direct consumer exposure to certain products where 1,4-dioxane is present as a byproduct is equally narrow and selective. Despite acknowledging the presence of the chemical in industrial and commercial, as well as consumer, products, EPA entirely ignores the former two. Consequently, EPA ignores:

- exposures of millions of workers[3] during the manufacture, use or disposal of industrial and commercial products containing the chemical as a byproduct, including:
    - at industrial and commercial operations using such products, such as industrial laundries and car washes; and
    - employed by businesses entailing the use of such products, such as building maintenance, housekeeping, painting or automotive services, or employed as insulation installers or in construction jobs,

  all of whom can be expected to be more highly and chronically exposed given that they use such products more frequently, for many more hours each day, and/or in higher-strength formulations than do consumers; and

[3] See section 3.C. below for statistics and sources on the number of workers employed in such activities.

- releases of and exposures to the chemical ensuing from wastewater discharges from the above activities.

Moreover, even with respect to consumer product-related exposures, as already noted, EPA has ignored releases of 1,4-dioxane into wastewater from residential activities ensuing from consumers' use of products containing the chemical.

Omission of relevant subpopulations:
Despite TSCA's mandate that EPA identify and evaluate potential risks to "potentially exposed or susceptible subpopulations":

- EPA has asserted without basis that there are no groups more susceptible to adverse health effects from 1,4-dioxane exposure, ignoring millions of people such as those with relevant pre-existing conditions. EPA unlawfully claims it can ignore such susceptibilities based on uncertainty and an asserted lack of quantitative information – gaps that it could have but failed to address by using the enhanced information authorities Congress granted the agency in the 2016 TSCA reforms.
- EPA has failed to analyze those subpopulations that face greater risk due to greater potential exposure, including children, workers and communities near sources of release of 1,4-dioxane.

Other major deficiencies in the Supplement include the following:

EPA ignores background or aggregate exposures: EPA has also failed to consider or address background or aggregate exposures to 1,4-dioxane. Despite acknowledging that this decision results in EPA underestimating the chemical's risks, the agency provides no justification for this decision. EPA has failed to consider even the most straightforward of combined exposures, such as for a consumer who uses more than one 1,4-dioxane containing product or is exposed through both dermal and inhalation routes. EPA also acknowledges its decision means that it will not account for exposures and risks "particularly for populations living near a facility emitting 1,4-dioxane" – in direct violation of TSCA's mandate that EPA address risks to those who may experience disproportionate exposures because of their proximity to conditions of use of a chemical.

EPA ignores relevant exposures and health endpoints in the analysis of product-related exposures: EPA inappropriately dismissed:

- chronic inhalation and dermal exposure to consumer users from spray polyurethane foam, antifreeze, textile dye, and paint and floor lacquer;
- cancer risks from acute exposure; and
- non-cancer risks from chronic exposure.

EPA failed to provide sufficient public comment opportunity and skipped peer review: EPA has not only provided an unlawfully short public comment period of only 20 days for its Supplement, it has failed to subject the Supplement and revised risk evaluation to peer review, in violation of its Risk Evaluation Rule. EPA declined to extend the comment deadline, despite receiving requests to do so from at least 14 organizations.

* * *

EPA's analyses are arbitrary and capricious because they fail to consider important aspects of the problem and adopt conclusions that run counter to the evidence before the agency. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

TABLE OF CONTENTS

INTRODUCTORY CONCERNS

1. EPA has failed to subject the Supplement to peer review, in violation of its Risk Evaluation Rule.

EPA has chosen not to subject the Supplement to any peer review, despite the fact that it effectively constitutes a new risk evaluation of eight conditions of use and an exposure pathway that were excluded from the draft risk evaluation. By way of explanation, the Supplement states only this (p. 7, emphasis added): "The draft supplemental analysis is not being peer reviewed *for the sake of expediency to finalize the first ten risk evaluations*."

Neither TSCA nor EPA's Risk Evaluation Rule[4] provides an exception from peer review of risk evaluations based on "expediency." The relevant provision in the Rule is codified at 40 CFR § 702.45, Peer review. It states: "Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A)." See further details in the text box below.

EPA's Rule anticipates situations in which EPA might issue a partial risk evaluation of a subset of the conditions of use of a chemical, as it has done here, although it was in the context of EPA's assertion of authority to make "early determinations" on a subset of a chemical's conditions of use. In the Federal Register notice establishing the Risk Evaluation Rule,[5] EPA states the following regarding a partial risk evaluation (i.e., one covering only "particular conditions of use") (p. 33740, emphasis added):

> Any risk evaluation for a chemical under particular conditions of use will therefore be consistent with all statutory requirements as well as the procedures established in this regulation. This would also include the requirement that EPA publish a draft risk evaluation for no less than a 60-day public comment period, *and the regulatory requirement for peer review*.

And on page 33736, EPA states:

> EPA may make an early risk determination on any condition of use included in the Agency's scope, *after peer review of the risk evaluation for that condition of use*.

In these statements, EPA made clear that issuance of a partial risk evaluation – as it has done in the Supplement – still requires that the document be subject to peer review – which it has not

[4] Available at https://www.govinfo.gov/content/pkg/FR-2017-07-20/pdf/2017-14337.pdf.
[5] Available at https://www.govinfo.gov/content/pkg/FR-2017-07-20/pdf/2017-14337.pdf.

Text Box: TSCA requirement for peer review

Lest there be any doubt that TSCA's peer review provision applies to 1,4-dioxane and the other chemicals included in the first 10 risk evaluations EPA is conducting under TSCA, TSCA's requirements referenced in that excerpt from the Rule are as follows:

15 U.S.C. 2605(b)(4)(A), referenced in EPA's Rule provision 40 CFR § 702.45 establishing the peer review requirement, reads:

> (4) Risk evaluation process and deadlines
> (A) In general
> The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

The Risk Evaluation Rule was promulgated pursuant to subparagraph (B) of this same section of TSCA, which cross-references subparagraph (A) and reads (emphasis added):

> (B) Establishment of process
> Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with *subparagraph (A)*.

Subparagraph (C) of this same section of TSCA identifies which chemicals are to undergo risk evaluations in accordance with the Rule required under subparagraph (B). It states that the risk evaluation requirement specifically applies to the first 10 chemicals that TSCA required EPA to identify pursuant to paragraph (2)(A) of this section, which includes 1,4-dioxane. These provisions read as follows (emphases added):

> (C) Requirement
> The Administrator shall conduct and publish risk evaluations, in accordance with the rule promulgated under *subparagraph (B)*, for a chemical substance—
> (i) *that has been identified under paragraph (2)(A)* or designated under paragraph (1)(B)(i); …
>
> (2) Initial risk evaluations and subsequent designations of high- and low-priority substances
> (A) Initial risk evaluations
> Not later than 180 days after June 22, 2016, the Administrator shall ensure that *risk evaluations are being conducted on 10 chemical substances* drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.

To summarize:

- EPA was required to identify the first 10 chemicals to undergo risk evaluations, pursuant to paragraph (2)(A). Among these was 1,4-dioxane.
- These chemicals were required to undergo risk evaluations pursuant to paragraph (4)(C) that were to be conducted in accordance with the Risk Evaluation Rule promulgated pursuant to paragraph (4)(B).
- The process established by the Rule was in turn required to accord with paragraph (4)(A).
- EPA's peer review requirement codified at 40 CFR § 702.45 specifies that peer reviews are required to be conducted on the risk evaluations identified in paragraph (4)(A).

done. It also makes clear that a risk determination cannot be made on a condition of use without peer review.

Moreover, the Rule makes clear that a peer review must be conducted on the "entire risk assessment." EPA states (p. 33744, emphasis added):

> In addition to any targeted peer review of specific aspects of the analysis, *the entire risk assessment will also undergo peer review*, as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination.

While EPA did subject its initial draft risk evaluation to peer review, it has now substantially expanded on that draft, adding "various underlying analyses" that mean its original draft no longer constitutes "the entire risk assessment." As EPA itself stated, these new pieces need to be "fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination" and that integrated document must be subject to peer review.

In that same Federal Register notice, EPA provided a lengthy discussion of comments it had received on the proposed Risk Evaluation Rule that suggested peer reviews would not always be needed. EPA flatly rejected those comments, stating that "EPA will require peer review on all risk evaluations" (p. 33744).

EPA must integrate its new analysis into an integrated risk evaluation and subject that full document to peer review before finalizing the risk evaluation and risk determinations.

2. EPA has provided an unreasonably short period of only 20 days for the public to comment on the Supplement.

EPA has provided an unreasonably short period of only 20 days for the public to comment on the Supplement, which is without precedent for risk evaluations under TSCA and we believe is unlawful. As noted in section 1 above, EPA's Risk Evaluation Rule anticipates situations in which EPA might issue a partial risk evaluation of a subset of the conditions of use of a chemical as it has done here, although it was in the context of EPA's assertion of authority to make "early determinations" on a subset of a chemical's conditions of use. The Federal Register notice establishing the Risk Evaluation Rule[6] clearly states that a 60-day public comment period is required even for a partial risk evaluation (i.e., one covering only "particular conditions of use") (p. 33740, emphasis added):

> Any risk evaluation for a chemical under particular conditions of use will therefore be consistent with all statutory requirements as well as the procedures

[6] Available at https://www.govinfo.gov/content/pkg/FR-2017-07-20/pdf/2017-14337.pdf.

established in this regulation. This would also include the *requirement that EPA publish a draft risk evaluation for no less than a 60-day public comment period*, and the regulatory requirement for peer review.

EDF joined other environmental NGOs in requesting an extension of the comment period for 40 additional days to provide the requisite 60-day comment period. That request is attached. Sixty days is the minimum amount of time required by EPA's regulations codifying its Risk Evaluation Rule. See 40 C.F.R. § 702.49(a). Similar requests were also made by other organizations, including the Association of State Drinking Water Administrators (ASDWA)[7] and the Association of Metropolitan Water Agencies (AMWA).[8] Despite these requests, EPA refused to grant an extension.

Moreover, EPA needs to integrate its Supplement into the broader draft risk evaluation and provide the public with an opportunity to comment on the integrated document. As noted in section 1 above in the context of peer review, EPA's Risk Evaluation Rule (p. 33744) makes clear why such review and comment is so important and needed. While EPA did subject its initial draft risk evaluation to public comment, it has now substantially expanded on that draft, adding "various underlying analyses" that mean its original draft no longer constitutes "the entire risk assessment." As EPA itself stated, these new pieces need to be "fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination" and the public must be afforded the opportunity to review and comment on that integrated document.

