January 30, 2024

Comments from Scientists, Academics, and Clinicians in Response to EPA's Draft Revised Technical Guidance for Assessing Environmental Justice in Regulatory Analysis

Submitted online via regulations.gov docket No. EPA-HQ-OA-2013-0320, FRL-11531-01-OA

These comments are submitted on behalf of the undersigned scientists, academics, and clinicians. 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 imply institutional endorsement or support. We appreciate the opportunity to provide comments on the draft revision of the "Technical Guidance for Assessing Environmental Justice in Regulatory Analysis" hereafter referred to as the "EJ Technical Guidance."

Individuals living in the United States experience exposure to multiple chemicals daily and certain populations are more susceptible to harm from these exposures due to either intrinsic (e.g. pre-existing disease, life-stage, reproductive status, age, sex, genetic traits) or extrinsic factors (e.g., food insecurity, geography, poverty, socioeconomic status, racism, discrimination, culture, workplace) factors.[1] Traditional approaches for exposure and risk assessment apply a "single-chemical" approach and do not capture real-world exposures and risks including exposure to multiple chemical and non-chemical stressors. EPA has appropriately released several important documents that take into account multiple chemical exposures in risk assessment and guidelines for conducting a cumulative risk assessment for which we have submitted comments highlighting the need to incorporate intrinsic and extrinsic factors that increase the susceptibility to chemical exposures in cumulative risk assessment.[2,3] The EJ Technical Guidance is the latest document from EPA in response to Executive Order (E.O.)14096[4] and is an important step toward developing recommendations to account for real-world chemical exposures and the differential impacts of environmental stressors experienced by susceptible subgroups for regulatory decision-making. The EJ Technical Guidance continues to advance EPA's role in considering and mitigating the impact of environmental contaminants, including the contribution of non-chemical stressors to exposure disparities and adverse health outcomes.

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[1] Woodruff, T. J., Rayasam, S. D. G., Axelrad, D. A., Koman, P. D., Chartres, N., Bennett, D. H., Birnbaum, L. S., Brown, P., Carignan, C. C., Cooper, C., Cranor, C. F., Diamond, M. L., Franjevic, S., Gartner, E. C., Hattis, D., Hauser, R., Heiger-Bernays, W., Joglekar, R., Lam, J., … Zeise, L. (2023). A science-based agenda for health- protective chemical assessments and decisions: Overview and consensus statement. *Environmental Health*,*21*(1), 132. https://doi.org/10.1186/s12940-022-00930-3.

[2] Program on Reproductive Health and the Environment (2023). *Comments on the Draft Guidelines for Cumulative Risk Assessment Planning and Problem Formulation*. [Submitted via regulations.gov docket No. EPA-HQ-ORD-2013-0292 & FRL-11021-01-ORD] https://www.regulations.gov/comment/EPA-HQ-ORD-2013-0292-0200.

[3] Program on Reproductive Health and the Environment. (2023). *Draft Proposed Principles of Cumulative Risk Assessment under the TSCA" and "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the TSCA.* [Submitted via regulations.gov docket No. EPA-HQ-OPPT-2022-0918]. https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0918-0014.

[4] Executive Order 14096. (2023). *Revitalizing Our Nation's Commitment to Environmental Justice for All* (Vol. 88, No. 80). https://www.govinfo.gov/content/pkg/FR-2023-04-26/pdf/2023-08955.pdf.

We support EPA's efforts to establish frameworks and guidance for incorporating environmental justice (EJ) concerns into exposure assessment, risk evaluation and risk management processes. We agree with the definitions of intrinsic and extrinsic factors as described in the EJ Technical Guidance; the recommendation to involve stakeholders early in the risk assessment process; and the recommendation to report data in a disaggregated, non-technical, and transparent manner so that impacted individuals and communities may understand and make their own determination of risk.

Although resources and methods are continuing to be developed by EPA and others to identify and address EJ concerns at EPA, there are several areas where the EJ Technical Guidance document could be improved to provide more concrete recommendations for risk assessors to consider EJ in the risk assessment process and better account for real world exposures in EJ communities and groups. By EPA's own description, the EJ Technical Guidance is not prescriptive. However, the lack of concrete recommendations and tools for incorporating EJ into exposure and risk assessment could lead to inappropriate disregard of EJ-relevant hazards and risks due to unsupported claims of issues with feasibility, data quality, data availability, and statistical significance.[5] Ignoring EJ concerns in risk assessment and other regulatory analyses will result in continued underestimation of exposure and risk to environmental contaminants and chemicals, and continued disparities in exposure and adverse health outcomes for susceptible populations. EPA should adopt the recommendations outlined below to strengthen the EJ Technical Guidance and ensure that Agency actions most accurately account for and mitigate risks posed to EJ communities from harmful environmental stressors.

