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Comments from Academics, Scientists and Clinicians on Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government

Submitted online via Regulations.gov to docket OMB-2021-0005

These comments are submitted by the University of California, San Francisco's Program on Reproductive Health and the Environment (UCSF PRHE) on behalf of the undersigned academics, scientists, and clinicians. The Program is in a top ranked obstetrics and gynecology department in one of the most prestigious medical centers in the US. The mission of UCSF PRHE is to create a healthier environment for human reproduction and development through advancing scientific inquiry, clinical care and health policies that prevent exposures to harmful chemicals in our environment.[1] Our research illuminates how chemicals can harm health, and we promote evidence-based actions to prevent such harms. Through internal and external partnerships, we implement a multi-pronged strategy to transform environmental science into improved public policy by: (1) producing the best science; (2) bringing the science to decision-making through direct engagement and communications; (3) engaging scientist and health professional leaders in promoting better policy; and (4) developing innovative tools to harness the science to prevention-focused decisions in clinical and policy arena.

We are the only academic scientific institution substantively engaged on implementation of the Toxic Substances Control Act (TSCA) and U.S. Environmental Protection Agency (EPA) rulemaking. Since 2017 we have provided unique scientific expertise via 62 written comments (garnering collectively over 1000 signatures and totaling over 1300 pages) as well as oral testimony. [2] We developed evidence-based priority recommendations to improve hazard and risk assessment to prevent harms from chemicals and pollutants and strengthen EPA and its mission to protect public health in six critical areas: Chemical Policy, Systematic Review; Conflicts of Interest; Environmental Justice; Data Infrastructure, and Funding. These were signed by the International Society for Environmental Epidemiology, North American Chapter, Natural Resources Defense Council, Children's Environmental Health Network, Autism Science Foundation and over 70 individual signatories.[3]

We declare collectively that we have no direct or indirect financial or fiduciary interest in any chemical or product that is the subject of these comments. The co-signers' institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support.

Questions regarding these comments may be directed to the Program's Associate Director of Science and Policy, Nicholas Chartres at Nicholas.Chartres@ucsf.edu.

[1] UCSF Program on Reproductive Health and the Environment. Available: prhe.ucsf.edu/about
[2] UCSF Program on Reproductive Health and the Environment. Chemical Policy Available: https://prhe.ucsf.edu/chemical-policy
[3] UCSF Program on Reproductive Health and the Environment. Prioritizing Science and Public Health. Available:https://prhe.ucsf.edu/recommendations-epa

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We appreciate the opportunity to provide written comments on the Office of Management and Budget's (OMB) Request for Information (RFI) around Advancing Equity and Support for Underserved communities.[4] Executive Order 13985 signals an important commitment to advancing "equity, civil rights, racial justice, and equal opportunity," and we strongly agree "that the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality." In order to achieve this vision, substantial improvements to the policies and programs of the U.S. Environmental Protection Agency (EPA) are critical. Inequities in exposures to environmental contaminants are an important contributing factor in health inequities and can have a significant effect on the quality of life in underserved communities.[5] Improved approaches that support community participation in EPA's programs, and not just the opportunity for community input, are critical to ensuring that EPA is advancing equity for all.[6] Principles of environmental justice and community participation must be integrated into every aspect of environmental policy and EPA's work.[7]

The first step to addressing environmental health inequities is to adopt environmental justice principles to guide policymaking. In October 1991, the People of Color Environmental Leadership Summit [8,9] affirmed principles of Environmental Justice that include:

- That public policy be based on mutual respect and justice for all peoples, free from any form of discrimination or bias
- Ethical, balanced, and responsible uses of land and renewable resources in the interest of a sustainable planet for humans and other living things
- Universal protection from extraction, production and disposal of toxics and hazardous wastes and poisons that threaten access to clean air, land, water, and food
- The right to participate as equal partners at every level of public environmental decision-making, including needs assessment, planning, implementation, enforcement, and evaluation
- The right of all workers to a safe and healthy work environment without being forced to choose between an unsafe workplace and loss of livelihood

These principles should be adopted by EPA.

Our following comments address Area 1 (Equity Assessments and Strategies) and Area 5 (Stakeholder and Community Engagement) of the RFI with a particular focus on EPA programs. [10] We also note that OMB has a critical role to play in the implementation of policies and procedures to advance equity at

[4] US OMB. (2021). Methods and Learning Practices for Advancing Equity in Support for Underserved Communities Through Government. Available: https://www.regulations.gov/docket/OMB-2021-0005

[5] Environmental Health Perspectives. (2020). Environmental Racism Collection: Exposure and Health Inequities in Black Americans. Available: https://ehp.niehs.nih.gov/curated-collections/environmental-racism

[6] Solomon, G. M., Morello-Frosch, R., Zeise, L., & Faust, J. B. (2016). Cumulative Environmental Impacts: Science and Policy to Protect Communities. *Annual Review of Public Health*, *37*(1), 83–96. https://doi.org/10.1146/annurev-publhealth-032315-021807

[7] UCSF PRHE. (2020). Recommendations to Strengthen EPA and its Mission to Protect Public Health, Environmental Justice. Available: https://prhe.ucsf.edu/recommendations-epa#EJ

[8] Mohai, P., Lantz, P. M., Morenoff, J., House, J. S., & Mero, R. P. (2009). Racial and socioeconomic disparities in residential proximity to polluting industrial facilities: evidence from the Americans' Changing Lives Study. *American Journal of Public Health*, *99 Suppl 3*(Suppl 3), S649–S656. https://doi.org/10.2105/AJPH.2007.131383

[9] Mohai P, Bryant B. (2020). Thirty Years Working for Environmental Justice: Commemorating the 1990 Michigan Conference on Race and the Environment and Looking Toward the Future. *New Solutions : a Journal of Environmental and Occupational Health Policy,* 30(3):204-210. DOI: 10.1177/1048291120961342.

