Better data is essential to protect people from harmful chemicals, contaminants.

Recommendation

To ensure people are not made sick from toxic chemicals EPA must invest in systems to support collecting, organizing, and making more accessible environmental and health data and evidence that allow the Agency and the public to understand, monitor, and act on environmental factors that influence health.

SUMMARY

EPA's databases and data systems provide public access to a wealth of environmental data, including historical information regarding pollutants in the air, in the water and on land. These data infrastructures are essential for policymakers to better understand and address health risks associated with chemicals and pollutants, identify opportunities for intervention and prevention, and track progress toward meeting environmental health goals and policies. Thus, it is critical that EPA not only maintain, but enhance public access to these information resources that enable people to know about environmental contaminants in their communities.

PROPOSED ACTIONS

To ensure people are protected from harmful chemicals and that data about chemicals and contamination are accurate and readily accessible, **we recommend that EPA:**

1. **Leverage all sources of existing data and use its legal authority to require testing and submission of data and information as needed to fill data gaps.**
2. **Maintain and protect credibility and increase access to the results of its funded scientific research.**
3. **Protect personal information about study subjects as a condition of using a human study in a scientific assessment.**
4. **Continue long-term funding and improvements for current systems, methods, and tools that are critical for environmental health decision-making.**
5. **Reaffirm the value of animal testing as necessary for human health protection, conducted in accordance with animal welfare protections to inform chemical evaluations and health-protective policies.**
6. **Develop a consistent and science-based framework across all programs and offices to integrate evidence from new approach methodologies (NAMs) in scientific evaluations that impact policy or regulation.**

SUPPORTING EVIDENCE

EPA should leverage all sources of existing data and use its legal authority to require testing and submission of data and information as needed to fill data gaps.

EPA needs adequate data and information about chemicals and pollutants exposures and effects to fulfill its obligations to protect the public's health. EPA should use both existing data to comprehensively assess exposures and health effects and its legal authorities to fill data gaps.

EPA should use multiple data sources where available to answer critical exposure and health questions, including combining data from multiple existing data sources to support scientific assessments. For example, EPA should combine data from multiple chemical release databases that it maintains, including the National Emissions Inventory (NEI), the Toxics Release Inventory (TRI) and Discharge Monitoring Reports (DMR), to more comprehensively examine chemical releases at the national, state, or community level. EPA can rely on existing tools, like the Standardized Emission and Waste Inventories (StEWI) tool,[1] to quantitatively combine data from these sources while accounting for overlapping releases. EPA should also evaluate and regulate chemicals by category and rely on read-across, where it EPA has reliable data on a scientifically defensible and health-protective analog.

EPA should use its legal authority to require chemical testing or the submission of existing information to fill data gaps in exposures and health effects. For example, the Toxic Substances Control Act ("TSCA") requires EPA to consider all "reasonably available information" when evaluating chemicals,[2] which includes information that EPA "possesses or can reasonably generate, obtain, and synthesize for use."[3] Under TSCA section 8, EPA can require reporting about chemical uses, exposures, and effects, and it can compel the submission of existing studies and other information about a chemical's adverse impacts.[4] EPA can also issue subpoenas for the inspection of sites and the production of documents under TSCA section 11.[5]

If insufficient information about a chemical exists, EPA can order chemical manufacturers and processors to conduct testing under TSCA section 4.[6] EPA also has the authority to require the production of documents and information under the Clean Air Act, Comprehensive Environmental Response, Compensation and Liability Act, and other environmental laws. Finally, any chemicals that are being considered for evaluation should expeditiously be added to the Toxics Release Inventory so reporting data is available by the time that EPA commences its risk evaluation process.