MAJOR OMISSIONS

3. EPA's new inclusions of exposures from ambient water and consumer product conditions of use are far too narrow in scope and not supported by public and peer review comments EPA received.

In the Federal Register notice announcing the availability of the Supplement, EPA stated:

> Public and peer review comment on the 1,4-dioxane draft risk evaluation suggested that the Agency had omitted both conditions of use associated with 1,4-dioxane as a by-product in consumer products and potential exposure from the ambient surface water pathway. EPA has provided a supplemental analysis to the draft risk evaluation to include these two additions and seeks public comment.

[7] Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0075.
[8] Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0076.

While this statement is correct insofar as it goes, it is highly selective.

A. Public and peer review comments EPA previously received identified numerous additional omissions related to water and consumer product exposures that EPA has now failed to include in its Supplement.

Public and peer review comments EPA received addressed the following omissions:

- EPA's failure to include *all exposures through water* – including drinking water, groundwater, and sediment, as well as ambient surface water. See, for example:
    - EDF's earlier comments on the draft risk evaluation:[9]
        - EPA has entirely ignored the presence of 1,4-dioxane in drinking water; see section II.5.C.
        - EPA has entirely ignored the presence of 1,4-dioxane in groundwater; see sections I.5.A.v. and II.5.E.
        - EPA has dismissed sediment as an exposure source based on insufficient information and analysis; see section I.5.A.i.c.
    - The Science Advisory Committee on Chemicals' (SACC) peer review report,[10] which states (emphases added):
        - "Exposure scenarios that include consumers should be included in the 1,4-Dioxane Hazard Determination. The presence of 1,4-Dioxane in plastic, other commercially available products, *surface water, drinking water, groundwater, and in sediments* is well documented and the risks to human health are as yet unassessed by the Agency." (p. 45)
        - "The omission of *exposure through drinking water leaves the 1,4-Dioxane Evaluation incomplete*." (p. 43)
        - "Exposure assessment through groundwater and other environmental pathways must be evaluated. … *Omission of groundwater in the exposure assessment means that risks to consumers of groundwater are unknown*." (p. 42)
        - "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*." (p. 71)

[9] Environmental Defense Fund, Comments on the Draft Risk Evaluation of 1,4-dioxane, submitted August 30, 2019, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0058.

[10] SACC Final Report/Meeting Minutes for 1,4-Dioxane, transmitted Oct. 31, 2019, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0237-0064.

        - "Include estimates of risk to general population and susceptible populations, *especially in other pathways of exposure such as drinking water*." (p. 77)
- EPA's failure to consider direct exposures to ambient water through activities such as cooking, bathing or showering.
    - EDF discussed this omission in our earlier comments; see sections I.2.B and II.2.
- EPA's failure to address all exposures associated with the presence of 1,4-dioxane as a byproduct or contaminant. See, for example, EDF's earlier comments calling on EPA to include and analyze:
    - *industrial and commercial products* as well as consumer products, including *associated worker exposures from the use of such products*; see sections I.2.A., I.5.B.ii.c., and II.1.A.v.;
    - commercial activities entailing the use of such products, including *car washes, industrial laundries, housecleaning and building maintenance services, and the like*; see section I.2.A.ii., where EDF cited evidence that 1,4-dioxane can be present in high concentrations in products used in such operations; and
    - releases to the environment (e.g., surface waters) from such industrial or commercial operations; see section I.2.A.ii.

  This issue is discussed further in subsection C. below.

In addition, it is not at all clear whether EPA's Supplement factored in elevated exposures to 1,4-dioxane present in consumer products when they are used in hot or warm water – an issue EDF also raised in our earlier comments; see section II.2.

B. EPA has not included releases of and exposures to 1,4-dioxane in residential wastewater discharges associated with consumer product use and disposal.

EPA has limited its analysis of exposures from consumer product conditions of use to direct inhalation/dermal exposures of consumers. In doing so, EPA fails to consider the contribution of those consumer products to water releases, from down-the-drain disposal of those products into residential wastewater. Even within its narrow analysis limited to ambient water exposures, EPA has excluded residential sources of release. This is apparent from the following descriptions of EPA's analysis of the ambient water pathway:

- EPA's conceptual model for ambient water (Figure 1-2, p. 11) displays only wastewater from industrial/commercial uses as inputs.[11]

[11] EPA doesn't appear to have actually included any assessment of releases from commercial activities, however, and focused only on companies reporting under TRI or DMR.

- Table 1-2 (p. 9) and section 2.1.1 (p. 15) only show industrial/commercial conditions of use – i.e., those having an associated *occupational* exposure scenario (OES) – as contributing to the releases to ambient water EPA included in its analysis.

EPA has not provided any evidence or analysis supporting its decision to ignore residential discharges of 1,4-dioxane as a contributor to its presence in ambient water (let alone drinking water). The chemical when present in residential wastewater can enter water systems via various pathways. If the residential wastewater is routed to wastewater treatment facilities, 1,4-dioxane will only be removed to the limited extent that EPA (see the draft risk evaluation at p. 45) and many others have documented for this chemical; 1,4-dioxane is not degraded to a significant extent in all but the most sophisticated treatment systems and instead ends up in the effluent from such facilities that is discharged to surface waters. For the significant fraction of households that rely on septic systems for disposing of residential wastewater, available information – including that cited in EDF's earlier comments; see section I.2.A.ii. – indicates very limited removal and resulting transport into groundwater or surface water. Our comments cited evidence that the chemical can be readily transported from septic systems directly into domestic drinking water wells typically relied on by the same households.

Analyses conducted by the California Department of Toxic Substances Control (DTSC) Safer Products and Workplaces Program have found that 1,4-dioxane released to the environment from personal care and cleaning products is a significant contributor to the amount of the chemical released from wastewater treatment plants.[12]

EPA has failed to consider this important pathway in its Supplement, omitting it from its analyses of both the ambient water pathway and the consumer product conditions of use.

C. EPA has excluded releases of and exposures to 1,4-dioxane as a byproduct in industrial and commercial products arising from their manufacture, use or disposal.

In seeking to explain why it now includes consumer product-related exposures, EPA acknowledges that 1,4-dioxane is present in industrial and commercial, as well as consumer products. On page 8 of the Supplement, EPA states (emphases added):

> As explained in the scope document for 1,4-dioxane, EPA anticipates the production of 1,4-dioxane as a byproduct from ethoxylation of other chemicals and presence as a contaminant in *industrial, commercial and consumer products*.

[12] California Department of Toxic Substances Control Safer Products and Workplaces Program, "1,4-Dioxane in Personal Care and Cleaning Products: Seeking Input on Alternatives Analysis Threshold," August 2019, available at: https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/08/14-Dioxane-Draft-AAT-for-August-2019-Workshop.pdf.

> In the Draft Risk Evaluation for 1,4-Dioxane, the manufacture of 1,4-dioxane as a byproduct from ethoxylation of other chemicals, use and disposal of 1,4-dioxane at residual concentrations in *industrial, commercial and consumer products* containing ethoxylated chemicals were excluded from the scope of the risk evaluation. In response to peer review and public comments, in this Draft Supplemental Analysis, EPA evaluated *eight consumer uses of products* that contain 1,4-dioxane as a contaminant to determine if there was unreasonable risk of injury to consumers' and bystanders' health.

Despite this acknowledgment, EPA arbitrarily limits its new product analysis to consumer products, entirely ignoring industrial and commercial products. It provides absolutely no argument or evidence for this selective decision that is contradicted by its own statements and evidence.[13]

EPA's exclusion of industrial and commercial products from its Supplement leaves out numerous relevant and significant releases and exposures, including:

- exposures of millions of workers during the manufacture, use or disposal of industrial and commercial products containing the chemical as a byproduct, including:
    - at industrial and commercial operations using such products, such as industrial laundries and car washes; and
    - employed by businesses entailing the use of such products, such as building maintenance, housekeeping, painting or automotive services, or employed as insulation installers or in construction jobs,

  all of whom can be expected to be more highly and chronically exposed given that they use such products more frequently, for many more hours each day, and/or in higher-strength formulations than do consumers; and
- releases of and exposures to the chemical ensuing from wastewater discharges from the above activities.

[13] Perhaps this has something to do with the apparent motive for EPA to act at the 11th hour to include consumer uses at all: the formulated product industry's request that EPA do so, spurred by the former's desire to have EPA's actions on this chemical have preemptive effect on states' authority to regulate the chemical in consumer products, which New York and California are doing. But EPA acted narrowly, including only those products it considers subject to state action, presumably because including other products would only increase the likelihood EPA could find risk that would require federal regulation.

Extent of occupational exposures from use of 1,4-dioxane containing industrial and commercial products

Millions of workers are exposed to products containing 1,4-dioxane as a byproduct on a daily basis, leading to chronic as well as acute exposures. Below we provide profiles of various industries and businesses where workers are exposed to the same categories of products EPA has included with respect to consumer exposures based on the presence of 1,4-dioxane as a byproduct that: detergents, paints, coatings, lacquers, antifreeze, and spray polyurethane foam. EPA has ignored all of these workers' exposures in its byproduct analysis.

Industrial Laundries and Dry Cleaners

Industrial laundries use detergents that may contain 1,4-dioxane as a byproduct. While dry cleaning itself likely does not, many or most dry cleaning facilities also provide wet cleaning (i.e., laundry) services. Below are some statistics on the size and employment of these businesses.

- Industrial Laundry & Linen Supply in the US industry statistics:[14]
  - Number of Businesses: 3,073
  - Industry Employment: 101,667
  - Market Size: $14 billion
- Dry Cleaners in the US industry statistics:[15]
  - Number of Businesses: 30,411
  - Industry Employment: 124,553
  - Market Size: $8 billion
- The U.S. Bureau of Labor Statistics (BLS) reports 283,760 employees under the NAICS code 812300 – "Drycleaning and Laundry Services."[16]

Commercial Vehicle Washing

Workers employed in the professional vehicle washing industry are likely to be regularly exposed to detergents containing 1,4-dioxane as a byproduct. These include those employed in the car washing and auto detailing industry, as well as those responsible for cleaning the millions of planes, trains, buses, trucks, and automobiles in the U.S. transportation fleet. There are also 19,216 car rental businesses in the U.S., which typically conduct their own car washes. Below are some statistics on the size and employment of these businesses.

