Recommendation

EPA urgently needs to update its scientific methods to more accurately identify hazards and risks of chemicals and pollutants to ensure people are not made sick from toxic chemicals.

SUMMARY

EPA's methods for evaluating scientific evidence have not kept pace with the significant advances in understanding how chemicals in commerce and environmental pollutants impact health. Extensive scientific evidence shows that everyday exposure to widely used chemicals results in an increased risk of multiple adverse health outcomes.[1,2] These risks are magnified by multiple chemical and non-chemical factors, including exposures to multiple pollutants, underlying health conditions, genetic predispositions, social stressors such as poverty and discrimination, and lifestage.[3]

The risk assessment process is time-consuming and resource-intensive, susceptible to industry influence, and so technical and opaque that it often excludes the people most impacted by toxic chemicals. Where risk assessment is legally required, agencies like the EPA must update their scientific methods to more accurately identify and quantify the chemical health risks. Additionally, EPA and similar agencies should use hazard-based approaches and cumulative impact assessment where feasible and legally appropriate. This is particularly pressing given the escalating chemical production, usage,[4] and rising chronic disease trends.[1]

PROPOSED ACTIONS

To ensure that the Agency's decisions uphold the best available science and evaluate and address all health risks of chemicals, **we recommend that EPA should:**

1. **Use established methods to quantify risks of non-cancer health effects at all exposure levels.**
2. **Increase the human variability adjustment factor to at least 42X, and include an additional 10X to account for early life susceptibility to capture the full range of variability in health impacts of chemical exposures.**

3. **Adopt a consistent approach to account for all foreseeable exposures and for combinations of exposures in chemical assessments, and better account for highly-exposed individuals by assessing exposures for at least the 99th percentile of the population.**
4. **Assess chemicals by class to accelerate the pace of chemical assessment and avoid regrettable substitution.**

5. **Conduct cumulative risk assessments and cumulative impact assessments to better account for real-world chemical exposures and risks.**
6. **Fully consider health risks from all evidence streams, including human, animal, and in vitro, and not dismiss signals of harm in regulatory decision-making.**

SUPPORTING EVIDENCE

EPA should use established methods to quantify risks of non-cancer health effects at all relevant levels of exposure.

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. For any chemical EPA is assessing, it should assume that all demonstrated or suspected cancer and non-cancer health effects have some probability of occurring at relevant exposure levels, unless there is strong evidence demonstrating otherwise, and should quantify these risks accordingly.

Multiple authoritative review bodies and scientists have called for improved approaches for hazard and risk assessment.[5–11] Of particular concern is EPA's reliance on an assumption that risks posed by chemical exposures are negligible below an assumed "safe" threshold, a policy that does not reflect the best available science or adequately account for human variability or susceptibility, particularly for infants, children, pregnant women, and historically marginalized communities.[11,12] This approach assumes a "safe level" below which there is no risk. However, this does not mean that there are actually no effects in the exposed population below this safety "threshold."

Research examining exposures to pollutants, including particulate matter, air pollution, and lead, illustrate how intrinsic (e.g. underlying disease, age, sex) and extrinsic (e.g. healthcare inequity, lack of access to healthy foods, racism, discrimination, extreme weather) factors increase risk of adverse health outcomes.[5(pp9-10),6,13–19] Thus, adverse effects can occur at exposures levels previously deemed "safe."

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, life stage, external stressors), risks will extend to all foreseeable population exposures.[6,14,18,19] The National Academies of Sciences, Engineering, and Medicine (NASEM)[5,20] recommended that EPA adopt methods that quantify non-cancer risk at levels of exposure commonly experienced by workers, consumers, and the general population. **Yet, EPA continues to use scientifically unsupported "bright-line" methods, which incorrectly imply a zero-risk level.**

Quantifying non-cancer risks for all exposure levels, similar to what is done for cancer, provides more actionable information to the public and decision-makers about environmental health risks, and allows policymakers to better estimate the health benefits of environmental regulations.[11,12]

Robust methods are available and have been demonstrated to effectively estimate the risk of non-cancer health effects at relevant exposure levels by making better use of available data on human variability.

We recommend that EPA:

- Use established methods to evaluate dose-response relationships for non-cancer health effects at levels of exposure relevant for workers, consumers, and the general public in all chemical dose-response assessments.
- Derive dose-response functions from epidemiologic evidence when suitable studies are available.[21–26]
- Apply the probabilistic methodology of the World Health Organization to derive dose-response estimates using animal toxicology studies for non-cancer health endpoints lacking suitable epidemiological data.[12,27–30]
- Develop training materials that can explain to a variety of stakeholder audiences why these methods are useful, and how they can be implemented in all Agency scientific assessments.

Estimating the population exposure level for different risk levels (e.g., 1-in-100,000, 1-in-10,000, 1-in-1,000) for all relevant health effects will give decision-makers better information about how exposures in the population translate into population risks for different health outcomes. Expressing non-cancer health risks as probabilities of effects in the exposed population will also enable EPA to estimate risk reductions resulting from policies to reduce exposures.[31]

EPA should increase the human variability adjustment factor to at least 42X, and include an additional 10X to account for early life susceptibility to capture the full range of variability in human responses to chemical exposures.

