STATE OF WASHINGTON

DEPARTMENT OF ECOLOGY

Olympia, Washington 98504

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

November 7, 2025

Nancy Beck
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington DC 20460-0001
Beck.nancy@epa.gov

Re: Docket EPA-HQ-OPPT-2025-0260

Dear Principal Deputy Assistant Administrator Beck:

The Washington State Departments of Ecology and the Washington State Department of Health write to express scientific concerns about EPA's proposed amendments to the framework rule for conducting existing chemical risk evaluations under the Toxic Substances Control Act (TSCA). The proposed changes will weaken chemical risk evaluations and harm workers, the public, and the environment. Failing to properly regulate uses of toxic chemicals will ultimately increase mitigation and cleanup costs which are often passed on to American families and business owners.

If adopted, the proposed rule will limit the exposure pathways EPA considers when evaluating risks from toxic chemicals. If EPA fails to consider all the sources of chemical exposure, analyses will not find the real risks from toxic chemicals and therefore the agency will be unable to develop necessary protections for people and the environment. We are concerned these changes will increase the likelihood that EPA will find minimal or no risk from toxic chemicals and therefore fail to adopt necessary protective regulations. If that were to happen, states could be preempted from adopting their own, more protective requirements, even if people and wildlife are still at risk. The Environmental Council of the States, a bipartisan organization of 50 states and U.S. territories, unanimously passed a resolution in September of this year urging EPA to limit its preemption of state authority[1].

Below we highlight key changes that will likely lead to underestimation of risk, create gaps in protections, particularly for workers, and undermine EPA's stated goal to "better protect health and the environment." Other areas for which EPA requested comments are described in the technical appendix.

EPA should retain the whole chemical approach. Without fully understanding the extent to which the chemical under evaluation impacts health and the environment, EPA cannot appropriately identify actions needed to protect people and the environment. The proposed amendments to the rule direct EPA to evaluate risk for individual conditions of use. Exposures from drinking water, consumer products, air pollution, and the work environment all collectively impact risk. While exposures from individual conditions of use by themselves may not present an unreasonable risk, they still contribute to the overall risk. The importance of cumulative and aggregate risk assessments has been supported in multiple reports by the National Research Council[2]. We recognize that risk mitigation decisions may need to be nuanced, and not all sources of exposure need regulation. However, to decide which exposures may need

[1] Environmental Council of the States Resolution 16-3: https://www.ecos.org/documents/resolution-16-3-on-implementing-the-toxic-substances-control-act-reforms/

[2] National Research Council 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press.

mitigation, EPA must first understand and evaluate the exposures and risks from all the potential exposure pathways.

EPA should consider Personal Protective Equipment (PPE) as part of risk reduction efforts but not make assumptions around PPE use during risk evaluation. Assumptions on PPE use, including statements from manufacturers without accompanying data, should not be used to estimate exposures to workers. The use of PPE and engineering controls should be considered after risk evaluation as part of risk mitigation. Assuming PPE use lowers exposure can significantly underestimate risk. This creates a regulatory gap that leaves workers, particularly those without access to PPE, unprotected.

EPA should thoroughly and promptly evaluate and mitigate risks to protect health and the environment and save money. Consider the example of lead exposure and impacts on children's health. Because the developing brain is so sensitive to lead exposure, there is no known safe level of exposure of lead for children[3]. For many children in the United States, the biggest source of lead exposure is old house paint. Lead was banned from paint in some European countries as early as 1909. However, the US did not ban lead in paint until 1978, resulting in many more housing units potentially exposing children to lead paint. In fact, the Center for Disease Control and Prevention estimates that there are still 29 million housing units in the US with lead paint[4]. For each housing unit, lead paint remediation can cost between $10,000 and $30,000 – costs that could have been avoided but now must be borne by small businesses and other property owners. Cleaning up and mitigating exposures from toxic chemicals is much more expensive than properly regulating their use in the first place.