Our comments focus on the following main points:

1. **EPA should provide structured recommendations and methodologies on how to identify potential impacts of multiple chemical and non-chemical stressors and relevant exposure sources for susceptible groups and EJ communities.**
2. **EPA should rely on the best available scientific methods to address uncertainty and data gaps.**
    a. **EPA should identify new and alternative data sources for evaluating exposure and risk when traditional data sources are not available.**
    b. **EPA should incorporate recommendations for the use of science-based default uncertainty factors when data is not available to fully characterize the range of responses to multiple chemical and non-chemical stressors.**
3. **EPA should provide recommendations to use robust systematic review methodologies for evidence evaluation.**
4. **EPA should delete or substantially revise the text regarding the distribution of regulatory costs in overburdened communities, which is not a consideration in the pursuit of environmental justice.**
5. **EPA's proposed "fit for purpose" model is inconsistent with expert recommendations and "intended purpose and context of use" should be used instead.**

[5] U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-. Data quality p 44; data availability p 56; Statistical significance p 74.

6. **EPA should expand its proposed definition of "overburdened" in the EJ Technical Guidance to include higher chemical exposures.**

Respectfully,

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Detailed comments:

1. **EPA should provide structured recommendations and methodologies on how to identify potential impacts of multiple chemical and non-chemical stressors and relevant exposure sources for susceptible groups and EJ communities.**

The EJ Technical Guidance lays out five overarching recommendations "to ensure high quality analysis that is feasible and appropriate." Considering these recommendations are a "starting point [and] should not be interpreted as limiting the scope of the EJ analysis" they fail to include instructions to systematically consider EJ concerns before determining the feasibility of incorporating EJ in risk assessment. Recommendations listed by the EJ Technical Guidance should not be determined by feasibility alone and should include the recommendation that specific EJ concerns be considered in the context of the risk assessment, including systematically identifying communities and populations with higher vulnerability to harm from chemical exposures at the earliest stages of human health risk assessment.

To accomplish this, EPA should remove the words "feasible and appropriate" on page 17 and amend Section 3.3 to say: "This technical guidance makes five overarching recommendations to ensure high quality analysis (see Section 3.2), while also recognizing the need for flexibility to reflect policy considerations and technical challenges within a particular regulatory context." [6]

Additionally, the first overarching recommendation: "**While analysts should use best professional judgement to decide on the type of analysis that is feasible and appropriate**, when risks, exposures, outcomes, or benefits of the regulatory action are quantified, some level of quantitative EJ analysis is recommended"[7] [emphasis our own] should be amended to remove the bolded language, and the phrase "when achievable" should be removed from the first bullet.[8]

By emphasizing the determination of feasibility of addressing EJ concerns in a risk assessment without first defining the criteria for what is not considered feasible, the current EJ Technical Guidance leaves the risk assessor vulnerable to inadequately implementing the suggestions and recommendations for incorporating EJ into risk assessment because of lack of clarity on how to define or decide feasibility. To address this, the EJ Technical Guidance should recommend evaluating potential EJ factors systematically to identify susceptible communities or populations impacted by the exposure or site before determining the feasibility of evaluating EJ concerns, and then integrate the results of this evaluation into human health risk assessment (HHRA). The first question should not be "is it feasible;" instead, risk assessors should ask the question "is there a susceptible population that is affected by the exposure or site?" and apply systematic methods to identify communities, groups or populations that may be most susceptible. While we understand that feasibility may play a role in the overall risk assessment or management process, this should not be the first question.

[6] U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. p 17.
[7] *Id.* at p 17.
[8] *Id.* at p 18.

Limitations of EPA's current approach to considering EJ impacts in risk assessment, which should be addressed by the EJ Technical Guidance, are illustrated by the risk evaluations and risk management rules conducted under the amended Toxic Substances Control Act ("TSCA"). EPA did not employ a consistent or structured approach in identifying susceptible or vulnerable populations in its first 10 completed TSCA chemical risk evaluations, or in the scope documents for more than 20 ongoing chemical risk evaluations. EPA's approach and terminology for identifying susceptible populations varied considerably in the first 10 risk evaluations.[9] Among the inconsistencies are differences in whether all relevant health conditions related to a chemical's hazards were considered and whether fenceline communities were identified or included.[10,11] Further, in several of EPA's recent draft TSCA risk management rules, EPA failed to identify or mitigate fenceline community risks. To remedy the problem of inconsistent and incomplete identification of susceptible groups, Rayasam et al. recommended that "EPA should prepare a comprehensive methodology to identify susceptible groups and quantify their risks consistently within and across the TSCA risk evaluations."[12] The EJ Technical Guidance should include such a structured and systematic methodology that considers susceptible subpopulations impacted by toxic chemical exposures. One example where EPA has provided a structured approach for identifying susceptible groups is in the draft supplemental risk evaluation for 1,4-dioxane,[13] for which we provided comments.[14] Table 5-11 of the draft supplemental risk evaluation for 1,4-dioxane provides explicit consideration to each of the following: life stage, pre-existing disease, lifestyle activities, occupational exposures, geographic factors, socio-demographic factors, nutrition, genetics, unique activities, aggregate exposures, other chemical and non-chemical stressors. Although there were significant shortcomings in EPA's identification of susceptible subpopulations in the 1,4-dioxane draft supplemental risk evaluation, it was a useful first step in developing a consistent approach to considering numerous susceptibility factors that can be incorporated into the EJ Technical Guidance.

