November 7, 2025

Comments from Scientists, Academics, Clinicians, and Advocates on the Procedures for Chemical Evaluation Under the Toxic Substances Control Act (TSCA)
Submitted online via Regulations.gov to docket EPA–HQ–OPPT–2025–0260-0001

These comments are submitted on behalf of the undersigned scientists, academics, clinicians, and advocates. We declare that we have no direct or indirect financial or fiduciary interests in the subjects of these comments. The co-signers' institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support, unless indicated otherwise by an asterisk.

We appreciate the opportunity to provide written comments on provide comment on EPA's proposed rule on Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act ("Proposed Rule")[1] conducted under the Toxic Substances Control Act (TSCA), which requires EPA to evaluate chemical risks based on the "best available science."[2]

The 2016 updates to TSCA via the Frank Lautenberg Chemical Safety for the 21st Century Act ("Amended TSCA") require EPA to conduct risk evaluations for chemicals in commerce that must consider risks to "potentially exposed or susceptible subpopulations" (PESS), and determine if a chemical poses an "unreasonable risk" without consideration of cost. Amended TSCA also requires EPA to regulate any existing chemical determined to pose an unreasonable risk "to the extent necessary so that the chemical substance no longer presents such risk."[3] Finally, it requires EPA to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."[4]

In June 2017, EPA issued the original Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, also referred to as the Risk Evaluation Framework Rule, to establish procedures for EPA to follow in preparing risk evaluations. The procedural framework rule was subsequently revised in 2024, providing important improvements in procedures and approaches for ongoing and future TSCA risk evaluations. The current Proposed Rule aims to revise or rescind many of the improvements adopted in the 2024 Final Rule.

Based on our review of the 2024 Risk Evaluation Framework Rule and the Proposed Rule, and considering the implementation challenges that the TSCA Program has faced since enactment of the Lautenberg Act, we recommend EPA rescind the proposed rulemaking. The proposed rulemaking does not enhance the risk evaluation framework; instead, it dangerously modifies the approach and methods for hazard and risk assessment, resulting in low-quality and biased science. Additionally, we recommend a series of revisions to strengthen the Proposed Rule, ensuring that risk evaluations utilize the "best available science" and methodologies, thereby protecting public health.

[1] U.S. EPA (2025). Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), Proposed Rule. 90 FR 45690.
[2] 15 U.S.C. § 2625(h).
[3] Toxic Substances Control Act (TSCA). In Vol. 15 U.S.C. ch. 53 subch. I §§ 2601–2629.
[4] 15 U.S.C. § 2625(h).

Our detailed comments on the flaws in the proposed rulemaking address the following issues:

1. **EPA should adopt improved definitions of key terms relevant to how it assesses and evaluates the reasonably available and relevant scientific evidence in its TSCA risk evaluations.**

    a. **EPA's proposed definition of "weight of scientific evidence" would only increase the confusion regarding this term, and this flawed term should not be included in the Proposed Rule; EPA should instead add definitions for "strength of evidence" and "systematic review" to the Proposed Rule.**
    b. **EPA should not restore the 2017 definition of "best available science."**

2. **EPA should not delete the current provisions regarding aggregate exposure assessment and instead strengthen them to be consistent with best available science, which is necessary to meet the requirements of TSCA.**

3. **EPA should retain the existing commitment to assess all COUs and pathways, as required by TSCA.**

4. **EPA should expand the definition of potentially exposed or susceptible subpopulations (PESS) to focus greater attention on susceptibility, instead of narrowing the definition.**

5. **EPA should ensure panel peer review of TSCA risk evaluations.**

    a. **EPA's recent reliance on letter reviews is inconsistent with established EPA standards.**
    b. **EPA should implement full SACC panel reviews for all TSCA risk evaluations to promote scientific integrity and public accountability.**

6. **EPA should revise the Proposed Rule to prohibit the consideration of personal protective equipment (PPE) in TSCA risk evaluations.**

        a. **EPA's historical reliance on PPE assumptions ignores the best available science and leads to a systematic underestimation of risk.**
        b. **Workers frequently lack access to adequate PPE and training as shown through empirical evidence.**

We appreciate the opportunity to provide public input. Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,

Daniel Axelrad, MPP
Independent Consultant

Washington, DC

Rashmi Joglekar
Associate Director, Science and Policy
Program on Reproductive Health and the Environment
University of California, San Francisco

Abena BakenRa, MPH
Science Associate, Science and Policy
Program on Reproductive Health and the Environment
University of California, San Francisco

Jessica Trowbridge, PhD, MPH
Associate Research Scientist, Science and Policy
Program on Reproductive Health and the Environment
University of California, San Francisco

Emily Lasher, MSPH
Science Associate, Science and Policy
Program on Reproductive Health and the Environment
University of California, San Francisco

Tracey Woodruff, PhD, MPH
Director
Program on Reproductive Health and the Environment
University of California, San Francisco

Nicholas Chartres, PhD
Senior Research Fellow
School of Pharmacy, Faculty of Medicine & Health, The University of Sydney

Tyler Roberts
Truckers Movement for Justice

Delaney Ding, BS
MD-PhD Student
University of Florida

Rainer Lohmann, PhD
Professor of Oceanography
Graduate School of Oceanography, University of Rhode Island

Ronald H White, MST
Principal
RHWhite Consulting

David Michaels, PhD, MPH
Professor
Department of Environmental and Occupational Health, George Washington University Milken Institute School of Public Health

Patrice Sutton, MPH
Research Collaborator
UCSF Program on Reproductive Health and the Environment

Marya Zlatnik, MD, MMS
Professor, Obstetrics, Gynecology, & Reproductive Sciences
UCSF

Mary Gant, M.S.*
Director of Government Affairs
Kids for Saving Earth

Timothy H. Ciesielski, ScD, MD, MPH
Research Scientist
Department of Population and Quantitative Health Sciences,
Case Western Reserve University School of Medicine

Phil Brown, PhD
University Distinguished Professor of Sociology and Health Sciences
Northeastern University

Robert M. Gould, MD
Adjunct Assistant Professor
UCSF Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences

Robert M. Gould, MD*
President
San Francisco Bay Physicians for Social Responsibility

Daniel Akselrad, PhD
Postdoctoral Fellow
Center to End Corporate Harm, UCSF

Christopher LeBoa, PhD
Post-doctoral scholar
UC Berkeley

Detailed Comments:

1. **EPA should adopt improved definitions of key terms relevant to how it assesses and evaluates the reasonably available and relevant scientific evidence in its TSCA risk evaluations.**

    a. **EPA's proposed definition of "weight of scientific evidence" would only increase the confusion regarding this term, and this flawed term should not be included in the Proposed Rule; EPA should instead add definitions for "strength of evidence" and "systematic review" to the Proposed Rule.**

EPA proposes to adopt a new definition of "weight of scientific evidence:"

> Weight of scientific evidence means an approach to scientific evaluation in which each piece of relevant information is considered based on its quality and relevance, and then transparently integrated with other relevant information to inform the scientific evaluation prior to making a judgment about the scientific evaluation. Quality and relevance determinations, at a minimum, should include consideration of study design, fitness for purpose, replicability, peer review, and transparency and reliability of data.[5]

The National Academies of Sciences, Engineering, and Medicine (NASEM) has advised EPA that the term is not useful:

> The committee views weight-of-evidence analysis as a judgment-based process for evaluating the strength of evidence to infer causation. However, it found that **the phrase as used in practice has become too vague and is of little scientific use.**[6] (emphasis added)

> the phrase *weight of evidence* has become far too vague as used in practice today and thus is of little scientific use…its use in the literature and by scientific agencies, including EPA, is vague and varied.[7]

Similarly, a 2019 publication reviewing methods for hazard identification across 14 agencies found a lack of clarity or consistency:

> Several organisations state that they use "weight-of-evidence" methods in the assessment process. However, the steps involved in this process and how it is described vary considerably across organisations…Formal procedures and consistent nomenclature for weight-of-evidence methods are lacking.[8]

[5] U.S. EPA (2025). Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), Proposed Rule. 90 FR 45690.
[6] National Research Council (2014). Review of EPA's Integrated Risk Information System (IRIS) Process, p. 4.
[7] National Research Council (2014). Review of EPA's Integrated Risk Information System (IRIS) Process, p. 86.
[8] Chartres N, Bero LA, Norris SL (2019). A review of methods used for hazard identification and risk assessment of environmental hazards. Environment International 123:231-239. https://doi.org/10.1016/j.envint.2018.11.060

EPA's proposed definition is not useful and will not advance efforts to improve implementation of TSCA and will lead to assessments that are of lower scientific quality. The definition is vague and ambiguous, rather than providing any clarification of how risk evaluations should be conducted. The definition includes phrases that are unrelated to the quality of the evidence and instead raises questions regarding how terms like "fitness for purpose" and "reliability" are determined, and how those determinations will inform a judgment regarding the body of evidence. The proposed definition thus perpetuates the confusion, lack of clarity and inconsistency regarding the term "weight of evidence." This will result in evaluations that are less transparent and lead to inconsistent evaluation of the science, which the NASEM has commented as a flaw in the TSCA risk evaluation process.[9]

The proposed definition also allows for extraneous considerations to be applied in determining which evidence is relevant. Relevance of studies should be determined only by applying pre-specified criteria in a standardized format, such as (for health effects studies) a PECO (population – exposures – comparators – outcomes) statement.[10,11] Any other procedure for determining relevance will be subject to bias and lacking in transparency.