EPA has used its data-gathering authority under TSCA insufficiently in the past, resulting in risk evaluations where EPA lacked critical exposure and toxicity data. EPA acknowledges that it had "limited exposure monitoring data" for diisodecyl phthalate ("DIDP"),[7(p84)] and in its recent risk evaluation for tris(2-carboxyethyl) phosphine ("TCEP"), EPA was unable to measure the risks posed by several uses of the chemical because the Agency lacked adequate data.[8] EPA should issue a TSCA data reporting rule that mandates the collection and generation of necessary and comprehensive data at the earliest stages of the risk evaluation process to avoid similar gaps in the future and provide for timely decision making. Additionally, EPA must develop a target data set with guidance from scientific and community experts, which includes health end points, physical characteristics and PESS (potentially exposed susceptible sub population) considerations, To identify human health risks, robust and sensitive assays would be required to identify a broad scope of health effects (e.g., cardiovascular, reproductive and neuro developmental toxicity, carcinogenesis) across sensitive life stages (e.g., preconception, fetal and child development, aging).[9] Finally, EPA should also require that an analytic data standard be provided for all chemicals, particularly new chemicals, which gives capacity to measure these chemicals in appropriate biological and environmental media.

EPA should maintain and protect the credibility of and increase access to the results of its funded scientific research.

In 2016, EPA published a Plan to Increase Access to Results of EPA-Funded Scientific Research[10] (The Plan), in consultation with the National Science and Technology Council and public input. The Plan was developed to enhance the transparency and accessibility of EPA-funded research by promoting open data practices and ensuring that research findings are readily available to the public and stakeholders. The goal was to improve the usability of scientific data and enhance public trust in EPA's research efforts.

The Plan is scientifically and technically sound for three key reasons:

1. The scope of the Plan prospectively covers peer-reviewed scientific research publications and digital research data that result from EPA-funded research and does not apply retroactively. Thus, it would not impact past research underpinning regulations like the Clean Air Act, which comes up for periodic review.

2. The validity of scientific conclusions drawn from research publications or their associated research data, or EPA's ability to consider those conclusions and data in its actions, does not depend on compliance with this Plan.[10(p6)]
3. The Plan is in compliance with EO 12291, acknowledging the costs to researchers that data access may impose and setting up a mechanism to address those costs.[10(p11)]

This Plan is in stark contrast to EPA's now-vacated 2021 Science Transparency Rule, which instead required research data to be publicly accessible in order to be used for regulatory actions. EPA should secure funding to continue to implement and uphold recommendations in The Plan to ensure transparency and access to the results of its publicly-funded research

EPA should protect personal information about study subjects as a condition of using a human study in a scientific assessment.

Epidemiologic and other types of human studies are essential scientific information for EPA decision-making. Researchers collect individual and confidential data from individuals as part of these studies. Medical ethics and existing legal requirements, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), expressly preclude disclosure of confidential or sensitive data obtained during human studies. Medical records, including those used for research, are regulated under HIPAA, which requires researchers to protect identifiable information and mandates that such information may only be disclosed for research purposes with the written consent of the person providing the information.[11] There are both civil and criminal penalties for violations related to data disclosures.[12]

The Trump Administration issued a rule in 2021 titled the "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information," commonly referred to as the Science Transparency Rule, which would have essentially required disclosure of confidential or sensitive personal data about study subjects as a condition of using a human study in a scientific assessment.[13] This rule was not consistent with the best available science, as EPA can determine the validity of scientific methods and conclusions without access to this information and use these studies to inform decisions. It further put human subjects' personal data at risk and was inconsistent with the principles of open science.[14,15] The rule was vacated by a federal court in May 2021, but EPA has not affirmatively declared that disclosure of individual-level data is not required to assess scientific study quality. EPA must ensure that its policies do not require the disclosure of confidential or sensitive data provided by participants in human studies as a condition of using study findings in any scientific assessment to ensure EPA uses the best available science.

EPA should continue and expand long-term funding and improvements for current systems, methods, and tools that are critical for environmental health decision-making.