For these reasons, EPA should retain the current rule and focus its efforts on thoroughly and promptly evaluating existing chemicals to reduce exposures and avoid future costs. Thank you for the opportunity to share feedback on the proposed amendments to the TSCA risk evaluation rule.

Sincerely,

Casey Sixkiller

Director
Washington State Department of Ecology

Dennis E. Worsham

Secretary of Health
Washington State Department of Health

[3] Center for Disease Control and Prevention: Lead Exposure Prevention.
[4] Center for Disease Control and Prevention: Lead Exposure Prevention Lead Paint.

Technical Appendix

Below are our comments in response to the questions asked by EPA and organized with the numbering system in the Federal Register notice.

1. In Unit I.C., EPA requests comment on how the requirements of this rule, when finalized, would apply to risk evaluations initiated prior the effective date of the final rule, and whether these requirements shall not apply retroactively to risk evaluations already finalized.

EPA should continue to rely on the risk evaluations conducted under the 2024 rule. Much of EPA's rationale for changing the 2024 rule focuses on timely and efficient implementation of TSCA. Redoing risk evaluations already completed will put EPA further from this goal. It would also likely weaken protections for people and the environment and cause regulatory uncertainty.

2. In Unit I.E, EPA requests specific comment on the burden estimate and assumptions associated with the calculation associated with the burden (*e.g.,* number of manufacturer requests for risk evaluations that EPA expects). More generally, EPA requests comment on whether and how the proposed rule would reduce burdens, and welcomes detailed information, examples, and data addressing the impacts of the rule.

We believe that conducting one, thorough risk evaluation per chemical is the most efficient and effective path EPA can take. The proposed rule increases the burden to EPA by limiting the risk evaluation done under TSCA to certain conditions of use. If EPA does not conduct a full risk evaluation under TSCA, other regulatory programs at EPA will have to conduct risk evaluations on the same chemical to evaluate additional exposures and EPA may need to update their risk evaluation if they miss an important condition of use.

3. In Unit III.A.2, EPA requests comment on the proposed amendments to 40 CFR 702.37(a)(3) and (4), including whether the revisions are sufficiently clear as to EPA's intent regarding appropriately scoped, fit-for-purpose risk evaluations under TSCA section 6(b). EPA is also interested in comments on how to address conditions of use that are identified after the conclusion of a risk evaluation on a chemical substance.

We agree with EPA about the importance of complete risk evaluations and not doing piecemeal assessments, which is why we urge EPA to retain the whole chemical approach. A complete risk evaluation that includes all conditions of use, even pathways and exposures not regulated under TSCA, would streamline the work of EPA, so the agency would not need to redo risk evaluations for other statutes.

If EPA identifies a new condition of use after a risk evaluation has been finalized, then EPA should use its existing authority to revisit that risk evaluation and risk reduction if needed. However, we believe that if EPA were to maintain the whole chemical approach, there would be fewer instances of additional conditions of use to evaluate later. This would save work and be more efficient and better protect people and the environment. It would also create more regulatory certainty for manufacturers.

4. In Unit III.A.3, EPA requests comment on whether the Agency should include regulatory text that specifies that EPA has discretion to exclude conditions of use as well as exposure pathways and routes. Further, EPA requests comment on specific instances where EPA should exercise its authority to exclude conditions of use and exposure pathways and routes. EPA also requests comment on whether to add regulatory text that states that EPA can coordinate actions with other federal laws administered by EPA to ensure that chemical risks "could be eliminated or reduced to a sufficient extent" by other EPA actions, pursuant to TSCA section 9(b). Finally, EPA welcomes suggested regulatory text that could be considered.

All exposures must be included to assess the real risk to people and wildlife. In some instances, it's appropriate for EPA to reduce risks through other federal laws that are administered by EPA or to work with other federal agencies to reduce risks. EPA should work through existing processes and procedures to coordinate within the agency and with other agencies as needed.

This Unit also addresses the consideration of accidents, leaks, spills, and extreme weather events. While these are not planned, they do occur and should be considered in risk evaluation and risk reduction. While it is difficult to predict specific incidents, it is reasonable to assume that such events will occur somewhere. We encourage EPA to continue to consider exposures from accidents, leaks, spills, and extreme weather events to fully assess exposures.

