Petition

for Reconsideration of the U.S. Environmental Protection Agency's Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA); Final Rule, 89 Fed. Reg. 37028 (May 3, 2024)

and

Rulemaking to Amend 40 CFR Part 702, subpart B

May 15, 2025

Via Electronic Mail

Lee Zeldin, Administrator
Environmental Protection Agency
Office of the Administrator, 1101A
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Petition for Reconsideration of EPA's Final Rule Regarding Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) and Rulemaking to Amend 40 CFR Part 702, subpart B

Dear Administrator Zeldin:

Pursuant to 5 U.S.C. §553(e) and 15 U.S.C. §2620(a), the Center for Environmental Accountability (CEA) respectfully requests that the U.S. Environmental Protection Agency (EPA) reconsider the final rule entitled *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, 89 Fed. Reg. 37028 (May 3, 2024), and initiate notice-and-comment rulemaking to amend certain provisions in 40 C.F.R. Part 702, subpart B.

EPA's current regulation impermissibly expands the scope of the TSCA risk evaluation process in a manner that is not only impracticable, but also untethered to TSCA's statutory text, structure, and Congressional intent. At the same time, the current regulation reduces scientific transparency and intra-agency collaboration – key tenants underlying TSCA's statutory scheme. Experience demonstrates that the current process has resulted in more complicated, voluminous, and time-consuming risk evaluations, dashing any hopes of meeting TSCA's 3-to-3.5-year statutory deadline. The current process has led to overly conservative risk conclusions and, in turn, unnecessary risk management rules that force industry to abandon well-studied chemistries that provide beneficial uses in our daily lives.

CEA respectfully requests that EPA reconsider its risk evaluation procedural rule and amend 40 CFR Part 702, subpart B to be consistent with the plain language and legislative intent of TSCA. Specifically, EPA's risk evaluation procedural regulations should:

- Provide additional definitions for key terms, offering increased transparency and clarity regarding methods and goals of the risk evaluation process;
- Bolster intra- and interagency collaboration throughout the risk evaluation process, including requirements that EPA document the outcome of those efforts;

- Confirm EPA's authority to determine which conditions of use fall within the scope of a risk evaluation;

- Explain the criteria EPA may use in determining the conditions of use it expects to consider;

- Provide for a *de minimis* level below which the Agency may exclude conditions of use from the scope of the risk evaluation;

- Explicitly require consideration of existing regulations administered by EPA and other agencies when determining exposure estimates for each condition of use for a chemical substance;

- Require that any assumptions, uncertainty factors, models, and/or screening approaches used in the risk evaluation reasonably reflect the conditions of use of the chemical substance in practice;

- Require EPA to make an unreasonable risk determination for each condition of use of a chemical substance assessed in a risk evaluation;

- Clarify when determinations regarding unreasonable risk or no unreasonable risk are considered final agency actions;

- Explicitly require peer review for all risk evaluations;

- Create a clear regulatory pathway for the development and submission of draft risk evaluations by requesting manufacturers and other interested persons; and

- Extend applicable comment periods and include opportunities for further extensions.

CEA respectfully submits that the revisions requested in this letter and its enclosures will empower EPA to efficiently and transparently meet its obligations under TSCA consistent with the law.

Sincerely,

Marc Marie
President
Center for Environmental Accountability
marc@environmentalaccountability.org

Enclosures: Petition for Reconsideration
Appendix A

cc: Chad McIntosh, Acting Deputy Administrator
Travis Voyles, Assistant Deputy Administrator
Nancy Beck, Principal Deputy Administrator
Lynn Dekleva, Deputy Assistant Administrator

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PETITION FOR RECONSIDERATION OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S PROCEDURES FOR CHEMICAL RISK EVALUATION UNDER THE TOXIC SUBSTANCESF CONTROL ACT (TSCA); FINAL RULE, 89 FED. REG. 37028 (MAY 3, 2024), AND REQUEST FOR RULEMAKING TO AMEND 40 CFR PART 702, SUBPART B

Pursuant to 5 U.S.C. §553(e) and 15 U.S.C. §2620(a), the Center for Environmental Accountability (CEA) petitions the U.S. Environmental Protection Agency (EPA) to reconsider the final rule entitled *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, 89 Fed. Reg. 37028 (May 3, 2024), and initiate notice-and-comment rulemaking to amend certain provisions in 40 C.F.R. Part 702, subpart B.