To be useful, a definition of any terms related to evaluating a body of evidence needs explicit steps and processes that can be applied when conducting a risk evaluation. Once EPA has identified the body of evidence relevant to a particular issue, the critical components to evaluating and characterizing the evidence are to assess the quality and strength of evidence following clear, consistent, structured, transparent and pre-specified methods that consider all of the relevant studies, with clear documentation of how relevant factors were considered and applied in the process of reaching a final conclusion and concise rating of the evidence.

The Navigation Guide and National Toxicology Program (NTP) Office of Health Assessment and Translation (OHAT) systematic review methods each provide explicit procedures for judging a body of evidence to reach a clear, concise conclusion.

The Navigation Guide procedures for evaluating a body of evidence include specific steps with pre-specified factors and considerations for rating the quality of the evidence, and then the strength of evidence, leading to a clearly stated conclusion such as "presumed to be a hazard to humans."[12]

Similarly, the OHAT Handbook outlines detailed methods for "Assessing Confidence in the Body of Evidence" (similar to Navigation Guide rating of quality of the evidence) and

[9] National Academies of Sciences, Engineering, and Medicine (2021). The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations. https://doi.org/10.17226/25952
[10] U.S. EPA (2022). ORD Staff Handbook for Developing IRIS Assessments, Chapter 2.
[11] National Toxicology Program (2019). Handbook for conducting a literature-based health assessment using OHAT approach for systematic review and evidence integration, pp. 13-15.
[12] Chartres N, Cooper CB, Bland G, Pelch KE, Gandhi SA, BakenRa A, Woodruff TJ (2024). Effects of Microplastic Exposure on Human Digestive, Reproductive, and Respiratory Health: A Rapid Systematic Review. Environmental Science & Technology, 58(52): 22843–22864, Figure 1.

determining the "level of evidence" (e.g. High or Moderate)[13] (similar to Navigation Guide strength of evidence conclusion).

EPA should adopt definitions for "strength of evidence" and "systematic review" that clarify the steps in drawing key conclusions in risk evaluations rather than adopting a definition of "weight of scientific evidence" that only deepens the ambiguity of this term and adds no clarity to the risk evaluation process. Appropriate definitions of strength of evidence and systematic review in the Proposed Rule are critical for clarifying what constitutes the "best available science" in risk evaluations.

EPA should adopt this definition for "strength of evidence:"

> "Strength of evidence" is a clearly-stated conclusion regarding the level of certainty in a body of evidence developed using rigorous, objective, predefined, transparent methods that minimize bias, consider all relevant studies, and assess the quality of the evidence. In instances where more than one evidence stream is evaluated (e.g., human and animal health effects evidence), strength of evidence is first determined for each evidence stream (i.e., evidence synthesis) separately, and those determinations are then combined for an overall strength of evidence conclusion (i.e., evidence integration). Strength of evidence is expressed by selecting from a pre-specified set of terms such as "high," "medium," or "low;" "sufficient," "limited," or "inadequate;" or "known," "presumed," "suspected," or "not classifiable."

EPA should adopt the following definition of "systematic review," which is adapted from existing definitions published by the Institute of Medicine[14] and Cochrane,[15] and from advice to EPA in the NASEM report[16] on systematic review under TSCA:

> Systematic review is an approach to scientific investigation that uses explicit scientific methods, pre-specified in an assessment-specific protocol, to identify, select, assess, summarize, and integrate all the empirical evidence that meets pre-defined eligibility criteria to answer a specific research question with a clear statement regarding the level of confidence in the conclusion. Systematic reviews use structured, transparent and consistent methods that are aimed at minimizing bias to produce objective and reliable findings to inform decision making.

Inclusion of these definitions for strength of evidence and systematic review will provide a foundation for significant improvement in TSCA risk evaluations and result in risk evaluations that are consistent with best available science.

---

[13] National Toxicology Program (2019). Handbook for conducting a literature-based health assessment using OHAT approach for systematic review and evidence integration, Figures 6 and 7.
[14] Institute of Medicine (2011). Finding What Works in Health Care: Standards for Systematic Reviews, p. 1. https://doi.org/10.17226/13059
[15] Cochrane Library. About Cochrane Reviews: What is a systematic review? https://www.cochranelibrary.com/about/about-cochrane-reviews [accessed 14 October 2025]
[16] National Academies of Sciences, Engineering, and Medicine (2021). The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, p.10. https://doi.org/10.17226/25952

b. EPA should not restore the 2017 definition of "best available science."

EPA's 2017 final framework rule included this definition of "best available science:"

> *Best available science* means science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable:
>
> (1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
>
> (2) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
>
> (3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
>
> (4) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
>
> (5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.[17]

The definition was removed in the 2024 final framework rule. EPA now requests comment on whether the 2017 definition should be restored.

Restoring the 2017 definition would not improve the process of conducting risk evaluations, as it does not provide clear guidance to EPA risk assessors or the public. Similar to EPA's proposed definition of "weight of scientific evidence," restoring the 2017 definition of "best available science" would only increase confusion regarding how risk evaluation is conducted. The definition merely lists a number of considerations for assessing an individual study – and not all of these considerations necessarily reflect the quality of the study. Some terms in the definition, such as "unbiased" and "objective," are useful but can be better addressed in a more practical manner by adopting the suggested definitions for "strength of evidence" and "systematic review" above, where they are presented in a broader context that informs how a risk evaluation is conducted, including consideration of all relevant evidence.

If EPA does decide to adopt a new definition of "best available science" in the Proposed Rule, it should focus on the methods used to conduct a risk evaluation, rather than evaluating the

[17] U.S. EPA (2017). Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, Final Rule. 82 FR 33726.

methods used to conduct the available studies. EPA has repeatedly failed to apply methods constituting the best available science in its risk evaluations, and rarely even attempts to describe why its approaches constitute the best available science. An improved definition would be:

> Best available science means the application of methods that make the best use of the relevant reasonably available information in conducting a risk evaluation, including methods recommended by the National Academies of Sciences, Engineering, and Medicine or other authoritative bodies. Examples of best available science include systematic review, benchmark dose modeling, probabilistic dose-response assessment of non-cancer effects, aggregate exposure assessment, and cumulative risk assessment.

2. EPA should not delete the current provisions regarding aggregate exposure assessments and instead strengthen them to be consistent with the best available science, which is necessary to meet the requirements of TSCA.

The 2024 framework rule states that:

> EPA will consider aggregate exposures to the chemical substance, and, when supported by reasonably available information, consistent with the best available science and based on the weight of scientific evidence, include an aggregate exposure assessment in the risk evaluation, or will otherwise explain in the risk evaluation the basis for not including such an assessment.[18]

EPA is now proposing to delete this passage entirely, removing any requirement that it simply "consider aggregate exposure" and explain any decision to disregard aggregate exposure in a risk evaluation.

Aggregate exposure assessment enables EPA to consider all of the exposures that an individual may experience both at work and at home, and resulting from use of multiple products containing the chemical in question along with total exposures from ambient air, drinking water and in food. Without aggregate exposure assessment, EPA only considers exposures in separate bins or by use, subdividing an individual's total exposure into the components and thus smaller quantities. By only assessing the components of the true exposure rather than the total, EPA will underestimate exposures and health risks, and the chemical is then more likely to be judged not to pose an unreasonable risk. The scientific problems with this approach have been discussed extensively in peer-reviewed journal articles.[19,20]

EPA's proposed deletion signals its intention to disregard aggregate exposure, similar to what was done for 8 out of the first 10 risk evaluations issued in 2020-2021. Many of the draft and

[18] 40 CFR 702.39(d)(8).
[19] Rayasam SDG, Koman PD, Axelrad DA, Woodruff TJ, Chartres N (2022). Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States. Environmental Science & Technology, 56 (17):11969-11982. doi:10.1021/acs.est.2c02079
[20] McPartland J et al. (2022). Charting a Path Forward: Assessing the Science of Chemical Risk Evaluations under the Toxic Substances Control Act in the Context of Recent National Academies Recommendations. Environ. Health Perspect 130(2).

final risk evaluations issued in 2024-2025 have considered aggregate exposure, but only to a limited extent. So EPA has yet to fully and accurately reflect human exposures. Nonetheless, EPA should be improving their exposure assessment methods, not degrading them.

