

# Scientific Principles to Protect Public Health

Chronic diseases, including cancer, diabetes, and neurological harm, are on the rise, driven in part by harmful chemicals in everyday products, food, water, and emitted by fossil fuels and plastics. At the same time, an overwhelming majority of Americans want government to do a better job of protecting people from harmful chemicals.

Government agencies like the U.S. Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) must transform to meet these expectations. Scientists at the University of California, San Francisco Program on Reproductive Health and the Environment (PRHE) collaborated with top scientists, chemical policy experts, and community organizations to recommend how the government can meet this moment to safeguard all people—especially those most susceptible to harm.



## WE RECOMMEND THAT GOVERNMENT:



## **Safeguard Science Integrity**

Promote scientific integrity at all levels of decision-making and safeguard environmental health research from financial and political influence.



## Stop Corporate Interference in Regulatory Decision-making

Ensure all industry financial conflicts of interest are identified, disclosed, and eliminated on advisory boards and accounted for in scientific assessments of chemicals.



#### **Use Best Available Science**

Adopt up-to-date peer-reviewed scientific methods recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM) and other authoritative bodies for identifying hazards and risks of toxic chemicals and quantify risks for all health effects, both cancer and noncancer, at all anticipated levels of exposures with no threshold.



#### **Protect Health for All**

Prioritize identifying and eliminating health harms in communities that are more highly impacted by chemicals and other stressors.

JANUARY 2025 prhe.ucsf.edu

## **DETAILED RECOMMENDATIONS**

## **Scientific Integrity and Corporate Influence**

Integrity of the scientific process—spanning the conduct, management, use, and communication of scientific research—is critical to ensuring that the best available science is produced, valued, and used to safeguard public health and reduce health inequities. Threats to scientific integrity often arise from those with a financial stake in the outcome of regulatory decisions, such as the chemical industry and its allies. Industry capture has allowed corporate-conflicted individuals to serve on agency advisory committees, where they can exert undue pressure on career scientists, gaining improper influence over scientific analysis and decision-making. Similarly, interference by political appointees in regulatory agencies and elsewhere in the executive branch also places improper pressure on government scientists, further undermining the credibility and integrity of the scientific process.

Research has shown that corporate influence over the funding, generation, use, dissemination, and evaluation of scientific evidence and data corrupts the impartiality of the scientific process and biases its findings in favor of outcomes that support industry interests.<sup>1-4</sup> The NASEM held a workshop<sup>5</sup> in December 2022 that presented results of decades of research showing that tobacco, pharmaceutical, and other industries influence all aspects of the research process, including the selection of studies to conduct, study methods, data reporting, and data interpretation, resulting in findings and conclusions that favor industry sponsors.<sup>6-8</sup>

The NASEM workshop proposed solutions to break the "cycle of bias" that results from industry-sponsored studies. This includes recognizing industry funding and conflicts of interest (COI) as significant sources of bias in scientific research and accounting for them, as well as eliminating sponsor-associated bias at a structural level through policy reforms.<sup>6-8</sup> The NASEM has also recommended in multiple reports that EPA considers funding as a source of bias when evaluating the quality of a study.<sup>5,9</sup> Furthermore, the influence of financial conflicts must be distinguished from non-financial interests, such as personal beliefs and interests, theoretical perspectives, or aspirations for academic advancement, which do not introduce the same systematic biases.<sup>10</sup> The NASEM also emphasizes that financially conflicted members of government scientific review panels can compromise the impartiality of a panel's advice and that simple disclosure of conflicts does not eliminate the bias of the panel —in some cases, it may even exacerbate it.11

Over the past several decades, corporations have waged aggressive campaigns to delay and undermine health-protective regulations by influencing and attacking scientific assessments that inform the regulatory process.<sup>12-16</sup> This includes industry and political influence within the EPA,

which has compromised efforts to ensure that the scientific assessments guiding health-protective decision-making are unbiased and do not underestimate risk. For example, EPA has systematically failed to account for financial COI, such as study sponsorship or authors with financial ties, when evaluating scientific research. Additionally, political and financial COIs have not been effectively removed from the scientific process underpinning hazard and risk assessments, with individuals who have a financial stake in EPA decisions often serving on scientific peer review panels.<sup>17</sup> The result has been weakened chemical regulations, increased exposure to harmful chemicals, and greater risks to the health of families, workers, and communities.