[14] https://www.ibisworld.com/united-states/market-research-reports/industrial-laundry-linen-supply-industry/.
[15] https://www.ibisworld.com/united-states/market-research-reports/dry-cleaners-industry/.
[16] https://www.bls.gov/oes/current/naics4_812300.htm.

- Car Washing & Auto Detailing in the US industry statistics:[17]
    - Number of Businesses: 62,161
    - Industry Employment: 187,797
    - Market Size: $10 billion
- Car washes:[18]
    - In-Bay Automatic/ Roll-over: 28,999
    - Conveyor: 17,487
    - Self Service: 16,182
    - Total: 62,668
- Fleets:
    - Planes: "In 2019, there were about 7,628 aircraft in the U.S. commercial aircraft fleet."[19]
    - Trains: In 2018, there were 26,086 locomotive fleet of U.S. class I railroad operators.[20]
    - Trucks: In 2019, there were 4.7 million trucks in the U.S. fleet.[21]
    - Buses: In 2017, there were approximately 992,000 buses registered in the U.S.[22]
    - Cars:
        - In 2019, there were 3.4 million automobiles in the U.S. fleet, which includes government cars, police cars, taxis, utility vehicles, and the like but does not include fleets of fewer than 15 vehicles.[23]
        - In 2012, there were 1.86 million rental cars in the U.S.[24] and as of 2020, there are 19,216 car rental businesses.[25]

[17] https://www.ibisworld.com/united-states/market-research-reports/car-wash-auto-detailing-industry/.
[18] https://www.carwash.org/for-operators/industry-information.
[19] https://www.statista.com/statistics/193731/aircraft-fleet-of-us-commercial-mainline-air-carriers/#:~:text=In%202019%2C%20there%20were%20about,to%207%2C550%20aircraft%20in%202020.
[20] https://www.statista.com/statistics/185222/us-class-i-railroad-locomotive-fleet-since-1990/.
[21] https://www.bts.gov/content/us-automobile-and-truck-fleets-use.
[22] https://www.bts.gov/content/bus-profile.
[23] https://www.bts.gov/content/us-automobile-and-truck-fleets-use.
[24] https://www.statista.com/statistics/264315/total-car-fleet-of-the-rental-car-industry-in-the-united-states/#:~:text=Car%20rental%20in%20the%20U.S.%20%2D%20total%20cars%20in%20service%202002%2D2012&text=In%202012%2C%20there%20were%20about,around%2023.6%20billion%20US%20dollars.
[25] https://www.ibisworld.com/united-states/market-research-reports/car-rental-industry/.

Motor Vehicle Repair and Maintenance Industry

Workers employed in the motor vehicle repair and maintenance industry may regularly come into contact with antifreeze, which can be contaminated with 1,4-dioxane as a byproduct. Oil change services, for example, often include the service of checking and refilling/replacing antifreeze, so the 93,223 people employed by the oil change services industry may be at risk of exposure. Below are some statistics on the size and employment of these businesses.

- As of 2020, there are about 233,400 auto repair and maintenance centers in the U.S.[26]
- As of 2020, there are 32,516 businesses in the oil change services industry specifically, employing 93,223 people.[27]

Cleaning Services

Millions of cleaning workers are exposed to detergents likely containing 1,4-dioxane on a daily basis. Below are some statistics on the size and employment of these businesses.

- As of 2018, there were over 3.24 million people employed in the cleaning services industry in the U.S, including janitors, cleaners, maids, and housekeepers.[28]
- As of May 2019, there were 926,960 maids and housekeeping cleaners in the U.S.[29]

Construction and Painting

While not all construction workers will come into contact with products containing 1,4-dioxane as a byproduct, those in the painting and coating industry as well as those working with spray polyurethane foam and lacquers are at risk of exposure. Below are some statistics on the size and employment of these businesses.

- Preliminary BLS data demonstrate that in July 2018, there were 7.2 million construction jobs in the U.S.[30]
- According to BLS, in 2019 there were 164,200 painting and coating workers in the U.S.[31]

---

[26] https://www.statista.com/statistics/436416/number-of-auto-repair-and-maintenance-shops-in-us/.
[27] https://www.statista.com/statistics/750836/selected-figures-oil-change-service-market-in-the-united-states/.
[28] https://www.statista.com/topics/2201/commercial-cleaning-services-industry-in-the-us/.
[29] https://www.statista.com/statistics/324419/employees-in-cleaning-occupations-by-job-type-us/
[30] https://www.bls.gov/careeroutlook/2018/article/careers-in-construction.htm#:~:text=Preliminary%20BLS%20data%20show%20that,however%2C%20employment%20has%20trended%20upward.
[31] https://www.bls.gov/ooh/production/painting-and-coating-workers.htm.

> There simply is no logic to or basis for EPA's narrow approach. All of these activities, releases and exposures are relevant to understanding the risks presented by 1,4-dioxane. EPA must expand its analysis to include them.

One final note in this subsection: To the extent that EPA corrects its deficiencies in the Supplement to include workers exposed to products containing 1,4-dioxane as a byproduct, EPA must not distort OSHA standards or assume universal and effective use of personal protective equipment (PPE), as it did in the draft 1,4-dioxane risk evaluation. Likewise, EPA should not assume adherence with recommendations included in safety data sheets (SDSs), which are not mandatory, often of insufficient quality to be useful and frequently not understood. In the draft risk evaluation, EPA itself acknowledged that the existing permissible exposure limit (PEL) for 1,4-dioxane is very old (1989) and that OSHA considers it inadequate to protect workers. We incorporate our extensive comments on these issues on the draft 1,4-dioxane risk evaluation here by reference.[32]

D. EPA continues to ignore 1,4-dioxane's use in oil and gas production.

Another illustration of the selective approach EPA has taken to the ambient water pathway is its continued exclusion of releases of 1,4-dioxane arising from its use or presence in both hydraulic fracturing fluids and produced water. EDF provided an extensive discussion of this topic in our earlier comments (see section I.2.D.), documenting the presence of the chemical and these activities as a source of release to and contamination of ambient water, a pathway EPA claims to now address. Yet such uses and releases are not even mentioned, let alone analyzed, in EPA's Supplement, which purports to include all relevant industrial and commercial conditions of use linked to ambient water.

4. EPA's selective invoking of another statute as a basis for its 11th-hour decision to include the ambient water pathway, while excluding other relevant pathways, is contradictory and arbitrary and capricious.

On page 8 of the Supplement EPA states:

> [B]ecause there is no nationally recommended Ambient Water Quality Criteria under the CWA [Clean Water Act], EPA included exposures to the general population via ambient surface water in this supplemental analysis. EPA did evaluate hazards or exposures to the general population from ambient surface water for the conditions of use in the draft risk evaluation (see Table 1-2), and the

[32] EDF Comments on the Draft Risk Evaluation of 1,4-dioxane. Submitted August 30, 2019. Available: https://beta.regulations.gov/comment/EPA-HQ-OPPT-2019-0238-0058.

> draft unreasonable risk determinations for relevant conditions of use account for exposures to the general population via surface water.

This rationale – that the lack of a national standard for a chemical under another law warrants inclusion of the unregulated exposure pathway – makes sense as far as it goes.[33]

But EPA violates its own "policy" by excluding other exposure pathways from its risk evaluation despite the absence of any national standard. On page 5 of the Supplement EPA stakes out the same position it did earlier in its draft risk evaluation, stating (emphasis added):

> 1,4-Dioxane exposures to the general population may occur from the conditions of use due to releases to air, water or land. … *EPA 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.

On page 77 EPA gets even more specific (emphasis added):

> **Section 6(b)(4)(A) unreasonable risk determination from any of the conditions of use of 1,4-dioxane**: Does not present an unreasonable risk of injury to health (general population). *EPA did not assess exposures from ambient air, drinking water, and sediment pathways because they fall under the jurisdiction of other environmental statutes administered by EPA, i.e., CAA, SDWA, RCRA, and CERCLA.*

Consider the Safe Drinking Water Act (SDWA). There is no Maximum Contaminant Level (MCL) for 1,4-dioxane set under SDWA that would regulate the level of the chemical allowed in drinking water. See section II.5.C. of EDF's earlier comments. Yet EPA has wholly excluded consideration of drinking water from the scope of its risk evaluation.

Adding to the irony of this hypocritical decision by EPA, the agency's Office of Water had an opportunity earlier this year to start the multi-year process of establishing an MCL for 1,4-dioxane under SDWA. It declined to do so. Its stated rationale was that the Office of Chemical Safety and Pollution Prevention, which administers TSCA, is in the process of conducting a risk evaluation of the chemical. Yet that draft TSCA risk evaluation – and now the Supplement –

[33] As discussed at considerable length of in our earlier comments, however, the converse situation – the existence of a national standard – is not a sufficient basis for excluding a pathway from a TSCA risk evaluation. See sections I.2.B. and II.5. of our earlier comments.

make clear that the TSCA risk evaluation will ignore drinking water exposures, on the basis that they are already addressed by the Office of Water under SDWA, when in fact they are not.[34]

5. EPA has failed to consider or address background or aggregate exposures to 1,4-dioxane.

The Supplement has added several conditions of use and exposure pathways to EPA's risk evaluation of 1,4-dioxane. Analyzed properly, these additions contribute to the overall exposures and risks the chemical poses to the general public, workers, consumers, communities living or working near sources of release; groups more susceptible to the effects of exposure; and organisms in aquatic, sediment, terrestrial and soil environments.

In the draft risk evaluation, EPA failed to mention background exposures to the chemical. EPA also refused to aggregate any of the exposures it did identify, paying scant attention to the issue and only stating (draft risk evaluation, p. 152): "As a result of the limited nature of all routes of exposure to individuals (i.e., occupational) 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." EDF's earlier comments identified numerous deficiencies in EPA's cursory statements on the issue; see section I.6.C.

In the Supplement, EPA acknowledges that background exposures to 1,4-dioxane exist, but it makes clear it has not considered them at all, let alone through any aggregation of multiple exposures. In the context of ambient water exposures, EPA states (p. 31):

> Background levels of 1,4-dioxane from other sources are not considered or aggregated in this analysis; therefore, there is a potential for underestimating exposures, particularly for populations living near a facility emitting 1,4-dioxane or living in a home with other sources of 1,4-dioxane, such as other 1,4-dioxane-containing products stored and/or used in the home such as personal care products that are not covered under TSCA. Similarly, there was no aggregation of incidental oral and dermal exposures from swimming, which would be expected to be concurrent.