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 range of non-chemical factors that can occur across the population and contribute to differences in response to chemical exposures.[3] *Intrinsic* and *extrinsic* factors can individually or collectively increase susceptibility to harm from chemical exposures.[3,11,13–18]

EPA typically does not quantify how these susceptibility factors impact the risk to affected groups, and instead applies an intra-species (human) variability adjustment factor of 10X that **underestimates human variability and risk**. This method

is based on a science policy recommendation made nearly 70 years ago. Since then, decades of scientific evidence find this adjustment factor does not capture the full range of human responses to chemical exposures, especially for susceptible groups.[3]

EPA should first focus on identifying susceptible populations based on either chemical-specific evidence or the broader literature on intrinsic and extrinsic susceptibility factors, and then, as a separate step, consider how to adequately account for the elevated risks for each group, in some cases by using scientifically-supported uncertainty factors.[3] The initial identification of susceptible populations should not be contingent on chemical-specific data to quantify risk for a susceptible group. Once the appropriate groups are identified, EPA should then consider the availability of chemical-specific quantitative data to account for the elevated risk. When such data are absent, the application of science-based adjustment factors beyond EPA's current default human variability adjustment factor should be applied.[3]

Many authoritative scientific bodies currently use or have recommended science-based adjustment factors that better account for human variability and susceptibility.

We recommend that EPA:

- Increase the current default human variability uncertainty factor to **at least 42X, as recommended by the WHO, to better account for human variability in response to chemical exposures.[27]**

- Apply an additional adjustment factor of **at least 10X to account for the enhanced susceptibility to chemical exposures in younger age groups**, including children, infants, and the developing fetus. This is necessary because the WHO-estimated 42X adjustment factor for human variability does not account for early life susceptibility, necessitating additional adjustment to capture the full range of variability in responses to chemical exposures at younger ages.[27]

- Apply an additional adjustment factor of **at least 10X to account for additional chemical and non-chemical stressors experienced by residents of fenceline communities and other susceptible subgroups who experience disproportionately high levels of chemical and non-chemical stressors compared to the general population.** This includes non-chemical stressors, such as psychosocial stress from income inequality, violence, racism, healthcare inequity, food insecurity, and additive effects of exposure to chemical mixtures.[3]

EPA should adopt a consistent approach to account for all foreseeable exposures and for combinations of exposures in chemical assessments, and better account for highly-exposed individuals by assessing exposures for at least the 99th percentile of the population.

Chemical exposure assessments are key to determining risks to the general population and for specific subpopulations given that exposures differ among groups. Exposure assessments are also critical to understanding where interventions should be targeted. Scientific assessments that support public health-protective policies and regulations should, therefore, comprehensively identify all chemical exposures and exposure levels associated with harmful chemicals and implement mitigation strategies to prevent such exposures before harmful effects occur.

EPA currently relies on chemical exposure assessments that are inconsistent across programs and offices and fail to comprehensively consider all exposure routes, pathways, and sources, ultimately leading to underestimation of exposure and risk. These practices are particularly harmful to groups experiencing disproportionate chemical exposures, like fenceline communities. For example, residents of fenceline communities are more likely to be people of color and Indigenous people who live in areas with multiple polluting facilities clustered close together, putting them at greater risk of harm from exposure to multiple chemicals.[32]

EPA's current exposure assessment approaches that support scientific assessments often: 1) fail to consider all relevant exposure routes, pathways, and sources individually or in combination, 2) inappropriately assume that workers are fitted with personal protective equipment (PPE), and 3) fail to consider cumulative exposures to multiple chemicals and environmentally-relevant chemical mixtures.4 For example, EPA's assessment of fenceline exposures for the perchloroethylene risk management rule under TSCA failed to consider the combination of chemical exposures from more than one facility, more than one exposure route or pathway, and more than one chemical release database, vastly understating exposure and risk to communities experiencing disproportionate harm.[33]

If EPA's scientific assessments understate exposure, they will understate risk. It is therefore critical that EPA accurately characterize exposure from all sources, routes, and pathways under which chemicals are used or disposed.

To ensure EPA comprehensively considers chemical exposures in its scientific assessments, we recommend that EPA:

- **Consistently and comprehensively evaluate all foreseeable aggregate chemical exposure routes, pathways, and sources in its scientific assessments across all programs and offices.** This must, at minimum, include consideration of 1) chemical release data from multiple chemical release databases (like the Toxics Release Inventory, National Emissions Inventory, Discharge Monitoring Reports, and data indicating accidental chemical spills and releases); 2) chemical exposures from the indoor environment; 3) occupational exposures; 4) co-exposures to chemicals found in environmentally-relevant mixtures, 5) chemical exposures reported by communities through lived experiences, and 6) any relevant combinations of these sources and pathways (for example, people exposed to a chemical in the workplace may also be exposed to the same chemical at home).

- **Have a consistent approach across all offices for characterizing high-end exposures using the 99th percentile of the population.** Considering just the 95th percentile of the population as representing more highly-exposed individuals potentially leaves a large portion of the population – 16 million people[34] – with exposure levels higher than EPA's estimates and thus unprotected.

