

Strengthen EPA and Its Mission to Protect Public Health

It is time to put science and public health front and center at the Environmental Protection Agency (EPA) to ensure that the most significant and pervasive threats to health from harmful chemical exposures are properly addressed. There have long been serious problems with using the best science to inform chemical policy in the United States. Changes to the Toxic Substances Control Act (TSCA) in 2016 attempted to address these problems; however, the current administration's implementation of TSCA illustrates how the changes [fall short](#).

To that end, the Program on Reproductive Health (PRHE) at the University of California, San Francisco — a world-renowned health sciences institution — has been at the forefront of defending science and promoting health-protective policies around harmful chemicals. Their comments have continued to shine a light on EPA practices that fail to protect health or

consider vulnerable populations. Their recommendations have been cited and validated by EPA's own scientific peer-review panel regarding best practices for assessing hazard and risk.

Now, to help EPA put science and public health front and center, PRHE has organized top scientists and chemical policy experts from around the country to develop evidence-based recommendations to improve hazard and risk assessment, and prevent harms from chemicals and pollutants.

We can boldly imagine and incorporate the best science to support policies that enhance health for all people — in our communities, in land and natural resource management, the products in our homes and schools, and actions in our workplaces.

KEY RECOMMENDATIONS

Health-Protective Chemical Policy Reform

Use the best available science to assess hazards and risks of chemicals to ensure better public health decisions, including a more representative definition of susceptible populations and using approaches to quantify risks for all health effects, both cancer and noncancer, at all anticipated levels of exposures.

Science-Based Systematic Review as the Foundation for Health-Protective Policy

Adopt a science-based, validated systematic review method to ensure transparent and unbiased evaluation of chemical harms.

Environmental Justice in Chemical Policy

Ensure that the routine outcome of our environmental laws and policies at all levels of government is equal protection, not environmental disparities.

Financial Conflict of Interest in Funding and Assessment of Science

Act to make science free of financial conflicts of interest from industry influence, so environmental health decision-making can protect public health and EPA can rebuild public trust.

Investing in Research and Data to Support More Equitable Public Health Decisions

Invest in the most up-to-date research and data infrastructure to allow EPA to better identify and prioritize potential harms, evaluate risks, and analyze the effectiveness of interventions.

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Using the Best Available Science to Assess Hazards and Risks of Industrial Chemicals Will Ensure Better Public Health Decisions

RECOMMENDATION

EPA must use the most scientifically up-to-date approaches to evaluate the hazards and risks of chemicals and environmental pollutants that inform decision-making to protect public health.

ISSUE SUMMARY

Science has advanced on how industrial chemicals and environmental pollutants can adversely influence people's health, but methods for evaluating the evidence to use in policy decision-making has not kept pace with this science. There is well-supported evidence showing there are health risks from common every-day exposures to harmful chemicals due to factors that amplify the risks such as background exposures to multiple pollutants, pre-existing disease, genetic and social vulnerabilities, ongoing disease processes and susceptible life stages such as fetal and child development. Well-documented examples include particulate matter,¹ other forms of air pollution,² and lead.³ Further, these factors can influence risks such that risks can occur at any level.

Despite some methodological improvements, EPA's overall framework for using scientific evidence in hazard and risk assessment has stayed largely the same since the 1970s even though multiple authoritative review bodies and scientists have called for improved approaches.^{4,5,6,7,8,9} Of particular concern is that EPA continues to use an approach that assumes no risks below a level assumed to be "safe" for the general population, including sensitive groups, such as infants, children, pregnant women and marginalized communities. The lack of progress in updating approaches for identifying and evaluating environmental health risks is especially problematic considering the continued increases in chemical manufacture and use,¹⁰ and increasing trends in chronic disease,¹¹ particularly among the most vulnerable. EPA urgently needs to update its framework for incorporating current scientific knowledge into evidence-based science policies and practices to better reflect how industrial pollutants affect health with the goal of reducing harmful exposures and improving health and health equity.

PROPOSED ACTIONS

- 1. EPA should assume that all health effects, both cancer and noncancer, have some probability of occurring at any level of exposure and should quantify risks accordingly,** unless proven otherwise, as recommended by authoritative scientific bodies.
- 2. EPA should correct its definition of potentially exposed and susceptible populations,** similar to the definition in the 2017 TSCA proposed risk evaluation framework rule.
- 3. EPA should implement an improved default human variability adjustment factor** of at least 30 fold for human risk assessment for all health endpoints to capture the wide range of factors contributing to differences in human response to chemical exposures including early life vulnerabilities, pre-existing health disparities, and common disease processes.
- 4. EPA's rulemaking should have a consistent approach** for characterizing exposures to environmental pollutants and contaminants.
- 5. EPA should consider classes of chemicals to accelerate risk management and avoid regrettable substitutions.** Specifically, EPA should consider, at a minimum, the 6 phthalates banned by CPSC under review as a group under TSCA Sec 26(c).

SUPPORTING EVIDENCE

EPA should assume that all health effects, both cancer and noncancer, have some probability of occurring at any level of exposure and should quantify risks accordingly, unless proven otherwise, as recommended by authoritative scientific bodies.

Human health risk assessment, and subsequent policy and regulatory decisions, can be substantially improved by using

quantitative methods to estimate health risks for all identified health effects. Currently, noncancer risk estimates are based on a bright line that does not specify a particular risk level (e.g., Reference Dose, RfD or concentration RfC) and assumes a threshold, below which there is no observed effect — but this does not mean that there is no/zero effect in the population.¹² Cancer risks on the other hand are expressed as probabilities (e.g., 1 in a million risk) based on the assumption that there is no exposure level of a chemical without some cancer risk.¹³ Treating noncancer risk estimates similarly to how cancer risk estimates are treated would better reflect current scientific understanding of health risks, provide more useful and actionable information to the public and decision-makers about environmental health risks, and allow policymakers to better estimate the health benefits of environmental regulations.