To ensure that agency decisions uphold the best available science free of political interference and the influence of financially conflicted stakeholders, we specifically recommend that the government:

- 1. Assess study funding sources and author financial conflicts of interest when evaluating the quality of studies that support agency assessments and include industry sponsorship as a risk of bias that can influence study outcomes.
- When identifying candidate members for peer review bodies and advisory committees, agencies must
  - define financial conflicts of interest to include industry funding for research, analysis, or advocacy related to products or chemicals under assessment, and
  - ensure all financial conflicts are identified, disclosed, and eliminated early in the process.
- Protect career scientists within agencies from improper pressure to alter their scientific findings.

#### **Best Available Science**

The methods that agencies like EPA use to evaluate scientific evidence for policy and decision-making have not kept pace with significant advances in our understanding of how chemicals in commerce and environmental pollutants impact human health. Extensive scientific evidence shows that everyday exposures to widely used chemicals pose significant health risks, particularly to susceptible populations such as children, pregnant people, workers, and fenceline community residents. <sup>18,19</sup> These risks are magnified by multiple chemical and non-chemical factors, including exposures to multiple pollutants, underlying health conditions, genetic

predispositions, social stressors like poverty and racism, and sensitive life stages, such as fetal development.<sup>20</sup>

Research examining pollutants, including particulate matter, air pollution, and lead, illustrates how intrinsic factors (e.g., underlying disease, age, sex) and extrinsic factors (e.g., healthcare inequity, lack of access to healthy foods, racism, discrimination, extreme weather) can increase the risk of adverse health outcomes from pollutant exposures.<sup>21–29</sup> As a result, some adverse effects can occur in the exposed population at any relevant exposure level, including those previously considered "safe."

Multiple authoritative review bodies and scientists have called for improved scientific approaches to hazard and risk assessment that better account for real-world chemical exposures and risks. 9,21,28,30-33 These approaches must start with the best methods for evaluating the scientific evidence specifically, systematic review methods. Systematic review provides a transparent, consistent framework for evaluating scientific evidence and reducing bias. When applied correctly, systematic review gives a more objective, accurate, and reliable foundation for environmental health assessments, leading to more trustworthy policy decisions that effectively protect public health.<sup>34,35</sup> Currently, federal agencies, including offices within EPA, have failed to fully apply systematic review methods endorsed by leading expert bodies. These established methods, which include clear protocols for literature searches, study selection, evidence evaluation, and evidence synthesis, should be implemented without delay to ensure robust, defensible, and health-protective chemical evaluations.

Agencies like EPA must also update their risk assessment methods, which have been identified by multiple authoritative review bodies and scientists as outdated and no longer reflective of the best available science. 36,37 Of particular concern is agencies' reliance on the assumption that risks from chemical exposures are negligible below an assumed "safe" threshold. This flawed approach fails to reflect the best available science on the potential harms from very low-level exposures and does not adequately account for human variability, including increased susceptibility in populations such as infants, children, pregnant people, and historically marginalized communities. 38

Additionally, while many current laws require agencies like EPA to regulate chemicals based on findings from risk assessments, the risk assessment process is inherently time-consuming and resource-intensive, susceptible to industry influence, and so technical and opaque that it often excludes the communities and populations most impacted by toxic chemicals. In cases where risk assessment is legally required, agencies like the EPA must update their scientific methods to more accurately identify the hazards and risks associated with chemicals and industrial pollutants. Where risk assessment cannot provide meaningful and timely information, we urge EPA and similar agencies to

move beyond risk-based regulation and utilize strategies like cumulative impact assessment and hazard-based approaches.