I. Introduction

The Toxic Substances Control Act (TSCA) requires EPA to conduct risk evaluations, the culmination of which is a determination "whether a chemical substance presents an unreasonable risk of injury to health or the environment, without a consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, ***under the conditions of use***."[1] In cases where EPA's risk evaluation results in a finding of unreasonable risk under the conditions of use, EPA must initiate rulemaking to eliminate that unreasonable risk "to the extent necessary."[2] TSCA Section 6(b)(4)(B) requires EPA to establish, by rule, a process to conduct risk evaluations.[3]

On July 20, 2017, just over a year after the 2016 TSCA amendments were adopted, EPA published a final rule setting forth procedures for chemical risk evaluations.[4] These regulations provided clarity surrounding the risk evaluation process, while ensuring that risk evaluations were appropriately tailored to the ways in which chemical substances are actually used (*i.e.*, the "conditions of use"), allowing the Agency to meet the strict statutory deadlines imposed under

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[1] 15 U.S.C. § 2605(b)(4)(A) (emphasis added). The statute defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

[2] 15 U.S.C. § 2605(a).

[3] 15 U.S.C. § 2605(b)(4)(B).

[4] 82 Fed. Reg. 33726 (July 20, 2017).

TSCA.[5] The 2017 final rule included definitions for certain statutory terms, including "best available science" and "weight of scientific evidence," providing a measure of transparency regarding EPA's approach to considering scientific information in the risk evaluation process. The 2017 final rule also confirmed that determinations as to unreasonable risk would be made on the basis of each condition of use of a chemical substance as required by TSCA. The 2017 final rule also hewed to the legislative intent of TSCA by requiring EPA to consider how the risks of chemical substances are mitigated by existing EPA regulations, as well as regulations from other federal agencies. This was key to creating additional efficiencies in the risk evaluation process and to guard against duplicative federal action.

The 10 initial risk evaluations finalized between June 2020 and January 2021 reflected the requirements of the 2017 final rule, discussed above. These evaluations were poised to undergo risk management rulemaking by the Biden Administration pursuant to TSCA sections 6(a) and (c), which require EPA to propose a risk management rule within one year of having finalized a risk evaluation in which an unreasonable risk determination was made.[6]

Instead of immediately initiating risk management on the initial 10 chemicals as required under TSCA, EPA decided to re-review all 10 risk evaluations "in accordance with the [Biden] Administration's Executive Orders and other directives, including those on environmental justice, scientific integrity, and regulatory review."[7]

Based on this review, EPA issued a June 30, 2021, announcement ("Announcement") indicating its intent to revise most of the completed risk evaluations so that they reflected "important policy changes."[8] In particular, EPA signaled that it would adopt a "whole chemical approach" to unreasonable risk determinations. Instead of each condition of use reflecting its own unreasonable risk determination, EPA would now make a *single* unreasonable risk determination for the *whole* chemical. This would have the practical effect of branding all uses of a chemical as presenting unreasonable risk, even if just one of the uses presented unreasonable risk. Under this approach, EPA also telegraphed that it would "withdraw the previously issued

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[5] EPA must publish the scope of the risk evaluation within 6 months after the risk evaluation begins. For high-priority substances, the scope of the risk evaluation must be published within 12 months after the beginning of the prioritization process. Risk evaluations must be completed within 3 years (with an option to extend for an additional 6 months). *See* 15 U.S.C. § 2605(b)(4)(D); 2605(b)(4)(G).

[6] 15 U.S.C. § 2605(c)(1)(A).

[7] *See* U.S. Environmental Protection Agency, *Updates on Chemical Safety Actions* (Feb. 5, 2021), *available at* https://www.epa.gov/chemicals-under-tsca/updates-chemical-safety-actions.

[8] *See* U.S. Environmental Protection Agency, *EPA Announces Path Forward for TSCA Chemical Risk Evaluations* (June 30, 2021), *available at* https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

orders for those conditions of use for which no unreasonable risk was found for all the first 10 risk evaluations."[9] Finally, the announcement indicated that EPA would expand the scope of risk evaluations to include all exposure routes and would no longer assume that workers were using personal protective equipment to manage occupational exposures to chemicals, even where such equipment was required by other federal regulations.[10]

On October 30, 2023, EPA moved a step closer to enshrining its policy changes in its regulations at 40 C.F.R. Part 702 by issuing a Proposed Rule on Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA),[11] which included not only the changes telegraphed in the Announcement but others as well, including but not limited to:

- Considering *all* conditions of use, however *de minimis* the potential exposures may be, for a given chemical during the risk evaluation process;

- Rendering meaningless those provisions in TSCA that preempt state regulation of chemicals that have been found by EPA not to pose an unreasonable risk under the intended conditions of use;

- Eliminating key regulatory definitions for "best available science" and "weight of scientific evidence," leaving stakeholders in the dark about the factors EPA will consider in balancing the available scientific evidence for a given chemical and providing the Agency almost unfettered discretion to ignore these important, risk-based concepts; and

- Expanding the definition of "potentially exposed or susceptible subpopulations" to include any "overburdened community"

On May 3, 2024, EPA published the final rule (2024 Final Rule), which maintained the sweeping changes from the proposed rule that serve to expand the risk evaluation process beyond any reasonable reading of the statute, let alone the "best" reading. *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 373, 144 S. Ct. 2244, 2247, 219 L. Ed. 2d 832 (2024). These provisions from the final rule are codified in 40 C.F.R. Part 702, subpart B.