EPA resources should continue to expand and improve current key data infrastructure including America's Children and the Environment,[16] the Air Toxics Screening Assessment (AirToxScreen).[17] Additional funding support is needed for other related data across the federal government that are critical for environmental health decision-making (e.g., surveys conducted by the National Center for Health Statistics).

EPA should also continue to use, evaluate, and improve environmental justice related screening tools such as the White House Council on Environmental Quality's Climate and Environmental Justice Screening Tool (CEJST),[18] EPA's EJScreen,[19] California EPA's CalEnviroScreen,[20] and the CDC Environmental Justice Index.[21] Significant progress has been made to expand and develop these federal screening tools over the past four years, which provide EPA and the public a better understanding of exposures to multiple chemicals as well as overlapping susceptibilities in the population.

EPA should reaffirm the value of animal testing conducted in accordance with animal welfare protections to inform chemical evaluations and health protective policies.

Decades of scientific evidence and rulemaking at EPA have established animal testing as a proven method for assessing how environmental chemicals can affect human health. The use of animal testing, particularly rodent studies, therefore, remains critical for assessing chemical risks, especially as EPA works to replace these tests with New Approach Methodologies (NAMs), or *in vitro, in silico,* and other high-throughput toxicity testing methods that are still under development.

While NAMs hold promise, they do not yet have the biological coverage needed to fully replace rodent studies, especially for evaluating complex health systems like reproduction, neurobehavior, immune function, and metabolism. Moreover, under TSCA, EPA cannot replace animal testing with NAMs until it can assure that the replacement methods are "scientifically valid" and "will provid[e] information of equivalent or better scientific quality"[22] than animal tests. Accordingly, EPA cannot prematurely reduce or eliminate rodent testing until NAMs can provide data of equivalent or greater scientific quality.

Unfortunately, most NAMs currently used by EPA are not validated for determining health effects in a manner comparable to animal tests,[23] and EPA has acknowledged this concern in its 2021 New Approach Methods Workplan.[24(p16)]

Due to the limitations of NAMs, prematurely curtailing rodent testing will deprive EPA of the data and tools it needs to protect the health of individuals and overburdened communities, potentially exacerbating health disparities.

EPA should reaffirm its commitment to rodent testing conducted in accordance with animal welfare protections until NAMs are scientifically validated and capable of providing equivalent information. EPA should also reject any policy or directive that reduces animal testing without ensuring that alternative methods are ready for regulatory use and can sufficiently identify health effects to the public, fully accounting for human variability including sensitive subpopulations. Additionally, EPA must remain transparent in its decision-making, involving impacted communities to ensure that the transition to NAMs does not compromise the health of overburdened populations.

EPA must also not use NAMs to discredit existing data from rodent tests or epidemiologic studies, which may lead to regulatory delays at the expense of workers and overburdened communities. For example, EPA's Office of Pesticide Programs (OPP) recently delayed finalizing its registration reviews for several organophosphate pesticides—a class of chemicals that for decades have been linked to neurodevelopmental harm in children and severe neurotoxicity in adults– in part, to unnecessarily develop and promote a developmental neurotoxicity NAMs battery. OPP also used data obtained from this NAMs battery to waive protections for infants and children in its risk assessments for several organophosphate pesticides.[25] These delays and reduced protections have left farmworkers and their families and pregnant people at continued risk of severe and irreversible health harms from organophosphate pesticide exposures.[26]

EPA should develop a consistent and science-based framework across all programs and offices to integrate data from new approach methodologies (NAMs) in scientific evaluations that impact policy or regulation.

Improved methods to more rapidly or sensitively identify the influence of chemicals on health, including new *in vitro* and *in silico* methods and improved animal testing, are increasing in use. NAMs hold great promise to improve our ability to identify toxic chemicals, but there are many factors that have to be considered in their use. For example, while some NAMs have been developed to identify health effects for complex health systems like reproduction and neurobehavior, they are not yet as sensitive as animal testing.

