August 30, 2023

Dr. Christopher Frey
Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Request for Comment: Cumulative Risk Assessment Guidelines for Planning and Problem Formulation (Agency/Docket Number: EPA-HQ-ORD-2013-0292)

Dear Dr. Frey,

We at the Environmental Data and Governance Initiative (EDGI) are grateful for the opportunity to comment on EPA's draft Guidelines for Cumulative Risk Assessment Planning and Problem Formulation. We appreciate the agency's recognition that understanding and addressing environmental risks as they occur in aggregate and concert with other vulnerabilities, is paramount for protecting public health. However, we are disappointed that the agency's effort to provide guidance on cumulative risk assessment (CRA) largely focuses on generalized excuses to *avoid* conducting cumulative risk assessments, rather than guiding agency personnel to address and incorporate inherent uncertainties to make the most comprehensive assessment possible.

There are three key issues, which we will describe in detail below, that EDGI urges the EPA to address and incorporate into its final guidelines for cumulative risk assessments.

(1) The draft guidelines suggest that CRAs are unsuitable for environmental justice communities due to the inherent complexities of exposures and stressors. Dismissing real-world exposure scenarios as too complex and uncertain runs entirely contrary to the purpose of CRAs and severely limits the utility of CRAs to safeguard human health meaningfully.
(2) The lack of specificity in the draft guidelines regarding what is an acceptable level of uncertainty opens the door to pushback and exploitation and does not actually guide personnel in assessing, addressing, or incorporating uncertainties into CRAs.

(3) The draft guidelines undermine the potential impact of CRAs as tools to protect human health by converting them into a flawed risk assessment paradigm.

I. Incorporate complexities and address uncertainties

Complexities are inherent with aggregate exposures and compounding vulnerabilities, and these complexities have driven the need for cumulative risk assessments. However, rather than presenting or describing strategies for including factors with relatively high complexities, the draft guidelines repeatedly state that many factors will not be able to be included in a CRA, or a CRA may not be possible at all if the situation is too complex or if the uncertainty is too high. On EPA's risk assessments webpage, the EPA acknowledges the need to incorporate real-world complexities, stating, "In real life, however, information is usually limited…risk assessors often must estimate exposures and use judgment to calculate risks…a key part of all good risk assessments is a fair and open presentation of the uncertainties, including data gaps and limitations of models used to estimate exposure and effects" (www.epa.gov/risks/about-risk-assessment). However, in these draft guidelines that are explicitly about formulating *cumulative* risk assessments, the EPA does not make any attempt to guide personnel on estimation or incorporation of uncertainties and instead dismisses real-world complexities as too challenging to incorporate into CRAs. The overall dismissal of complexities understood as beyond the scope of CRAs undermines the purpose and utility of CRAs.

The dismissal of real-world complexities in these draft guidelines sidelines the last two decades of progress recognizing the role of nonchemical stressors in cumulative exposures. While these draft guidelines state they are in response to Executive Order 13985 *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*, the guidelines specifically identify the conditions of environmental justice communities as those that are too uncertain to include in CRAs, stating, for example, "The lack of available methods for assessing and quantifying these [nonchemical] stressors may limit their incorporation into an analysis plan" (p 12, lines 38-39), and that CRA may not be suitable "when there are concentrated burdens of multiple and different hazards lacking health effect data or concerns of disproportionate impacts among populations" (p 4, line 23).

We appreciate that these CRA draft guidelines point to emerging cumulative impacts assessments (CIA) as better equipped to incorporate complex stressor and

exposure-response modifiers such as nonchemical stressors. We agree that this is an exciting and fruitful field. We applaud the agency's attention to this critical issue. However, the EPA has not cited or presented anything that distinguishes the authorities, outcomes, or impacts of conducting a CIA instead of a CRA in these draft guidelines. Moreover, the EPA has not published guidelines or a framework for CIA, even though the EPA's Congressional Budget Justification for FY 2024 states, "By September 30, 2023 EPA expects to develop and implement a cumulative impacts framework" (p iv). Without a fully described alternative with "adequate" methods for incorporating nonchemical stressors and exposure-response modifiers in CIAs, the CRA draft guidelines' dismissal of complex situations and suggestion to apply CIAs rings hollow. CIAs are not yet an option, so excluding complexities from CRAs excludes real-life vulnerabilities from agency consideration and decision-making for the foreseeable future.

EDGI appreciates the anticipation of future research and the evolution of CRA described in Appendix A. We also support the investments the EPA makes in cumulative risk and cumulative impacts research. However, greater emphasis on applying the progress achieved thus far and the research strides over the last few decades is critical. Based on materials EDGI received through Freedom of Information Act requests, we calculate that the EPA has invested approximately $67 million in extramural research related to cumulative exposure, risk, and impacts since 2000. The EPA has also stated in every strategic plan since 1997 (except the strategic plan released in 2018), that the agency will prioritize cumulative exposures/risks/impact research. For example, in the 1997 strategic plan EPA stated, "EPA research activities will pursue the development of new tools to better characterize exposures (including consideration of cumulative exposures described above) and overall risks…" (p 36). Subsequent strategic plans and Congressional budget justifications were more specific, such as the FY 2012 Congressional Budget Justification that stated, "In FY 2012, the EJ program will work with Regional and program offices to apply effective methods suitable for decision-making involving disproportionate environmental health impacts on minority, low-income, and Tribal populations" (p 336). EPA Annual Performance and Accountability reports indicate that the agency consistently meets 100% of its cumulative risks and impacts goals. However, the tangible results of these research and program investments are unclear as we see the EPA asking the same questions ten and twenty years.