[34] This remarkable series of developments is documented, with links to the relevant documents, in a recent post to EDF's Health blog titled "Passing the buck: The Trump EPA's mind-boggling efforts to ignore the risks of 1,4-dioxane in drinking water," available at http://blogs.edf.org/health/2020/09/03/passing-the-buck-the-trump-epas-mind-boggling-efforts-to-ignore-the-risks-of-14-dioxane-in-drinking-water/.

And in the context of consumer exposures, EPA states (p. 50):

> Background levels of 1,4-dioxane in indoor and outdoor air are not considered or aggregated in this analysis; therefore, there is a potential for underestimating consumer inhalation exposures, particularly for populations living near a facility emitting 1,4-dioxane or living in a home with other sources of 1,4-dioxane, such as other 1,4-dioxane-containing products stored and/or used in the home such as personal care products that are not covered under TSCA. Similarly, 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.

These statements are disturbing on numerous fronts. *First*, EPA acknowledges that both background exposures (which EPA is not considering at all) and exposures of the same individual to multiple sources that EPA *has* considered (but only in isolation from each other) exist. It then makes clear it is entirely ignoring such exposures even while acknowledging that this decision results in an underestimation of risk. Astoundingly, EPA offers no rationale for its decision whatsoever.

EPA has received numerous comments raising serious concerns over this failing. EDF's earlier comments prominently flagged the issue; see sections I.5.B.ii.a., II.3, and II.8.B. The SACC was also highly critical of this omission. In its peer review report the SACC stated (p. 45): "The decision not to further analyze background levels of 1,4-Dioxane in any matrix (Problem Formulation: page 47) cannot be supported by any risk assessment principle." The SACC report also stated that "EPA should evaluate combined exposures through several pathways, including pathways that were not evaluated such as drinking water" (p. 77).

Second, neither TSCA nor EPA's Risk Evaluation Rule grants EPA the authority to ignore known or reasonably foreseen exposures to a chemical it is evaluating. See the supplemental comments posted by EDF and other environmental, health and labor groups to the docket for the 1,4-dioxane draft risk evaluation notifying EPA of this lack of authority as a result of the Ninth's Circuit's decision in *Safer Chemicals v. United States EPA*, 943 F.3d 397 (9th Cir. 2019).[35] See

[35] Comment of Petitioners Safer Chemicals, Healthy Families; Asbestos Disease Awareness Organization; Vermont Public Interest Research Group; Environmental Defense Fund; Alliance of Nurses for Healthy Environments; Cape Fear River Watch; Natural Resources Defense Council; Alaska Community Action on Toxics; Environmental Health Strategy Center; Environmental Working Group; Learning Disabilities Association of America; Sierra Club; Union of Concerned Scientists; WE ACT for Environmental Justice; and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO/CLC on the meaning of *Safer Chemicals, Healthy Families v. EPA* for risk

also EDF's extensive discussion of this issue in section II.1. of our comments on another draft risk evaluation, that for trichloroethylene (TCE).[36]

Third, EPA explicitly calls out that it is ignoring relevant exposures "particularly for populations living near a facility emitting 1,4-dioxane." Yet TSCA requires EPA to evaluate a chemical across all of its conditions of use; see section II.1. of EDF's earlier comments on the 1,4-dioxane draft risk evaluation. This clearly includes conditions of use occurring at facilities "emitting 1,4-dioxane," whether they are manufacturing, processing, distributing, using, or disposing of the chemical or products or wastes containing it. TSCA section 6(b)(4)(A) also requires EPA to identify and evaluate the potential risks chemicals present to "potentially exposed or susceptible subpopulations," which includes those who may experience disproportionate exposures because of their proximity to conditions of use of a chemical. EPA acknowledges as much, both in the excerpts above and in the draft risk evaluation (see pp. 32-3), yet intentionally ignores such risks nonetheless, providing no rationale. By so doing, EPA is utterly failing to fulfill its obligations under TSCA.

Fourth, there are numerous, obvious ways in which individuals or groups are known or reasonably foreseen to experience exposures to 1,4-dioxane from multiple sources EPA is or should be examining. The excerpts above even identify some of them. Other examples of such combined exposures include:

- A consumer using more than one product containing 1,4-dioxane each day (e.g., washing a load of clothes and cleaning a kitchen or bathroom surface) which is likely to be the rule rather than the exception.
- A worker exposed at work and also as a consumer at home through product use.
- A worker or consumer exposed both dermally and via inhalation simultaneously from the same product use or sequentially even in the short term through different product use.
- A worker or consumer who is also a member of the general population, and therefore may be exposed through product use and also through ambient water, not to mention the drinking water pathway EPA is ignoring.
- A resident of a community near a facility releasing 1,4-dioxane, who is also a consumer and a member of the general population.
- A swimmer who swallows ambient water as well as being immersed in it.
- Someone who is exposed both dermally and through inhalation while bathing or showering in hot water contaminated with 1,4-dioxane and who may simultaneously be using, in hot water, a product containing the chemical.

---

evaluations, submitted March 3, 2020, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0065.

[36] Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0108.

EPA ignores all of this. EPA's statement that under such scenarios "there is a *potential* for underestimating exposures" (emphasis added) is simply wrong: EPA's failure to address such scenarios *absolutely* underestimates exposure.

Fifth, TSCA section 6(b)(4)(F) requires EPA to "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, *and the basis for that consideration*" (emphasis added). Here, while EPA has made clear it hasn't aggregated anything, there is no indication it has instead applied a sentinel exposure approach – the term never appears in the Supplement – nor has it described the basis for the approach it has taken, in direct violation of TSCA.

6. EPA fails to comply with TSCA's mandate to address potentially exposed or susceptible subpopulations.

A. EPA erroneously asserts that there are no potentially susceptible subpopulations for 1,4-dioxane.

With regard to potentially susceptible subpopulations for 1,4-dioxane EPA indicates (p. 5):

> The results of the reasonably available human health data for all routes of exposure evaluated (i.e., dermal and inhalation) indicate that there that there is no evidence of increased susceptibility for any single group relative to the general population. However, there is limited data on reproductive and developmental toxicity and a lack of quantitative information on how genetics, pre-existing disease, or other factors may contribute to increased susceptibility.

EPA's assertion ignores those with relevant pre-existing conditions. EDF's earlier comments described several such subpopulations; see section I.1.A, which we reiterate here. Relevant pre-existing conditions include those that affect the liver or impair metabolism (e.g., nonalcoholic fatty liver disease, which is estimated by the Mayo Clinic to impact between 80-100 million individuals in the United States),[37] or the kidneys, upper respiratory system, or other organs targeted by 1,4-dioxane. Individuals with elevated alcohol intake may also exhibit increased liver sensitivity. Additionally, in the original draft risk evaluation EPA acknowledges (p. 108):

> variations in CYP enzyme expression may contribute to susceptibility because multiple CYP enzymes are involved in metabolism of 1,4-dioxane, including

[37] NONALCOHOLIC FATTY LIVER DISEASE, https://www.mayoclinic.org/diseases-conditions/nonalcoholic-fatty-liver-disease/symptoms-causes/syc-20354567 (last visited Jul. 19, 2019).

> 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.

EPA acknowledges that the database for potential reproductive and developmental toxicity of 1,4-dioxane—effects of particular relevance to pregnant women—is limited. EPA should not equate the absence of information to an absence of susceptibility or risk. Pregnant women are expressly identified as a potentially exposed or susceptible subpopulation under TSCA, yet EPA ignores any potential concern and has taken no steps to fill this crucial data gap.

More broadly, while EPA acknowledges "limited data" exist on potential susceptibilities, it proceeds to ignore them by asserting there is a "lack of quantitative information." But TSCA provides no such exception; in fact, Congress' inclusion in TSCA of "potential" preceding "susceptible subpopulations" makes clear that it intended for EPA to identify, assess and protect against risks even to those for which evidence indicates a possible greater susceptibility than the general population. In reforming TSCA in 2016, Congress also enhanced EPA's authority to obtain information necessary to conduct risk evaluations under sections 4 and 8, which EPA could and should have utilized from the outset but steadfastly refused to employ. Instead, EPA now hides behind these asserted data gaps, effectively asserting that any uncertainty in the data is equivalent to a total lack of risk.

EPA must do what TSCA directs. At a minimum, EPA must account for these susceptibilities in its uncertainty analyses and augment hazard and risk characterizations to reflect these relevant subpopulations, including by considering the use of additional uncertainty factors and/or by adjusting the magnitude of uncertainty factors applied.

B. EPA needs to analyze those subpopulations that face greater risk due to greater potential exposure.

With regard to subpopulations potentially exposed to 1,4-dioxane EPA asserts (p. 5):

> For consideration of the most highly exposed groups in this Draft Supplemental Analysis, EPA considered 1,4-dioxane exposures to be higher amongst consumers and bystanders that are exposed through the use of consumer products containing 1,4-dioxane as a byproduct as compared to the general population based on greater exposure.

i. EPA must identify workers as a potentially exposed subpopulation, given exposures to 1,4-dioxane at levels higher than the general population.

TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to

either greater susceptibility *or greater exposure*, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." 15 U.S.C. § 2602(12).

In its Supplement, EPA erroneously omits exposures of workers to 1,4-dioxane under the conditions of use assessed. As discussed in section 3.C., workers may use products containing 1,4-dioxane as a byproduct in the course of their work in industrial or commercial settings and may be even more highly exposed to 1,4-dioxane than are consumers (workers are of course also consumers when they are not working). EPA must consider and analyze worker exposures to 1,4-dioxane as a byproduct.

ii. EPA must identify groups near sources of release of 1,4-dioxane as a potentially exposed subpopulation, given exposures to 1,4-dioxane at levels higher than the general population.

In the problem formulation for 1,4-dioxane, EPA correctly recognized that a potentially exposed or susceptible subpopulation includes those "groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution, use or disposal sites)." *See, e.g.*, Problem for 1,4-Dioxane at p. 32. But EPA then ignored the vast majority of pathways that cause these groups to face greater exposures—such as through releases to air, water, and land. EPA provided no rational explanation for how it will accurately and effectively evaluate the actual risk faced by these subpopulations while ignoring these exposures. Moreover, EPA's (correct) recognition that these groups face greater exposure highlights that it is irrational for EPA to ignore the pathways leading to these exposures.