The most current scientific understanding shows that due to ongoing background exposures from multiple chemicals, common pre-existing diseases (e.g., diabetes), and factors that contribute to variability in response to chemical exposures (e.g., genetics and life stage vulnerabilities), risks will extend to all foreseeable population exposures.^{14,15,16,17} This was affirmed by the NAS in 2009,¹⁸ that recommended transitioning away from an assumption of “safety” and toward dose-response methods that quantify risk at doses within the experimental range as well as below it. Yet EPA continues to use scientifically unsupported “bright-line” methods which incorrectly imply a zero-risk level.

Methods are available and have been demonstrated as a way to implement an approach for estimating risk of all health effects that also includes factors to account for life stage vulnerability, coexposures to other pollutants, genetics, pre-existing conditions, and social factors including poverty and racism/discrimination.

We specifically recommend that EPA:

- Use established methods (e.g., probabilistic assessment) to quantify the level of risk for all identified health effects in parallel with RfD/point of departure calculation for every newly proposed noncancer benchmark (e.g., RfD) in an EPA IRIS assessment.^{19,20,21}
 - Estimating the exposure level to the population for different risk levels (e.g., -1 in 100,000, 1 in 10,000, 1 in 1,000) of all identified health effects, including noncancer ones, in all EPA regulatory programs, including TSCA and SDWA, will give decision-makers better information about how exposures in the population translate into population risks for different health endpoints.
- Use established methods (e.g., probabilistic assessment) to quantify health risks from exposures and produce risk estimates under TSCA as part of risk evaluations. EPA should also use these risk calculations to quantify benefits under TSCA and better identify policy options to reduce exposures.²²

- Develop training materials that can explain to a variety of stakeholder audiences why these methods are useful, and how they can be implemented in a risk assessment and risk management framework.

EPA should correct its definition of potentially exposed and susceptible populations, similar to the definition in the 2017 TSCA proposed risk evaluation framework rule.

Current scientific understanding indicates that intrinsic factors (such as pre-existing diseases) and extrinsic factors (such as stress due to food insecurity and/or poverty) can increase susceptibility to environmental chemical exposure risks. Under the current law, EPA must consider impacts of chemicals on potentially susceptible subpopulations; however its current definition does not capture the reality of susceptibility.

Naming the factors that should be considered for susceptible populations is an important step to ensure consideration of these factors in hazard and risk assessment. In 2017 EPA proposed an expanded definition of susceptible populations as part of its TSCA risk evaluation framework rule, and EPA should incorporate a more robust definition into existing and proposed policies and guidelines.

An expanded version of EPA's 2017 proposed definition is below:

Potentially susceptible subpopulation means a group of individuals within the general population who, due to greater susceptibility 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 both intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits) and acquired (e.g., pre-existing disease, geography, socioeconomic, racism/discrimination, cultural, workplace) factors when identifying this population.

EPA should implement an improved default human variability adjustment factor of at least 30 fold for human risk assessment for all health endpoints to capture the wide range of factors contributing to differences in human response to chemical exposures including early life vulnerabilities, pre-existing health disparities, and common disease processes.

Development of risk-based estimates of harm from environmental chemical exposures are typically based on animal and human studies that do not necessarily reflect the full range of human variability/susceptibility that may occur across the population (**see Proposed Actions 1, 2, and 3**) Many authoritative scientific bodies currently use or have recommended adjustment factors which better account for human variability than EPA's current default factor of 10.

We recommend the following which could be easily adopted while enhancing the current data that informs these factors:

- A default adjustment factor for human variability in response to chemical exposures of at least 30, unless there are chemical-specific data to the contrary, should be applied to all health endpoints.^{23,24,25} This would align with using the same methodological approach for all health endpoint risks.
 - EPA's current assessment method for cancer does not adjust for individual variability in cancer susceptibility.
- The International Programme on Chemical Safety (IPCS) report found that human variability in response to chemical exposures was larger than 10 when human toxicokinetic and toxicodynamic (TK and TD) data was combined probabilistically.²⁶

U.S. regulatory authorities should have a consistent approach for characterizing exposures to environmental pollutants for rulemaking.

EPA offices do not take the same approach in considering what extent of the population is exposed to industrial chemicals and/or pollution for the purposes of rulemakings. For example, EPA's Pesticide Office often calculates exposures for at least the 99th percentile of the population, while other offices only account for exposures of the 95th percentile of the population.

Considering just the 95th percentile of the population potentially leaves a large portion of the population — 16 million people²⁷ — at higher exposure levels and thus not considered in the decision-making and are subsequently left unprotected. In order to adequately protect the population, policy and regulatory exposure rules should all consider the same percentile of the population and should encompass at least the 99.9th percentile, similar to the Pesticide office. Those that are left unprotected by the exposure estimates (the top .1 percentile) should be robustly characterized with regard to susceptibility factors such as their geography and demographics in order to ensure transparency around who is and is not potentially protected.

EPA should consider classes of chemicals to accelerate risk management and avoid regrettable substitutions. Specifically, EPA should consider, at a minimum, the 6 phthalates banned by CPSC under review as a group under TSCA Sec 26(c).

Chemicals are usually assessed for their risk and addressed through public policy via a chemical-by-chemical approach. While this can be useful, it is also time- and resource-intensive. Chemicals that are more studied and identified as hazardous may be replaced with less well-studied chemicals, under the assumption that little data indicates no risk.²⁸ This can result in substitution of hazardous chemicals with chemicals that have similar structure and function (e.g., bisphenols), may be relatively untested, and can be as or more harmful

than the original chemical; otherwise known as a regrettable substitution.²⁹ Further, assessing chemicals one at a time can underestimate hazard and risks as scientific evidence shows that multiple chemical exposures acting on the same health endpoint can result in increased risk compared to individual chemical exposures. For example, assessing phthalates individually will result in underestimation of risk because multiple phthalates can act together to affect the same health endpoint (male reproductive development), and thus there is increased risk from cumulative exposures. Additionally, assessing cumulative exposures better reflects exposures experienced by the public, providing a more accurate estimate of risk.^{30,31,32}

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To Ensure Transparent and Unbiased Evaluation of Chemical Harms, EPA Should Use Science-Based Systematic Review Methods

RECOMMENDATION

To ensure EPA is making decisions based on the best available science, EPA must implement a science-based, validated systematic review method to inform policy and decision-making to save lives and money.