Over the last 40 years, environmental justice leaders have asked for the acknowledgment and accounting of cumulative exposure. While the EPA has slowly funded and conducted

related research, the communities affected have experienced immense harm. This pattern cannot continue. We need action now.

We agree that we need rigorous science to underlie decisions, but further delays only harm communities. If the EPA doesn't have sufficient data or methods to address complex, real-world situations, the default does not need to be to dismiss community exposures and vulnerabilities. The default could and should be to halt the expansion of industrial interests. The EPA and the scientific community have extensive data demonstrating industrial harm to human and environmental health. We need such rigorous science applied with the explicit recognition that people are being harmed every day under our current risk assessment and decision-making paradigm, and with the explicit goal of improving ecosystem and human health, not only to set a high bar for attempting to protect people.

EDGI urges the EPA to revamp these draft guidelines to focus on including complex factors with multiple uncertainties in cumulative risk assessments. We respect the EPA's indication that the history of an issue can be an initiating factor (p 12, lines 1-7), and we recommend that the EPA work to incorporate risks and exposures across temporal scales more in CRA analyses. We appreciate the diversity of fields recognized as contributing to CRA science (p 24, lines 17-20) and recommend EPA invite round tables of leaders in these respective fields to jumpstart more thorough and effective guidelines for assessing and addressing cumulative risks.

II. Be specific about uncertainties

The draft guidelines frequently suggest that there is an unacceptable level of uncertainty in the conceptual model or relationships between stressor, exposure, and response in complex situations like those found in environmental justice communities (e.g., p 4, lines 25-31). However, the guidelines do not provide any specificity about what might or might not be an acceptable threshold of uncertainty. As the draft guidelines currently read, a risk assessor could reasonably determine that there are no real-world situations for which a CRA is a suitable approach. This vagueness about what is too high a level of uncertainty, particularly while implying that that threshold has been crossed, opens the entire CRA process to pushback and exploitation of fundamental concepts of scientific uncertainty and data limitations, while offering risk assessors no tangible guidance that they might apply.

Similarly, the three screening steps provided to help determine whether a CRA is feasible once it has been deemed appropriate (p 4, lines 8-11), are sufficiently vague to provide no tangible value to assessors, but offer an excuse to avoid conducting CRAs. The draft guidelines do not define “adequate” data or methods, nor “acceptable” levels of uncertainty, nor “sufficient” resources, but instead, leverages each of these as a screen to choose not to conduct a CRA.

Given the long, storied history of industry and allied politicians' attacks on science and the standard concepts of uncertainty (e.g. the failed Honest Act of 2017), it is irresponsible of the EPA to publish guidelines that explicitly refrain from guiding, and themselves sow more doubt. Rather than simply stating misgivings related to uncertainty and the suitability and feasibility of CRAs, the EPA should provide structure about uncertainty goals, strategies for achieving those goals, and alternatives for when that is not possible.

III. Embrace expansiveness and introduce precautionary principles to leverage CRAs for real change

Existing risk assessment frameworks have failed to protect environmental justice communities from disproportionate environmental harms. The failure derives from neglecting to account for real, layered exposures and varied responses, and their primary purpose is to distinguish between artificially constrained, capitalism-based risk management choices. Fitting CRAs into this flawed existing risk management paradigm severely limits the potential effectiveness of CRAs.

Throughout the draft guidelines, the EPA states and implies ways to scale down CRAs rather than suggesting ways to ensure they account for *cumulative* exposures. Beyond suggesting that CRAs are inappropriate for situations with real-world complexities (as discussed above), the guidelines also seek to narrow the scope of CRAs that are deemed appropriate with adequate data. For example, the guidelines state, “The consultation might include obtaining insight on how to narrow the focus to fewer or more readily addressed stressors” (p 19, lines 24-25). The agency loses the potential benefits of expansive, cumulative risk assessments by narrowing the focus to easily addressed risks.
As written, the draft guidelines can damage communities affected by risk assessments and risk management decisions. The guidelines allow risk assessors to entirely dismiss negative health impacts if they have not developed interventions to address them. Specifically, the

guidelines state, “Other stressors or health outcomes that would presumably not be affected through implementation of any of the interventions under consideration could be eliminated from the CRA” (p 18, lines 13-15). While the guidelines say that factors screened out could be reintroduced in later analyses, this approach to let established interventions guide our assessment of the problem inherently constrains and obscures our understanding of the problems and, therefore, our future solutions.

EDGI applauds the flexibility and seeds of more expansive CRAs possible using the three different approaches described in the draft guidelines: stressor-based, effects-based, and vulnerability-based approaches (p 23). Combining these approaches lends the process adaptability necessary to incorporate various stressors and responses. We urge the EPA to apply this broad and more encompassing approach to all facets of CRA.

IV. Conclusion

The draft Guidelines for Cumulative Risk Assessment Planning and Problem Formulation include some strides forward in the agency’s approach to CRAs. However, we at EDGI are disappointed that the guidelines provide very little guidance for risk assessors to actually integrate cumulative risks into their assessment process. Rather, the guidelines quickly dismiss the applicability of CRAs to complex real-world situations. The guidelines undermine the potential utility of CRAs, and open the whole practice of CRAs to attacks on relevant, rigorous science. We urge the EPA to provide more specificity regarding data and methods metrics, and adopt an explicitly health-protective and precautionary approach to CRAs and resulting actions. Doing so may well require a reconsideration of assumptions and practices governing the entire risk assessment process, as the agency currently defines it. We urge the agency to expand its search for alternatives that may take better account of the many variations in vulnerability revealed by today’s science, and that can better ground the ongoing reorientation of its regulatory work to better protect the most vulnerable Americans.