Additionally, EPA has limited experience using NAMs for risk evaluation and management, and there is no established Agency-wide legal or scientific framework for incorporating data from NAMs into regulatory decision-making. EPA recognized this as a significant issue in its 2021 NAMs Work Plan, stating that "EPA needs to continually build more scientific confidence in information from NAMs while also establishing the appropriate expectations for their performance and demonstrating their application to regulatory decisions."[27(p12)] TSCA requires EPA to ensure that NAMs will "support regulatory decisions" before they can be used.[22] Without such a framework, there is a risk that NAMs could be used to exonerate chemicals prematurely, not because they are proven safe, but due to the inability of NAMs to consistently detect all health effects. Additionally, discontinuing rodent testing in favor of NAMs could stall the chemical risk evaluation process, as it would greatly reduce EPA's ability to fill crucial data gaps necessary for conducting health-protective risk assessments for many chemicals.

Accordingly, the EPA should develop a consistent and science-based framework that outlines actionable steps to implement data obtained from new approach methodologies (NAMs), which will result in regulatory decision-making that promotes public health and environmental justice. EPA should incorporate key principles from a recent NASEM report[28] into the framework to ensure transparency, rigor, and adherence to best available evidence evaluation approaches. The NASEM, in an EPA-sponsored study, recommended that EPA adhere to systematic review best practices by defining the intended regulatory purpose for NAMs and ensuring the NAMs tests fully and adequately address the relevant questions.[28] The framework should therefore include: 1) scientifically-sound systematic review to examine all evidence streams, including NAMs; and 2) actionable recommendations for how results from the systematic review can inform decision-making. For example, NAMs studies demonstrating strong or moderate associations between chemicals and adverse health effects can be used to inform regulatory decisions, while weak or inconclusive associations require further examination via animal testing, but *cannot be used to make regulatory decisions or determine chemical safety.*

EPA should also partner with key stakeholders early in the development of this framework, including fenceline communities, farmworkers, and other groups disproportionately impacted by chemical exposures, to ensure an open, transparent, and inclusive decision-making process.

While this framework is being developed, EPA can use existing NAMs as a screening tool to identify potential health effects and prioritize chemicals for further evaluation. For example, new yeast and *C. elegans* assays recently identified a number of chemicals that are harmful to reproduction and are currently not being prioritized for evaluation by EPA.[29–31]