Amended TSCA requires EPA to eliminate the unreasonable risk posed by a chemical substance from:

> the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or **any combination of such activities**.[21] (emphasis added)

Determination of whether unreasonable risks from combinations of activities have been eliminated or remain necessarily requires EPA to consider the total exposures resulting from combinations of activities, which is precisely the information produced by an aggregate exposure assessment. To comply with TSCA, EPA must therefore assess aggregate exposure in each risk evaluation. Without aggregate exposure assessment, a risk evaluation will underestimate exposures, and this can lead to erroneous findings of no unreasonable risks, when unreasonable risks would be found from combinations of activities. EPA's 2024 framework rule provision, requiring only that EPA "consider" aggregate exposure and providing latitude to disregard aggregate exposure by simply providing an explanation, does not satisfy the requirements of TSCA nor best available science. The EPA should strengthen, rather than delete, the 2024 framework rule provision regarding aggregate exposure.

EPA considered aggregate exposure to a limited extent in only two of the first 10 risk evaluations – conducted prior to the revisions of the framework rule promulgated in 2024. For NMP, EPA aggregated dermal and inhalation exposure but did not consider combinations of COUs or exposure settings (e.g., both at work and at home).[22] For HBCD, EPA aggregated general population exposures from all environmental media using population biomonitoring data.[23] In the remaining 8 risk evaluations completed in 2020-2021, EPA did not consider aggregate exposure. Instead, EPA considered worker exposures, consumer exposures and general population exposures separately. This assumes that individuals exposed in the workplace are never exposed to the same chemical in consumer products or ambient air, and as if exposed consumers are never exposed to the same chemical in drinking water, which is not scientifically supported. Furthermore, EPA assessed inhalation and dermal exposures separately, without calculating combined exposure for workers exposed via both routes. EPA also assessed consumer exposures for individual products without calculating the combined exposure for consumers using multiple products containing the same chemical. Finally, EPA did not aggregate the exposures of individuals who have combinations of occupational, consumer, and general population exposures, such as individuals exposed at both work and home. EPA therefore likely underestimated exposures and risks in those risk evaluations, and may have failed to identify all COUs that contribute to unreasonable risk for those chemicals.

EPA consistently considered aggregate exposure to only a limited extent in the draft and final risk evaluations issued in 2024-2025. Several of these risk evaluations (DBP, DCHP, DEHP,

[21] 15 USC 2605(d)(3)(A)(i)(I).
[22] U.S. EPA (2020). Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP).
[23] U.S. EPA (2020). Risk Evaluation for Cyclic Aliphatic Bromide Cluster (HBCD).

DIDP, DINP and TCEP) aggregated across routes of exposure – combining inhalation, oral and dermal exposures – but aggregated only for individual COUs and did not aggregate across settings (at work and at home) and did not consider individuals exposed to the same chemical in multiple consumer products (e.g. consumers exposed to the chemical from multiple cleaning products or multiple paints that might all be used in a single day). For 1,3-butadiene, EPA conducted limited aggregation of exposure from air releases, considering some combinations of facility releases; EPA disregarded some of its aggregate exposure findings when determining unreasonable risk.[24] EPA then released a supplementary analysis of 1,3-butadiene air releases that assessed concentrations and risks based only on single-facility emissions, even though there are multiple facilities concentrated in relatively small areas in locations such as Orange, Texas.[25] The 1,3-butadiene risk evaluation did not consider other aspects of aggregate exposure such as combinations of COUs. In the formaldehyde risk assessment, EPA similarly failed to account for aggregate exposures from multiple facilities, multiple COUs, multiple products, multiple exposure pathways, and combinations of worker, consumer and general population exposure.

The Science Advisory Committee on Chemicals (SACC) has repeatedly recommended that EPA conduct comprehensive aggregate exposure assessments.[26,27] In its 2024 review of the formaldehyde draft risk evaluation, the SACC provided a critical perspective on the importance of assessing aggregate exposure:

> Including a broader range of exposure possibilities will present assessments relevant to what people actually experience and will provide perspective on the TSCA related exposures. Such transparent, and complete, aggregated assessments can satisfy the public's real question---"what am I exposed to?"-- and provides credible information to the TSCA risk managers and leadership for regulatory decision-making.[28]

The SACC recently reiterated its concerns regarding EPA's repeated failures to evaluate aggregate exposure:

> the Committee was unanimous that EPA should have been able to compute the aggregate and cumulative exposure estimates with competent probabilistic models and a complete array of properly informed exposure scenarios for the general population and PESS groups, including healthcare workers. There is no aggregate assessment for any condition

[24] Earthjustice (2025). Comments on 1,3-butadiene Risk Evaluation, pp. 7-9. https://www.regulations.gov/comment/EPA-HQ-OPPT-2024-0425-0088
[25] University of California San Francisco (2025). Comments from Scientists, Academics, and Clinicians on the Draft Risk Evaluation for 1,3-Butadiene Under TSCA. Submitted online via Regulations.gov to docket EPA-HQ-OPPT-2024-0425-0071.
[26] U.S. EPA (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-01, DOCKET ID NUMBER: EPA–HQ–OPPT–2021–0415, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0.
[27] U.S. EPA (2023). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2023-02, Docket ID: EPA–HQ–OPPT–2022–0905, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation.
[28] U.S. EPA (2024). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2024-01, Docket ID: EPA-HQ-OPPT-2023-0613, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Peer Review of the 2024 Draft Risk Evaluation for Formaldehyde.

of use (COU) (or other parameter), and the cumulative assessment excludes many important exposure scenarios and background exposure scenarios, and does not use standard principles of probabilistic, person-oriented (thus time relevant) exposure and risk assessment—even by EPAs own guidelines and requirements for adequate science.[29]

EPA cited "lack of data" as an impediment to contemporary assessment approaches. The SACC concludes again that the critical issue is whether EPA provides the resources to support their scientists and technical capacity for doing competent aggregate and cumulative exposure/risk estimation—a capacity essential for scientific credibility and environmental protection.[30]

The Committee strongly recommends that the EPA leadership provide the resources and support that their scientists need to create or adopt methods and models which provide competent, person-oriented probabilistic aggregate and cumulative exposure assessments with comprehensive analysis options to assess the relevance and effectiveness of relative contribution and risk mitigation options. This should be complemented with the resources and support that their scientists need for comprehensive data collection and contemporary data analysis, and to use all of the models in the many relevant sciences that contribute to these important chemical review dossiers. The Committee recommends that the EPA leadership accomplish these actions—highlighted by SACC over the past several years—without further delay.[31]

EPA cites a lack of specific measured data availability for addressing consumer use of and exposure to COU articles together as the reason for not aggregating across COUs for consumer exposure: "EPA did not consider aggregate exposure scenarios across COUs because the Agency did not find any evidence to support such an aggregate analysis, such as statistics of populations using certain products represented across COUs or workers performing tasks across COUs." Many members of the Committee find this an insufficient reason for excluding exposure scenarios to address aggregate and cumulative exposure across TSCA COUs for phthalates. Probabilistic modeling tools, some developed within EPA's own Office of Research and Development could be brought to bear on the real-world exposure problem posed by the concurrent use of phthalates in products and processes throughout commerce. This issue was raised in the 2023 SACC review of the draft cumulative risk documents of that year. Further, risks from consumer

[29] U.S. EPA (2025). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2025-2, Docket ID: EPA-HQ-OPPT-2024-0551, For the Peer Review of the Draft Risk Evaluations for Dibutyl phthalate (DBP)…and Cumulative Risk Assessment TSDs, p. 15.
[30] U.S. EPA (2025). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2025-2, Docket ID: EPA-HQ-OPPT-2024-0551, For the Peer Review of the Draft Risk Evaluations for Dibutyl phthalate (DBP)…and Cumulative Risk Assessment TSDs, p. 93.
[31] U.S. EPA (2025). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2025-2, Docket ID: EPA-HQ-OPPT-2024-0551, For the Peer Review of the Draft Risk Evaluations for Dibutyl phthalate (DBP)…and Cumulative Risk Assessment TSDs, p. 97.

> COUs can intersect with occupational risks or general population exposures, which would ask for aggregation and cumulation across these exposure scenarios.[32]

Despite these recommendations and observations noting the deficiencies of EPA's risk evaluations concerning aggregate exposure, EPA is now proposing to delete a very mild provision from the risk evaluation framework that merely requires the agency to "consider" aggregate exposure assessment, and to explain any instances where it does not aggregate exposures. EPA does not offer any scientific or substantive rationale for the proposed deletion, but claims that explaining its decision is too much work:

> the burden of explaining the absence of an aggregate risk evaluation is significant and cumulative with the challenging undertaking already required to complete a risk evaluation and is not mandated by the statute.[33]

Using the best available science, as required by TSCA, means EPA must quantify aggregate exposures, combining quantitative exposure estimates across exposure pathways, settings, COUs, and multiple consumer products in the same or different COUs. Failure to do so will result in underestimation of exposure for members of the population exposed in multiple ways and will consequently understate the extent of unreasonable risks. EPA should be conducting aggregate exposure in each risk evaluation, and a requirement that EPA explain itself when it chooses not to aggregate exposures is not excessively burdensome; rather it is a minimal step toward public accountability for decisions that result in exposure underestimation. EPA should therefore retain and strengthen the current regulatory text concerning aggregate exposure, with revision to say that EPA will conduct aggregate exposure assessment in each risk evaluation.