ISSUE SUMMARY

Systematic review methods are used to collect and evaluate scientific evidence using transparent, consistent methods that reduce bias in evidence evaluation. They have been implemented in clinical medicine because it has been demonstrated that these methods produce a less-biased evaluation of evidence for making decisions about patient care that saves lives and money. They set the “rules” of the game for assembling and interpreting the scientific evidence.^{1,2,3}

Scientifically valid systematic reviews are recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM) to better evaluate environmental chemicals and inform policy and decision-making.^{4,5,6}

The Toxic Substances Control Act (TSCA) requires that EPA make decisions about chemical risks based on the “best available science” and use of systematic reviews to evaluate the weight of the scientific evidence.⁷ These systematic review “rules” will determine what evidence EPA will consider, and how it will evaluate that evidence when making decisions about potentially hazardous chemicals. However, the current administration does not comply with current, established, best-available empirical methods for systematic review and has resulted in underestimating risks of environmental chemicals and pollutants; this noncompliance has been identified by EPA’s Science Advisory Committee on Chemicals (SACC).

With the public’s health at stake, EPA’s incomplete TSCA method (see TCE case study below) is deeply concerning as it has excluded quality research that found health effects from exposures to toxic chemicals from EPA’s decision-making. Thus, continued use of this method would mean that risks from industrial chemicals and pollutants could be undervalued and underestimated — leaving the public and the most vulnerable populations that Congress explicitly mandated EPA to protect at risk from harmful chemical exposures.

PROPOSED ACTIONS

- 1. EPA should implement a science-based systematic review method** that aligns with the NASEM’s definition of a systematic review, including but not limited to, using explicit and pre-specified scientific methods for every step of the review.
- 2. EPA should immediately implement a science-based systematic review method for the ongoing TSCA risk evaluations** and use the same systematic review method for hazard identification, characterization and risk assessment across the Agency that has been demonstrated for use in environmental health, and which has been endorsed and utilized by the NASEM i.e., the National Toxicology Program’s OHAT method and the Navigation Guide developed by the University of California, San Francisco.
- 3. EPA should invest in training and implementation for risk assessors in best practices in systematic review** across the Agency. This would allow for greater consistency across the Offices within the Agency for how these assessments are conducted, the ability to share knowledge, learning and resources, and allow the Agency to be at the forefront of cutting-edge methodological advancements for systematic review methods globally. It would allow for consistency across Agency offices that conduct hazard identification, hazard characterization and risk assessment.

HOW HAS THE TSCA METHOD EXCLUDED QUALITY RESEARCH FROM EPA'S DECISION-MAKING?

Example: Failure to Consider Prenatal Exposures to TCE and Fetal Heart Defects in Draft Risk Evaluation for Trichloroethylene⁸

- Scientific evidence and EPA scientists find that TCE can increase the risk of fetal heart malformations and that this is the most sensitive outcome (endpoint) for exposure to TCE.
- However, EPA's conclusions about the science ignore this evidence and instead focus on immunosuppression and autoimmunity as the key endpoints for determining whether or not a condition of use presents "unreasonable risks." The critical exposure level for immunological effects occur almost 500x higher than for fetal heart malformations. Thus, using the immunological endpoint will put pregnant women and their fetuses at risk.
- If EPA had used a systematic review method that complied with current, established, and best-available empirical methods, EPA could not ignore the fetal heart defect endpoint, as there was **sufficient to high evidence** to show these harms. EPA stated that there was "medium confidence" in the relevance of the endpoint to human toxicity based on the results of the Weight of Evidence analysis⁹ and that the Johnson et al., 2003 study considered in the dose-response analysis for acute exposure scenarios, measuring the effect on congenital heart defects, was of medium quality.¹⁰ Instead, **EPA created arbitrary decision-making criteria after the evidence** had already been evaluated to select a far less sensitive endpoint. **There is no credible scientific justification for ignoring evidence of fetal heart defects in evaluating TCE's risks to health.**

explicit, **pre-specified scientific methods** to identify, select, assess, and summarize the findings of similar but separate studies."¹¹ However, the TSCA method does not comply with these current, established, empirical methods for systematic review and could result in underestimating risks to environmental chemicals and pollutants. Several of these fundamental systematic review deficiencies in the TSCA method have been identified by EPA's Science Advisory Committee on Chemicals (SACC). The SACC has made several comments and critical recommendations necessary to improve the TSCA method, which EPA has not addressed in the draft risk evaluations to date; therefore, the scientific flaws in the TSCA method persist.^{12,13,14,15,16}

CRITICAL CONCERNS IN THE TSCA SYSTEMATIC REVIEW METHOD IDENTIFIED BY THE EPA'S SCIENCE ADVISORY COMMITTEE ON CHEMICALS (SACC) INCLUDE:

- Failure to use a published protocol for any of the chemicals that have undergone draft risk evaluations
- Failure to use a complete literature review process, which incorporates only select best practices for conducting a systematic and transparent literature review
- The use of a quantitative scoring method that is incompatible with the best available science in fundamental ways and can exclude relevant studies from consideration in the risk evaluation
- Failure to adequately define how EPA integrates the evidence from different streams to come to a determination on whether a chemical exposure presents an "unreasonable risk"

We recommend EPA implement a systematic review method that is compatible with empirically based existing methods and aligns with the National Academy of Medicine's definition of a systematic review, including but not limited to, using explicit and pre-specified scientific methods for every step of the review.

SUPPORTING EVIDENCE

EPA should implement a science-based systematic review method that aligns with the National Academy of Medicine's definition of a systematic review, including but not limited to, using explicit and pre-specified scientific methods for every step of the review.