[10] US OMB. (2021). Methods and Learning Practices for Advancing Equity in Support for Underserved Communities Through Government. Available: https://www.regulations.gov/docket/OMB-2021-0005

EPA: by ensuring that EPA budgets have sufficient resources to ensure full community participation in EPA's programs, by updating OMB's guidance to regulatory agencies (such as Circular A-4[11]) to appropriately emphasize the importance of equity considerations in regulatory analysis and regulatory policy, and finally by fully supporting equity objectives in EPA's assessments, policies and regulatory actions. We also recommend that there be a specific plan of implementation of changes to address our recommendations. Further, this plan should include deadlines for actions that should begin within the next year. Finally, in areas where scientific assessment is ongoing, federal agencies can us provisional values or default values as interim methods or estimates that can be used in policy and rulemaking while data is being collected.

Comments on Area 1: Equity Assessments and Strategies. Approaches and methods for holistic and program- or policy-specific assessments of equity for public sector entities, including but not limited to the development of public policy strategies that advance equity and the use of data to inform equitable public policy strategies.

We present recommendations in three broad areas related to equity assessments and strategies at EPA and concerning regulatory policy more generally:

- Baseline assessments of equity in exposures, risks, and health outcomes;
- Assessment of the equity consequences of regulatory actions; and
- Research to better understand and characterize inequities.

Baseline assessments of equity in exposures, risk, and health outcomes

EPA should conduct broad assessment activities to identify inequities by social determinants of health (e.g. race/ethnicity and socioeconomic status) in exposures to environmental contaminants, inequities in risks resulting from those exposures, and inequities in health outcomes that are influenced by environmental exposures. Although EPA has some existing efforts to assess exposures or risks within various program areas, they should be expanded to encompass more environmental contaminants and more EPA program areas; and to be more focused on identifying inequities (rather than whole-population assessment without subgroup comparison).

These baseline assessments are a critical element in holistic assessment of agency practices and policies, as they identify important disparities that have not been ameliorated by policies implemented to date. This approach, separate from regulatory analyses (discussed below) are necessary for identifying and addressing systemic inequities.

EPA's National Air Toxics Assessment (NATA) is an excellent example of a baseline assessment of exposure and risk.[12] NATA presents an assessment of outdoor air quality for Clean Air Act hazardous air pollutants across the entire country, at the census tract level, and because of NATA, estimates of air toxics concentrations, updated every three years, are available for every community in the United States. The most recent NATA represents air quality in the year 2014 and was instrumental in identifying communities in Louisiana's "cancer alley" that are overwhelmingly Black and low-income,

[11] US Office of Management and Budget. (2003). Circular A-4. Available: https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf

[12] Environmental Protection Agency. (2021). National Air Toxics Assessment. Available: https://www.epa.gov/national-air-toxics-assessment.

and that also have extremely high cancer risks as a result of air toxics exposures, particularly chloroprene and ethylene oxide, from nearby industrial facilities.[13,14]

Strengths of NATA include its comprehensive coverage – it provides estimates for 180 air toxics, considering all known sources of emissions, in every community in the United States – and applies a consistent framework to generate estimates on a regular periodic basis in a format that is familiar to state and local governments, academic and NGO scientists, and reporters. A further important strength of NATA is that it is not tied to any particular risk management action; it is a regularly-updated assessment that assesses risks from all air toxics exposures rather than just exposures affected by a particular regulation or in selected locations. For many communities, NATA is the *only* source of information on concentrations of environmental contaminants in the local environment.

Building on the existing strengths of NATA, EPA should continue to improve NATA by gathering better local-level data on emissions, especially in highly-impacted communities, in order to correct its tendency to underestimate exposure and risk. EPA should also enhance its approach to releasing NATA results to shine a greater light on the equity implications of the NATA results and to do so annually. To date, assessment of air toxics inequities using NATA results has been conducted by outside parties – academics, non-governmental organizations, and journalists. Analysis of equity impacts of air toxics risks should be incorporated into EPA's release of NATA. For example, EPA should provide information about the demographic composition (race/ethnicity, income) of populations living in the census tracts exposed to the highest cancer and non-cancer risks from air toxics.

An important set of additional activities for EPA to undertake in conducting baseline assessment of equity is to expand the NATA approach to other critical EPA program areas. To fully understand how EPA programs may be better targeted to address exposure and health inequities, it is critical that the Agency take this broader view that assesses whether and where inequities are occurring across geographic locations, considering multiple pollutants, multiple pathways of exposure, and multiple health outcomes.[15] These assessments should also consider pollutants that are not currently regulated as well as regulated pollutants. For example, any assessment of inequities from drinking water exposures must consider exposure to 1,4-dioxane, PFOS and PFOA – highly hazardous chemicals with widespread occurrence in drinking water, none of which have a National Primary Drinking Water Regulation.

Another approach to broad assessment of baseline exposures, risks and health outcomes is represented by EPA's environmental indicators programs, including America's Children and the Environment (ACE),[16] the Report on the Environment (ROE),[17] and Air Trends.[18] These indicator reports provide excellent status and trends data for various aspects of environmental quality, exposure, and health outcomes in an easy-to-access format. In many cases, these reports provide assessments of equity, but this could be

[13] EPA Office of Inspector General. (2021). EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene and Ethylene Oxide-Emitting Source Categories to Protect Human Health. Available: https://www.epa.gov/sites/production/files/2021-05/documents/_epaoig_20210506-21-p-0129.pdf

[14] Lerner, S. (2019, February 24). *The EPA's Bungled Response to an Air Pollution Crisis Exposes a Toxic Racial Divide*. The Intercept. Available: https://theintercept.com/2019/02/24/epa-response-air-pollution-crisis-toxic-racial-divide/.