3. EPA should retain the existing commitment to assess all COUs and pathways, as required by TSCA.

The 2024 framework rule states that:

> EPA will not exclude conditions of use from the scope of the risk evaluation.[34]
>
> EPA will assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, including those that are regulated under other federal statutes.[35]

EPA is now proposing to remove both requirements, claiming that it has discretion under TSCA to select the conditions of use and pathways of exposure to include in a risk evaluation, rather

---

[32] U.S. EPA (2025). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2025-2, Docket ID: EPA-HQ-OPPT-2024-0551, For the Peer Review of the Draft Risk Evaluations for Dibutyl phthalate (DBP)…and Cumulative Risk Assessment TSDs, pp. 102-103.
[33] U.S. EPA (2025). Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), Proposed Rule. 90 FR 45690.
[34] 40 CFR 702.37(a)(4).
[35] 40 CFR 702.39(d)(9).

than including all COUs and pathways. This is contrary to the text of amended TSCA, which requires EPA to:

> integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance.[36]

This language does not allow EPA to pick and choose but instead directs EPA to assess all COUs and their exposure pathways. The proposed revision will lead to underestimation of risk, especially to highly-exposed groups. The pitfalls of this approach have been discussed extensively in peer-reviewed journal articles.[37,38]

In the first 10 risk evaluations completed under amended TSCA, EPA similarly claimed it had discretion to tailor the scope by excluding COUs and pathways. EPA's final Asbestos Part 1 risk evaluation considered only current uses, excluding ongoing exposures from COUs representing legacy uses (e.g., past uses of asbestos, as in automotive brakes or housing materials, that can result in current exposure) and associated disposal. This claim was rejected in a 2019 appeals court ruling.[39]

EPA made similar claims in the carbon tetrachloride risk evaluation. Small amounts of carbon tetrachloride may be present in industrial, commercial and consumer products such as cleaning products and paints. EPA excluded exposures to these products from the risk evaluation, saying it had "a sufficient basis to conclude" that these conditions of use "would present only de minimis exposure or otherwise insignificant risk."[40,41] No calculations or definitions were provided to support this conclusion.

EPA's application of its claimed discretion in evaluating 1,4-dioxane in particular demonstrates how this approach enables EPA to disregard import risks. 1,4-dioxane is an unintended byproduct in the production of ethoxylated chemicals and is in products such as paints, detergents, and antifreeze. Conditions of use related to 1,4-dioxane byproducts were excluded from EPA's 2019 draft risk evaluation.[42] In the 2020 final risk evaluation, this decision was modified, with consumer exposures to 1,4-dioxane byproducts included (with analysis added to the risk evaluation late in the process), but industrial and commercial products and all worker exposures associated with 1,4-dioxane byproducts remained excluded.[43] In 2024, EPA appropriately disavowed the claim of discretion and completed a supplement to the risk evaluation that assessed exposure and risk resulting from general population exposure pathways,

---

[36] 15 USC 2605(b)(4)(F)(i).
[37] Rayasam SDG, Koman PD, Axelrad DA, Woodruff TJ, Chartres N (2022). Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States. Environmental Science & Technology, 56 (17):11969-11982. doi:10.1021/acs.est.2c02079
[38] McPartland J et al. (2022). Charting a Path Forward: Assessing the Science of Chemical Risk Evaluations under the Toxic Substances Control Act in the Context of Recent National Academies Recommendations. Environ. Health Perspect 130(2).
[39] Safer Chems., Healthy Families v. EPA. In Federal Reporter 3rd Series; United States Court of Appeals, 9th Circuit: 2019; Vol. 943.
[40] U.S. EPA (2018). Problem Formulation of the Risk Evaluation for Carbon Tetrachloride.
[41] U.S. EPA (2020). Final Risk Evaluation for Carbon Tetrachloride.
[42] U.S. EPA (2019). 1,4-Dioxane Draft Risk Evaluation.
[43] U.S. EPA (2020). Final Risk Evaluation for 1,4-Dioxane.

including down-the-drain releases leading to drinking water exposures, and all byproduct COUs including industrial and commercial products. At least 9 COUs identified as contributors to unreasonable risk in 2024 were not identified as such in the 2020 risk evaluation because EPA had initially claimed it had discretion to disregard those COUs.[44] EPA identified unreasonable risks to fenceline communities and unreasonable risks via drinking water exposures that also were not identified in the 2020 risk evaluation because of EPA's claimed discretion.[45] EPA's claim of discretion is not only inconsistent with the law, but also inconsistent with best available science. Furthermore, as demonstrated by the 1,4-dioxane supplement, it enabled EPA to exclude important exposure pathways and COUs from the risk evaluation that posed significant risks to workers and the general population.

Further, for eight out of the first 10 risk evaluations, EPA excluded multiple general population exposure pathways (e.g. ambient air, drinking water) based on its argument that any exposure addressed, or that could be addressed, under another EPA-administered statute did not need to be considered in a TSCA risk evaluation.[46]

EPA's exclusions of conditions of use in three of the first 10 risk evaluations and exposure pathways in eight of the first 10 mean these evaluations systematically underestimated exposure and risk. The logic of assuming that coverage by another statute results in sufficient risk reductions is flawed as it requires EPA to assume equal levels of protection from different statutes. Although other statutes such as the Clean Air Act (CAA) and Safe Drinking Water Act (SDWA) may have some overlapping jurisdiction, they do not necessarily meet the health-protective standards required by amended TSCA.

For example, EPA does not consider risks of combined emissions from different industries to fenceline communities under the CAA. Deferring risk management of these emissions to other statutory authorities which, unlike TSCA, do not contain explicit language to consider unreasonable risks to PESS could result in increased risks in communities already experiencing elevated respiratory and cancer risks.

EPA's exclusions also involved instances where a chemical was not regulated, even though it was within jurisdiction of another statute. For example, EPA's 1-bromopropane (1-BP) risk evaluation, finalized in August 2020,[47] did not assess the ambient air pathway, even though 1-BP was not listed as a CAA hazardous air pollutant (HAP) until January 2022, and any new or revised CAA standards for industry sectors emitting 1-BP may not be established for several years.[48]

EPA's 2020 1,4-dioxane risk evaluation similarly excluded the drinking water pathway, even though under the SWDA, EPA has not established a National Primary Drinking Water

[44] U.S. EPA (2024). Supplement to the Risk Evaluation for 1,4-Dioxane.
[45] U.S. EPA (2024). Supplement to the Risk Evaluation for 1,4-Dioxane.
[46] Rayasam SDG, Koman PD, Axelrad DA, Woodruff TJ, Chartres N (2022). Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States. Environmental Science & Technology, 56 (17):11969-11982. doi:10.1021/acs.est.2c02079
[47] U.S. EPA (2020). Risk Evaluation for 1-Bromopropane (n-Propyl Bromide).
[48] U.S. EPA (2022). Clean Air Act Section 112 List of Hazardous Air Pollutant: Amendments to the List of Hazardous Air Pollutants (HAP), Final Rule. 87 FR 393.

Regulation for 1,4-dioxane or even decided whether one is necessary. EPA's 2024 supplement corrected the exclusion of this pathway and found widespread unreasonable risk of cancer downstream of industrial release points, including lifetime risks of cancer as high as 5-in-1000, and unreasonable risk of cancer resulting from down-the-drain releases from consumer and commercial products containing 1,4-dioxane as a byproduct.[49] Thus EPA's improper claim of discretion in the 2020 risk evaluation led it to disregard important and widespread risks; the omissions were corrected by EPA in 2024 after it changed its approach to scoping risk evaluation to include all COUs and pathways. EPA's proposed rule would revert to the critically deficient 2020 approach and lead to exclusion of important risks from future risk evaluations.

Furthermore TSCA, unlike other statutes, offers the opportunity for primary prevention (eliminating risk at the source), which can be more effective than regulatory tools available under other statutes and has been promoted as an EPA strategy since the 1990s.[50] For example, it may be more effective and less costly to use TSCA to prevent releases of certain chemicals (such as 1,4-dioxane) to water, rather than trying to use the SDWA and Clean Water Act to address water contamination after the fact. EPA can only determine whether regulations under other statutes are sufficient to meet TSCA's "unreasonable risk" determination by assessing all conditions of use and exposure pathways in the risk evaluation first. In addition, even when exposures are within jurisdiction of other statutes they may be important contributors to aggregate exposures and affect the determination of whether or not a chemical poses an unreasonable risk.