As a result, in the draft risk evaluation, EPA entirely failed to analyze this potentially exposed or susceptible subpopulation (pp. 151-52). See EDF's earlier comments on the draft risk evaluation; section I.5.B.ii. EPA severely limited its analysis of greater exposure to workers, and EPA completely ignored the greater exposure experienced by individuals living in proximity to conditions of use. As a result, EPA failed to consider an important aspect of the problem because EPA failed to analyze the risks posed to a potentially exposed or susceptible subpopulation that EPA previously acknowledged.

In addition, TSCA specifically requires that EPA protect these subpopulations because they face greater potential exposure. EPA's invoking of other statutes it administers as a basis for ignoring releases and exposures affecting such groups is unwarranted and unlawful. And, any existing regulations EPA may have developed under other statutes, which may not have been developed with a focus on these particular subpopulations, may not always be "sufficient" under the TSCA

standard. EDF discussed these concerns at length in our earlier comments on the draft risk evaluation; sections I.5.B.ii., II.5. and II.8.

The California Department of Toxic Substances Control (DTSC) Safer Products and Workplaces Program has examined the increased exposures to 1,4-dioxane experienced by groups near sources of release of 1,4-dioxane, whether from legacy contamination or 1,4-dioxane present in ambient media.[38]

As discussed in section 5, EPA's Supplement perpetuates its earlier unlawful exclusions through its exclusion of background exposures to 1,4-dioxane from consideration and its explicit acknowledgment of, but failure to analyze, exposures "particularly for populations living near a facility emitting 1,4-dioxane" (pp. 31, 50). As noted in section 5, by so doing, EPA is utterly failing to fulfill its obligations under TSCA.

iii. Reasonably available information reveals that consumers who use multiple cosmetics and cleaning products and "do-it-yourselfers" may be at greater risk due to greater exposure.

EPA should include consumers who use multiple cosmetics[39] and cleaning products as potentially exposed or susceptible subpopulations, given EPA's prior identification of those subpopulations as particularly likely to be exposed. In EPA's 2015 Problem Formulation and Initial Assessment for 1,4-dioxane, EPA stated:

> EPA/OPPT concludes that exposure to consumers can result from the use of soaps and detergents and other products that contain 1,4-dioxane as a contaminant. Adult women who use multiple cosmetics and cleaning products are likely the most exposed population as determined in the Canada assessment.[40]

---

[38] California Department of Toxic Substances Control Safer Products and Workplaces Program, "1,4-Dioxane in Personal Care and Cleaning Products," May 23, 2019, available at https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/05/Background-Document_14-dioxane.pdf; and "1,4-Dioxane in Personal Care and Cleaning Products Public Meeting," August 21, 2019, available at https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/08/14-dioxane_SCP-Presenation.pdf.

[39] EDF recognizes that cosmetics are not regulated under TSCA. However, non-TSCA uses and occurrences of 1,4-dioxane contribute to the background and hence overall exposures people and the environment face, which in turn determines their risk. Section 5 of these comments further addresses the need for EPA to address background exposures to 1,4-dioxane.

[40] *See* U.S. EPA, *TSCA Work Plan Chemical Problem Formulation and Initial Assessment, 1,4-Dioxane, CASRN: 123-91-1* at 28 (Apr. 2015), https://www.epa.gov/sites/production/files/2017-06/documents/14_dioxane_problem_formulation_and_intial_assessment.pdf.

EPA has failed to address these disproportionate exposures as a result of its decisions to exclude consideration of background and aggregate exposures; see section 5.

As discussed in section 10.A. below, greater exposures of "do-it-yourselfers" (DIY), including chronic exposures, must be included in EPA's evaluation.

iv. Children may be more highly exposed to 1,4-dioxane under the conditions use EPA has evaluated and the pathways of exposure it has ignored.

Children may be disproportionately exposed to 1,4-dioxane by virtue of relevant behavioral differences. Relative to adults, children particularly younger children, engage in significant hand-to-mouth activity and spend more time on the floor.[41] As a result, children may be disproportionately exposed to residual 1,4-dioxane present, for example, from the use of surface and floor cleaners.

As discussed elsewhere in these comments (sections 3.A. and 4), EPA's omission of drinking water as a pathway of exposure, both for conditions of use EPA assessed and conditions of use it negligently excluded, is a fundamental gap in the agency's risk evaluation of 1,4-dioxane. EPA's exclusion ignores disproportionate exposures to children from this pathway. Analyzing exposure through drinking water is particularly important for EPA to obtain an accurate estimate of the exposure of infants and children, often a potentially exposed or susceptible subpopulation. *See, e.g.*, U.S. EPA, Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro) (May 2018), p.48, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0080 ("Drinking water could be a significant source of perchloroethylene ingestion exposure for children, who drink roughly four times as much water as adults.").

EPA needs to identify children as a potentially exposed or susceptible subpopulation.

WATER-RELATED RELEASES AND EXPOSURES

7. EPA ignored relevant and significant TRI data in its ambient water exposure analysis.

EPA ignored much of its own data obtained through the Toxics Release Inventory (TRI) in its ambient water exposure analysis. EPA's Enforcement and Compliance History Online (ECHO)

[41] EPA's 2011 Exposure Factors Handbook provides detailed information on hand-to-mouth and object-to-mouth contact frequencies for various ages. See https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252.

Water Pollution Search database,[42] which allows users to search TRI pollutant discharges to water, provides significant data ignored in EPA's analysis.

In 2018, 100,083 pounds of 1,4-dioxane were reported as directly released into water and an additional 180,322 pounds were indirectly released to POTWs – for a total of 280,405 pounds discharged. However, EPA arbitrarily chose to limit its analysis to facilities fitting select Occupational Exposure Scenarios it developed for the risk evaluation (EPA Table 2-4), leading it to omit many emitting facilities as well as contaminated watersheds.

The ECHO database demonstrates that in 2018, numerous U.S. watersheds received discharges of 1,4-dioxane that EPA did not include in its analysis. These include three watersheds receiving more 1,4-dioxane than those that EPA used for its analysis of ambient water exposures. These watersheds and their associated facilities are: Spring Creek-Mud Creek in Alabama (Indorama Ventures), Kendrick Creek-South Fork Holston River in Tennessee (Eastman Chemical Co Tennessee operations), and Back Creek in North Carolina (Starpet Inc.). APG Polytech LLC also had a greater discharge, although its associated watershed is not reported in the public database.

The watershed receiving the greatest discharges in 2018, Spring Creed-Mud Creek in Alabama, had indirect discharges more than *six times higher* than the watershed EPA relied on as its upper bound (Ninemile Creek polluted by Suez WTS Solutions USA Inc.) based on the 2018 data.[43] EPA also ignored 1,4-dioxane discharges into three other watersheds: Back River-Cooper River in South Carolina (Dak Americas LLC Cooper River Plant), Singleton Swamp in South Carolina (Nan Ya Plastics Corp America), and Brushy Creek-Enoree River in South Carolina (Mitsubishi Polyester Film Inc.). See Tables 1 and 2 below for additional detail.

EPA's arbitrary narrowing of its analysis – based on the irrelevant criterion of where it had developed an occupational exposure scenario – has resulted in an underestimation of both the extent and magnitude of 1,4-dioxane discharged to ambient water.

It is also worth noting that we discovered what appears to be a major transcription error in Table 2-4 for the releases into Ninemile Creek from Suez WTS Solutions USA Inc. EPA's error led it to use a higher discharge than actually reported in the 2018 TRI (see footnote 44). However, this should not reduce the upper bound of EPA's predicted surface water concentrations; rather, EPA should use the significantly higher level discharged by Indorama Ventures into Spring Creek-Mud Creek, Alabama.

[42] https://echo.epa.gov/trends/loading-tool/water-pollution-search/.
[43] 131,131 / 20,517 = 6.39. (Using EPA's inaccurate value of 37,304 lb/year, Spring Creed-Mud Creek had discharges 3.5 times greater than Ninemile Creek: 131,131 / 37,304 = 3.5).

Table 1. 2018 TRI Data Obtained from ECHO database – Top 10 Watersheds

Watershed Name	State	Direct TRI Pounds (lb/yr)	Indirect TRI Pounds (lb/yr)	Included in EPA Supplement?
Spring Creek-Mud Creek	AL	0	131,131	No
Kendrick Creek-South Fork Holston River	TN	33,440	0	No
Back Creek	NC	0	23,876	No
Ninemile Creek	MN	0	20,517 [44]	Yes
Back River-Cooper River	SC	18,789	0	No
Locks Creek-Cape Fear River	NC	9,133	0	Yes
Tyler Creek-Kanawha River	WV	8,419	0	Yes
Singleton Swamp	SC	0	2,713	No
Brushy Creek-Enoree River	SC	0	1,995	No
Bayou Fortier	LA	1,826	0	Yes

Table 2. 2018 TRI Data Obtained from ECHO database – Top 10 Polluting Facilities

Facility Name	City	County	State	NAICS Code	Watershed Name	Direct TRI Pounds (lb/yr)	Indirect TRI Pounds (lb/yr)
INDORAMA VENTURES	DECATUR	MORGAN	AL	325211	Spring Creek-Mud Creek	0	131,131
EASTMAN CHEMICAL CO TENNESSEE OPERATIONS	KINGSPORT	SULLIVAN	TN	325211	Kendrick Creek-South Fork Holston River	33,440	0

[44] Table 2-4 of the Supplement indicates that Suez WTS Solutions USA Inc. releases 16,920.83 kg/year (or 37,304 lbs/year) of 1,4-dioxane into South Fork Nine Mile Creek. The same values are reported the Supplemental File on Exposure Modeling Inputs, Results, and Risk Estimates for Incidental Ambient Water Exposure (https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0069). However, searching both EPA's ECHO tool as well as TRI Explorer yields the value of 20,517 for indirect/POTW discharges in 2018. See https://enviro.epa.gov/triexplorer/release_fac?p_view=USFA&trilib=TRIQ1&sort=RE_TOLBY&sort_fmt=2&state=All+states&county=All+counties&chemical=000123911&industry=ALL&year=2018&tab_rpt=1&fld=RELLBY&fld=TSFDSP&ONDISPD=Y&OTHDISPD=Y&OFFDISPD=Y&OTHOFFD=Y.