By including a framework for systematically considering susceptible groups, communities and

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[9] Rayasam, S. D. G., Koman, P. D., Axelrad, D. A., Woodruff, T. J., 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. https://doi.org/10.1021/acs.est.2c02079.

[10] *Id.*

[11] McPartland, J., Shaffer, R. M., Fox, M. A., Nachman, K. E., Burke, T. A., Denison, R. A. (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. Environmental health perspectives, 130(2), 25003. https://doi.org/10.1289/EHP9649.

[12] Rayasam, S. D. G., Koman, P. D., Axelrad, D. A., Woodruff, T. J., 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. https://doi.org/10.1021/acs.est.2c02079.

[13] US EPA (2023) Draft Supplement to the Risk Evaluation for 1,4-Dioxane . Table 5-11. Available: https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0905-0032.

[14] Program on Reproductive Health and the Environment. (2023).*Comments from UCSF Program on Reproductive Health and the Environment on the Supplemental Draft Risk Evaluation for 1,4-Dioxane* [Submitted online via Regulations.gov to docket EPA-HQ-OPPT-2022-0905-0032]. https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0058.

populations, EPA will further the inclusion of EJ considerations in EPA risk assessment and ensure that exposure is considered holistically among the population and that protections extend to susceptible groups.[15]

We agree that proximity to a toxic source is commonly and appropriately used when a direct measure of risk or exposure is not available. We also agree that an important limitation of proximity-based approaches is that they "assume that the effects of the stressor(s) occur only within the designated boundary... And that all individuals residing within the boundary are equally exposed. As such a proximity-based analysis is not able to determine which populations within the boundary may face higher risk or adverse health effects."

However, the EJ Technical Guidance should also provide structured recommendations for how toxic sites or toxic chemical exposure sources will be identified in addition to using proximity as a proxy for exposure to toxic sites. For example, relying on community knowledge is an important way to identify these sites, however, the burden of reporting toxic sites or releases should not fall on the impacted communities alone. The EJ Technical Guidance should include the use of mandated reporting databased such as the Toxics Release Inventory ("TRI"), the National Emissions Inventory ("NEI"), and Discharge Monitoring Reports ("DMR"), as well as federal- and state-level environmental monitoring data and other data sources that could indicate chemical accidents, releases, or spills, and these data should trigger the evaluation and quantification of EJ exposures and risks around toxic chemical exposure sources.

Chemical spills in the U.S. occur at a rate of approximately one per day, the majority of which are linked to the fossil fuel industry including the use, transport, production and disposal of fossil fuels or fossil fuel-derived products.[16] This demonstrates that identifying the locations of toxic sites must include transportation routes where toxic spills may occur (e.g. East Palestine).[17] To do this, EPA could start by considering the off-site consequences analyses in facilities' Risk Management Plans to estimate the impacts of chemical accidents and spills.[18]

2. EPA should rely on the best available scientific methods to address uncertainty and data gaps.

a. EPA should identify new and alternative data sources for evaluating exposure and risk when traditional data sources are not available.

The EJ Technical Guidance fails to provide adequate recommendations for identifying and filling data gaps when traditional data sources (e.g. biomonitoring, chemical release databases) are not available. Its discussion of the data requirements for human health risk assessment (HHRA) also is likely to discourage incorporation of EJ analysis into risk assessments due to statements that data on EJ concerns and disaggregated data on exposure and health effects are not often

[15] U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. p 58.
[16] https://www.theguardian.com/us-news/2023/nov/09/how-many-chemical-accidents-spills-explosion
[17] https://www.theguardian.com/us-news/2023/aug/04/ohio-train-derailment-east-palestine-health-chemical-symptom
[18] *See* EPA, Rep. No. EPA 550-B-99-009, *Risk Management Program Guidance for Offsite Consequence Analysis* (2009), https://19january2017snapshot.epa.gov/sites/production/files/2013-11/documents/oca-chps.pdf.

available. EPA should draw on multiple data sources to inform EJ analyses in risk assessments, including chemical-specific epidemiological evidence on susceptibilities as well as broader literature on intrinsic and extrinsic susceptibility factors.[19,20]

b. EPA should incorporate recommendations for the use of science-based default uncertainty factors when data is not available to fully characterize the range of responses to multiple chemical and non-chemical stressors.