EPA's exclusion of conditions of use and exposure pathways from risk evaluations may result in continued disproportionate risks to overburdened communities. For example, communities near manufacturing facilities and contaminated sites are often those with lower wealth, poorer health, and with a majority of residents who are people of color. Chemical exposures from industry emissions to air and releases to water frequently result in disproportionate exposures to these communities, even after accounting for regulatory controls under other statutes, particularly as communities of color are more likely to have water systems with repeat violations under the SDWA, leading to higher exposures.[51] [52,53] As TSCA has an explicit charge to consider PESS, it is important to consider how conditions of use and exposure pathways pose risks to overburdened communities, as it allows EPA to make informed decisions about how to best regulate.

[49] U.S. EPA (2024). Supplement to the Risk Evaluation for 1,4-Dioxane.
[50] U.S. EPA (1993). Pollution Prevention Policy Statement.
[51] Association of State Drinking Water Administrators (ASDWA) and the Association of Metropolitan Water Agencies (2021). Letter to Dr. Michal Freedhoff Acting Assistant Administrator Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency. https://www.asdwa.org/wp-content/uploads/2021/04/2021-April-20-ASDWA-and-AMWA-Letter-to-OSCPP-Final.pdf
[52] Tessum CW et al. (2021). PM 2.5 polluters disproportionately and systemically affect people of color in the United States. Sci. Adv. 7 (18). DOI: 10.1126/sciadv.abf4491
[53] McDonald YJ, Jones NE (2018) Drinking Water Violations and Environmental Justice in the United States, 2011−2015. Am. J. Public Health 108(10): 1401−1407.

4. **EPA should expand the definition of potentially exposed or susceptible subpopulations (PESS) to focus greater attention on susceptibility, instead of narrowing the definition.**

The mandate for EPA to identify and eliminate unreasonable risks to PESS is one of the critical improvements of the amended TSCA. However, EPA has not adequately identified relevant PESS and quantified risk to these groups in its TSCA risk evaluations. EPA has consistently failed to sufficiently account for the factors that enhance susceptibility to harm from the chemicals subject to risk evaluation.

The 2024 framework rule took a useful step toward better defining PESS by adding "overburdened communities" to the previous definition, provided in the 2016 TSCA amendments. The definition of PESS in the 2024 framework rule is:

> Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by EPA 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, the elderly, or overburdened communities.[54]

This definition should be substantially improved by expanding the text (as detailed below) regarding the groups to be considered as candidate PESS in each risk evaluation. The importance of applying an expanded understanding of PESS has been discussed extensively in peer-reviewed journal articles.[55,56,57] A broader, more inclusive definition of PESS would help the Agency meet its responsibility under TSCA to ensure identification and elimination of unreasonable risks to susceptible groups. Instead, EPA is now proposing to go in the opposite direction by deleting the term "overburdened communities" and reverting to the narrower statutory definition without any expansion or elaboration.

The addition of "overburdened communities" to the definition of PESS was particularly important because communities near manufacturing facilities and contaminated sites are not only more highly exposed than other members of the general population, but they are often more

---

[54] 40 CFR 702.33

[55] Rayasam SDG, Koman PD, Axelrad DA, Woodruff TJ, Chartres N (2022). Toxic Substances Control Act (TSCA) Implementation: How the Amended Law Has Failed to Protect Vulnerable Populations from Toxic Chemicals in the United States. Environmental Science & Technology, 56(17):11969-11982. doi:10.1021/acs.est.2c02079

[56] Woodruff TJ et al. (2023). A science-based agenda for health- protective chemical assessments and decisions: Overview and consensus statement. Environmental Health, 21(Suppl 1):132. https://doi.org/10.1186/s12940-022-00930-3

[57] McPartland J et al. (2022). Charting a Path Forward: Assessing the Science of Chemical Risk Evaluations under the Toxic Substances Control Act in the Context of Recent National Academies Recommendations. Environ. Health Perspect 130(2).

susceptible due to lower wealth and poorer health, and with a majority of residents who are people of color.[58,59,60,61,62]

TSCA requires a thorough consideration of how risks to susceptible populations differ from the general public, as it explicitly mandates consideration of risks to PESS in the determination of unreasonable risk:

> 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.[63] (emphasis added)

Appropriate and complete identification of PESS is therefore a critical element in conducting TSCA risk evaluations. The 10 risk evaluations completed in 2020-2021, under the 2017 framework rule that included the narrower PESS definition, were deficient in failing to identify all relevant highly exposed and susceptible subpopulations, including fenceline communities. Prior to the addition of "overburdened communities" to the framework rule definition of PESS in 2024, EPA did not consistently identify fenceline communities as PESS. For example, the risk evaluation for HBCD considered "People living close to a facility with HBCD releases" as PESS,[64] but the risk evaluations for 1,4-dioxane, 1-bromopropane, and C.I. Pigment Violet 29 made no mention of fenceline communities as PESS. While inclusion of any particular group in the definition of PESS is not necessary for EPA to identify that group as PESS in a particular risk evaluation, inclusion of "overburdened communities" in the definition has been a useful and constructive signal to EPA staff and managers, and the public, of the importance of considering the potential for elevated risks (due to both higher exposure and enhanced susceptibility) to fenceline communities in each risk evaluation. EPA should therefore not proceed to finalize its proposal to delete "overburdened communities" from the PESS definition.

The deficiencies in EPA's approach to evaluating risks to PESS in TSCA risk evaluations has extended to other aspects of exposure and susceptibility beyond the important consideration of overburdened communities, as has been consistently demonstrated in both the first 10 risk

---

[58] Mohai P, Lantz PM, Morenoff J, House JS, Mero RP (2009). Racial and socioeconomic disparities in residential proximity to polluting industrial facilities: evidence from the Americans' Changing Lives Study. Am J Public Health, 99 Suppl 3, S649-56. https://www.ncbi.nlm.nih.gov/pubmed/19890171

[59] Houston D, Li W, Wu J (2014). Disparities in exposure to automobile and truck traffic and vehicle emissions near the Los Angeles-Long Beach port complex. Am J Public Health, 104(1), 156-64. https://www.ncbi.nlm.nih.gov/pubmed/23678919

[60] U.S. EPA (2022). Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0.

[61] Johnston J, Cushing L (2020). Chemical Exposures, Health, and Environmental Justice in Communities Living on the Fenceline of Industry. Curr Environ Health Rep Mar;7(1):48-57. doi: 10.1007/s40572-020-00263-8.

[62] Cushing L, Morello-Frosch R, Wander M, Pastor M (2015). The Haves, the Have-Nots, and the Health of Everyone: The Relationship Between Social Inequality and Environmental Quality. Annual Review of Public Health 3(1):193-209. https://doi.org/10.1146/annurevpublhealth-031914-122646

[63] 15 USC 2605(b)(4)(A).

[64] U.S. EPA (2020). Risk Evaluation for Cyclic Aliphatic Bromide Cluster (HBCD).

evaluations completed in 2020-2021 as well as the more recent draft and final risk evaluations issued in 2024-2025.

EPA's approach to identifying susceptible groups varied considerably in the first 10 TSCA risk evaluations. For example, there are significant differences in whether health conditions related to a chemical's hazards were considered in these four risk evaluations:

- 1,4-dioxane: People with liver disease were identified as PESS, but people with kidney, neurological or respiratory conditions (all identified hazards in the risk evaluation) were not identified as PESS.
- 1-bromopropane: No PESS were identified based on health conditions related to the hazards of the chemical, such as liver toxicity, kidney toxicity and neurotoxicity.
- Hexabromocyclododecane (HBCD): People with pre-existing health conditions were mentioned as PESS, but no specific health conditions were named in connection with identifying PESS. Thyroid and liver effects were identified as hazards in the risk evaluation, but people with thyroid or liver conditions were not identified as PESS. The SACC review of the draft risk evaluation stated that there was a "need to…add consideration of several preexisting health conditions that result in higher fat content in the liver."[65] The final risk evaluation did not address this SACC recommendation.

In 2024-2025, risk evaluations continued to overlook susceptible groups when identifying PESS. EPA has consistently focused much more attention on identifying "potentially exposed" groups while excluding most or all "susceptible subpopulations" from the listed PESS in each risk evaluation. For example, the 2024 TCEP risk evaluation says:

> susceptibility factors that are generally considered to increase susceptibility of individuals to chemical hazards…include pre-existing diseases, alcohol use, diet, stress, among others. The effect of these factors on susceptibility to health effects of TCEP is not known; therefore, EPA is uncertain about the magnitude of any possible increased risk from effects associated with TCEP exposure.[66]

In the D4 draft risk evaluation released for public comment in September 2025, EPA says:

> factors that may increase susceptibility include chronic disease, genetic factors, co-exposures, and behavior/lifestyle. For example, people with reduced fertility may be more susceptible to the reproductive effects of D4. Similarly, co-exposure to other chemical or non-chemical stressors that increase risk of adverse reproductive outcomes may increase susceptibility to the effects of D4 on the related health outcomes. EPA applied a $10 \times UF_H$ factor to account for human toxicokinetic and toxicodynamic variability associated with these factors.[67]

[65] U.S. EPA (2019). TSCA Science Advisory Committee on Chemicals Peer Review for EPA Draft Risk Evaluations for 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD). Meeting Minutes and Final Report. https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0063
[66] U.S. EPA (2024). Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), p. 462.
[67] U.S. EPA (2025). Draft Risk Evaluation for Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-) (D4), p. 210.