[15] Koman PD, Singla V, Lam J, Woodruff TJ (2019) Population susceptibility: A vital consideration in chemical risk evaluation under the Lautenberg Toxic Substances Control Act. PLOS Biology 17(8): e3000372. https://doi.org/10.1371/journal.pbio.3000372

[16] Environmental Protection Agency. (2020). America's Children and the Environment. Available: https://www.epa.gov/americaschildrenenvironment.

[17] Environmental Protection Agency. (2021). *EPA's Report on the Environment (ROE)*. EPA. Available: https://www.epa.gov/report-environment.

[18] Environmental Protection Agency. (2021). National Air Quality: Status and Trends of Key Air Pollutants. Available: https://www.epa.gov/air-trends.

done more extensively and with greater prominence. For example, ACE provides data by race/ethnicity and income for most of its indicators, including criteria air pollutant, contaminated lands, blood lead levels, and asthma prevalence.[19,20,21,22] For some topics, the indicator values by race/ethnicity and income are displayed prominently in graphics, while for other indicators the demographic break-outs are available only in downloadable tables. An important next step in the evolution of ACE is to upgrade the website design so that indicator values by race/ethnicity and income are readily accessible and prominently displayed in graphics. An important additional step for other EPA indicators programs is to expand their presentation of data with consideration of race/ethnicity and income. For example, the presentations of criteria pollutants concentrations in the ROE and Air Trends do not incorporate demographic data that would enable comparisons of air quality experienced by different race/ethnicity and income groups.

A third approach to assessing and visualizing baseline exposures, risk and health outcomes is represented by EPA's EJSCREEN,[23] EPA's environmental justice (EJ) mapping and screening tool that provides a nationally consistent dataset and approach for combining environmental and demographic indicators. EJSCREEN includes 11 "EJ indexes" that each present demographic data associated with a single environmental indicator (such as air toxics risk, particulate matter and ozone concentrations, and proximity to hazardous waste sites). While EJSCREEN is useful in combining environmental data with demographic data, and in allowing comparison of different geographic locations, an important shortcoming is that it considers environmental indicators only one-at-a-time. This approach fails to account for the reality of exposures in what are termed as "environmental justice communities," where residents are exposed to multiple types of hazards. For example, EJSCREEN does not directly address the combination of multiple hazards - such as high particulate matter exposures plus proximity to hazardous waste sites, in a community with low incomes or a majority non-white population– which is a critical element of what makes overburdened communities overburdened. In addition, while consideration of race/ethnicity and income are central elements of EJSCREEN, it does not account for other vulnerability factors, such as measures of health status which have been identified by the National Academy of Sciences (NAS)[24] as contributing to increase risks from chemical exposures (e.g. family medical history, chronic disease prevalence).

A better approach is provided by CalEnviroScreen from the state of California.[25, 26] CalEnviroScreen is a mapping tool designed to identify communities that are most affected by many sources of pollution in combination and provides a relative ranking of communities. CalEnviroScreen incorporates 12 pollution burden indicators and 8 indicators of population characteristics that identify relative population vulnerabilities to the effects of pollution exposure. Additionally, the indicators used in CalEnviroScreen

[19] Environmental Protection Agency. (2020). America's Children and the Environment ed. 3, Appendix A: Data Tables, Environments and Contaminants. Available: https://www.epa.gov/sites/production/files/2019-07/documents/enviro-contam-criteria-pollutants-data-tables.pdf

[20] Environmental Protection Agency. (2020). America's Children and the Environment ed. 3, Environments and Contaminants - Contaminated Lands. Available: https://www.epa.gov/americaschildrenenvironment/ace-environments-and-contaminants-contaminated-lands

[21] Environmental Protection Agency. (2020). America's Children and the Environment ed. 3, Biomonitoring - Lead. Available: https://www.epa.gov/americaschildrenenvironment/ace-biomonitoring-lead#B2

[22] Environmental Protection Agency. (2020). America's Children and the Environment ed. 3, Indicator H2, Asthma Prevalence. Available: https://www.epa.gov/americaschildrenenvironment/ace-health-respiratory-diseases#H2

[23] Environmental Protection Agency. (2021). EJSCREEN: Environmental Justice Screening and Mapping Tool. Available: https://www.epa.gov/ejscreen.

[24] National Research Council (US) Committee on Improving Risk Analysis Approaches Used by the U.S. EPA. Science and Decisions: Advancing Risk Assessment. Washington (DC): National Academies Press (US); 2009. PMID: 25009905.