With regards to accounting for the cumulative impact of multiple chemical and non-chemical stressors, the EJ Technical Guidance states that the science is "evolving"[21] and "in the meantime, even when utilization of a more formal approach to assessment is not feasible, this guidance recommends that analysts consider the potential implications of exposure to multiple stressors, both chemical and non-chemical, when planning and scoping for a HHRA."[22] The document then recommends via a footnote that to address human vulnerability:

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[19] Vesterinen, H. M., Morello-Frosch, R., Sen, S., Zeise, L., & Woodruff, T. J. (2017). Cumulative effects of prenatal-exposure to exogenous chemicals and psychosocial stress on fetal growth: Systematic-review of the human and animal evidence. *PLOS ONE*, *12*(7), e0176331. https://doi.org/10.1371/journal.pone.0176331; Varshavsky, J. R., Rayasam, S. D. G., Sass, J. B., Axelrad, D. A., Cranor, C. F., Hattis, D., Hauser, R., Koman, P. D., Marquez, E. C., Morello-Frosch, R., Oksas, C., Patton, S., Robinson, J. F., Sathyanarayana, S., Shepard, P. M., & Woodruff, T. J. (2023). Current practice and recommendations for advancing how human variability and susceptibility are considered in chemical risk assessment. Environmental Health, 21, 1–20. https://doi.org/10.1186/s12940-022-00940-1; McHale, C. M., Osborne, G., Morello-Frosch, R., Salmon, A. G., Sandy, M. S., Solomon, G., Zhang, L., Smith, M. T., & Zeise, L. (2018). Assessing health risks from multiple environmental stressors: Moving from G×E to I×E. Mutation research. Reviews in mutation research, 775, 11–20. https://doi.org/10.1016/j.mrrev.2017.11.003; Payne-Sturges, D. C., Scammell, M. K., Levy, J. I., Cory-Slechta, D. A., Symanski, E., Carr Shmool, J. L., Laumbach, R., Linder, S., & Clougherty, J. E. (2018). Methods for Evaluating the Combined Effects of Chemical and Nonchemical Exposures for Cumulative Environmental Health Risk Assessment. International Journal of Environmental Research and Public Health, 15(12). https://doi.org/10.3390/ijerph15122797.

[20] Casey, J. A., Daouda, M., Babadi, R. S., Do, V., Flores, N. M., Berzansky, I., González, D. J. X., Van Horne, Y. O., & James-Todd, T. (2023). Methods in Public Health Environmental Justice Research: A Scoping Review from 2018 to 2021. *Current environmental health reports*, *10*(3), 312–336. https://doi.org/10.1007/s40572-023-00406-7; Vandenberg, L. N., Rayasam, S. D. G., Axelrad, D. A., Bennett, D. H., Brown, P., Carignan, C. C., Chartres, N., Diamond, M. L., Joglekar, R., Shamasunder, B., Shrader-Frechette, K., Subra, W. A., Zarker, K., & Woodruff, T. J. (2023). Addressing systemic problems with exposure assessments to protect the public's health. *Environ Health*, *21*(Suppl 1), 121. Medline. https://doi.org/10.1186/s12940-022-00917-0; Woodruff, T. J., Rayasam, S. D. G., Axelrad, D. A., Koman, P. D., Chartres, N., Bennett, D. H., Birnbaum, L. S., Brown, P., Carignan, C. C., Cooper, C., Cranor, C. F., Diamond, M. L., Franjevic, S., Gartner, E. C., Hattis, D., Hauser, R., Heiger-Bernays, W., Joglekar, R., Lam, J., ... Zeise, L. (2023). A science-based agenda for health-protective chemical assessments and decisions: Overview and consensus statement. *Environ Health*, *21*(Suppl 1), 132. Medline. https://doi.org/10.1186/s12940-022-00930-3; Liu, Z., Liu, C., & Mostafavi, A. (2023). Beyond Residence: A Mobility-based Approach for Improved Evaluation of Human Exposure to Environmental Hazards. *Environmental science & technology*, *57*(41), 15511–15522. https://doi.org/10.1021/acs.est.3c04691; McHale, C. M., Osborne, G., Morello-Frosch, R., Salmon, A. G., Sandy, M. S., Solomon, G., Zhang, L., Smith, M. T., & Zeise, L. (2018). Assessing health risks from multiple environmental stressors: Moving from G×E to I×E. *Mutation research. Reviews in mutation research*, *775*, 11– 20. https://doi.org/10.1016/j.mrrev.2017.11.003; Pullen Fedinick, K., Yiliqi, I., Lam, Y., Lennett, D., Singla, V., Rotkin-Ellman, M., & Sass, J. (2021). A Cumulative Framework for Identifying Overburdened Populations under the Toxic Substances Control Act: Formaldehyde Case Study. *International journal of environmental research and public health*, *18*(11), 6002. https://doi.org/10.3390/ijerph18116002

[21] U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. p 45.

[22] *Id.*

> In the absence of scientific data to fully characterize the range of responses to chemical exposures, the EPA employs default assumptions, such as uncertainty factors used in non-cancer risk assessments, to account for human variability. As noted by the Science Advisory Board (SAB, 2015), however, "...the use of uncertainty factors in developing dose-response assessments for an individual level chemical might address the general population as a whole but does not specifically address differential or disproportionate vulnerability."[23]

Default assumptions, such as uncertainty factors for non-cancer risk assessment, are typically applied when sufficient chemical-specific evidence is not available. When evaluating the risk posed by chemicals, EPA relies on a 10X default adjustment factor to account for intra-species variability nearly 70 years ago.[24] Since then, decades of scientific evidence suggests that this adjustment factor falls short of capturing the full range of human responses to chemical exposures, especially for susceptible subgroups.[25]

The World Health Organization International Programme on Chemical Safety ("IPCS")[26] found that an adjustment factor of approximately 42X was needed to account for the range in human variability in response to chemical exposure when estimating a risk-specific dose intended to protect 99% of the population, with larger factors necessary for protection at lower risk levels.[27] The EJ Technical guidance should provide a discussion of the limitations of a 10X uncertainty factor for addressing EJ concerns and recommend a factor of at least 42X to account for a broader range of dose-response variability in the population.