> for many factors EPA did not identify any reasonably available information to support quantitative adjustment of hazard/risk values. For these other factors, the Agency acknowledges either direct or indirect information suggesting additional susceptibility of certain subpopulations.[68]

Even though EPA recognizes that groups with particular chronic diseases, genetic factors, individual activities and co-exposures are potentially susceptible subpopulations for TCEP and D4, it does not then include these groups in the list of identified PESS groups. Instead of identifying these groups as PESS, as required by TSCA, EPA assumes that the customary 10-fold factor for human variability – which understates the extent of differential response in susceptible groups – is sufficient to address all elevated risks to susceptible populations and that no further analysis is necessary or appropriate. To satisfy TSCA's requirement of identifying unreasonable risks to PESS, EPA should give greater consideration to the quantification of elevated risks to PESS beyond rote application of the traditional 10-fold adjustment factor, as this value is insufficient to account for variability due to life stage, genetics, underlying disease status, and external stressors that may be due to poverty or other difficult life conditions and frequently results in underestimation of risk.[69,70,71,72,73] For example, the World Health Organization recommends a 42-fold adjustment factor to capture human variability in response to chemical exposures for a risk level of 1% (1-in-100), and this value is based primarily on data from healthy adults.[74]

EPA's default approach seems to be that a susceptible group will not be identified as PESS when there are not chemical-specific quantitative data on the magnitude of increased susceptibility for a given susceptibility factor. TSCA does not require chemical-specific quantitative data to identify or evaluate risk to PESS; TSCA simply requires EPA to rely on the "best available science" when evaluating risks to PESS. The best available science demonstrates that both intrinsic factors, which include biological traits like age, genetic makeup, and preexisting health conditions, and extrinsic factors, which include psychosocial stress from experiencing income inequality, violence, racism, healthcare inequity, or food insecurity, can

---

[68] U.S. EPA (2025). Draft Human Health Hazard Assessment for Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-) (D4), p. 98.
[69] National Research Council (2009). Science and Decisions: Advancing Risk Assessment.
[70] World Health Organization, International Programme on Chemical Safety (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization, 2nd edition. https://www.who.int/publications/i/item/9789241513548
[71] Varshavsky JR, Rayasam SDG, Sass JB, Axelrad DA, Cranor CF, Hattis D, Hauser R, Koman PD, Marquez EC, Morello-Frosch R, Oksas C, Patton S, Robinson JF, Sathyanarayana S, Shepard PM, Woodruff TJ (2023). Current practice and recommendations for advancing how human variability and susceptibility are considered in chemical risk assessment. Environmental Health 21(Suppl 1):133. doi:10.1186/s12940-022-00940-1
[72] California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (2008). Technical Support Document For the Derivation of Noncancer Reference Exposure Levels. http://oehha.ca.gov/media/downloads/crnr/noncancertsdfinal.pdf
[73] California Environmental Protection Agency. Office of Environmental Health Hazard Assessment (OEHHA). Child-Specific Reference Doses (chRDs) Finalized to Date. http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds
[74] World Health Organization, International Programme on Chemical Safety (2017). Guidance document on evaluating and expressing uncertainty in hazard characterization, 2nd edition, Table 4.5.

individually or collectively increase susceptibility to harm from chemical exposures.[75,76,77,78,79,80,81] EPA should therefore focus first on identifying susceptible subpopulations based on either chemical-specific evidence or the broader literature on intrinsic and extrinsic susceptibility factors, and then, as a separate step, consider how to account for the elevated risks for each group. The initial identification of PESS, however, should not be contingent on chemical-specific data to quantify risk for a susceptible subgroup. Once the appropriate groups are identified as PESS, EPA should then consider the availability of chemical-specific data. When such data are absent, the application of adjustment factors (beyond the customary 10x factor for human variability) should be applied to ensure that risks to PESS are not underestimated.[82]

As an important step toward improving its risk evaluations and better meeting the requirements of TSCA, EPA should expand its definition of PESS in the Proposed Rule to reflect additional considerations that influence susceptibility to risks. Explicitly naming factors that qualify groups as PESS is an important step to ensure their exposures and susceptibilities are consistently addressed in hazard and risk assessments.

EPA's January 2017 proposed framework rule provided a broader definition of PESS, referencing intrinsic and extrinsic factors that influence susceptibility, but these factors were not included in the June 2017 final rule. The National Academies recently published a definition of human biological variability that also includes intrinsic and acquired (or extrinsic) factors for purposes of identifying susceptible populations. [83] Explicit recognition of intrinsic and extrinsic factors that influence susceptibility would significantly improve the PESS definition. Specifically, EPA should revise the definition of PESS to the following:

---

[75] Woodruff TJ et al. (2023). A science-based agenda for health- protective chemical assessments and decisions: Overview and consensus statement. Environmental Health, 21(Suppl 1):132. https://doi.org/10.1186/s12940-022-00930-3

[76] Morello-Frosch R et al. (2011). Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy, Health Affs. 30(5) 879, https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.0153

[77] McHale CM et al. (2018). Assessing Health Risks from Multiple Environmental Stressors: Moving from GxE to IxE, Mutational Rsch. 775:11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5863617/

[78] Payne-Sturges DC et al. (2018). Methods for Evaluating the Combined Effects of Chemical and Nonchemical Exposures for Cumulative Environmental Health Risk Assessment, 15 Intl. J. Envt Rsch. & Pub. Health 15:2797. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313653/

[79] Gee GC et al. (2004). Environmental Health Disparities: A Framework Integrating Psychosocial and Environmental Concepts, Envt Health Persps. 112:1645. https://doi.org/10.1289/ehp.7074

[80] Solomon GM et al. (2016). Cumulative Environmental Impacts: Science and Policy to Protect Communities 37 Ann. Rev. Pub. Health 83, 87–88. https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-032315-021807

[81] Koman PD et al. (2019). Population Susceptibility: A Vital Consideration in Chemical Risk Evaluation Under the Lautenberg Toxic Substances Control Act, PLoS Biol 17(8):e3000372. https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3000372.

[82] Varshavsky JR et al. (2023). Current Practice and Recommendations for Advancing How Human Variability and Susceptibility Are Considered in Chemical Risk Assessment, Environmental Health, 21(Suppl 1):133. https://doi.org/10.1186/s12940-022-00940-1.

[83] National Academies of Sciences, Engineering, and Medicine (2023). Building Confidence in New Evidence Streams for Human Health Risk Assessment: Lessons Learned from Laboratory Mammalian Toxicity Tests, p. 31. https://doi.org/10.17226/26906.

> Potentially exposed or susceptible subpopulation means a group of individuals or communities within the general population identified by EPA 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, including but not limited to infants, children, pregnant people, workers, the elderly, or overburdened communities. Susceptibility can be due to either intrinsic (e.g., preexisting disease, life stage, reproductive status, age, sex, genetic traits) or extrinsic (e.g., food insecurity, geography, poverty, socioeconomic status, racism, discrimination, culture, workplace) factors when identifying this population.

This revised definition will help improve TSCA risk evaluations by informing risk assessors, peer reviewers and the public of the broader set of considerations that should be evaluated in the process of identifying PESS and will better focus EPA's efforts in risk evaluations to address risks to those with elevated susceptibility.

An improved definition of PESS is an important step toward improved identification of PESS, but further revisions should be made to the Proposed Rule directing risk assessors to apply a more systematic approach to considering groups that are PESS for the chemical under evaluation. EPA should add provisions to the Proposed Rule to establish that scope documents and risk evaluations must specify how PESS were identified for each risk evaluation and how differential risks to PESS were quantified in the risk evaluation.

Improved identification of PESS must begin with the Proposed Rule's requirements for the scope document for each risk evaluation. The existing framework rule provisions regarding the scope contains only a brief mention of PESS, stating that the scope of the risk evaluation will include "The potentially exposed populations, including any potentially exposed or susceptible subpopulations as identified as relevant to the risk evaluation."[84] This language should be expanded to require an explanation of how PESS were identified for the chemical being evaluated, with reference to thorough and systematic assessment of both intrinsic and extrinsic factors, identification of specific overburdened communities, and discussion of how exposures and risks to overburdened communities and other PESS will be assessed.