The National Academy of Medicine, which has 21 standards covering the entire systematic review process that, if adhered to, result in a scientifically valid, transparent, and reproducible systematic review, defines a systematic review as a "scientific investigation that focuses on a specific question and uses

EPA should immediately implement a science-based systematic review method for the ongoing TSCA risk evaluations and use the same systematic review method for hazard identification, characterization and risk assessment across the Agency that has been demonstrated for use in environmental health, and which has been endorsed and utilized by the National Academies of Sciences, Engineering, and Medicine (NASEM) i.e., the National Toxicology Program's OHAT method and the Navigation Guide developed by the University of California, San Francisco.

Almost a decade ago, these empirically proven methods for research synthesis were adapted through an interdisciplinary collaborative effort for environmental health beginning with the development and implementation of the University of California, San Francisco (UCSF) "Navigation Guide Systematic Review Method."¹⁷ This was followed by the publication of the National Toxicology Program's Office of Health Assessment and Translation (OHAT) "Approach for Systematic Review and Evidence Integration for Health Effects Evaluations."¹⁸ Both the Navigation Guide and the OHAT method have been used or recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM), and demonstrated in six case studies^{19,20,21,22,23,24,25,26} in the peer-reviewed literature. The World Health Organization and International Labor Organization (WHO/ILO) are using the Navigation Guide to conduct systematic reviews to assess the global burden of work related injury and disease due to exposure to occupational risk factors.²⁷ Therefore, these proven methods could be easily transferred and used immediately for all ongoing evaluations conducted under TSCA.

Further, EPA should use the same systematic review method for hazard identification, characterization and risk assessment across the Agency. The NASEM has cited both of these systematic review methods as exemplary of the type of methods EPA should use in hazard and risk assessment.^{4,5,6} Further, the NASEM utilized both methods in its 2017 assessment of the potential health impacts of endocrine active environmental chemicals.⁴ Specifically, in its 2017 review the NASEM found:

"The two approaches [OHAT and Navigation Guide] are very similar... and they are based on the same established methodology for the conduct of systematic review and evidence assessment (e.g., Cochrane Collaboration, AHRQ Evidence-based Practice Center Program, and GRADE). Both the OHAT and Navigation Guide methods include the key steps recommended by a previous National Academies committee (NRC 2014) for problem formulation, protocol development, specifying a study question, developing PECO statement, identifying and selecting the evidence, evaluating the evidence, and integrating the evidence."²⁸

To assess the harms in human studies, instead of conducting an entirely new review, NASEM used the Navigation Guide published systematic review on PBDE flame retardant exposure and IQ and concluded that:

"To assess the human evidence, the committee critically evaluated the methods of a recent systematic review conducted by Lam et al... Judging that this existing review fulfilled the requirements of a systematic review and that there was no evidence of risk of bias in the assessment, the committee used the Lam et al. review as a basis for its own assessment."²⁹

Further, systematic reviews have been adopted by EPA's Integrated Risk Information System (IRIS) program and in 2014, NASEM recommended that the IRIS Program use the OHAT method.

EPA should invest in training and implementation for risk assessors in best practices in systematic review across the Agency. This would allow for greater consistency across the Offices within the Agency for how these assessments are conducted, the ability to share knowledge, learning and resources, and allow the Agency to be at the forefront of cutting-edge methodological advancements for systematic review methods globally. It would allow for consistency across Agency offices that conduct hazard identification, hazard characterization and risk assessment.

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We Need the Best Science Free of Financial Conflicts of Interest so Environmental Health Decision-Making Can Protect Public Health

RECOMMENDATION

To reduce biased findings, financial conflicts of interest from industry funding in environmental health research must be considered a risk of bias and industry financial ties on EPA advisory committees should be eliminated to the extent possible.

ISSUE SUMMARY

"The biggest threat to [scientific] integrity [is] financial conflicts of interest," *JAMA's* deputy editor observed in 2010.¹ Actions by the tobacco and pharmaceutical industries over decades demonstrate that when industry sponsors research, the results are more favorable to the sponsoring industry.^{2,3} Similar patterns are seen in the research funded by the chemical industry.⁴

The National Academies of Sciences, Engineering and Medicine (NASEM) recommended to the EPA that "funding sources should be considered" when evaluating the quality of a study.⁵ Yet EPA does not account for how it will consider funding sources when reviewing scientific evidence. Nor has EPA sufficiently addressed conflicts of interest among those the Agency appoints to scientific advisory boards by failing to rigorously and transparently apply its own rules.

Financial conflicts of interest from industry funding should be eliminated on advisory committees and boards to the extent possible. The influence of financial ties on research can be traced to a variety of types of biases, and this conflict of interest needs to be distinguished from non-financial interests in the research.⁶

PROPOSED ACTIONS

- 1. EPA should assess study-funding source and author financial conflicts of interests when evaluating study quality** for hazard and risk assessment, and consider it a risk of bias.
- 2. Financial conflicts of interest from industry funding should be eliminated to the extent possible** among individual advisory members. If individuals with financial conflicts of interest are accepted onto advisory boards, their effects must be minimized and should be recused when discussions and decisions that have financial implications for their profession are made. They must also be balanced by members from the environmental and/or public health nonprofit community that do not have industry funding.
- 3. Financial conflicts of interest among EPA advisory board members should be disclosed and eliminated.** Before finalizing the selection of individual advisory members the vetting process of conflicts of interest should include: identifying and publicly disclosing any conflicts that include financial ties with industry; determining whether a conflict of interest exists with the committee member; and finally implementing the necessary procedures to manage any conflicts of interest. Further, the committee chair must be free of any financial conflicts of interest.

SUPPORTING EVIDENCE

EPA should assess study-funding source and author financial conflicts of interests when evaluating study quality for hazard and risk assessment, and consider it a risk of bias.