The best available scientific evidence also indicates that EPA should incorporate one or more additional uncertainty factors to account for multiple chemical and non-chemical stressors when assessing risk to potentially exposed or susceptible subpopulations, particularly when quantitative data supporting response-modifier relationships are not available.[28] Several governmental and scientific authorities have supported the use of an additional uncertainty factor to account for potential interactions among chemicals found in mixtures.[29] Additional uncertainty

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[23]U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. Footnote 43, p28.

[24]Lehman, AJ; Fitzhugh, OG 1954. 100-fold margin of safety. Quarterly Bulletin. Association of Food & Drug Officials of the United States 18:33-35.

[25] Varshavsky, J. R., Rayasam, S. D. G., Sass, J. B., Axelrad, D. A., Cranor, C. F., Hattis, D., Hauser, R., Koman, P. D., Marquez, E. C., Morello-Frosch, R., Oksas, C., Patton, S., Robinson, J. F., Sathyanarayana, S., Shepard, P. M., & Woodruff, T. J. (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.

[26] WHO IPCS, Guidance Document on Evaluating and Expressing Uncertainty in Hazard Characterization (2d. ed. 2017), http://www.inchem.org/documents/harmproj/harmproj/harmproj11.pdf.

[27] *Id.*

[28] Varshavsky, J. R., Rayasam, S. D. G., Sass, J. B., Axelrad, D. A., Cranor, C. F., Hattis, D., Hauser, R., Koman, P. D., Marquez, E. C., Morello-Frosch, R., Oksas, C., Patton, S., Robinson, J. F., Sathyanarayana, S., Shepard, P. M., & Woodruff, T. J. (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.

[29] Swedish Chems. Agency, *An Additional Assessment Factor (MAF) – A Suitable Approach for Improving the Regulatory Risk Assessment of Chemical Mixtures?* (2015), http://www.thomasbackhaus.eu/wp-content/uploads/2015-Backhaus-MAF-Rapport-5-15.pdf; ; Nat'l Rsch. Council, *Drinking Water and Health, Volume*

factors should be considered to account for the potential interactions between chemical and non-chemical stressors. This is particularly relevant when assessing risk to residents of fenceline communities or other susceptible subgroups who experience disproportionately high levels of non-chemical stressors compared to the general population. Detailed scientific rationales supporting these recommendations can be found in the attached publication: *Current Practice and Recommendations for Advancing How Human Variability and Susceptibility Are Considered in Chemical Risk Assessment*.[30] This paper specifically recommends "development of a separate default extrinsic variability factor (in addition to the 42X and age-related factors above) that would account for exposure to multiple chemical and non-chemical stressors."[31]

Given the risk assessment practices of other agencies, and newer understanding of human variability, EPA's current default adjustment factor of 10X does not accurately reflect human variability and susceptibility. For decades, scientific studies have shown that there is a greater-than-tenfold variation among the human population in response to chemical exposures. The best available scientific evidence indicates that higher uncertainty factors should be used to represent variability more accurately within the general population, especially when quantitative or relevant exposure-modifying dose-response data is not available. EPA should distinctly recommend in the EJ Technical Guidance that the application of uncertainty factors of at least 42X are applied to adequately account for human variability and vulnerability in the absence of quantitative data.

3. EPA should provide recommendations to use robust systematic review methodologies for evidence evaluation.

The EJ Technical Guidance does not include any mention of systematic review for evidence evaluation, apart from the stated definition of a Health Impacts Assessment, which is broadly defined as "a systematic process that uses an array of data sources and analytic methods."[32] The EJ Technical Guidance also fails to include any requirement for systematic review when evaluating evidence for EJ analysis. The lack of structured recommendations on how to evaluate scientific evidence for EJ analysis is a critical gap that could result in risk assessment that

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9: Selected Issues in Risk Assessment 99, 127–29 (1989), https://nap.nationalacademies.org/catalog/773/drinking-water-and-health-volume-9-selected-issues-in-risk

[30] Varshavsky, J. R., Rayasam, S. D. G., Sass, J. B., Axelrad, D. A., Cranor, C. F., Hattis, D., Hauser, R., Koman, P. D., Marquez, E. C., Morello-Frosch, R., Oksas, C., Patton, S., Robinson, J. F., Sathyanarayana, S., Shepard, P. M., & Woodruff, T. J. (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.