[25] California Office of Environmental Health Hazard Assessment. (2017). CalEnviroScreen 3.0. Available: https://oehha.ca.gov/media/downloads/calenviroscreen/report/ces3report.pdf

[26] California Office of Environmental Health Hazard Assessment. (2021). CalEnviroScreen. Available: https://oehha.ca.gov/calenviroscreen.

are regularly updated and added in direct consultation with impacted communities in order to meet their needs and realistically address exposures.[27]

EPA should upgrade EJSCREEN by applying the methods and tools of CalEnviroScreen to compile nationally consistent data for identifying overburdened communities, creating a detailed visualization tool for the exposures and factors that increase a population's susceptibility to industrial chemicals. A national version of CalEnviroScreen, or "US-EnviroScreen," should consider mapping of sensitive populations with asthma, cardiovascular disease, and low birthweight, as well as socioeconomic factors with evidence of heightened vulnerability to environmental contaminant exposures, such as educational attainment, housing burden, linguistic isolation, poverty, and unemployment.[28]However the ultimate selection of particular factors or metrics in this tool should be determined through a participatory process with underserved communities.[29] Creating a US-EnviroScreen will provide EPA and the public with a better understanding of exposures to multiple chemicals as well as overlapping susceptibilities in the population. A cumulative approach that combines data for various hazards and vulnerabilities will allow EPA to better identify overburdened communities. With improved data visualization, local governments will have improved information to help with siting and managing industrial facilities and infrastructure in a more environmentally just manner and protect vulnerable populations from cumulative exposures.

Assessment of the equity consequences of regulatory actions

Executive Order 12898 requires EPA to assess the "disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations."[30] As part of implementation of this requirement, the Federal Register notice for each EPA proposed and final rulemaking includes a section presenting its evaluation of how the rule relates to the Executive Order. This section is typically very cursory and provides little, if any, quantitative analysis of disparate exposures, risks, or health outcomes. EPA must provide meaningful—not boilerplate—publicly available environmental justice analyses of its risk management actions, examining impacts on overburdened communities and opportunities to address pollution disparities. Analyses should be shared as part of the public record and methodologies shared with state and local governments.

Communities at risk must be better defined

The analytic foundation for regulatory assessments of equity impacts must begin with how EPA conducts its hazard and risk assessments. Each hazard and risk assessment must consider the extent of potential differences in risk of adverse effects in susceptible populations, including at-risk communities where health problems from chemical exposures and pollutants may be exacerbated by discrimination, poverty, and other chronic stressors.

An appropriate EPA definition of susceptible populations is necessary to ensure that EPA risk assessments have appropriately considered all factors that may contribute to susceptibility. In the

[27] California Office of Environmental Health Hazard Assessment. (2021). Draft CalEnviroScreen 4.0. Available: https://oehha.ca.gov/calenviroscreen/report/draft-calenviroscreen-40.

[28] California Office of Environmental Health Hazard Assessment. (2017). CalEnviroScreen 3.0. Available: https://oehha.ca.gov/media/downloads/calenviroscreen/report/ces3report.pdf

[29] County Health Rankings & Roadmaps. *Measures & Data Sources: 2021 Measures*. https://www.countyhealthrankings.org/explore-health-rankings/measures-data-sources/2021-measures.

[30] 59 FR 7629

context of the Toxic Substances Control Act, EPA promulgated a narrow definition of "potentially exposed or susceptible subpopulations." We recommend that EPA adopt an expanded definition of susceptible populations, adapted from the definition found in EPA's January 2017 proposed TSCA risk evaluation framework rule,[31] which focuses on identifying intrinsic and extrinsic factors. Our proposed definition includes consideration of racism and other acquired factors, and the role of communities:

> *"A susceptible, which includes vulnerable, population is a group of individuals or communities within the general population who 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 women, workers, or the elderly. Susceptibility can be due to intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits, health status) and extrinsic (e.g., pre-existing disease, geography, socioeconomic, racism/discrimination, cultural, immigration status, workplace) factors when identifying this population."*

It is critical that EPA explicitly name parameters that qualify groups as susceptible or vulnerable populations, as it is an important step to ensure their needs are addressed in hazard and risk assessments. Hazard assessments should affirmatively examine any population characteristics that may be associated with differential response to a hazardous exposure to determine the equity implications. For example, if evidence indicates that a particular genetic polymorphism results in greater likelihood of an adverse effect, it is important to examine any available data regarding the prevalence of that polymorphism by race/ethnicity. Findings of epidemiological studies, if available, must be examined to determine whether there are differences in effects by race/ethnicity. Potential interactions of environmental contaminant exposures with non-chemical stressors, including stress due to discrimination or poverty, must be considered to avoid underestimation of risk to susceptible populations.

In some cases, EPA's risk assessors may not find evidence concerning susceptibility and vulnerability for the particular chemical(s) that are the subject of a risk assessment. EPA should not cite a lack of evidence regarding differences in susceptibility or vulnerability as a basis for not considering potential differences in a risk assessment. EPA should develop a set of default adjustment factors, based on chemicals and/or health outcomes with sufficient data concerning risk modification by intrinsic or extrinsic susceptibility and vulnerability factors, to be incorporated when chemical-specific data are lacking. Such an approach has been recommended by the NAS[32,33,34] and several scientific articles[35,36,37,38] which conclude that default approaches to treatment of human variability in risk assessments need to

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[31] 82 FR 7562

[32] National Research Council. Science and Decisions: Advancing Risk Assessment [Internet]. Washington, D.C.: The National Academies Press; 2009 [cited 2011 Oct 15]. Available from: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=202175

[33] National Research Council. Toxicity Testing in the 21st Century: A Vision and a Strategy [Internet]. Washington, D.C.: The National Academies Press; 2007. Available from: https://www.nap.edu/download/11970#

[34] National Research Council. Phthalates and Cumulative Risk Assessment: The Task Ahead [Internet]. Washington, D.C.: The National Academies Press; 2008 [cited 2011 Oct 15]. Available from: https://doi.org/10.17226/12528

[35] Chiu WA, Rusyn I. Advancing chemical risk assessment decision-making with population variability data: challenges and opportunities. Mamm Genome. 2018;29:182–9.