- **Stop assuming that workers are adequately fitted with PPE in its exposure assessments.** For example, in its occupational risk assessments under FIFRA, EPA estimates risk to workers wearing full PPE and/or utilizing engineering controls. In reality, workers are often not provided with adequate PPE or do not receive adequate training on PPE usage.[35] If EPA assumes that workers are fitted with maximum PPE, its exposure assessments will understate risk.

EPA should move beyond its single-chemical hazard and risk paradigm and assess chemicals by class to accelerate the pace of chemical assessment and avoid regrettable substitution.

EPA typically assesses chemicals for their hazard or risk using a chemical-by-chemical approach. This is time-consuming, resource-intensive, and often fails to capture the complexity of real-world chemical exposures. Instead, EPA should assess classes of chemicals that have shared characteristics as a group, so that the knowledge about one chemical can be applied to other chemicals in the class with less information. Grouping chemicals by class for assessment, such as PFAS, can be particularly beneficial when dealing with substances that share similar chemical structures, functions, or health hazards.[36] Grouping chemicals by class can streamline the hazard assessment process, reduce duplication of efforts, and improve the accuracy of risk assessments, both making better use of EPA resources and improving the efficiency in protecting public health.

A failure to regulate chemicals by class has led to "regrettable substitutions" of chemicals with less well-researched and similarly hazardous replacements, such as replacing one bisphenol with another that may be equally or more harmful. By evaluating chemicals by class rather than individually, the EPA could better address the cumulative and synergistic effects of chemical exposures, thus enhancing public health protection and avoiding the unintended consequences of chemical substitutions.

We recommend that EPA:

- 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 avoid regrettable substitution and accelerate the pace of chemical assessments.

EPA should conduct cumulative risk assessments and cumulative impact assessments to better account for real-world chemical exposures and risks.

Cumulative risk assessment (CRA), which is defined by EPA as the "analysis, characterization, and possible quantification of the combined risks to health or the environment posed by multiple agents or stressors,"[37] is the best available tool to account for real-world risk. CRA can incorporate multiple chemicals along with non-chemical stressors, which may include intrinsic (e.g., pre-existing disease, life stage) and extrinsic (e.g. geography, socioeconomic status, racism) factors that can enhance the risk of harm from chemical exposures.[3,11]

EPA's current chemical-by-chemical approach can lead to a significant underestimation of risk, as it does not account for the cumulative effects of exposures to multiple chemicals and non-chemical stressors, which can combine to influence the same health outcomes.[6,17,38(p13)] EPA itself has acknowledged that "[t]he single pollutant/single exposure paradigm is not well suited to the reality that individuals, communities, and tribes are exposed to numerous pollutants from a wide array of sources through multiple media and pathways over time."[39]

Robust scientific frameworks for accounting for cumulative risk exist and have been recommended by authoritative bodies, like the NASEM.[6] EPA has taken some limited steps to implement these frameworks for selected chemicals. For example, in EPA's recent draft method for phthalates CRA, six anti-androgenic phthalates were grouped for evaluation based on shared

endpoints.[40] EPA could have also considered other chemicals in the CRA chemical grouping, such as additional anti-androgenic phthalates and other chemicals that also act on the same adverse health outcomes and contribute to the overall burden of exposure in the population, as has been recommended by the NASEM.[6]

In cases where quantitative hazard or exposure data are not available, EPA can use cumulative impacts assessment to characterize the impacts of multiple interacting chemical and non-chemical stressors.[39] Cumulative impact assessments aggregate factors that reflect exposures to combinations of chemical and non-chemical stressors and their effects on health.[41] Cumulative impact assessments should be used in the prioritization of resources to ensure that enforcement actions, cleanups, and permitting are informed with an understanding of what communities are most impacted by chemical and non-chemical stressors.

We recommend that EPA:

- **Utilize cumulative risk assessment to quantify real-world risks of combined exposures to multiple chemical and non-chemical stressors when adequate data are available.**
- **Utilize cumulative impacts assessment to better account for real-world risks of combined exposures to multiple chemical and non-chemical stressors, particularly when quantitative exposure or hazard data is not available.**

EPA should fully consider identified health risks from all evidence streams in regulatory decisions.

EPA needs to incorporate all relevant scientific data and evidence streams into risk assessments, including data from epidemiologic, in vivo, and in vitro evidence streams. By doing so, EPA can ensure that its regulatory decisions are based on the most comprehensive understanding of potential health hazards, ultimately leading to more effective protection of the public's health. Some of EPA's recent draft risk evaluations have not done so and represent a concerning departure from the best available science. For example, in EPA's risk evaluations of di-isononyl phthalate (DINP),[42] di-isodecyl phthalate (DIDP),[43] and formaldehyde[44] under the Toxic Substances Control Act (TSCA), the Agency disregarded critical epidemiologic evidence and ignored or downplayed certain high-end exposure scenarios in making findings of unreasonable risk, resulting in decisions that fail to fully reflect the potential dangers posed by these chemicals.

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