[31] Varshavsky, J. R., Rayasam, S. D. G., Sass, J. B., Axelrad, D. A., Cranor, C. F., Hattis, D., Hauser, R., Koman, P. D., Marquez, E. C., Morello-Frosch, R., Oksas, C., Patton, S., Robinson, J. F., Sathyanarayana, S., Shepard, P. M., & Woodruff, T. J. (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.

[32] *See* U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. p 90. Health impact assessment is defined as: "a systematic process that uses an array of data sources and analytic methods and considers input from affected individuals, communities, and other members of the public to identify the potential effects of a proposed regulatory action, policy, or project on the health of a population and the distribution of those effects within the population."

underestimates exposures and risks for susceptible populations, including EJ communities.

Based in part on recommendations provided by the National Academy of Sciences, Engineering, and Medicine (NASEM),[33] as well as developmental work at the National Toxicology Program, the University of California, San Francisco ("UCSF") and elsewhere, multiple EPA programs have adopted systematic review procedures to structure the identification, evaluation and integration of scientific evidence and to provide a robust foundation for drawing conclusions. To adhere to the best available scientific methods, EPA should provide specific recommendations in the EJ Technical Guidance to require systematic review for identifying, evaluating and integrating evidence as a necessary process for conducting an EJ analysis in any health regulation. Existing robust systematic review methods can be easily implemented by EPA. Both the UCSF Navigation Guide and the National Toxicology Program's Office of Health Assessment and Translation (OHAT) Approach for Systematic Review and Evidence Integration for Health Effects Evaluations have been used or recommended by the NASEM,[34,35,36] and their use and robustness have been demonstrated in case-studies in peer reviewed literature.[37] Further,

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[33] National Academies of Science, Engineering, and Medicine (NASEM). (2017).*Application of systematic review methods in an overall strategy for evaluating low-dose toxicity from endocrine active chemicals*[Report]. The National Academies Press. https://www.nap.edu/catalog/24758/application-of-systematic-review-methods-in-an-overall-strategy-for-evaluating-low-dose-toxicity-from-endocrine-active-chemicals

[34] National Academies of Science, Engineering, and Medicine (NASEM). (2017).*Application of systematic review methods in an overall strategy for evaluating low-dose toxicity from endocrine active chemicals*[Report]. The National Academies Press. https://www.nap.edu/catalog/24758/application-of-systematic-review-methods-in-an-overall-strategy-for-evaluating-low-dose-toxicity-from-endocrine-active-chemicals;

[35] National Academies Press. (2014).*Review of EPA's Integrated Risk Information System (IRIS) Process*. National Academies Press (US). https://www.ncbi.nlm.nih.gov/books/NBK230074/;

[36] National Academies of Science, Engineering, and Medicine (NASEM). (2018).*Progress toward transforming the Integrated Risk Information System (IRIS) program: A 2018 evaluation*(Report 9780309474917). The National Academies Press. https://doi.org/10.17226/25086

[37] Johnson, P. I., Sutton, P., Atchley, D. S., Koustas, E., Lam, J., Sen, S., Robinson, K. A., Axelrad, D. A., & Woodruff, T. J. (2014). The Navigation Guide—Evidence-Based Medicine Meets Environmental Health: Systematic Review of Human Evidence for PFOA Effects on Fetal Growth.*Environmental Health Perspectives*,*122*(10), 1028–1039. https://doi.org/10.1289/ehp.1307893; Koustas, E., Lam, J., Sutton, P., Johnson, P. I., Atchley, D. S., Sen, S., Robinson, K. A., Axelrad, D. A., Woodruff, T. J. (2014). The Navigation Guide—Evidence-based medicine meets environmental health: Systematic review of nonhuman evidence for PFOA effects on fetal growth. In *Environmental Health Perspectives*. https://doi.org/10.1289/ehp.1307177; Lam, J., Koustas, E., Sutton, P., Johnson Paula, I., Atchley D., S., Sen, S., Robinson K. A., Axelrad D. A., Woodruff T. J. (2014). The Navigation Guide—Evidence-Based Medicine Meets Environmental Health: Integration of Animal and Human Evidence for PFOA Effects on Fetal Growth. In *Environmental Health Perspectives*(Vol. 122, Issue 10, pp. 1040–1051). https://doi.org/10.1289/ehp.1307923; Lam, J., Koustas, E., Sutton, P., Johnson Paula, I., Atchley D., S., Sen, S., Robinson K. A., Axelrad D. A., Woodruff T. J. (2014). The Navigation Guide—Evidence-Based Medicine Meets Environmental Health: Integration of Animal and Human Evidence for PFOA Effects on Fetal Growth. In *Environmental Health Perspectives*(Vol. 122, Issue 10, pp. 1040–1051). https://doi.org/10.1289/ehp.1307923; Vesterinen, H. M., Johnson, P. I., Atchley, D. S., Sutton, P., Lam, J., Zlatnik, M. G., Sen, S., Woodruff, T. J. (2015). Fetal growth and maternal glomerular filtration rate: A systematic review. In*J Matern Fetal Neonatal Med* (Vol. 28, Issue 18, pp. 2176–2181). https://doi.org/10.3109/14767058.2014.980809; Johnson, P. I., Koustas, E., Vesterinen, H. M., Sutton, P., Atchley, D. S., Kim, A. N., Campbell, M., Donald, J. M., Sen, S., Bero, L., Zeise, L., Woodruff, T. J. (2016). Application of the Navigation Guide systematic review methodology to the evidence for developmental and reproductive toxicity of triclosan. In*Environ Int*(Vols. 92–93, pp. 716–728). https://doi.org/10.1016/j.envint.2016.03.009; Lam, J., Sutton, P., Kalkbrenner, A., Windham, G., Halladay, A., Koustas, E., Lawler, C., Davidson, L., Daniels, N., Newschaffer, C., & Woodruff, T. (2016). A systematic review and meta-analysis of multiple airborne pollutants and autism spectrum disorder. In*PLoS ONE*.