[36] Axelrad DA, Setzer RW, Bateson TF, DeVito M, Dzubow RC, Fitzpatrick JW, et al. Methods for evaluating variability in human health dose–response characterization. Human and Ecological Risk Assessment: An International Journal [Internet]. 2019 [cited 2020 Mar 2];0:1–24. Available from: https://doi.org/10.1080/10807039.2019.1615828

[37] Bhat VS, Meek ME (Bette), Valcke M, English C, Boobis A, Brown R. Evolution of chemical-specific adjustment factors (CSAF) based on recent international experience; increasing utility and facilitating regulatory acceptance. Critical Reviews in Toxicology [Internet]. 2017 [cited 2020 Feb 12];47:733–53. Available from: https://doi.org/10.1080/10408444.2017.1303818

[38] Janssen S, Sass J, Solomon G, Schettler T. Strengthening toxic chemical risk assessments report [Internet]. NRDC; 2012 [cited 2012 Feb 12]. Available from: https://www.nrdc.org/sites/default/files/strengthening-toxic-chemical-risk-assessments-report.pdf

be updated to appropriately incorporate current scientific knowledge regarding human susceptibility and vulnerability factors. As a first step, the default adjustment factor for intra-species variability used by the U.S. EPA should be increased to a minimum of 30, as adopted by the California EPA (OEHHA) in 2008, unless there are chemical-specific data to the contrary.[39] A lack of data should not be regarded as absence of risk, but 30 should be the default if insufficient data are available to shift it upwards or downwards.

Communities at risk must be better evaluated

Risk assessments must also explicitly consider how chemical exposures vary by demographic characteristics. Risk assessment should routinely report how exposures vary by race/ethnicity, income group, and life stage. Census data for populations living in proximity to particular facilities that may be associated with exposure (any point of release, such as a manufacturing or processing facility, or location of chemical storage near a drinking water source) should be reported in each risk assessment. EPA should also develop strategies for gathering data on demographic characteristics of exposed populations for exposure pathways, such as consumer product usage, that cannot be represented with census data.

Information in risk assessments concerning differential exposure or differential response to a chemical hazard may be critical in determining whether risk management is necessary. The demographic information provided in the risk assessments can then also be used for analysis of how risk management alternatives will benefit disadvantaged, vulnerable, or marginalized communities. Risk management analyses, including benefit-cost analyses, must consider not just the aggregate health benefits to the exposed population as a whole but also the distribution of those benefits by race/ethnicity and socioeconomic status indicators, such as but not limited to income group, educational attainment, and immigration status. These analyses should explicitly quantify risks to each susceptible population in the current (baseline) scenario, the risks expected to remain for each susceptible population after implementation of a regulatory option, and the resulting risk reduction for each susceptible population.

Working with communities in highly-exposed settings as well as other public health partners is a critical element of ensuring that EPA risk assessments have appropriately considered factors that may contribute to inequities in exposure, risk, and health outcomes. EPA's risk assessments tend to have a programmatic focus that considers only the exposures that are within the jurisdiction of a single environmental statute. Community participation is essential for ensuring that each risk assessment considers the broad range of factors that may enhance vulnerability of an exposed population, including co-exposures to other chemicals, non-chemical exposures, and existing health conditions and disease prevalence.

Non-cancer benefits tell fuller story of health impact for communities at risk

To ensure that risk assessments for non-cancer effects of chemical exposures are truly informative regarding differential risks to susceptible populations and communities, EPA must adopt methods for quantifying how risk varies at differing levels of exposure.

[39] Air Toxicology and Epidemiology Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. Technical Support Document For the Derivation of Noncancer Reference Exposure Levels [Internet]. 2008. Available from: https://oehha.ca.gov/media/downloads/crnr/noncancertsdfinal.pdf

EPA's standard default hazard and risk assessment approach for health outcomes other than cancer (e.g., reproductive, developmental, neurological and cardiovascular effects) is to assume there is a threshold, or a "safe" level of exposure, below which there is no (or negligible) risk of adverse health effects.[40] This approach rests on the assumption that physiological defense systems and repair mechanisms can overcome any adverse effects of low-dose exposure.[41,42] However, from consideration of existing health inequities we know that the diverse human population is comprised of individuals who have varying health vulnerabilities and susceptibilities from intrinsic and extrinsic factors and are simultaneously exposed to multiple industrial chemicals through multiple pathways (e.g., air, food, water)).[43] As observed by the NAS, the diversity of exposures and risk factors in a population lead to an expectation of dose-response relationships in the population that extend to low, commonly experienced doses, with probability of risk at doses below the traditional RfD and RfC. A recent application of these probabilistic methods found that most reference values fall into the 1 in 1000 to 1 in 100 risk range (95% confidence) but with considerable variability. Some RfDs are associated with < 1 in 10,000 risk while at the other extreme are RfDs that represent a probabilistic risk of up to 62%.[44] The authors describe the wide range of endpoint severity associated with these different RfDs suggesting that analysis of the acceptability of an existing RfD needs to consider both probability of effect and its severity. It should therefore be assumed that low levels of exposures are associated with some level of risk in a diverse exposed population, unless there are sufficient data to indicate a threshold level below which there is no risk for the entire exposed population

In place of the traditional RfD and RfC, we recommend applying methods to quantify risks of non-cancer effects proposed by authoritative bodies such as the NAS[45] and World Health Organization[46] and demonstrated in published case studies.[47,48,49] Such methods, which provide estimates of the number of cases of disease in a population with a given level of exposure, are necessary for a complete characterization of health inequities in EPA's regulatory assessments. In the absence of such methods, equity analysis will be limited to more qualitative comparisons of whether exposures are above or below an RfD or RfC, which does not correspond to any specific probability of risk. Additionally, since many regulatory decisions integrate quantitative benefits analysis, the lack of quantitative data effectively results in noncancer benefits being assumed equal to zero despite rigorous science and demonstrated community health concerns. Advancing the quantification of non-cancer benefits would therefore be an

[40] National Research Council (US) Committee on Improving Risk Analysis Approaches Used by the U.S. EPA. Science and Decisions: Advancing Risk Assessment. Washington (DC): National Academies Press (US); 2009. PMID: 25009905.