5. In Unit III.B.2, EPA requests comment on the change to the regulatory requirements for risk determinations discussed in Unit III.B.2., as well as the changes regarding occupational exposure assumptions discussed in Unit III.C.1. In addition, EPA requests comments more generally on TSCA section 6(b)(4)(A) risk determinations, including whether there should be more specific requirements for how EPA is to make and document its risk determinations.

The whole chemical approach is the most efficient way to understand all of the exposures from a chemical. It is important for EPA to first identify and evaluate the exposures and risks from the chemical to decide which exposures may need risk reduction. As the risk evaluation itself is not a regulation, the whole chemical approach to evaluation should not cause confusion as to what exposures require risk mitigation. Consideration of uses in the risk mitigation phase is a necessary part of the evaluation process.

States can lead on developing and implementing chemical regulations. By limiting federal preemption, EPA can leverage the work done at the state level to extend benefits to the nation as a whole. We agree with EPA on the benefits of having protective federal regulations both for the regulated community and for the protection of human health and the environment. It is also important that individual states retain their authority to prioritize and address unique risks in their state promptly. It is important for states to retain their ability to act with limited federal preemption.

We do not think it is necessary to define "unreasonable risk" in this rule. EPA needs flexibility to assess and mitigate risk in fit-for-purpose risk evaluations and risk reductions.

6. In Unit III.C, EPA requests comment on all aspects of the proposed regulatory modifications and clarifications to provisions from the 2024 final rule related to risk evaluation.

In the first ten risk evaluations completed after TSCA was amended in 2016, EPA assumed that workers were provided and used PPE such that the stated assigned protection factor was met without adequate supporting data. Assumptions on PPE use, including statements from manufacturers without accompanying data, should not be used to estimate exposures to workers. The use of PPE and engineering controls should be considered after risk evaluation in the risk reduction phase.

7. In Unit III.C.2 EPA requests comment on the clarity and utility of the current definition of "aggregate exposure."

We support EPA's continued use of the current definition of aggregate exposure. However, EPA should retain the requirement to justify their decision to narrow their risk evaluation. Under the current rule, EPA is not obligated to always assess aggregate exposures and can narrow their focus, provided they transparently justify their decision. The proposed amendments to the rule remove this transparency requirement. This language is critical to ensuring that when there is a practical, scientific or legal reason to narrow the analysis, EPA does so transparently. Further, explaining this decision allows interested parties to provide comments to EPA, ensuring the final decision is based on all available information and perspectives.

8. In Unit III.C.3, EPA requests comment on the extent to which the regulatory definition of PESS and other terms should depart from the definitions provided by TSCA.

We urge EPA to retain the term "overburdened communities" in the definition of PESS. It is important that EPA recognize the variability in exposures across populations. People who have higher exposure to toxic chemicals because of where they live or what they do for work should also be protected by TSCA regulations. By retaining the term "overburdened communities," EPA will continue to consider this variability in exposure and ensure their regulations protect everyone.

9. In Unit III.D.1, EPA requests comment on whether the 2017 language describing peer review provisions should be restored, or whether other amendments to peer review should be considered. More generally, EPA requests comment on how to ensure transparency and accountability in the peer review of risk evaluations.

Peer review is an important part of what is considered best available science. In 2016 the amendments to TSCA in Sec. 26(o) created the Scientific Advisory Committee on Chemicals (SACC) to "provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to implementation of this rule." SACC has been limited to peer review of draft risk evaluations under Sec. 6, but could be more broadly utilized for more aspects of implementation, including identification of high priority chemicals and scoping of risk evaluations.

We agree with EPA that referencing specific versions of guidance documents may limit EPA's ability to use updated guidance documents and it is appropriate to refer to EPA guidance on peer review.