EPA's Office of Research and Development has adopted a systematic review methodology as part of its Integrated Risk Information System (IRIS) program.[38] Although we have provided comments regarding some inadequacies in the current IRIS method, it provides a strong basis for the inclusion of systematic review in the EJ Technical Guidance.

4. **EPA should delete or substantially revise the text regarding the distribution of regulatory costs in overburdened communities, which is not a consideration in the pursuit of environmental justice.**

EPA correctly focuses the EJ Technical Guidance on distributional assessment of health risks and benefits, but also includes discussion of the distribution of costs. EPA's fifth recommendation is:

> As relevant, analysts should consider any economic challenges that may be exacerbated by the regulatory action for relevant population groups of concern.
>
> - For instance, per E.O. 14008, it may be appropriate to consider how low-income populations are affected by price increases or to consider the distribution of economic costs (i.e., private and social costs) more broadly from an EJ perspective.[39]

The draft further states:

> This EJ Technical Guidance mainly focuses on approaches to assess the potential for differential exposure, risk, or health effects associated with regulatory actions on population groups of concern. However, certain directives (e.g., E.O. 13175, E.O. 14008, and OMB Circular A-4) identify the distribution of economic costs or challenges as an important consideration in developing policy alternatives and for regulatory analysis.[40]
>
> In the context of EJ, the distribution of health or environment effects alone might convey an incomplete – and potentially biased – picture of the overall burden faced by population groups of concern. For instance, if costs are unevenly distributed such that low-income households bear a larger relative share, it is possible that they may experience net costs even after accounting for environmental improvements.[41]

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https://doi.org/10.1371/journal.pone.0161851; Lam, J., Lanphear, B. P., Bellinger, D., Axelrad, D. A., McPartland, J., Sutton, P., Davidson, L., Daniels, N., Sen, S., Woodruff, T. J. (2017). Developmental PBDE Exposure and IQ/ADHD in Childhood: A Systematic Review and Meta-analysis. In*Environ Health Perspect*(Vol. 125, Issue 8, p. 086001). https://doi.org/10.1289/EHP1632; Lam, J., Koustas, E., Sutton, P., Padula, A. M., Cabana, M. D., Vesterinen, H., Griffiths, C., Dickie, M., Daniels, N., Whitaker, E., Woodruff, T. J. (2021). Exposure to formaldehyde and asthma outcomes: A systematic review, meta-analysis, and economic assessment. In*PLoS One*(Vol. 16, Issue 3, p. e0248258). https://doi.org/10.1371/journal.pone.0248258

[38] U.S. EPA. (2022).*ORD Staff Handbook for Developing IRIS Assessments*[Reports & Assessments]. U.S. Environmental Protection Agency, Office of Research and Development. available at: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370

[39] U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. p 18.

[40] *Id.* at p 75

[41] *Id.* at p 76

> Whether to undertake an analysis of economic costs as it pertains to EJ is a case-by-case determination. It will depend on the relevance of the information for the regulatory decision at hand, the likelihood that economic costs of the regulatory action will be concentrated among particular types of households, and the availability of data and methods to conduct the analysis.[42]

Distributional analysis of costs may be a pertinent consideration for some regulations, but it is questionable whether this is properly considered relevant to environmental justice. As quoted in the draft EJ Technical Guidance, environmental justice is defined by Executive Order 14096 as:

> the just treatment and meaningful involvement of all people, regardless of income, race, color, national origin, Tribal affiliation, or disability, in agency decision-making and other Federal activities that affect human health and the environment so that people:
>
> (i) are fully protected from disproportionate and adverse human health and environmental effects (including risks) and hazards, including those related to climate change, the cumulative impacts of environmental and other burdens, and the legacy of racism or other structural or systemic barriers; and
>
> (ii) have equitable access to a healthy, sustainable, and resilient environment in which to live, play, work, learn, grow, worship, and engage in cultural and subsistence practices.[43]

This definition contains no mention of costs or prices. The EJ Technical Guidance discusses the potential for net costs to low-income households as a reason for considering the distribution of costs, but by definition, environmental justice is specifically concerned with addressing the disproportionate and adverse health effects, not the net benefits (or net costs) of regulations. In putting forward the notion of potential net costs to residents of EJ communities, EPA's draft indirectly raises the potential of scenarios in which overburdened populations could be asked to trade away health risk reductions focused on their community to avoid the prospect of increased prices. Asking EJ communities to consider such a tradeoff is contrary to the objective of the Executive Order to mitigate disproportionate health burdens.