[41] National Research Council (US) Committee on Improving Risk Analysis Approaches Used by the U.S. EPA. Science and Decisions: Advancing Risk Assessment. Washington (DC): National Academies Press (US); 2009. PMID: 25009905.

[42] National Research Council. Toxicity Testing in the 21st Century: A Vision and a Strategy [Internet]. Washington, D.C.: The National Academies Press; 2007. Available from: https://www.nap.edu/download/11970#

[43] Koman PD, Singla V, Lam J, Woodruff TJ (2019) Population susceptibility: A vital consideration in chemical risk evaluation under the Lautenberg Toxic Substances Control Act. PLOS Biology 17(8): e3000372. https://doi.org/10.1371/journal.pbio.3000372

[44] Chiu WA, Axelrad DA, Dalaijamts C, Dockins C, Shao K, Shapiro AJ, Paoli G: Beyond the RfD: Broad Application of a Probabilistic Approach to Improve Chemical Dose-Response Assessments for Noncancer Effects. Environ Health Perspect 2018, 126(6):067009.

[45] National Research Council (US) Committee on Improving Risk Analysis Approaches Used by the U.S. EPA. Science and Decisions: Advancing Risk Assessment. Washington (DC): National Academies Press (US); 2009. PMID: 25009905.

[46] WHO/IPCS. 2014. "Guidance Document on Evaluating and Expressing Uncertainty in Hazard Characterization." Geneva, Switzerland: World Health Organization; http://apps.who.int/iris/bitstream/10665/259858/1/9789241513548-eng.pdf?ua=1

[47] Ginsberg GL. Cadmium risk assessment in relation to background risk of chronic kidney disease. J Toxicol Environ Health A. 2012;75(7):374-90. doi: 10.1080/15287394.2012.670895. PMID: 22524593.

[48] Chiu, W. A., Axelrad, D. A., Dalaijamts, C., Dockins, C., Shao, K., Shapiro, A. J., & Paoli, G. (2018). Beyond the RfD: Broad Application of a Probabilistic Approach to Improve Chemical Dose-Response Assessments for Noncancer Effects. *Environmental health perspectives*, *126*(6), 067009. https://doi.org/10.1289/EHP3368

[49] Blessinger T, Davis A, Chiu WA, Stanek J, Woodall GM, Gift J, Thayer KA, Bussard D. Application of a unified probabilistic framework to the dose-response assessment of acrolein. Environ Int. 2020 Oct;143:105953. doi: 10.1016/j.envint.2020.105953. Epub 2020 Aug 5. PMID: 32768806; PMCID: PMC7877001.

important step forward in implementation of Executive Orders 12866 and 13563 which encourage use of benefit-cost analysis and quantification of regulatory benefits to the extent possible.

OMB also has an important role to play in improving evaluation of equity in regulatory analyses. OMB Circular A-4, issued in 2003, provides guidance to federal agencies on conducting regulatory analysis.[50] However, Circular A-4 says very little regarding consideration of equity in regulatory analysis, placing much greater weight on analysis of efficiency (consideration of total costs and benefits without regard to distribution of benefits among population groups). OMB should revise Circular A-4 to provide guidance to federal agencies on analysis of equity, incorporating the points stated above concerning equity analysis in the context of EPA regulations. For example, statements in the Circular that emphasize efficiency such as "benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society" should be accompanied with additional language stressing equity considerations:

> *Benefit-cost analysis should also provide decision-makers with information related to important considerations other than efficiency, such as public health and safety, racial justice and equity. Benefit-cost analysis informs these considerations when it provides information regarding the distribution of benefits among population groups defined by race/ethnicity, income and lifestage.*

Further, in describing "Key Elements of a Regulatory Analysis," the revised Circular A-4 should incorporate language from President Biden's memorandum on "Modernizing Regulatory Review," stating that a good regulatory analysis should "take into account the distributional consequences of regulations, including as part of any quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities." [51]

Research to better understand and characterize inequities

To fully implement the above recommendations for assessing equity in baseline assessments and regulatory assessments, EPA will need to allocate additional resources for assessing exposure and risk in all communities across the U.S., including increased environmental monitoring and human biomonitoring in overburdened communities, and approaches for modeling exposures where measurements are not available.

EPA must continue to expand its research to identify factors that contribute to health disparities from environmental contaminant exposures, including risk factors that may vary by race/ethnicity or income and contribute to differential outcomes.

EPA is lacking robust exposure data for many pathways. In other instances, EPA has ample exposure data but has not applied research tools to analyze disparities in exposure. EPA must continue to fund and develop better tools and methods for exposure assessment, including environmental contaminant monitoring and modeling, and data visualizations. There may be a need for new surveys by EPA or in partnership with other federal agencies to address gaps in exposure assessment data. For example, a

[50] US Office of Management and Budget. (2003). Circular A-4. Available: https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf

[51] Presidential Memorandum, *Modernizing Regulatory Review*, § 2(b)(i) (Jan. 20, 2021).

survey on consumer product usage is needed to inform TSCA risk evaluations and to ensure that these evaluations are able to assess disparities in consumer exposure by race/ethnicity and income. EPA should also explore approaches to obtain exposure data in formats that enable analysis of inequities, including new or enhanced efforts to measure environmental contaminants in population-representative samples of supermarket and restaurant foods, household tap water, and house dust.