Research of pharmaceutical, tobacco and nutrition industries has shown that research sponsored by industry were more likely to have results that favored the sponsor even when the

studies were of the same methodological quality.^{7,8,9} Industry sponsorship can bias research through various mechanisms, including how they design and conduct a study, selectively report the results, code events, analyze the study data, spin conclusions, as well as frame the questions that are asked.^{10,11,12,13}

A 2017 Cochrane systematic review of industry sponsorship and research outcomes concluded that “industry sponsorship should be treated as bias-inducing and industry bias should be treated as a separate domain” when evaluating a study’s internal validity (study quality).⁷ The NASEM in its review of the EPA Integrated Risk Information System (IRIS) program’s systematic review method found that “Funding sources should be considered in the risk-of-bias assessment conducted for systematic reviews that are part of an IRIS assessment.”⁵ Therefore, as EPA assessments depend on an evidence base that should be as free as possible of bias, EPA should assess study-funding source and author financial conflicts of interests when evaluating study quality for hazard and risk assessment, and consider it a risk of bias.

Importantly, including funding as a risk of bias domain does not mean excluding industry sponsored studies from EPA’s hazard and risk assessment; it only means documenting funding as one of many domains of potential bias and evaluating its impact on the overall quality of the body of evidence.

Financial conflicts of interest from industry funding should be eliminated to the extent possible among individual advisory members and financial conflicts of interest among EPA advisory board members should be disclosed and eliminated.

EPA’s own *Peer Review Handbook* (Science and Technology Policy Council, U.S. EPA, *Peer Review Handbook* at 22, 80 (4th ed. 2015)) requires prospective peer reviewers, such as the Science Advisory Committee on Chemicals (SACC) members, to “disclose any activities or circumstances that could pose a conflict of interest or create an appearance of a loss of impartiality,” and calls for EPA to screen for potential conflicts “[b]efore finalizing the selection of reviewers.”

Federal ethics regulations also require EPA to “[a]ssure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes” (41 C.F.R. § 102-3.105(h)). When EPA solicited nominations for the SACC in March 2020, the Agency announced its selection criteria, including the “[a]bsence of financial conflicts of interest or the appearance of a loss of impartiality.” (85 Fed. Reg. 16,094-01 (Mar. 20, 2020)).

Therefore, it is critical that before finalizing the selection of individual advisory members, EPA’s vetting process of conflicts of interest must include: determining whether a conflict of interest exists with the committee member; the identification and public disclosure of any financial ties with industry; and

finally implementing the necessary procedures to manage any conflicts of interest. Further, the committee chair must be free of any financial conflicts of interest.

Importantly, conflicts of interest due to financial ties from companies that manufacture or distribute chemicals that undergo EPA evaluation, or from any trade associations that may represent those companies, must be distinguished from *nonfinancial interest*, as these *conflicts of interest* can create a bias that extends beyond the individual as sponsorship amplifies the certain viewpoint of industry and guarantees widespread dissemination and representation in the decision-making process.¹⁴ This was demonstrated when the tobacco industry distorted an entire body of published research on the harms of secondhand smoke.¹⁵ Therefore, multiple members of an EPA advisory committee may have financial ties with chemical manufacturers or other companies that could financially benefit from the findings of an evaluation or the recommendations of the advisory committee that states a chemical does not pose harms to human health.⁶ While in contrast, committee members with a combination of nonfinancial interests such as personal beliefs, theoretical viewpoint, or desire for glory could influence evaluation in different directions and thus not be an overall bias.

IMPLICATIONS OF FAILING TO DISCLOSE FINANCIAL CONFLICTS OF INTEREST

EPA did not disclose whether any of the candidates under consideration for appointment to the Toxic Substances Control Act (TSCA) SACC in October 2020 received industry funding from companies that manufacture or distribute the next 22 chemicals that will undergo TSCA risk evaluation, or from any trade associations that may represent those companies. In addition, before requesting public comments on the candidates, EPA failed to make known if the candidates had been screened for any such conflicts of interest. This lack of disclosure is particularly concerning as the SACC will be expected to provide input and advice related to those chemicals.

Therefore, individuals who serve on EPA advisory committees with financial relationships with companies that can benefit from the recommendations of the advisory committee should be excluded from the committee, or those with certain affiliations should be recused when decisions that have financial implications for their profession are made. In addition, advisory committees must always be balanced out by members from the environmental and/or public health nonprofit community that does not have industry funding.⁶ However, nonfinancial interests of individuals should not be used as the basis of exclusion from EPA advisory committees, as this would reduce the necessary diversity of thought and perspective required

for an EPA advisory committee. Further, such an approach may lead to the overrepresentation of financially conflicted individuals whose interests could financially benefit from the findings of a risk evaluation or the recommendations of the advisory committee.¹⁶

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The Routine Outcome of Our Environmental Laws and Policies at All Levels of Government Must Be Equal Protection, Not Environmental Disparities

RECOMMENDATION

We must adopt environmental justice (EJ) principles in chemical policymaking and implement environmental statutes such as the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act [Public Law No. 114-182] (known as TSCA) as Congress intended to fundamentally transform chemical policy to address health disparities from harmful chemicals.

ISSUE SUMMARY

Communities of color are disproportionately exposed to harmful chemicals, pesticides, air pollution, and industrial releases (both deliberate and accidental).^{1,2} Although our U.S. laws aspire to protect health, the way the government implements these laws and policies do not ensure equal, socially just safeguards for environmental health.^{1,2}

The science linking environmental pollution to poor health, especially for children, low-income families, and communities of color has led medical societies such as the American College of Obstetricians and Gynecologists (ACOG), the International Federation of Gynecology and Obstetrics (FIGO), and the American Academy of Pediatrics (AAP) to recognize the threat toxic chemicals pose to public health and call for policies to prevent harmful exposures.³⁻⁶ Environmental exposures to harmful industrial chemicals are a preventable source of adverse health consequences.^{3,7}

Science should guide chemical policy to promote healthy outcomes for diverse communities not just for the privileged and powerful.⁸ The U.S. Environmental Protection Agency (EPA) must require and evaluate data for population disparities in chemical exposures and health risks in implementing the law. Only those companies with full evidence that their products are safe should have access to lucrative U.S. markets, and U.S. decision-making must include meaningful community participation as equal partners at every step of the regulatory process for evaluating chemicals, from needs assessment to enforcement and evaluation.