REFERENCES

1. Young B, Ingwersen WW, Bergmann M, et al. A System for Standardizing and Combining U.S. Environmental Protection Agency Emissions and Waste Inventory Data. *Appl Sci Basel Switz*. 2022;12(7):1-16. doi:10.3390/app12073447
2. *15 U.S.C. § 2625(h).*
3. *40 U.S.C. § 702.33.*
4. *15 U.S.C. 2607(b), (c), (d).*
5. *15 U.S.C. 2610.*
6. *15 U.S.C. 2603(a)(1).*
7. U.S. EPA. Draft Risk Evaluation for Di-isodecyl phthalate (1,2-Benzene-dicarboxylic acid, 1,2- diisodecyl ester) (DIDP). Published online 2024.
8. U.S. EPA. Risk Evaluation Tris(2-chloroethyl) Phosphate (TCEP). Published online 2024.
9. 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. *Environ Sci Technol*. 2022;56:11969-11982. doi:10.1021/acs.est.2c02079
10. U.S. EPA. Plan to increase access to results of EPA-funded scientific research. Published online 2016. https://www.epa.gov/sites/default/files/2016-12/documents/plan_to_increase_access_to_results_of_epa-funded_scientific_research_v1.1_0.pdf
11. National Research Council. *Expanding Access to Research Data: Reconciling Risks and Opportunities*. National Academies Press; 2005. doi:10.17226/11434
12. National Research Council. *Improving Access to and Confidentiality of Research Data: Report of a Workshop*. National Academies Press; 2000. doi:10.17226/9958
13. Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. *Environ Health Perspect*. 2014;122(10):1007-1014. doi:10.1289/ehp.1307175
14. Nosek BA, Alter G, Banks GC, et al. Promoting an open research culture. Science. 2015;348(6242):1422-1425. doi:10.1126/science.aab2374
15. Thorp HH, Skipper M, Kiermer V, Berenbaum M, Sweet D, Horton R. Joint statement on EPA proposed rule and public availability of data (2019). *Science*. 2019;366(6470):eaba3197. doi:10.1126/science.aba3197
16. US EPA. America's Children and the Environment. April 3, 2015. https://www.epa.gov/americaschildrenenvironment
17. US EPA O. 2020 AirToxScreen. May 22, 2024. https://www.epa.gov/AirToxScreen/2020-airtoxscreen
18. White House Council on Environmental Quality. Climate and Economic Justice Screening Tool. Climate and Economic Justice Screening Tool. https://screeningtool.geoplatform.gov
19. US EPA. EJScreen: Environmental Justice Screening and Mapping Tool. September 3, 2014. https://www.epa.gov/ejscreen
20. California Environmental Protection Agency. CalEnviroScreen 4.0. OEHHA. September 20, 2021. https://oehha.ca.gov/calenviroscreen/report/calenviroscreen-40
21. CDC. Environmental Justice Index. Place and Health - Geospatial Research, Analysis, and Services Program (GRASP). December 3, 2024. https://www.atsdr.cdc.gov/place-health/php/eji/index.html
22. *15 U.S.C. § 2603(h)(1)(A).*
23. U.S. EPA. *New Approach Methods: Efforts to Reduce Use of Vertebrate Animals in Chemical Testing.*; 2022. www.epa.gov/research/epa-new-approach-methods-efforts-reduce-use-vertebrate-animals-chemical-testing
24. U.S. EPA. *New Approach Methods Work Plan: Section IV. Develop NAMs to Address Scientific Challenges and Fill Important Information Gaps.*; 2021. https://www.epa.gov/system/files/documents/2021-11/nams-work- plan_11_15_21_508-tagged.pdf
25. Perron M. Integration of New Approach Methodology (NAM) Data for Evaluating Potential Developmental Neurotoxicity. Presented at: U.S. EPA. www.epa.gov/sites/default/files/2020-10/documents/9_monique_perron_nam_conference_2020_508c.pdf
26. EarthJustice. Organophosphate Pesticides in the United States. Earthjustice. Accessed January 8, 2025. https://earthjustice.org/feature/organophosphate-pesticides-united-states
27. U.S. EPA. *New Approach Methods Work Plan: Section III. Establish Scientific Confidence in NAMs and Demonstrate Application to Regulatory Decisions.*; 2021. https://www.epa.gov/system/files/documents/2021- 11/nams-work-plan_11_15_21_508-tagged.pdf
28. National Academies of Sciences, Engineering, and Medicine. *Building Confidence in New Evidence Streams for Human Health Risk Assessment: Lessons Learned from Laboratory Mammalian Toxicity Tests*. National Academies Press; 2023. doi:10.17226/26906
29. Varshavsky JR, Lam J, Cooper C, et al. Analyzing high-throughput assay data to advance the rapid screening of environmental chemicals for human reproductive toxicity. *Reprod Toxicol*. 2025;131:108725. doi:10.1016/j.reprotox.2024.108725
30. Ulaganathan G, Jiang H, Canio N, et al. Screening and characterization of 133 physiologically-relevant environmental chemicals for reproductive toxicity. *BioRxiv Prepr Serv Biol*. Published online March 27, 2024:2024.03.22.584808. doi:10.1101/2024.03.22.584808
31. Kumar R, Oke A, Rockmill B, et al. Rapid identification of reproductive toxicants among environmental chemicals using an in vivo evaluation of gametogenesis in budding yeast Saccharomyces cerevisiae. *Reprod Toxicol Elmsford N*. 2024;128:108630. doi:10.1016/j.reprotox.2024.108630