Data from other federal agencies, along with EPA data, are often critical to the equity assessment efforts described above. For example, surveys conducted by the National Center for Health Statistics (NCHS) are critical for providing biomonitoring data representing environmental exposures (e.g. blood lead levels, and serum levels of PFAS chemicals), and for providing data on health status (e.g. asthma prevalence) and risk factors (e.g. high blood pressure, low iodide intake). These surveys provide nationally representative data, with ability to compare results by race/ethnicity and income. It is critical that these surveys be maintained and expanded, with particular attention on enhancement of NCHS survey data by race/ethnicity, income and geographic location while maintaining rigorous statistical standards. EPA and NCHS should collaborate on identifying and funding the enhancements to NHANES and other NCHS data collection programs needed to enable suitable equity assessments by EPA. In addition, data from the U.S. Census Bureau are critical for understanding the relationship of geographic patterns of environmental hazards (e.g. air pollutant concentrations, proximity to hazardous waste sites) to race/ethnicity and income. Recent years have seen a reduction in availability of Census demographic data at a high level of geographic resolution (block, block group, census tract), and recent news reports indicate current plans that would reduce the accuracy of demographic data at the local level.[52,53] Highly resolved Census demographic data are essential to identification of environmental inequities, and it is critical that Census Bureau continue to provide accurate data on population by race/ethnicity and income for small geographic areas (blocks, block groups, census tracts).

We also recommend that EPA work with the National Institutes of Health (NIH) Environmental Influences on Child Health Outcomes (ECHO) consortium.[54] ECHO is a consortium of cohorts across the United States recruiting and following ~50,000 children. The ECHO cohorts have good coverage of a diverse population (~50% nonwhite) and opportunities for evaluating multiple exposures via monitoring and biomonitoring that can inform cumulative exposures and child populations at risk. EPA should work with NIH to identify areas for improvement of additional coverage of specific racial/ethnic groups and/or exposures that can enhance EPA decision making.

Over the past decade, tight budgets at domestic departments and agencies have significantly affected federal government data gathering efforts and data infrastructure. At the same time, increased rates of non-response to surveys, along with challenges posed by decreasing use of land-line telephones, have significantly hampered federal government surveys. OMB has a significant role to play. First, OMB must ensure that agencies have sufficient funding for data collection and data infrastructure, including budgetary directions to focus data collection efforts on parameters necessary for equity assessments – for example, sufficient sample sizes and over-sampling strategies to ensure adequate coverage of races/ethnicities. Second, OMB should adopt policies and procedures to expedite Paperwork Reduction Act approval of data collection efforts that will be useful for equity assessment. Third, because

[52] Tara Bahrampour and Marissa J. Lang (2021). *New system to protect census data may compromise accuracy, some experts say*. The Washington Post. Available: https://www.washingtonpost.com/local/social-issues/2020-census-differential-privacy-ipums/2021/06/01/6c94b46e-c30d-11eb-93f5-ee9558eecf4b_story.html.

[53] Van Riper D, Schroeder J, and Ruggles S. (2021). Feedback on the April 2021 Census Demonstration Files. Available: https://users.pop.umn.edu/~ruggles/Articles/IPUMS_response_to_Census.pdf

[54] National Institutes of Health (NIH) Environmental Influences on Child Health Outcomes (ECHO) consortium. Available: https://www.nih.gov/research-training/environmental-influences-child-health-outcomes-echo-program

integration of data across agencies (e.g. combination of EPA data with data from NCHS and the Census) is critical to assessing equity, OMB should convene federal agencies to advance critical issues in data integration, such as upgrading/designing data infrastructure for interoperability within and across agencies.

Comments on Area 5: Stakeholder and Community Engagement. Approaches and methods for accessible and meaningful agency engagement with underserved communities.

EPA needs a to implement structural changes in its scientific, regulatory and public engagement programs to recognize that community residents are the experts concerning environmental conditions in their communities. For EPA's programs to be successful in protecting human health and reducing inequities in exposure, risk and health outcomes, EPA must increase and improve community participation and engagement to ensure accountability that EPA actions demonstrably reduce inequitable pollution exposures. To accomplish this objective, EPA needs to undertake a substantial re-orientation and expansion of its efforts to engage with underserved communities to better understand actual environmental conditions. EPA's structure leads to a consistent pattern of conducting assessments that do not account for the scientific and human realities in the community. Well-meaning staff are focused on completing their assigned tasks, which are usually organized to look at a specified piece of the larger exposure and risk puzzle – a specific pollutant, or emissions from a single facility – rather than the real-world experience of community residents who are affected by multiple pollutants from multiple sources through multiple exposure pathways, along with interacting influences on risk, like stress. To successfully ameliorate inequities, EPA must engage communities in tangible and accountable approaches to understand the broad set of chemical/pollutant exposures as well as the non-chemical/pollutant factors that contribute to health susceptibility to chemical and pollution exposures.

These structural changes in community participation and engagement need to be regarded as an essential element of the risk assessment process and the regulatory process in every EPA program. EPA needs to both provide an opportunity for public comment at open public meetings, and engage in active outreach – which includes measures to actively seek out and engage in discussions with representatives of underserved communities, providing resources to communities to support their interactions with EPA, and providing community-specific explanations of EPA's data and technical analysis. Enhancing outreach to communities should be a critical function of EPA's 10 regional offices, and a driving function for regional office participation in EPA's risk assessment and regulatory programs. Each EPA program office and regional office should employ specialists in communicating EPA's technical analysis to community representatives in understandable ways. An additional critical role for these communications specialists is eliciting from communities the questions they have regarding how the environment affects their health and responding back to the communities either with answers for their questions, or EPA plans for obtaining the necessary data and developing answers.