It is also important to recognize that the benefits of a regulation may be highly concentrated in an EJ community, but it would be rare for the costs of a regulation to be similarly concentrated in such a community. For example, if cost incidence is realized through increased prices, those costs would most likely be shared throughout the economy and not focused on a highly-exposed community. If those costs are so great as to call into question the desirability of a policy intervention, this should be done on the basis of economy-wide costs and not on distributional analysis that weighs costs and benefits to an overburdened community. The priority of EJ is to reduce the disproportionate burden.

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[42] U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. p 76.

[43] Executive Order 14096. (2023). *Revitalizing Our Nation's Commitment to Environmental Justice for All* (Vol. 88, No. 80). https://www.govinfo.gov/content/pkg/FR-2023-04-26/pdf/2023-08955.pdf.

If EPA decides to retain the section on distribution of costs in the final revision of the EJ Technical Guidance, it is critical to add important caveats. For example, analysts and risk managers should never presume that residents of EJ communities would be willing to forgo health-protective interventions when monetized costs to their community (e.g. in the form of projected price increases) exceed the monetized benefits to the community.

In addition, EPA should not cite Executive Orders 13175 and 14008 in support of including analysis of the distribution of costs in EJ analysis. E.O. 13175 discusses costs in the context of unfunded mandates to tribes, rather than as offsetting the health benefits of a regulation.[44] This is not pertinent to consideration of environmental justice. Contrary to the assertion in the EJ Technical Guidance, E.O. 14008 makes no mention of price increases or the costs of mitigating climate change; the word "cost" appears only in the context of oil and gas development on public lands.[45] The only mentions in the E.O. relevant to economics and EJ communities are the economic challenges associated with the adverse consequences of climate change, along with discussion of economic growth and opportunity. We recommend deletion of the text that references these Executive Orders to support the inclusion of distributional analysis of costs in the EJ Technical Guidance.

5. EPA's proposed "fit for purpose" model is inconsistent with expert recommendations and "intended purpose and context of use" should be used instead.

The EJ Technical Guidance doubles down on using "fit-for-purpose" language, which is vague and unclear. To accurately evaluate and address EJ concerns in relation to chemical exposures or toxic sites, EPA needs to apply consistent and transparent language that define the methods for exposure and risk assessment for its indented purpose.

The EJ Technical Guidance states:

> "Fit-for-Purpose refers to the concept that risk assessments and associated products should be suitable and useful for their intended purpose(s), particularly for informing choices among risk management options (U.S. EPA, 2014b)."[46]

Appropriately targeting a risk assessment to meet the needs of risk managers is an important part of planning a risk assessment and was recommended by the NRC in *Science and Decisions.* EPA has increasingly adopted the term "fit for purpose" as a shorthand representation of this concept in recent years. While the meaning of this term and its use in practice are frequently unclear, EPA often uses it to justify decisions that inappropriately narrow the scope of risk assessment, contrary to stakeholder requests. NASEM in their 2023 report Building Confidence in New Evidence Streams for Human Health Risk Assessment: Lessons Learned from Laboratory

[44] Executive Order 13175 (2000). Consultation and Coordination with Indian Tribal Governments. https://www.epa.gov/laws-regulations/summary-executive-order-13175-consultation-and-coordination-indian-tribal
[45] Executive Order 14008. (2023). *Tackling the Climate Crisis at Home and Abroad*. https://www.federalregister.gov/documents/2021/02/01/2021-02177/tackling-the-climate-crisis-at-home-and-abroad
[46] U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. p31.

Mammalian Toxicity Tests emphasized that "the term 'fit for purpose' is not clearly and consistently defined, so there is little guidance as to how to specify the intended use…The committee therefore uses the term 'intended purpose and context of use' to encompass these ideas, and this is further elaborated."[47] In line with this NASEM recommendation, EPA should stop using the term "fit for purpose" and instead use "intended purpose and context of use," while also elaborating on the details of the proposed methodology and justification for its use.

6. EPA should expand its proposed definition of "overburdened" in the EJ Technical Guidance to include higher chemical exposures.

While the document accurately defines "overburdened" populations, groups or communities as having higher vulnerability and susceptibility to the environmental harms and risks,[48] it is important to note that overburdened also includes higher chemical exposures including multiple and cumulative chemical exposure, in addition to the intrinsic and extrinsic factors as defined in the EJ Technical Guidance. EJ communities often experience an unequal burden of multiple chemical exposures contributing to the EJ concerns the Technical Guidance aims to address. Specifically including the increased burden of exposure to environmental chemicals in the definition of "overburdened" will ensure that the risks to a group, community or population are being fully considered.

[47] 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*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26906. p 74.

[48] U.S. EPA, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis, Draft 2023. EPA document number 2023-25126. p 20.