Given the escalating rates of chemical production and use, as well as rising chronic disease trends,<sup>18</sup> it is urgent that EPA and similar agencies:

- Implement a transparent, consistent, and sciencebased method of evaluating scientific evidence, using a systematic review method consistent with the best available science that considers all evidence streams for all scientific assessments that impact policy or regulation.
- 2. Adopt and apply scientific methods consistent with the best available science that better reflect realworld chemical exposures and risks for assessments that impact policy or regulation, including:
  - Methods developed by the World Health Organization (WHO) to quantify risks of noncancer health effects at all relevant levels of exposure;<sup>39</sup>
  - Science-based adjustment factors to capture the full range of variability in human responses to chemical exposures;<sup>20</sup>
  - Assessing chemical exposures for at least the 99th percentile of the human population to better account for highly exposed individuals;<sup>38</sup> and
  - A consistent approach to account for all foreseeable exposures and for combinations of exposures in chemical assessments, including cumulative risk assessment.<sup>26,28,40,41</sup>
- **3.** Regulate classes of chemicals to accelerate the pace of chemical assessments.
  - Prioritize the evaluation of chemical hazard and risk for new and existing chemicals by class—grouped by similar structure, function, and/or health hazards to accelerate the pace of chemical assessments and avoid regrettable substitution.
- 4. Assure that the data necessary for comprehensive and protective chemical assessments is developed and made available to agencies in a timely manner.
  - Leverage all sources of existing data across agencies and use legal authority to require testing and submission of data and information as needed to fill data gaps and support health protective policies and rulemaking.

 Continue long-term funding and improvements for current systems, methods and tools that are critical for environmental health decision-making, including America's Children and the Environment, the Air Toxics Screening Assessment (AirToxScreen), the White House Council on Environmental Quality's Climate and Environmental Justice Screening Tool (CEJST), EPA's EJ Screen, California EPA's CalEnviroScreen, and the CDC Environmental Justice Index.

## **Protect Health for All**

Communities near polluting facilities and contaminated sites are exposed to higher levels of toxic chemicals through air, water, soil, and food. Due to discriminatory land use policies, inequitable siting practices, and other forms of environmental racism, residents of fenceline communities are more likely to be people of color and Indigenous people who live in areas with multiple polluting facilities clustered together, amplifying the risk of harm from numerous concurrent chemical exposures. A

In addition, these same communities face heightened susceptibility to the cumulative health impacts of harmful exposures due to external stressors, including racism, food insecurity, and/or limited access to healthcare, all of which can exacerbate existing health disparities. <sup>22–29</sup> The NASEM has warned that failing to account for both internal and external stressors can lead to a significant underestimation of the risks posed by chemical exposures in the human population. <sup>21</sup>

Agencies like EPA can take immediate action to reduce health disparities and increase protections for communities facing disproportionate harm from chemical exposures. This includes:

- 1. making better use of existing tools and databases on chemical releases and indicators of cumulative impacts, ensuring that they are recognized and accessible,
- meaningfully incorporating community knowledge, partnerships, and research to identify communities that face disproportionate exposures, hazards, and risks from chemical exposures; and
- 3. taking targeted actions to eliminate these harms. 41,43-45

We urge Agencies like EPA to swiftly adopt the following recommendations to ensure that health harms are addressed and eliminated in all communities:

- Identify and eliminate health harms in communities that are more highly impacted by chemicals and other stressors.
  - Agencies should first rely on cumulative impacts assessment or cumulative risk assessment to identify health hazards and risks in communities facing harm from multiple chemical and nonchemical stressors, and then use legal authority to eliminate identified harms.
- Ensure that the voices and perspectives of those in highly impacted communities are central in the policy process.
  - Impacted community members should inform scientific assessments used to support health policy decisions to ensure that policies and regulations are inclusive, grounded in their lived experiences, and responsive to the needs of those most affected.
- Allocate additional resources and expand existing financial resources to build capacity for engaging in the policy process within overburdened communities.