An example of difficulty in accessing information is the EPA Toxics Release Inventory (TRI). TRI has a fairly steep accessibility barrier for communities not well-versed in chemical risk assessment, fails to carry exposure-related data across zip codes (which doesn't reflect the reality of pollution), does not contain information on all chemicals considered by EPA programs, and does not require every facility or every industry sector within the U.S to disclose information. EPA should actively go to communities to provide training in accessing and interpreting TRI and should work with local groups to verify (and, when necessary, correct) the information in TRI and other community-relevant tools in its possession.

As one component of improving community participation, EPA should initiate a grant program to support local organizations (non-governmental organizations, universities, local governments) who can assist communities in expressing concerns to Agency, and to compile data to demonstrate issues like health inequities. EPA should provide training to local organizations who may play this role, including both technical training (e.g. in accessing and interpreting data, understanding risk assessment, and in conducting citizen science projects such as environmental monitoring to inform EPA), and training on how to successfully apply for the grants. Finally, EPA should provide support for organizing a network of these universities and communities across the United States to share best practices and to develop mechanisms and tools to more efficiently inform EPA regarding local environmental conditions.

In addition, community participation must become a central part of EPA's research programs. Within the Office of Research and Development, EPA operates six research programs. One of these six programs, Sustainable and Healthy Communities, is in-part intended to provide useful information to affected communities. However, enhanced interactions with communities to shape research plans is necessary for all six research programs. In addition, EPA research grant programs should also place a high priority on university-community partnerships (i.e. community-based participatory research) in designing and conducting research on hazards and risks to human health and the environment. An example of this model has been successfully implemented by the Robert Wood Johnson Foundation Interdisciplinary Research Leaders program, and best practices from this effort may be replicated.[55]

Finally, community participation must also be extended into risk management decision-making. Publication of Federal Register notices and standard public comment processes – submitting written comments to a docket, signing up to provide oral comments at a public meeting that may not be easily accessible - work well for stakeholders like industry trade association that have ample resources and are familiar with the processes. These standard processes, however, are a barrier to participation by residents of overburdened communities. EPA needs to actively solicit community input in the risk management process and provide an accessible forum for community comment and discussion. Community participation may also be critical for developing effective risk management strategies – for example, identifying technical and financial support needed for adopting cleaner technologies at small businesses, which may often be owned by immigrants with limited English-language skills. All of the recommended process described above regarding community participation in EPA's science activities should have parallel effort for community participation in the risk management process.

Community participation is also critical in the development of evidence-based recommendations when quick action is needed to protect the health of the community. Evidence-to-decision (EtD) frameworks are used to apply evidence of exposures and related health effects to determine potential interventions or policies for implementation on a population scale. This is particularly important for the enduring issue of widespread environmental contamination and pollution through industrial manufacturing. Guideline Development Groups (GDGs) or other groups of experts use these frameworks to consider explicit criteria individually and in aggregate, as they develop recommendations and decide on the relative benefits, harms, values and preferences, and other effects and externalities of potential interventions.

There is a critical need to integrate scientific evidence within environmental health studies to inform decision making and policy. Decision making frameworks in environmental health must also incorporate key considerations for health equity and environmental justice to ensure that historically marginalized

[55] RWJF Interdisciplinary Research Leaders - Robert Wood Johnson Foundation. Interdisciplinary Research Leaders. Available: https://interdisciplinaryresearch-leaders.org/.

and neglected communities are not further subjected to health disparities. A recent a scoping review was conducted of existing EtD frameworks used in clinical, public, and environmental health sciences to make recommendations and inform decision and policy making.[56] The review authors established that improved approaches for decision-making in environmental health are possible with the development of a framework which integrates scientific evidence and other factors including health equity and human rights to make actionable recommendations across a range of evidence states, including cases of limited or where there is no available evidence.

The Program on Reproductive Health and the Environment is building from this scoping review and currently developing an EtD framework specifically tailored towards environmental health. The development and widespread use of frameworks like this in environmental health will facilitate comprehensive and transparent decision-making on the relative value of outcomes and the acceptability of interventions. This framework must be applied in collaboration with stakeholders of those communities most impacted by harmful chemical exposures, experts in environmental health, clinical and policy guidelines development, human and ethics, environmental justice, economics, behavioral science, and alternatives assessment, with expertise in qualitative and quantitative data and evidence synthesis. The use of this framework, would represent a new advance in decision-making for environmental health and will advance EPAs work to make decisions more transparent, fair and inclusive process for making collective decisions that amplifies the voices of those who are the most impacted by toxic chemicals and pollution. The framework could be used for high-priority topics identified by communities most impacted by toxic exposures, who can then co-develop recommendations for concrete, practical actions to mitigate or prevent exposures and the harms that are culturally sensitive, acceptable, appropriate, and therefore sustainable. This will strengthen civic engagement and redistribute decision making power towards those directly affected by environmental contamination. Viable policies and interventions within the scope of the EPA, and depending on the chemical pollutant may include banning, restricted manufacturing, production of safer alternatives, or community remediation.

[56] Norris SL, Aung MT, Chartres N, Woodruff TJ. Evidence-to-decision frameworks: a review and analysis to inform decision-making for environmental health interventions. medRxiv 2021.05.04.21256541; doi: https://doi.org/10.1101/2021.05.04.21256541