PROPOSED ACTIONS

- 1. Incorporate environmental justice principles** into every aspect of environmental policy and EPA's work.
- 2. Expand consideration of susceptible populations in risk assessment** to include at-risk communities where health problems from chemical exposures and pollutants may be worse due to discrimination, poverty and other chronic stressors.
- 3. Allocate additional resources to monitor and reduce environmental pollution and risks in overburdened communities** and build capacity for risk evaluations that comport with National Academies of Sciences' recommendations.
- 4. Increase and improve community input and engagement** to ensure accountability that EPA actions demonstrably reduce inequitable pollution exposures.

SUPPORTING EVIDENCE

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^{9,10} 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

With environmental justice principles as a guide:

We can boldly imagine and create U.S. policy in which the environment enhances health for all people—in land and natural resource management, the products in our homes and schools, and actions in our workplaces.

Incorporate environmental justice into every aspect of environmental policy and EPA's work.

- EPA must meaningfully incorporate EJ into its evaluation of chemicals under TSCA. This requires the use of cumulative environmental risk frameworks, full assessment of aggregate exposures, inclusion of legacy compounds and full health assessment of communities near manufacturing and disposal sites.
 - EPA must fully implement Executive Order 12898: "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations."
 - EPA leadership must require meaningful—not boilerplate—and publicly available environmental justice analyses of core EPA 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.
 - EPA must obtain White House support for reviving, expanding (including formally adding the White House Council on Environmental Quality), and revitalizing the federal Interagency Working Group on Environmental Justice (EJ IWG). Establish and utilize regional interagency working groups to prioritize action on health-protective chemical policy.
 - EPA should follow the methods outlined in *Guidance on Considering Environmental Justice During the Development of a Regulatory Action* at each step of developing significant rulemakings (including decision briefings) and other actions related to chemical policy.
 - EPA must measure Senior Executive Service performance based on environmental justice metrics.
- Expand consideration of susceptible populations in risk assessment to include at-risk communities where health problems from chemical exposures and pollutants may be worse due to discrimination, poverty and other chronic stressors.**
- EPA must utilize authorities under 2016 amended TSCA to obtain information to fully assess risks to all susceptible and potentially highly exposed groups using modern risk assessment techniques as recommended by NAS in *Science and Decisions* (2009) and other NAS reports.¹¹⁻¹³ With the exception of pesticides, most chemicals used in industrial processes or commercial products are not required to have adequate health testing to stay on the market. No formal risk assessment was performed because most chemicals on the market today were grandfathered in under the flawed 1976 TSCA, and their safety has never been assessed.¹⁴
- Under the weak 1976 law, even known harmful chemicals such as asbestos and methylene chloride were not banned. While the law was amended in 2016, the implementation of the new Lautenberg amendments has focused on speeding approvals of new chemicals rather than obtaining and sharing adequate safety data. And it is still not required for existing chemicals on the market to provide adequate data on health risks to stay on the market.
- Working with communities and groups representing workers in highly exposed settings as well as other public health partners, EPA must routinely evaluate likely chemical exposures and inequalities via mapping, biomonitoring, citizen science measurements (e.g., odor or symptoms tracking), cumulative environmental exposure frameworks, fenceline community monitoring of chemicals of concern, and other public health surveillance tools. Adequate budget and resources need to be acquired for these purposes.
 - In cooperation with the Centers for Disease Control (CDC), EPA must utilize sentinel surveillance and require systems to incorporate sociodemographic data to identify communities that are suffering the most from health threats. Thus, we can prioritize interventions to address inequities at their root causes and tailor public-health interventions to reach all vulnerable and highly exposed groups (e.g., in occupational settings, schools, nursing homes) rather than applying a one-size-fits-all approach.

Allocate additional resources to monitor and reduce environmental pollution and risks in overburdened communities; build capacity for risk evaluations that comport with National Academies of Sciences recommendations.

Meaningful engagement with impacted, frontline communities includes providing resources and building capacity within communities to participate in the risk management process. We envision expanded grants programs for EJ organizations, state and local government, and for scholars working on EJ issues and the policymaking process. This capacity can begin to reverse systemic racial discrimination and close racial disparities in exposures and harms from contact with harmful products on the market and their manufacture and disposal.

- EPA should support and facilitate the use of alternative dispute resolution mechanisms for communities addressing environmental challenges.
- EPA must disavow the Department of Justice (DOJ) memo “Supplemental Environmental Projects (SEPs) in Civil Settlements with Private Defendants” and encourage resumption and expansion of the use of SEPs as enforcement tools. SEPs should involve considerable outreach to and input from the community.
- Build EPA’s capacity to promote environmental justice through risk evaluations that comport with NAS recommendations. Develop equity metrics and seek input from the National Academy of Sciences.
- Consult with communities to develop improved mapping and screening tools (see CalEPA’s online mapping tool CalEnviroScreen) to assess cumulative and disproportionate impacts. Develop nationally consistent data for identifying overburdened communities to inform targeting of resources, track results, and encourage states to share best practices.

Increase community engagement and accountability to ensure that EPA actions demonstrably reduce inequitable pollution exposures.

- EPA must accelerate environmental education programs with input from community experiences to support education similar to NASA’s support for space sciences. We need to end systemic racism in K-12 education, including in science, technology, engineering, and mathematics (STEM), where diversity has not meaningfully changed for decades.¹⁵ EPA must ensure that diverse scientists are represented in its science and educational initiatives in STEM, environmental and social determinants of health..

- EPA should implement and expand its own 2016 Plan to increase access to results of EPA-funded scientific research. We must build a more complete, “whole fabric” understanding of health effects of environmental exposures to chemicals, and put some special focus on understanding overlapping threats as well as include diverse cultural perspectives, valuing the special knowledge held by communities.

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Invest in Data Infrastructure for More Equitable Environmental Health Decisions

RECOMMENDATION

EPA must invest in systems to support collecting, organizing and making accessible environmental and health data that allow the agency and the public to understand, monitor and act on environmental factors that influence health, resulting in more equitable public health safeguards.