APG POLYTECH LLC	APPLE GROVE	MASON	WV	325211	N/A	24,283	0
STARPET INC	ASHEBORO	RANDOLPH	NC	325211	Back Creek	0	23,876
SUEZ WTS SOLUTIONS USA INC	MINNETO-NKA	HENNEPIN	MN	333999	Ninemile Creek	0	20,517
DAK AMERICAS LLC COOPER RIVER PLANT	MONCKS CORNER	BERKELEY	SC	325211	Back River-Cooper River	18,789	0
DAK AMERICAS LLC	FAYETTEVIL LE	CUMBERL-AND	NC	325211	Locks Creek-Cape Fear River	9,133	0
UNION CARBIDE CORP INSTITUTE FACILITY	INSTITUTE	KANAWHA	WV	325199	Tyler Creek-Kanawha River	8,419	0
NAN YA PLASTICS CORP AMERICA	LAKE CITY	FLORENCE	SC	325211	Singleton Swamp	0	2,713
MITSUBISHI POLYESTER FILM INC	GREER	GREENVIL LE	SC	326113	Brushy Creek-Enoree River	0	1,995

8. EPA has not sufficiently explained its selection and exclusion of certain concentration data of 1,4-dioxane in ambient water.

EPA has not provided sufficient analysis or explanation to support its selection of concentrations to represent 1,4-dioxane in ambient water.

EPA indicates that it included monitoring data from Minnesota (MN) and North Carolina (NC) state agencies because the data were submitted during the 2019 comment period. Although data from NC, specifically Haw River and Cape Fear River, and MN were the only data submitted during the comment period, they are not the only states with available data on 1,4-dioxane concentrations in surface water.

While EPA appears to have used the concentrations at the upper end of the range of the MN and NC monitoring data, there is a lack of transparency regarding why only these data were used. The agency stated (on p. 28) that its predicted values (modeled using E-FAST) for surface water concentrations taken as a whole cover a range that encompasses the ranges reported by NC and MN; however, EPA did not explain why it excluded other available data.

In EDF's earlier comments on the draft risk evaluation, we noted that EPA had inappropriately excluded data points from its STORET database; section I.5.A.i.b.2. In the Supplement, EPA's references to the STORET data in Tables 4-1, 4-2, and 4-7 make clear it is repeating the same error. Our review of the STORET and NWIS data between the years 2009-2019[45] revealed that there were 59 samples with method detection limits (MDLs) greater than 100 ug/L. Of these, 34 were from surface water samples, some of which had MDLs as high as 28,000 ug/L– nearly six times higher than the upper end of the range of values in the Supplement that EPA derived using E-FAST (p. 28). EPA discarded all of these values – even though the "true" concentration of these surface water samples may be well above its E-FAST derived values EPA uses to estimate risk. In such cases, researchers would typically either use the MDL or a value that is one-half of the MDL. EPA simply eliminated the data from consideration without basis.

In addition, 1,4-dioxane was measured in various water systems from 2013-2015 as part of the Third Unregulated Contaminant Monitoring Rule (UCMR3). The UCMR3 provide relevant 1,4-dioxane water concentration data from multiple states (US EPA, 2016). In EDF's earlier comments on the draft risk evaluation, we criticized the agency's failure to use the UCMR3 data and its reasoning for not doing so; see section I.5.A.iv.[46]

PRODUCT-RELATED RELEASES AND EXPOSURES

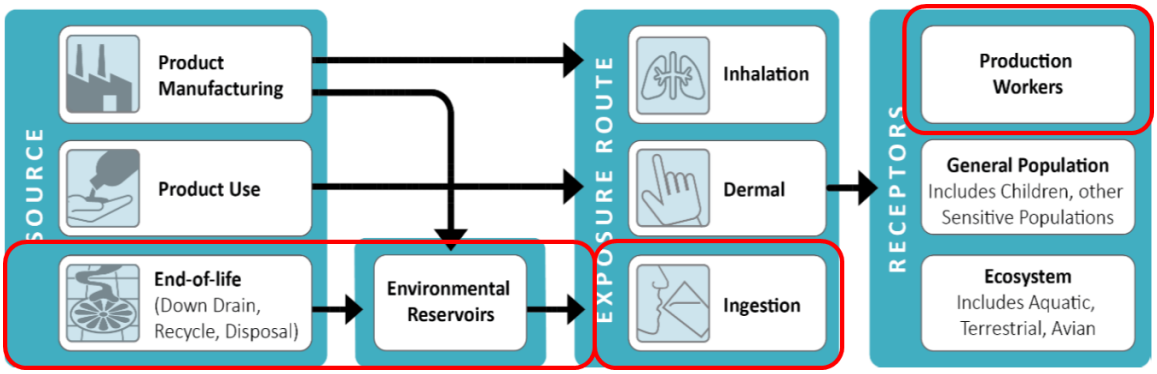
9. EPA's conceptual model relating to consumer product conditions of use is incomplete.

In its Supplement, EPA has not included all exposures and risks to the general population and relevant subpopulations in its 1,4-dioxane conceptual model relating to its consumer product conditions of use, thus underestimating the risks posed by the chemical. As noted in section 3.B., EPA has not included releases of and exposures to 1,4-dioxane in residential wastewater discharges associated with consumer product use and disposal. As noted in section 3.C., EPA's model does not include workers that may use products containing 1,4-dioxane as a byproduct in the course of their work.

The California Department of Toxic Substances Control (DTSC) Safer Products and Workplace Program displays a more comprehensive conceptual model of exposure, including 1,4-dioxane

[45] WATER QUALITY DATA, https://www.waterqualitydata.us/portal/#sampleMedia=Other&characteristicName=1%2C4-Dioxane&startDateLo=01-01-2009&mimeType=csv (last visited Aug. 9, 2019).
[46] While most UCMR data are from measurements of treated water, the poor removal efficiency for 1,4-dioxane through water treatment means these data are still relevant and useful in understanding the ubiquity and magnitude of 1,4-dioxane contamination of water.

exposures ensuing from its release in residential wastewater.[47] Notably it includes ingestion (oral) as a route of exposure to the chemical, which EPA excludes but is clearly relevant with respect to 1,4-dioxane's widespread presence in water. In addition, the DTSC model includes important subpopulations that EPA failed to consider in both its conceptual model and its risk estimates. Below we highlight in red those elements of the DTSC model that EPA has omitted.



10. EPA inappropriately limited its evaluation of exposure from consumer product conditions of use.

A. EPA's inclusion of chronic exposures to products is too limited.

One area of improvement relative to other draft risk evaluations is EPA's recognition that some consumer products containing 1,4-dioxane can be used in a manner that leads to chronic consumer exposures because they are used frequently. On p. 52 EPA states: "Chronic (lifetime) inhalation and dermal exposures were estimated for four product scenarios: surface cleaner, dish soap, dishwasher detergent, and laundry detergent. The inclusion of lifetime exposure estimates for these conditions of use is based on the anticipated daily or near-daily use of these products."

However, EPA inappropriately dismissed chronic inhalation and dermal exposure to consumer users from spray polyurethane foam, antifreeze, textile dye, and paint and floor lacquer. EPA's rationale for limiting its analysis to acute exposures is "based on expected infrequent and intermittent use frequencies" (p. 33) of such products by consumers. EPA provides no evidence to support this statement. In fact, products such as antifreeze, paints, and floor lacquer, may be used by "do-it-yourselfers" (DIY) with more regularity. While chronic exposure may not be typical for most consumers, EPA failed to assess DIY users as a "potentially exposed or susceptible subpopulation." Furthermore, EPA has not considered exposures arising from gradual release of 1,4-dioxane following use of such products, for example, from surfaces to

[47] California Department of Toxic Substances Control Safer Products and Workplaces Program, "1,4-Dioxane in Personal Care and Cleaning Products," May 23, 2019, available at: https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/05/Background-Document_14-dioxane.pdf.

which they have been applied or during subsequent storage. Moreover, many consumers are likely to use more than one product containing 1,4-dioxane in a given time period, in contrast to EPA model assumptions that treated each product in isolation and failed to aggregate exposures (see section 5 of these comments); as a result, actual exposures may be more frequent than EPA assumes in the modeling that assumed use of a single type of product and a single exposure scenario at a time. These activities that could result in longer-term exposure were identified by the SACC peer reviewers of EPA's draft risk evaluation for trichloroethylene with regards to consumer products used and stored in the home.[48,49]

It should be noted that EPA's failure to consider worker exposures to such products at all (see section 3.C. of these comments) means that it also failed to account for the fact that all of EPA's product scenarios lead to chronic exposures of workers. In addition to workers using surface cleaners, soaps, and detergents, those using paints, antifreeze, textile dyes, and SPF (e.g., employees of painting service companies, automotive garages, textile businesses and home insulation installers) must certainly be considered chronically exposed to such products. They are clearly exposed more than once a day, for multiple days per week, and for longer periods of time per exposure event than EPA assumed for consumers.

B. EPA inappropriately limited its evaluation of consumer product conditions of use to only a subset of potential health endpoints and without providing any justification.

Even with respect to consumer exposures, EPA has limited its analysis in ways that are not warranted and/or not acknowledged or explained.

On page 70 of the Supplement, EPA states: "EPA identified cancer and non-cancer adverse effects from acute and chronic inhalation and dermal exposure to 1,4-dioxane from the conditions of use described in this supplemental analysis." This statement is not accurate: EPA did NOT examine cancer risks from acute exposure and it did NOT examine non-cancer risks from chronic exposure. Instead, EPA examined only non-cancer effects in its analysis of acute exposure risks. And it examined only cancer in its analysis of chronic exposure risks. Each of these problems is addressed below.

i. EPA has failed to include any estimate of cancer risks from acute exposure.

In the Supplement, as was the case in the draft risk evaluation, EPA did not examine cancer in assessing risks from acute exposures. In neither document has EPA provided any explanation for this decision not to consider such risks. However, EPA made the same decision in its risk

[48] See page 98 of EDF Comments on Draft Trichloroethylene Risk evaluation, submitted April 27, 2020: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0500-0108.
[49] SACC Peer Review Report for Trichloroethylene, p. 279, available at https://beta.regulations.gov/document/EPA-HQ-OPPT-2019-0500-0111, page 58.

evaluations of other chemicals and in some cases did provide an explanation, albeit cursory and insufficient. For example, in its methylene chloride draft risk evaluation, despite acknowledging that the weight of the scientific evidence indicates methylene chloride is a mutagenic carcinogen and that linear extrapolation is warranted (p. 29), the agency explained its decision not to assess acute cancer risks by stating only that the "[r]elationship is not known between a single short-term exposure to DCM [methylene chloride] and the induction of cancer in humans" (p. 699).