Government agencies play a crucial role in safeguarding public health and the environment. To fulfill this responsibility, they must eliminate corporate influence, uphold scientific integrity, and adopt the best available science in their decision-making processes. By prioritizing unbiased, evidence-based approaches, they can ensure that policies and regulations effectively protect susceptible populations, address systemic inequities, and reduce harmful exposures to toxic chemicals. Only through these actions can we build healthier, more resilient communities and create a future where all people are protected from the harms of chemical exposures.

## **REFERENCES**

- Odierna DH, Forsyth SR, White J, Bero LA. The Cycle of Bias in Health Research: A Framework and Toolbox for Critical Appraisal Training. Account Res. 2013;20(2):127-141. doi:10.1080/08989621.2013.768931
- Fabbri A, Lai A, Grundy Q, Bero LA. The Influence of Industry Sponsorship on the Research Agenda: A Scoping Review. Am J Public Health. 2018;108(11):e9-e16. doi:10.2105/AJPH.2018.304677
- 3. Psaty BM, Prentice RL. Minimizing bias in randomized trials: the importance of blinding. JAMA. 2010;304(7):793-794. doi:10.1001/jama.2010.1161
- Psaty BM, Kronmal RA. Reporting mortality findings in trials of rofecoxib for Alzheimer disease or cognitive impairment: a case study based on documents from rofecoxib litigation. JAMA. 2008;299(15):1813-1817. doi:10.1001/ jama.299.15.1813
- National Academies of Sciences, Engineering, and Medicine. Sponsor Influences on the Quality and Independence of Health Research: Proceedings of a Workshop. The National Academies Press; 2023. https://doi.org/10.17226/27056
- White J, Bero L. Corporate Manipulation of Research: Strategies Are Similar Across Five Industries. Stanford law and policy review. Published online 2010. Accessed December 10, 2024. <a href="https://www.semanticscholar.org/paper/">https://www.semanticscholar.org/paper/</a> Corporate-Manipulation-of-Research%3A-Strategies-Are-White-Bero/ b50e79c1f56855120014d491534104345954c264
- 7. Bero L, Anglemyer A, Vesterinen H, Krauth D. The relationship between study sponsorship, risks of bias, and research outcomes in atrazine exposure studies conducted in non-human animals: Systematic review and meta-analysis. Environ Int. 2016;92-93:597-604. doi:10.1016/j.envint.2015.10.011
- Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. Cochrane Database Syst Rev. 2017;2(2):MR000033. doi:10.1002/14651858.MR000033.pub3
- 9. National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process. National Academies Press; 2014:79.
- Bero L. Addressing Bias and Conflict of Interest Among Biomedical Researchers. JAMA. 2017;317(17):1723-1724. doi:10.1001/jama.2017.3854
- 11. Parker L, Bero L. Managing risk from conflicts of interest in guideline development committees. BMJ. 2022;379:e072252. doi:10.1136/bmj-2022-072252
- Sass JB, Castleman B, Wallinga D. Vinyl Chloride: A Case Study of Data Suppression and Misrepresentation. Environ Health Perspect. 2005;113(7):809-812. doi:10.1289/ehp.7716