10. In Unit III.D.2, EPA is requesting comment on all aspects of the proposed definition of "weight of scientific evidence" and related terms, including whether the 2017 definition for "best available science" should be restored, whether other definitions for these terms should be considered, and whether EPA should promulgate a definition of systematic review. More generally, EPA requests comment on how to ensure transparency and accountability in conducting risk evaluations, including making of risk determinations.

For all TSCA implementation, including risk evaluations under Sec. 6, EPA must continue to be transparent on what information was relied upon, how it was used, and how it meets the required scientific standards in Sec. 26. EPA must also continue to consider comments from the Scientific Advisory Committee on Chemicals and others for the information used. Previously EPA has included definitions for "weight of scientific evidence" and "best available science" in its rules that include language from TSCA Sec. 26 and capture universal principles to maintain flexibility and promote scientific advancement. Those definitions were removed in 2024 and it is not necessary to include those definitions in rule. Similarly, we support the use of systematic review to identify and assess information, and it is not necessary to include a definition in rule. If EPA wishes to include a definition of "weight of scientific evidence," the proposed definition is acceptable. As EPA has stated, risk evaluations need to be flexible and fit-for-purpose to adequately assess different chemicals with different uses and exposures. Every piece of information should be examined for how it could be used in a risk evaluation, rather than deciding beforehand not to use certain types of information, as not using certain data creates bias in the evaluation. The rule language includes important principles for EPA to consider when evaluating information for use in a risk assessment, such as whether the methods were reasonable and well documented, the information is relevant, and the extent of peer review. These principles will continue to be relevant as new methods are developed and EPA continues to use the appropriate information for each part of its risk assessments.

11. In Unit III.D.3, EPA requests comment on whether EPA should establish occupational exposure values, and, if so, whether EPA should do so as part of the risk evaluation for a chemical substance, or in the subsequent risk management rule, or both. If both, EPA requests comments on what considerations should be taken into account in moving from the value established as part of the risk evaluation to the value established during risk management.

EPA evaluates risk without consideration of non-risk information such as cost. However, the risk management rules do take non-risk information into consideration. Therefore, it makes sense to have different occupational exposure values in the risk evaluation compared to the risk management rules.

12. In Unit III.E, EPA requests comment on the proposed changes to 40 CFR 702.43(g), the two alternatives EPA is considering in lieu of the proposed changes to 40 CFR 702.43(g), and also on

whether there are circumstances that would allow for the correction of a scientific error [5]without reopening the risk evaluation or going back to the draft risk evaluation stage.

We agree that it is important for risk evaluations to be based on the weight of scientific evidence and represent the best available science so interested parties can be confident in them. EPA should be able to correct risk evaluations when it becomes clear they do not meet the science standards in Sec. 26, but the proposed rule changes are not needed for EPA to do this. EPA should only be able to revise a risk evaluation to correct a scientific error without redoing the prioritization process when EPA has determined it to be in the interest of protecting human health or the environment. In the preamble, EPA gives the example of when a scientific error has led to a determination that a condition of use presents an unreasonable risk when it does not. Correcting an error like this is still in the interest of protecting human health and the environment.

13. In Unit III.F, EPA requests comment on all aspects of the changes being proposed to the requirements for manufacturer-requested risk evaluations, including whether the proposed revision to 40 CFR 702.45(a)(8) regarding information known to, or reasonably ascertainable by the manufacturer outlined in Unit III.F, or another such standard, is appropriate for manufacturer requests.

Currently EPA requires manufacturers to provide the necessary information for manufacturer- requested risk evaluations, not just information that the manufacturer has for its use(s). It is appropriate to have this requirement on the entity requesting the risk evaluation and not on EPA. While we recognize that it is a significant amount of work for the requestor to gather the information needed for a risk evaluation, these are risk evaluations for chemicals that EPA has not prioritized for protection of human health or the environment and for which the manufacturer has requested a risk evaluation, presumably due to benefits for themselves. EPA can still use its authority to gather additional information. The proposal to delay initiation of a manufacturer- requested risk evaluation for up to a year makes sense to allow EPA additional time as it has for other risk evaluations in the pre-risk evaluation process.