We can assume that EPA would offer the same rationale in the case of 1,4-dioxane. If so, EPA's rationale is not supported and is unwarranted. The National Research Council (NRC) states:[50]

> Guidance on the development of short-term exposure levels, published by the NRC, identified cancer as one of the potential adverse health effects that might be associated with short-term inhalation exposures to certain chemical substances (NRC 1993a). That guidance document discusses and recommends specific risk-assessment methods for known genotoxic carcinogens and for carcinogens whose mechanisms are not well understood. As a first approximation, *the default approach involves linear low-dose extrapolation from an upper confidence limit on theoretical excess risk*. Further, the NRC guidance states that *the determination of short-term exposure levels will require the translation of risks estimated from continuous long-term exposures to risks associated with short-term exposures*. Conceptually, the approach recommended for genotoxic carcinogens adopted the method developed by Crump and Howe (1984) for applying the linearized multistage model to assessing carcinogenic risks based on exposures of short duration.

Later in the same document (p. 118), the NRC summarizes: "Guidance published by the NRC (1993a) states that the setting of AEGLs (CEELs) [acute exposure guideline levels (for what are termed "community emergency exposure levels")] should involve linear low-dose extrapolation from an upper confidence limit on excess risk for genotoxic carcinogens."

As stated in this NRC report, the decision to conduct such extrapolation and modeling should be based on the "sound biological and statistical principles." EDF is concerned that EPA did not sufficiently consider such principles related to mode-of-action in deciding not to model acute cancer risk based on chronic exposure data. The agency recognized that "[l]inear extrapolation is the default approach when there is uncertainty about the MOA [mode of action]. 1,4-Dioxane is a multi-site carcinogen and may have more than one MOA. EPA estimates for excess cancer

[50] Nat'l Research Council, *Standard operating procedures for developing acute exposure guideline levels for hazardous chemicals*, pp. 111-112 (2001), https://www.epa.gov/aegl/standing-operating-procedures-developing-acute-exposure-guideline-levels-aegls-hazardous (emphasis added).

risk were based on the assumption of linearity in the relationship between 1,4-dioxane exposure and the probability of cancer." (draft risk evaluation, p. 150). Hence, a linear low-dose extrapolation from chronic to acute exposures would be the appropriate approach to take for 1,4-dioxane.

It is possible that even a linear extrapolation from chronic cancer bioassays may underestimate the cancer risk of short-term exposures. Halmes et al., 2000 lends support to the potential for short-term exposures to result in similar or higher cancer risks than even chronic lifetime exposures.[51] The study used NTP data where both shorter term and full lifetime studies had been conducted.

EPA's current approach assumes acute exposures to 1,4-dioxane, including to consumers via consumer products and the general population via ambient water, pose *zero* cancer risk – an assumption that is clearly not warranted. EPA needs to apply an extrapolation that provides a scientifically sound estimate for cancer risk from acute and short-term exposures to 1,4-dioxane. As EDF stated in our comments on EPA's problem formulations (p. 81):[52]

> EPA must closely examine any effect it believes to arise only from chronic exposures to determine whether in fact this is true across the diverse human population, including where potentially exposed or susceptible subpopulations may be at increased risk for effects after shorter periods of exposure compared to the general population.

ii. EPA has failed to include any estimate of non-cancer risks from chronic exposure.

In its Supplement, EPA has not included any analysis of non-cancer risks from chronic exposure. Note the absence of these effects in Table 4-8, pp. 67-9 and in the corresponding text, section 4.2.1.2.

This omission is all the more curious because EPA identifies such non-cancer effects attributable to 1,4-dioxane exposure and it calculates and displays corresponding dose-response values for these effects. See Table 3-1, pp. 57-58.

[51] N. Christine Halmes, et al., *Reevaluating cancer risk estimates for short-term exposure scenarios*, 58:1 TOXICOLOGICAL SCIENCES 32-42 (2000), https://academic.oup.com/toxsci/article/58/1/32/1658920/#24341943.

[52] EDF Comments on Problem Formulations for Risk Evaluations To Be Conducted Under Toxic Substances Control Act, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0083.

Nowhere in EPA's Supplement or the accompanying documents does it provide any rationale or explanation for this omission. EPA needs to assess and present its assessment of non-cancer risks from chronic exposure to 1,4-dioxane.

C. EPA underestimated consumer bystander exposure.

EPA underestimated consumer bystander exposure by ignoring both chronic inhalation exposures of this population as well as any dermal exposures.

EPA states: "EPA did not estimate chronic inhalation exposures to bystanders because bystanders would be exposed to lower levels than the user based on the model bystander placement in the home during the product's use" (p. 6). Bystanders, however, including young children, will be near sources (e.g., recently cleaned surfaces, recently washed clothes) on a continual basis. While their exposure may be lower than the user, lower exposure is not equivalent to zero exposure, as EPA has effectively assumed. By ignoring the potential for chronic inhalation exposures to bystanders, EPA has underestimated risk to this population.

EPA also states that it: "did not evaluate non-cancer effects from dermal exposures to bystanders because bystanders are not dermally exposed to 1,4-dioxane." EPA provides no basis for this statement.[53] Yet bystanders, including children, would likely have contact with, i.e., touch, recently cleaned surfaces (e.g., a kitchen or bathroom counter) or wear clothes recently washed with a detergent contaminated with 1,4-dioxane as a byproduct.

When considered in isolation, each of these bystander exposures may present relatively low risk; however, if EPA were to combine exposures in a manner that reflects the reality of consumer and bystander exposures, (see Section 5 of these comments), the total exposures could well be significant.

11. EPA's data collection process for 1,4-dioxane concentrations in consumer products lacks transparency.

EPA identifies eight categories of consumer products that it evaluates for direct consumer exposure to 1,4-dioxane. The sources of the 1,4-dioxane concentrations in these products presented by EPA (see Table 2-11) are unclear. The Supplement indicates that the concentrations of 1,4-dioxane in these consumer products came primarily from the 2015 TSCA Workplan Assessment. On page 33 EPA states:

[53] Later in the document EPA makes a similar statement without citation: "Generally, individuals that have contact with liquid 1,4-dioxane would be users and not bystanders. Therefore, direct dermal exposures are not expected for bystanders and are only estimated for users" (p. 33).

> Eight consumer conditions of use are evaluated based on the uses identified in EPA's 2015 TSCA Work Plan Chemical Problem Formulation and Initial Assessment of 1,4-Dioxane (U.S. EPA, 2015). An additional systematic review effort was undertaken for consumer exposures to identify, screen, and evaluate relevant data sources.

But the 2015 document does not clearly present the sources EPA used to derive the concentrations, nor has EPA presented concentration data it derived from any additional sources it identified through its systematic review. While the Consumer References Data Screening file includes a list of articles that EPA presumably used to extract 1,4-dioxane concentrations in consumer products, the file does not present any concentration data. Furthermore, EPA does not describe the process it employed for choosing which concentrations to use in its analysis. This lack of transparency hinders our ability to meaningfully comment on EPA's Supplement.

OTHER OVER-ARCHING PROBLEMS

12. EPA's derivation of its risk estimates is deficient in several respects.

A. EPA fails to include all necessary uncertainty factors in calculating the benchmark margins of exposure, resulting in inaccurate risk characterizations.

EPA has failed to include necessary uncertainty factors in its calculations of benchmark margins of exposure (BMOE) for risks of chronic non-cancer effects from inhalation and dermal exposures. (While EPA did not utilize these endpoints in the Supplement (although it should have done so, see section 10.B.ii.), it included them in Table 3-1 and is presumably intending to use them elsewhere in the risk evaluation.)

The BMOE that EPA applies is 30, resulting from the multiplication of two uncertainty factors—3 for interspecies variation (UF_A) and 10 for intraspecies variation (UF_H). However, at a minimum, EPA should have included an additional uncertainty factor for "the uncertainty associated with extrapolation from animal data when the database is incomplete" [54,55] for both chronic non-cancer inhalation and dermal BMOEs.

---

[54] U.S. EPA Risk Assessment Forum, *A Review Of The Reference Dose And Reference Concentration Processes* p. 4-38 (Dec. 2002), https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf.

[55] REFERENCE DOSE (RFD): DESCRIPTION AND USE IN HEALTH RISK ASSESSMENTS, https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments#1.4 (last visited Jan. 14, 2019).

With regard to the database uncertainty factor, the EPA Risk Assessment Forum notes in its 2002 report, *A Review of the Reference Dose and Reference Concentration Processes*:

> 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.[56]

The characterization of 1,4-dioxane's human health toxicity is clearly incomplete. EPA has no dermal toxicity data at all and for developmental toxicity has only a single short-term study; hence, the agency lacks any sub-chronic or chronic reproductive, developmental or neurotoxicity data. Thus, it is imperative that EPA apply an additional uncertainty factor of 10 to account for these data gaps.

In addition, EPA's reliance on route-to-route extrapolation for sub-chronic/chronic dermal effects – necessitated by the total absence of dermal toxicity data – also introduces uncertainty that EPA has failed to account for. As is recommended for route-to-route extrapolation generally[57] and oral-to-dermal extrapolation specifically,[58] EPA should apply an additional uncertainty factor of 10 to account for these uncertainties.

With respect to chronic non-cancer dermal effects, in the Supplement (Table 3-1) EPA indicates it has derived a HED of 1.6 mg/kg/day and cites two studies for this value: Kociba et al., 1974 and Kasai et al., 2009. EPA fails provide any explanation of how either or both studies were used to derive the HED, and it needs to do so. To the extent EPA relies on the Kasai et al., 2009 study, EPA may need to apply an additional UF_L uncertainty factor (LOAEL to NOAEL) as this study

---

[56] U.S. EPA Risk Assessment Forum, *A Review Of The Reference Dose And Reference Concentration Processes* p. 4-44 (Dec. 2002), https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf.

[57] *See, e.g.*, Schröder, K., et al., *Evaluation of route-to-route extrapolation factors based on assessment of repeated dose toxicity studies compiled in the database RepDose®*, 261 TOXICOLOGY LETTERS 32-40 (Nov. 2016), https://www.ncbi.nlm.nih.gov/pubmed/27553675; Dankovic, D.A., et al., *The scientific basis of uncertainty factors used in setting occupational exposure limits*, 12 J. OF OCCUPATIONAL & ENVTL. HYGIENE 55-68 (Nov. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4643360/.