Improved identification of PESS must be followed by appropriate quantification of risks to PESS. The current framework rule says that "hazard information…will be evaluated"[85] for all PESS and the "exposure assessment will consider"[86] all PESS without elaboration on the nature of that evaluation or consideration. This vague language fails to indicate what EPA considers necessary to conduct an assessment of risks to PESS. These sections should be strengthened with text stating that differences in exposure, hazard and dose-response for each PESS (relative to the general population) will be identified and quantified, either through the use of chemical- or endpoint-specific evidence or, in the absence of that, health-protective adjustment factors. Further, § 702.39(e) of the framework rule should be expanded to require that the risk characterization summary of each risk evaluation include an explanation of how estimates of human health risk account for the differences in risk to each identified PESS, and discussion of

[84] 40 CFR 702.39(b)(2).
[85] 40 CFR 702.39(c)(4).
[86] 40 CFR 702.39(d)(5).

whether the data and approaches employed are sufficient to fully account for the differences in risk to PESS.

Revising the Proposed Rule to ensure more thorough identification of PESS and estimation of risks to PESS, including overburdened communities, should lead to improved rigor and consistency in EPA's TSCA risk evaluations. We emphasize, however, that EPA must implement more robust consideration of PESS in its risk evaluations to satisfy the requirements of TSCA regarding PESS and "best available science," regardless of whether or not it makes these recommended revisions to the Proposed Rule

In addition to these recommended revisions to the Proposed Rule, we also strongly recommend that EPA prepare a guidance document presenting a comprehensive methodology for identifying PESS and incorporating community input on this topic, as well a separate guidance document on quantifying risks to susceptible subpopulations identified as PESS. Such guidance is necessary to ensure robust and consistent approaches to assessing PESS in TSCA risk evaluations and to ensure constructive engagement with affected populations and communities.

5. EPA should ensure panel peer review of TSCA risk evaluations.

The Proposed Rule solicits comment on "whether the 2017 language describing peer review provisions should be restored, or whether other amendments to the peer review provision should be considered."[87] The 2017 framework rule required EPA to conduct peer review on TSCA risk evaluations,[88] and EPA satisfied that requirement for the first 10 TSCA risk evaluations. However, in 2024, EPA updated these requirements to limit peer review only to "portions" of a risk evaluation.[89] Accordingly, EPA's current and proposed practices signal a shift away from the rigorous, independent peer review process that characterized the first 10 TSCA risk evaluations toward a limited, opaque, and fragmented system that relies increasingly on "letter reviews"[90] and panel peer reviews of only portions of a risk evaluation, rather than comprehensive panel reviews.[91]

EPA's approach to peer review is foundational to the credibility and scientific integrity of TSCA risk evaluations. Peer review ensures that risk evaluations are conducted using the "best available science,"[92] and provides a transparent process for public oversight of EPA's scientific judgments. EPA should therefore reaffirm its commitment to full, panel peer reviews by the SACC as the default procedure for all TSCA risk evaluations. This approach is consistent with the "best available science", recommendations by EPA's SACC, and long-standing EPA peer review policies, ensuring**.**

---

[87] 90 Fed. Reg. at 45,706.
[88] 82 Fed. Reg. at 33,752.
[89] 89 Fed. Reg. 37,042.
[90] https://www.epa.gov/chemicals-under-tsca/epa-releases-peer-review-comments-white-paper-asbestos-part-2-risk-evaluation ("EPA requested a letter peer review … of the quantitative approach to the human health assessment to be used in part 2 of the [asbestos] risk evaluation. The Agency submitted this white paper, rather than the full draft risk evaluation, for peer review … to make the most efficient use of the experts' time.")
[91] https://www.epa.gov/tsca-peer-review/peer-review-evaluating-risk-high-priority-phthalates
[92] 15 U.S.C. § 2625(h).

a. EPA's recent reliance on letter reviews is inconsistent with established EPA standards.

EPA's Proposed Rule references the *EPA Peer Review Handbook,* which clearly states that Influential Scientific Information (ISI) and Highly Influential Scientific Assessments (HISAs), which include all TSCA risk evaluations, should undergo "external peer review"[93] and that peer review panels "are preferable for influential products because they tend to be more deliberative than individual letter reviews and the reviewers can help inform one another."[94]

External panel reviews provide the highest level of scientific credibility because they involve qualified, independent experts free from conflicts of interest; promote deliberation and consensus across disciplines; operate through public meetings; and produce written reports that document both areas of agreement and scientific uncertainty. In contrast, "letter reviews," where individual experts provide isolated written comments without discussion, are intended only for non-controversial, narrow, or low-impact work products. TSCA risk evaluations are complex, multidisciplinary, and precedent-setting, and therefore demand robust external panel review.

In recent years, EPA has relied increasingly on letter reviews instead of SACC panel reviews. For example, in 2023, EPA convened a letter review for a white paper outlining the quantitative risk factors it intended to use for its Asbestos Part 2 risk evaluation,[95] despite that evaluation's far-reaching implications for occupational and community exposures. Similarly, EPA limited review of the TCEP risk evaluation to a letter process even though it introduced new modeling approaches for drinking-water contamination and infant exposure via human milk.

These truncated reviews are inconsistent with EPA guidance, which stipulates that panel reviews are appropriate for complex assessments and for products that form the basis of major policy decisions. Further, limiting peer review to discrete "portions" of risk evaluations or to individual technical documents can exclude critical analyses, such as aggregate exposure estimates, hazard identification, and unreasonable risk determinations, from independent scrutiny. Such piecemeal approaches compromise the transparency and completeness of the peer review and undermine confidence in the TSCA peer review process.

b. EPA should implement full SACC panel reviews for all TSCA risk evaluations to promote scientific integrity and public accountability.

SACC panel reviews provide a structured, transparent process that allows interaction among experts across disciplines and between reviewers and the public. This process yields higher-quality scientific feedback, reduces bias, and enhances public understanding of EPA's methods and findings. Importantly, SACC's continuity of membership allows it to identify and address recurring methodological issues across risk evaluations. For example, the SACC played an invaluable role in raising concerns about the unrealistic presumption of uniform use of personal protective equipment (PPE) in the first 10 TSCA risk evaluations. Similarly, the SACC reviews

[93] U.S. EPA (2015). Peer Review Handbook at 54.
[94] U.S. EPA (2015). Peer Review Handbook at 57.
[95] 88 FR 51309 (August 3, 2023).

of EPA's TSCA fenceline exposure and cumulative risk assessment methodologies raised important issues that are applicable to the 20 ongoing risk evaluations. Continuing this role in which the SACC provides feedback on how EPA applies these methodologies in individual risk evaluations would be invaluable to the Agency and the public.

Panel reviews would also help to ensure that the scientific peer review process remains free from financial conflicts of interest (COI), or a strong bias toward the perspective of regulated industries that may have a vested interest in minimizing EPA's regulation of hazardous materials and products. Research has established that financial COI results in recommendations from clinical guidelines and expert reviews that favor the interests of the industry providing financial support.[96,97,98,99,100] Moving to a process that prioritizes letter reviews could severely hamper the scientific collaboration, consensus, transparency, and public participation that is critical to limiting and addressing financial COI and promoting scientific integrity. Letter reviews should thus be the rare exception and not the norm.

In the interest of conserving resources and minimizing delays as it progresses with the 20 ongoing risk evaluations, EPA can adopt certain efficiencies that do not compromise the benefits of external peer review or the integrity of the TSCA risk evaluation and risk management process. Options might include, for example, asking a panel to review multiple evaluations which raise similar issues or reducing the size of review panels.

EPA must establish a clear, unbiased, well-justified scientific peer review process for TSCA risk evaluations. To comply with its *Peer Review Handbook* and TSCA's best-available-science standard, EPA should develop language in the Proposed Rule that requires a full SACC panel review for each TSCA risk evaluation, including conducting peer review of entire risk evaluations, not only selected sections or supporting documents, to ensure comprehensive assessment of methodologies, assumptions, and conclusions. EPA should also adopt language that requires the disclosure and elimination of potential financial conflicts of interest among peer reviewers and better ensures balanced representation across relevant disciplines, including representation from communities that are most impacted by exposure to TSCA chemicals.

To maintain and establish further credibility and accessibility in this process, EPA should also adopt language that requires it to consistently announce peer review meetings in the Federal Register, provide full drafts and charge questions well in advance of peer review meetings, accept oral and written public comments, and publish all peer review reports and EPA responses, in the risk evaluation docket well before a final rulemaking is released to allow the public to trace how EPA addressed scientific feedback.

---

[96] Nejstgaard CH, Bero L, Hróbjartsson A, et al. Association between conflicts of interest and favourable recommendations in clinical guidelines, advisory committee reports, opinion pieces, and narrative reviews: systematic review. BMJ2020;371:m4234.pmid:33298430.

[97] Coyne DW. Influence of industry on renal guideline development. Clin J Am Soc Nephrol2007;2:3-7, discussion 13-4. doi:10.2215/CJN.02170606 pmid:17699377.

[98] Blake P, Durão S, Naude CE, Bero L. An analysis of methods used to synthesize evidence and grade recommendations in food-based dietary guidelines.