- Lerner S, Shaw A. Formaldehyde Increases Your Cancer Risk No Matter Where you Live. ProPublica. December 3, 2024. Accessed December 10, 2024. <a href="https://www.propublica.org/article/formaldehyde-epa-trump-public-health-danger">https://www.propublica.org/article/formaldehyde-epa-trump-public-health-danger</a>
- Lerner S. How Pesticide Companies Corrupted the EPA and Poisoned America. The Intercept. June 30, 2021. Accessed December 10, 2024. <a href="https://theintercept.com/2021/06/30/epa-pesticides-exposure-opp/">https://theintercept.com/2021/06/30/epa-pesticides-exposure-opp/</a>
- Lerner S. Leaked Audio Shows Pressure to Overrule Scientists in "Hair-on-Fire" Cases. The Intercept. August 4, 2021. Accessed December 10, 2024. <a href="https://theintercept.com/2021/08/04/epa-hair-on-fire-chemicals-leaked-audio/">https://theintercept.com/2021/08/04/epa-hair-on-fire-chemicals-leaked-audio/</a>
- Lerner S. Whistleblowers Expose Corruption in EPA Chemical Safety Office. The Intercept. July 2, 2021. Accessed December 10, 2024. <a href="https://theintercept.com/2021/07/02/epa-chemical-safety-corruption-whistleblowers/">https://theintercept.com/2021/07/02/epa-chemical-safety-corruption-whistleblowers/</a>
- 17. UCSF PRHE. Comments from Scientists, Academics and Clinicians on the Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals of Formaldehyde Under TSCA.; 2024. https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0077
- Woodruff TJ. Health Effects of Fossil Fuel-Derived Endocrine Disruptors. N Engl J Med. 2024;390(10):922-933. doi:10.1056/NEJMra2300476
- National Academies of Sciences, Engineering, and Medicine. Guidance on PFAS Exposure, Testing, and Clinical Follow-Up. National Academies Press (US); 2022. Accessed November 19, 2024. <a href="http://www.ncbi.nlm.nih.gov/books/NBK582439/">http://www.ncbi.nlm.nih.gov/books/NBK582439/</a>
- Varshavsky JR, Rayasam SDG, Sass JB, et al. Current practice and recommendations for advancing how human variability and susceptibility are considered in chemical risk assessment. Environmental Health. 2023;21(1):133. doi:10.1186/s12940-022-00940-1
- 21. National Research Council. Science and Decisions: Advancing Risk Assessment. The National Academies Press; 2009. doi:10.17226/12209
- McHale CM, Osborne G, Morello-Frosch R, et al. Assessing Health Risks from Multiple Environmental Stressors: Moving from G×E to I×E. Mutat Res. 2018;775:11-20. doi:10.1016/j.mrrev.2017.11.003
- Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: implications for policy. Health Aff (Millwood). 2011;30(5):879-887. doi:10.1377/hlthaff.2011.0153
- Payne-Sturges DC, Scammell MK, Levy JI, et al. Methods for Evaluating the Combined Effects of Chemical and Nonchemical Exposures for Cumulative Environmental Health Risk Assessment. Int J Environ Res Public Health. 2018;15(12):2797. doi:10.3390/ijerph15122797
- Gee GC, Payne-Sturges DC. Énvironmental Health Disparities: A Framework Integrating Psychosocial and Environmental Concepts. Environmental Health Perspectives. 2004;112(17):1645-1653. doi:10.1289/ehp.7074