ISSUE SUMMARY

We cannot manage what we do not measure. Thus, we need investments in EPA and state partners to implement, house and maintain the most up-to-date data that will allow EPA to better identify potential harms, risks, and effectiveness of interventions as well as prioritize areas of need. This includes quantification of environmental contaminants both released and present in air, water, food and consumer products; health stressors such as poverty; as well as data on environmental health-related diseases. It is crucial that EPA modernize and digitize all its data to make it accessible and actionable.

Without adequate monitoring, modeling, and up-to-date data, exposures, hazards, and health effects will remain unknown to the public and unaddressed by the private sector, researchers and government. Thus, government funding of monitoring and data infrastructure should provide concrete, quantifiable measures and indicators for key factors relevant to the environment and health in the United States, and help policymakers understand health risks from chemicals and pollutants in order to identify both opportunities for intervention/prevention and their progress in meeting goals and policies.

PROPOSED ACTIONS

- 1. EPA should restore credibility and increase access to the results of its funded scientific research** by implementing its 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research.
- 2. EPA should apply the methods and tools of CalEnviroScreen nationally**, creating a detailed visualization tool for the exposures and factors that increase a population's susceptibility to industrial chemicals.
- 3. EPA should continue long-term funding and improvements for current systems in place**, such as the America's Children and the Environment Reports, the National Air Toxics Assessment, and other related data across the federal government that are critical for environmental health decision-making (e.g., NCHS related data).

SUPPORTING EVIDENCE

EPA should restore credibility and increase access to the results of its funded scientific research, by implementing its 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research.

Under statute, EPA is charged with multi-trillion-dollar decisions that impact the public health of the nation and the economy for generations. Making science-based decisions means that complex scientific data and modeling need to be available for public scrutiny through appropriate procedures. Responding to this need, in 2016 EPA developed a *Plan to Increase Access to Results of EPA-Funded Scientific Research*¹ (The Plan), in consultation with the National Science and Technology Council

and public input. 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 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.²
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.³

This Plan is in stark contrast to EPA's proposed Science Transparency Rule, which instead promulgates rules that would require research data to be publicly accessible in order to be used for regulatory actions. Further the Science Transparency Rule has been opposed by authoritative bodies including the University of California.^{4,5} EPA already has a draft plan that will achieve transparency goals and can be implemented now with broad scientific support.

EPA should apply the methods and tools of CalEnviroScreen nationally, creating a detailed visualization tool for the exposures and factors that increase a population's susceptibility to industrial chemicals.

Communities experience environmental exposures from multiple sources simultaneously, and the National Academies of Sciences in its report *Science and Decisions* (2009) recommended cumulative environmental exposure frameworks to avoid the systematic underestimation of risk.⁶ To address this shortcoming, creating a national-level CalEnviroScreen will provide EPA and the public with a better understanding of exposures to multiple chemicals as well as overlapping susceptibilities in the population. Rather than applying a one-size-fits-all approach, a cumulative approach will allow EPA to prioritize interventions that address inequities at their root causes, and then tailor public health interventions to reach different types of vulnerable groups (e.g., that live near multiple polluting facilities or schools near freeways). With improved data visualization, communities will be able to site and manage industrial facilities and infrastructure in a more environmentally just manner and protect vulnerable populations from cumulative exposures. Further, to ensure EPA can access robust and reliable data to inform this data visualization, EPA must continue to fund and develop better tools and methods for exposures assessment, including contaminant modeling and monitoring and biomonitoring, on a national level.

A national EnviroScreen tool should include the mapping of sensitive populations with asthma, cardiovascular disease, and low birthweight, as well as socioeconomic factors such as educational attainment, housing burden, linguistic isolation, poverty, and unemployment. EPA should utilize sentinel surveillance and incorporate key sociodemographic data to identify communities that are suffering the most from health threats. After updating the tool, the Agency should conduct a community listening tour to consider other indicators as necessary.

EPA should continue long-term funding and improvements for current systems in place, such as the America's Children and the Environment Reports, the National Air Toxics Assessment, and other related data across the federal government that are critical for environmental health decision-making (e.g., NCHS related data).

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Invest in Research and Training for Science on Understanding Chemical Exposures to Ensure Health-Protective Policies

RECOMMENDATION

EPA must invest in research and workforce training to ensure it has the right and best science for decision-making and that its workforce keeps pace with current scientific advances so that its regulatory decision-making is evidence-based.

ISSUE SUMMARY

The Environmental Protection Agency and its associated programs are the core of the nation's environmental protections of air, water, hazardous waste, climate, industrial chemicals, and environmental justice. In the face of EPA's mounting responsibilities to fulfill its mission to protect human health and the environment, its research budget has shrunk.

The Agency's ability to meet its mandate to be a driver of innovation and change in environmental health has been severely hampered by a systemic under-resourcing of the Agency's research stretching back as far as 1980. While new challenges are presented at every turn, with many addressed by scientists and authoritative bodies for the past decade, EPA and its staff have been financially and academically hindered from both investing in science that will allow the Agency to answer critical questions related to environmental contaminants and health, and from keeping pace with current scientific methods and best practices. This has resulted in Agency actions which utilize outdated science methodology and subsequently regulations which fail to comprehensively address public and environmental health challenges.

EPA must invest in research, keep abreast of the science and be better equipped to meet its statutory requirements. The Agency can only do that if it is adequately investing in research to help itself answer pressing questions on environmental exposures and human health. Below are some recommendations for research investments to fill critical research gaps and ensure that its research, staff, and thus regulations are in step with most up-to-date science.