[58] Rennen, MA, et al., *Oral-to-inhalation route extrapolation in occupational health risk assessment: a critical assessment*, 39:1 REG. TOXICOLOGY & PHARMACOLOGY 5-11 (2004), https://www.ncbi.nlm.nih.gov/pubmed/14746775.

did not identify a NOAEL. Our ability to comment further on this point is limited by the lack of detail EPA has provided on how it derived the HED 1.6 mg/kg/day value.

EPA also newly examines risks from acute oral and dermal exposure resulting from contact with 1,4-dioxane contaminated ambient surface water. Here EPA relies on Mattie et al., 2012, an inhalation study from which it derived a POD_{HED} of 35.4 mg/kg/day, to evaluate risk. The associated BMOE of 300 EPA applied does not account for either of the route-to-route extrapolations employed (inhalation-to-dermal and inhalation-to-oral). As with the sub-chronic and chronic dermal effects, an additional uncertainty factor should apply for the route-to-route extrapolations employed.

Application of even one of these aforementioned uncertainty factors dramatically alters EPA's risk characterizations and determinations, negating or calling into question most or all of EPA's assertions in the final risk evaluation that 1,4-dioxane does not present unreasonable risks to receptors under the various conditions of use it has analyzed.

See EDF's earlier comments on the draft risk evaluation in section I.5.B.i. for additional discussion of uncertainty factors in the risk evaluation of 1,4-dioxane.

B. The changes EPA has made to point-of-departure (POD) values lack transparency.

In the Supplement, EPA has changed several point-of-departure (POD) values for evaluating human health risks. However, EPA has provided no discussion or description of the basis for its changes to the POD values either in the Supplement or in the other documents it released along with it, other than this brief statement (p. 4):

> Several of the points of departure (PODs) for evaluating human health risks from acute and chronic dermal and inhalation exposure were revised in response to peer review and public comment.

We have reviewed the comments in the docket, and with one exception, there are no comments that explain the changes EPA has made to the POD values. In one instance, EPA appears to have made a change consistent with the comments it received from the New Jersey Department of Environmental Protection regarding the agency's earlier rejection of the oral cancer slope factor adopted by IRIS in its 2013 assessment of 1,4-dioxane (value = 0.12 $(mg/kg/day)^{-1}$). EPA has included this value in the Supplement as the starting point for its extrapolation to cancer risk from dermal exposure. Aside from this value, however, the previous comments from the public or the SACC peer review report do not explain EPA's decision to change some of the POD values.

EPA's lack of transparency regarding the basis for these changes hampers our ability to meaningfully comment on them and their implications for the risk evaluation.

13. EPA's risk determinations fail to acknowledge or account for even the uncertainties EPA identifies.

A. EPA's risk determinations do not reflect the level of confidence EPA has in the underlying data and methodology.

EPA has acknowledged that it lacks full confidence in most of its release and exposure assessments. Of the 10 release estimates for industrial/commercial conditions of use – i.e., those having an associated occupational exposure scenario (OES) – EPA examined, it had only medium confidence for five and low confidence for one (Table 2-5, pp. 22-5). Overall EPA stated (p. 32): "Based on the above considerations, the general population ambient water exposure assessment scenarios have an overall low to moderate confidence."

Despite the significant uncertainties in the available information, however, EPA still draws unqualified conclusions that human exposures to ambient water (from swimming and fish consumption) do not present unreasonable risk. While EPA states that it takes its degree of confidence in available information into account in making risk determinations (pp. 70, 71), EPA never explains how it does so; nor does it rationalize or adjust this particular risk determination with the fact that it has only low to moderate confidence in the data on which it is based.

The situation is also concerning with regard to consumer exposures, especially chronic. EPA states it has only moderate confidence in its chronic inhalation exposure estimates and only low to moderate confidence in its chronic dermal exposure estimates. Yet it firmly concludes that none of these exposures presents any unreasonable risk.

The basis for these rankings is less than clear and appears quite subjective. EPA describes the factors it states it considers in deciding on a confidence ranking, but never shows how those factors were actually applied to yield the confidence result it assigns to a specific exposure.

It is important to note that the uncertainties arise in large measure from EPA's failure to have used its TSCA information authorities to require the development and submission of the information EPA needed to inform its exposure assessments. This failure has been raised repeatedly to EPA by stakeholders over the past several years. EDF addressed this concern in specific detail in our earlier comments on the 1,4-dioxane draft risk evaluation; see sections I.4., II.5.D., and II.7.C.

EPA's derivation of firm, unqualified risk determinations based on information in which even EPA states it has low to moderate confidence is not supported by the available information. At the very least EPA should have conducted uncertainty analyses that reflect and address uncertainties engendered by the lack of confidence in the available release and exposure information; see subsection C. below.

B. EPA dismisses risks at or close to its benchmarks with insufficient justification.

The inhalation cancer risk EPA identifies for high-intensity users of surface cleaners is 1.0E-6, which equals EPA's cancer risk benchmark. EPA boldfaces this value in both Tables 4-4 (p. 63) and Table 4-8 (p. 67) as exceeding the cancer risk benchmark. Yet EPA fails to identify this unreasonable risk or provide any explanation for dismissing it. EPA's risk determination for surface cleaners erroneously states (p. 74): "For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation or dermal exposures or *of cancer from chronic inhalation* or dermal exposures at the *high intensity use*."

EPA's acute inhalation risk estimates (MOEs) for both users and bystanders of spray polyurethane foam (SPF) in basements – 317 and 384, respectively – are very close to its benchmark MOE of 300; see Table 4-3 on p. 63 and Table 4-8 on p. 68. EPA does not acknowledge this, however, or address how the sources of uncertainty it identifies (pp. 49-54) have been reflected in its decision not to regard this close margin as indicative of unreasonable risk. It should be noted that EPA's risk estimate assumes a given consumer has no other exposure to 1,4-dioxane whatsoever: no dermal exposure through SPF use; no exposure from the use of another consumer product; no exposure at work; no exposure through ambient water, no exposure through drinking water; no exposure from background sources. Otherwise what EPA asserts is not an unreasonable risk could quickly become one.

These examples show just how narrow and arbitrary EPA's approach to addressing this chemical's risk is, and how hard it has had to work to avoid finding any unreasonable risk.

C. EPA has failed to conduct any uncertainty analyses.

A key criticism of EPA's draft risk evaluations for 1,4-dioxane and other chemicals by stakeholders and the SACC has been EPA's failure to conduct uncertainty analyses to determine the effects of its assumptions, limited data, modeling defaults, and so forth.

In the Supplement EPA acknowledges this need. On pages 30 and 49, EPA states: "EPA's approach recognizes the need to include uncertainty analysis."

But in fact no uncertainty analysis has been conducted. While EPA identifies factors that contribute to uncertainty, it never evaluates their effect on its conclusions, and its determinations in effect ignore these factors.

One small exception is that EPA does present a sensitivity analysis of the consumer exposure model it used, CEM; see Appendix A. But that is a stand-alone analysis of the model itself, and does not extend to a characterization of the manner in which EPA uses the model outputs to estimate risks and then make risk determinations for this chemical.

14. EPA's systematic review procedures expose exposure pathway omissions and lack transparency.

Section 1.2 describes the Systematic Review procedures EPA applied in the Supplement. As discussed extensively in these comments, EPA negligently omitted exposures to consumers, workers, the general population, groups near emitting facilities, and the environment by ignoring 1) key pathways of 1,4-dioxane contamination of drinking water, 2) workers who use products containing 1,4-dioxane, and 3) general population and ecological exposures arising from the discharge of wastewater contaminated with 1,4-dioxane. These exclusions are evident in *Table 1-3: PECO Statement 1,4-Dioxane Consumer Exposure Assessment*. (p.13). The only **P**opulations EPA indicates it is considering are "consumers and bystanders, including children" (i.e., not workers, the general population, groups in proximity to releases, or ecological receptors). Likewise, the **E**xposures EPA indicates it is considering are extremely limited: "Source: Consumer products containing 1,4-dioxane as a byproduct, and associated air emissions and dermal contact. Pathway: Indoor air, contact with products. Routes: Indoor (inhalation), dermal (contact with products)." (p. 13)

Among the pathways of exposure to 1,4-dioxane EPA is ignoring are contaminated drinking water and exposure via ingestion. Consequently, EPA's literature search excludes key sources of exposure information relevant and necessary to comprehensively characterize actual risks to relevant receptors from the presence of 1,4-dioxane as a byproduct in consumer and commercial products. For example, Figure 1-3 indicates that 13,296 of 21,373 references were excluded as non-consumer references. While some of these may not be relevant to fully assessing risk from 1,4-dioxane as a byproduct, others may well be relevant to characterizing aspects of risk EPA has ignored.

EPA's supplemental literature selection process commenced with a search for references specific to assessing 1,4-dioxane exposure to consumers, yielding 8,077 filtered references. EPA then applied a machine learning model to rank "how similar the filtered references were to a pre-determined set of consumer references (positive seeds), and how unsimilar [sic] the filtered references were to a pre-determined set of non-consumer references (negative seeds)." (p.13) EPA used relevancy cut-offs of 0.1 (references with just titles) and 0.4 (references with abstracts) to advance or exclude references from data screening. Application of the machine learning model and relevancy cut-offs yielded 239 supplemental references for data screening. EPA does not appear to have provided the list of the positive and negative seeds in the risk evaluation, the

Supplement, or the supporting documents; it needs to do so. Additionally, EPA should explain the basis for its choice of relevancy cut-offs and the decision to use different relevancy cut-offs dependent on the presence or absence of an abstract; the latter seems especially arbitrary and potentially biased against sources of information that are not structured in the conventional peer-reviewed literature format. EPA's reliance on the machine learning model is clearly consequential as it reduced the number of supplemental information sources from 8,077 to 239. Additional explanation of key filtering/cut-off decisions by EPA is necessary if there is to be any confidence in the decisions that excluded so many sources from full consideration.

Finally, of the 545 references screened (239 supplemental references plus 272 initial references from the risk evaluation), only 37 were subject to formal data evaluation, in addition to 17 sources that were qualitatively evaluated. EPA does not but needs to provide some explanation for why the vast majority of studies it screened were not subject to evaluation.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.