[99] Tabatabavakili S, Khan R, Scaffidi MA, Gimpaya N, Lightfoot D, Grover SC. Financial conflicts of interest in clinical practice guidelines: a systematic review. Mayo Clin Proc Innov Qual Outcomes2021;5:466-75. Doi:10.1016/j.mayocpiqo.2020.09.016 pmid:33997642.

[100] Brems JH, Davis AE, Clayton EW. Analysis of conflict of interest policies among organizations producing clinical practice guidelines. PLoS One2021;16:e0249267. doi:10.1371/journal.pone.0249267 pmid:33930893.

6. EPA should revise the Proposed Rule to prohibit the consideration of personal protective equipment (PPE) in TSCA risk evaluations.

EPA proposes to revise the 2024 framework rule to allow consideration of "reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and personal protective equipment"[101] when determining unreasonable risk to workers. The Proposed Rule would give EPA the discretion to assume PPE use in occupational risk assessments, effectively treating PPE as a default exposure-control measure. This revision would substantially weaken worker protections, conflict with well-established occupational-safety standards and principles, and is inconsistent with the statutory requirements of TSCA, which mandate that EPA identify and eliminate unreasonable risks to potentially exposed or susceptible subpopulations (PESS),[102] including workers, using the best available science.[103]

The Occupational Safety and Health Administration (OSHA) standards prohibit the consideration of PPE when evaluating worker exposures and risks. In cases where worker risks are identified, PPE can only be used after all other control measures, such as elimination, substitution, engineering, and administrative controls, have been evaluated and found insufficient to eliminate risk.[104]

The 2024 rule is more closely aligned with these standards and with the occupational hierarchy of controls, under which PPE is considered the least reliable and least protective method of exposure control. However, the 2024 rule does not expressly stipulate that EPA should prohibit consideration of PPE use when evaluating risk to workers. EPA should therefore revise the Proposed Rule to further strengthen the existing 2024 rule language and prohibit EPA from considering PPE usage when conducting risk evaluations.

a. EPA's historical reliance on PPE assumptions ignores the best available science and leads to a systematic underestimation of risk.

EPA consistently underestimated the occupational risks posed by each of the first 10 risk evaluation chemicals by assuming that all workers exposed to those chemicals would be provided with and protected by personal protective equipment (PPE).[105] This assumption of universal and effective PPE use is not supported by evidence, as OSHA, the National Institute for Occupational Safety and Health (NIOSH), and EPA's SACC told EPA in their comments on EPA's first 10 chemical draft risk evaluations.[106] This assumption also contradicts the well-

[101] 90 Fed. Reg at 45,705.
[102] 15 U.S.C. § 2602(12).
[103] 15 U.S.C. § 2625(h).
[104] 29 C.F.R. § 1910.134(a)(1).

[105] See the OTNE Risk Evaluation Request also assumes the use of PPE, asserting that "[d]ue to the use of PPE, dermal exposure is expected to be negligible." OTNE Risk Evaluation Request App'x IV. For all of the reasons stated below, EPA should reject that assumption when conducting the OTNE Risk Evaluation.
[106] NIOSH, Comments on Draft Risk Evaluation for Methylene Chloride; OSHA, Comments on Draft Risk Evaluation for Methylene Chloride; TSCA Sci. Advisory Comm. on Chems., Report on Peer Review of the Draft

established occupational "hierarchy of controls," under which PPE is used only as a measure of last resort, after an employer has already evaluated risk without the assumption of PPE use, identified a significant risk to employers, and exhausted or ruled out all other means of addressing that risk, such as chemical elimination, substitution and engineering controls. EPA's proposed risk management rules for the first 10 chemicals also revealed that even after accounting for workplace protections, the levels of chemical exposure that workers face remain unacceptably high. Scientists from UCSF's Program on Reproductive Health and the Environment (PRHE) applied methods developed by the World Health Organization (WHO) to quantify non-cancer risk for occupational exposure scenarios in the proposed risk management rules for methylene chloride, perchloroethylene, and carbon tetrachloride, and found that allowable exposure levels after implementation of proposed workplace protection programs were associated with health risks as high as 1-in-200, a risk level *5,000 times higher* than the benchmark risk level of 1-in-1,000,000, commonly used by the Agency for cancer risk.[107] This particular value was the likelihood of developing decrements in visual memory function—the same that are observed in patients with Parkinson's disease—from exposure to perchloroethylene (PCE). Even with modeled workplace protections and control technologies in place, workers will continue to face dangerous health risks, underscoring that the Agency's reliance on assumed PPE use cannot meaningfully reduce risks to workers.

b. Workers frequently lack access to adequate PPE and training as shown through empirical evidence.

OSHA has acknowledged that there is only a nominal possibility that respirators will be properly worn at all times, because respirators are often not provided, workers may have little leverage to obtain protections, and respirators are known to cause worker discomfort, skin irritation or heat stress, impaired body movements, difficulties in communicating and vision limitations.[108] Even when respirators are provided, workers are frequently not provided the training, fit testing and medical examinations that are required to achieve the respirator's stated level of protection.[109] Finally, EPA has previously acknowledged that not all workers may be able to wear respirators. Workers with impaired lung function, such as those with asthma, emphysema, and chronic obstructive pulmonary disease or with facial hair may be inadequately protected by respirators.[110] Assuming effective PPE use in these contexts therefore results in systematic underestimation of occupational risk.

Risk Evaluation for 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD), at 53 (2019); TSCA Sci. Advisory Comm. on Chems., Report on Peer Review of the Draft Risk Evaluation for 1-Bromopropane, at 30 (2019). ("[T]he Committee has now received public testimony from two former highly distinguished Occupational Safety and Health Administration (OSHA) administrators expressing concerns regarding EPA's reliance upon . . . PPE to reduce risks to reasonable levels.").

[107] Program on Reproductive Health and the Environment. (2023). EPA's recent TSCA rulemakings fail to protect workers and communities of color. https://prheucsf.blog/2023/10/17/epas-recent-tsca-rulemakings-fail-to-protect-workers-and-communities-of-color/.

[108] 51 Fed. Reg. 22693.

[109] NIOSH, Respirator Usage in Private Section Firms, 2001 at 2 (Sept. 2003), https://www.cdc.gov/niosh/docs/respsurv/pdfs/respsurv2001.pdf

[110] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7481 (Jan. 19, 2017).

Firsthand accounts from workers in high-risk industries vividly illustrate why EPA must not assume the consistent or effective use of PPE in its risk evaluations. For example, a personal account from a truck driver and member of Trucker's Movement for Justice revealed that drivers in McDowell County, West Virginia hauling raw coal and coal ash—up to 35 loads a day—were doing so without PPE provided by the employer. Drivers were told that protective gear was unnecessary if truck cabin windows were rolled up and the air conditioning on, but several trucks had no functioning air conditioning. During summer months, when temperatures exceeded 100°F, drivers were forced to drive with the windows open, quickly becoming covered in a fine layer of coal dust. The company refused to provide respirators, citing their high cost. These experiences underscore the disconnect between regulatory assumptions of PPE use and the real conditions faced by workers whose employers routinely disregard safety requirements to cut costs.

Similar experiences are common among truck drivers who haul oil and gas waste who are regularly exposed to hazardous materials without proper training, protective equipment, or information about the substances they are transporting.[111] According to Truckers Movement for Justice, oilfield drivers often carry hazardous waste from drilling sites to storage and disposal facilities without being informed of the risks and without being provided adequate PPE. These drivers even report rarely receiving Safety Data Sheets for their loads, leaving them unaware of the specific chemicals they handle or how to protect themselves. Produced water, brine, and oilfield sludge routinely splash onto workers' skin and clothing as they load and unload tanks, often while wearing little to no PPE, leading to burns, rashes, respiratory distress, and long-term illnesses.[112]

The absence of enforceable PPE use and safety protocols in these industries exposes a much broader pattern of risk that EPA must consider in its TSCA risk evaluations. The assumption that PPE can be relied upon to reduce occupational exposure is contradicted not only by individual testimony but also by systemic failures in industry compliance and oversight. When shippers misclassify hazardous materials or fail to provide safety documentation, that failure ripples down the supply chain, leaving drivers, waste handlers, and maintenance crews unprotected. These conditions demonstrate why PPE cannot be assumed as a functional control measure in risk evaluations. For thousands of workers, including America's truck drivers represented by the Truckers Movement for Justice, PPE is not an everyday reality.

EPA must ensure that TSCA risk evaluations reflect real-world workplace conditions to align with the best available science and ensure that TSCA fulfills its statutory purpose to protect workers and other PESS from unreasonable risks. EPA should therefore revise the Proposed Rule to expressly prohibit consideration of PPE use in TSCA risk evaluations.

[111] Earthjustice. (2025). Request for Enforcement of Hazardous Materials Laws in U.S. Oil and Gas Fields. https://earthjustice.org/document/request-for-enforcement-of-hazardous-materials-laws-in-u-s-oil-and-gas-fields.
[112] Id.