PROPOSED ACTIONS

- 1. EPA must invest in next-generation methods for understanding and characterizing environmental stressors** — including biomonitoring, exposure methods and human epidemiologic studies — **to identify and measure chemical exposures**, major exposure sources (industry, consumer products, food, etc.), and to evaluate how they exacerbate health disparities, and increase the cumulative effects of chemical exposures and social stressors (poverty, food insecurity and racism) on health.
- 2. EPA needs basic laboratory science to rapidly identify which and how chemicals and pollutants harm health.** EPA must upgrade their approach to rapid in vitro tests to identify chemicals that may adversely affect development and human health along the lifespan to ensure it is responsive to population health needs and is anchored in whole animal testing.
- 3. EPA should prioritize the Children's Environmental Health and Disease Prevention Research Centers**, which study the impact of environmental factors, including air pollution and chemicals, on health conditions like asthma, birth outcomes, cancer, immune function, neurodevelopment, autism, obesity, and reproductive development. These risks are significant and worth investigating. A 2017 impact report from the EPA found that environmentally related diseases in U.S. children cost \$76.6 billion every year.
- 4. EPA Office of Research and Development (ORD) should require ongoing training to Agency risk assessors**, as a part of the workforce analyses recommended by EPA Office of Inspector General (OIG).

- 5. EPA must adopt translation, communication and promotion of evidence-based real-world solutions** to reduce and prevent harmful chemical exposures and deliver measurable health improvements.

SUPPORTING EVIDENCE

Next-generation methods for understanding and characterizing environmental stressors — including biomonitoring, exposure methods and human epidemiologic studies to identify and measure a broad range of chemical and social exposures found in the population, and to identify the major exposure sources (industry, consumer products, food, etc.) of chemicals, to evaluate how they can exacerbate disparities in health outcomes, and increase the load of cumulative effects of multiple chemical exposures, social stressors, such as poverty, food insecurity and racism, on health.

EPA should fund more, and make better use of existing, human epidemiologic data and novel methods, which facilitate analysis of chemical and nonchemical exposures and their potential additive or multiplicative effects.¹ The Agency should invest in mapping the top 5% for multiple chemicals and see whether the same groups are in that top 5% for multiple compounds. Such investment should include a nationwide mapping tool similar to CalEnviroScreen that can visually represent (for widespread consumption) environmental exposures, as well as a steady and accessible funding stream to support advancements in civic science and associated technologies (i.e., low-cost, widely available) to ensure these tools and technologies can advance community enforcement efforts and help reduce harmful exposures. EPA should also increase its funding streams for projects related to community-based participatory research/ environmental justice programs and focus more on R2A funding.

Additionally, EPA must fund research to develop better methods to incorporate these exposures and vulnerabilities into probabilistic models and produce data-driven models. EPA should use established methods (e.g., probabilistic assessment) to quantify health risks from exposures and develop the necessary data to support quantifying all risks and better benefits calculations. EPA should use these risk calculations to quantify benefits under TSCA and other relevant regulatory and science programs, and better identify policy options for different exposure scenarios.² This will allow the Agency to make better and more informed decisions that address the full population.

Basic laboratory science to rapidly identify which and how chemicals and pollutants harm health. EPA must upgrade their approach to rapid in vitro tests to identify chemicals

that may adversely affect development and human health along the lifespan to ensure it is responsive to population health needs and is anchored in whole animal testing.

EPA must expand funding and research to address the undefined predictive ability of in vitro and in silico models for predicting toxicity in humans, to develop improved representative models (e.g., tissue/organ bioengineered models) of human development, and to develop sophisticated statistical and mathematical approaches to model these data.³ The key areas that are a problem and that need to be addressed immediately include chronic doses, low doses, cumulative exposures and model systems that do not account for sensitive tissues as well as ages. Further in vitro systems need to be improved to fully capture human variability, and data need to be anchored in whole-animal and human results. Finally, the data and results need to be made accessible and informed by community input.

The Children's Environmental Health and Disease Prevention Research Centers (Children's Centers). The Children's Centers study the impact of environmental factors, including air pollution and chemicals, on health conditions like asthma, birth outcomes, cancer, immune function, neurodevelopment, autism, obesity, and reproductive development. These risks are significant and worth investigating — a 2017 impact report from the EPA found that environmentally related diseases in U.S. children cost \$76.6 billion every year.

The NIEHS and EPA Science to Achieve Results (STAR) grant program funded the Children's Centers jointly. These centers have been funded since 1998, and have been performing invaluable work in identifying and mitigating how these environmental factors can pose a health risk to children. This work has led to improved policies that help to reduce health risks and improve the quality of life for children and the public. The importance of this work cannot be overstated, and it is deeply concerning that EPA currently is not providing funds through the National Center for Environmental Research (NCER) Science to Achieve Results (STAR) grant program to continue investing in this effort. EPA must once again invest in this area of health.

EPA Office of Research and Development (ORD) should require ongoing training to Agency risk assessors as a part of the workforce analyses recommended by EPA Office of Inspector General (OIG).

EPA risk assessors are not currently providing any ongoing training to ensure that they keep up with the state of the science, which is rapidly changing. As a result, many of the regulatory assessments the Agency conducts may not incorporate the most current science. Having an EPA workforce that stays current will improve the efficiency and the accuracy

of risk assessments. This should include ongoing trainings to Agency risk assessors on key multilevel and mixture modeling approaches (e.g., Quantile-based G-comp, Monte Carlo, Markov, Bayesian, and Random Forrest), as a part of the workforce analysis recommended by EPA's Office of the Inspector General. Further, new methods in risk assessment, including probabilistic approaches to quantify health risks from exposures, better account for human variability, vulnerability, as well as baseline exposures and stressors, and thus better protect public health.

In a recent audit, EPA's OIG made specific recommendations for EPA to conduct a workforce analysis to assess capabilities to implement the newly amended Toxic Substances Control Act (TSCA), and as an outcome, specify what skill gaps must be filled to meet the TSCA requirements. EPA should also conduct a consistent and transparent review at regular intervals to identify new data from the health literature and ensure that assessors are using the best available science.

Translation, communication and promotion of evidence-based real-world solutions to reduce and prevent harmful chemical exposures and deliver measurable health improvements.

EPA must invest in a series of projects that will identify and communicate who is most vulnerable and at risk from environmental exposures to better inform prevention efforts; improve tools to measure the benefits of preventing harmful chemical exposure; and develop evidence-based recommendations and policies to prevent toxic chemical exposures. EPA must also support training programs to train scientists, clinicians and community leaders in how to effectively promote science-based policy. EPA should also invest in community based participatory research that is responsive to community needs and can inform EPA science and policies.

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