- Solomon GM, Morello-Frosch R, Zeise L, Faust JB. Cumulative Environmental Impacts: Science and Policy to Protect Communities. Annu Rev Public Health. 2016;37:83-96. doi:10.1146/annurev-publhealth-032315-021807
- Koman PD, Singla V, Lam J, Woodruff TJ. Population susceptibility: A vital consideration in chemical risk evaluation under the Lautenberg Toxic Substances Control Act. PLoS Biol. 2019;17(8):e3000372. doi:10.1371/journal.pbio.3000372
- National Research Council. Phthalates and Cumulative Risk Assessment: The Tasks Ahead. The National Academies Press; 2008. doi:10.17226/12528
- 29. Vesterinen HM, Morello-Frosch R, Sen S, Zeise L, Woodruff TJ. Cumulative effects of prenatal-exposure to exogenous chemicals and psychosocial stress on fetal growth: Systematic-review of the human and animal evidence. PLoS One. 2017;12(7):e0176331. doi:10.1371/journal.pone.0176331
- National Academies of Sciences, Engineering, and Medicine. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. The National Academies Press; 2018. doi:10.17226/25086
- 31. National Academies of Sciences, Engineering, and Medicine. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. The National Academies Press; 2017. doi:10.17226/24758
- 32. Trasande L. Updating the Toxic Substances Control Act to Protect Human Health. JAMA. 2016;315(15):1565-1566. doi:10.1001/jama.2016.2037
- 33. Rayasam SDG, Koman PD, Axelrad DA, Woodruff TJ, Chartres N. 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. 2022;56(17):11969-11982. doi:10.1021/acs.est.2c02079
- 34. Norris SL, Aung MT, Chartres N, Woodruff TJ. Evidence-to-decision frameworks: a review and analysis to inform decision-making for environmental health interventions. Published online May 7, 2021:2021.05.04.21256541. doi:10.1101/2021.05.04.21256541
- 35. Chartres N, Joglekar R. Invited Perspective: Why Systematic Reviews, Scoping Reviews, and Evidence-to-Decision Frameworks Are Critical for Transparent, Consistent, Equitable, and Science-Based Decision-Making in Environmental Health. Environmental Health Perspectives. 2024;132(3):031304. doi:10.1289/ EHP14346
- 36. Woodruff TJ, Rayasam SDG, Axelrad DA, et al. A science-based agenda for health-protective chemical assessments and decisions: overview and consensus statement. Environmental Health. 2023;21(1):132. doi:10.1186/s12940-022-00930-3
- Nielsen GH, Heiger-Bernays WJ, Levy Jİ, et al. Application of probabilistic methods to address variability and uncertainty in estimating risks for non-cancer health effects. Environmental Health. 2023;21(1):129. doi:10.1186/s12940-022-00018 7
- 38. Vandenberg LN, Rayasam SDG, Axelrad DA, et al. Addressing systemic problems with exposure assessments to protect the public's health. Environ Health. 2023;21(Suppl 1):121. doi:10.1186/s12940-022-00917-0
- World Health Organization, International Programme on Chemical Safety. Guidance Document on Evaluating and Expressing Uncertainty in Hazard Characterization. 2nd ed. World Health Organization; 2018. Accessed December 10, 2024. https://iris.who.int/handle/10665/259858
- Gennings C, Hauser R, Koch H. Report to the U.S. Consumer Product Safety Commission by the CHRONIC HAZARD ADVISORY PANEL ON PHTHALATES AND PHTHALATE ALTERNATIVES. US Consumer Product Safety Commission; 2014:13, 29-33. <a href="https://www.cpsc.gov/s3fs-public/CHAP-REPORT-FINAL%20(1).pdf">https://www.cpsc.gov/s3fs-public/CHAP-REPORT-FINAL%20(1).pdf</a>
- Ellickson K, Curtis K. The Community Guide to Cumulative Impacts: Using Science and Organizing to Advance Public Health Policy. Union of Concerned Scientists; 2024. doi:10.47923/2024.15622
- Bullard R, Mohai P, Saha R, Wright B. Toxic Wastes and Race at Twenty 1987— 2007: A Report Prepared for the United Church of Christ Justice & Witness Ministries.; 2007. <a href="https://www.nrdc.org/sites/default/files/toxic-wastes-and-race-at-twenty-1987-2007.pdf">https://www.nrdc.org/sites/default/files/toxic-wastes-and-race-at-twenty-1987-2007.pdf</a>
- National Academies of Sciences, Engineering, and Medicine. Constructing Valid Geospatial Tools for Environmental Justice. The National Academies Press; 2024. doi:10.17226/27317
- 44. US Environmental Protection Agency. EPA's Meaningful Engagement Policy. October 24, 2023. Accessed December 10, 2024. https://www.epa.gov/environmentaljustice/epas-meaningful-engagement-policy
- 45. US Environmental Protection Agency. EPA Legal Tools to Advance Environmental Justice: Cumulative Impacts Addendum.; 2023. https://www.epa.gov/system/files/documents/2022-12/bh508-Cumulative%20Impacts%20Addendum%20 Einal%202022-11-28 pdf