This petition requests that EPA rein in the overly expansive risk evaluation procedures contained in the 2024 Final Rule consistent with the scope and intent of TSCA and as mandated by the Administrative Procedure Act, originally enacted by Congress in 1946 "as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in

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[9] *Id.*

[10] The Announcement cites "data on violations of PPE use" as support for the proposition that PPE is not always provided or warn properly. No such data were provided in EPA's announcement or in the 2024 final rule.

[11] 88 Fed. Reg. 74292 (October 30, 2023).

legislation creating their offices."[12] *Id.* at 391, 144 S. Ct. at 2261 (quoting *United States v. Morton Salt Co.*, 338 U.S. 632, 644, 70 S. Ct. 357, 94 L. Ed. 401 (1950)). We ask EPA to conclusively correct a process that has thus far been mired by multiple interpretations and changing political whims, disrupting reliance interests and endangering rights Congress sought to protect in enacting TSCA and its subsequent amendments. *Id.* at 375, 144 S. Ct. at 2247. Ultimately, EPA now has an opportunity to effectuate the "best reading" of TSCA. *Id.* at 373, 144 S. Ct. at 2247.

II. Proposed Amendments

In the sections that follow, we explain the reasoning for the proposed amendments to 40 C.F.R. Part 702, subpart B, identified in Appendix I.

A. Unreasonable Risk Determinations

As noted above, the 2017 final rule made clear that determinations as to unreasonable risks of chemical substances would be made on the basis of each condition of use. This interpretation is afforded a measure of respect, considering that it was "issued roughly contemporaneously with enactment" of the 2016 TSCA amendments and applied consistently among the first risk evaluations conducted. *Loper Bright* at 386, 144 S. Ct. at 2258. However, EPA's 2024 final rule eliminated the Agency's ability to make determinations regarding the risks posed by the conditions of use of a chemical substance, instead requiring a single risk determination for a chemical substance as a whole regardless of the contribution to the risk of an individual condition of use. This interpretation was codified in Section 702.39(f)(1).[13]

This scheme is contrary to the plain language and intent of TSCA and has already created profound confusion within the Agency and among the states, regulated entities, and the general population regarding the risks posed by the chemical substance under its conditions of use. In addition, the 2024 Rule's "whole chemical" approach has rendered key sections of TSCA meaningless, including provisions relating to preemption and manufacturer-requested risk evaluations. The proposed amendments in this petition aim to correct these missteps.

1. EPA's "whole chemical" approach conflicts with the primary purpose and plain language of the statute.

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[12] *See* 5 U.S.C. § 706 (requiring courts to hold unlawful any agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; or in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" among other provisions).

[13] 89 Fed. Reg. at 37035; 40 C.F.R. § 702.39(f)(1)("As part of the risk evaluation, EPA will make a single determination as to whether the chemical substance presents an unreasonable risk… .")

TSCA explicitly states in its introductory "findings" section that "among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment."[14] Thus, Congress's initial finding in 1976, which was maintained in the 2016 TSCA Amendments, was not that chemical substances themselves may pose an unreasonable risk, but that particular applications of chemical substances had the potential to pose unreasonable risk (i.e., "manufacture, processing, distribution in commerce, use, or disposal" of a chemical substance). For example, Congress recognized that while the disposal of a chemical alone may pose an unreasonable risk, its manufacture, processing, or distribution in commerce may not.

To effectuate Congress's intent of addressing the actual uses of chemical substances that pose an unreasonable risk, Congress gave EPA the authority to impose tailored requirements on particular applications of chemical substances under Section 6. Section 6(a) states in relevant part:[15]

> If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture **to the extent necessary** so that the chemical substance or mixture no longer presents such risk….

The regulatory options available to EPA that follow ("the following requirements") incorporate the language from subsection (a) above, tying "risk management" of a chemical substance to its manufacture, processing, distribution in commerce, use, or disposal, rather than only referencing the chemical itself.[16] Certain options even permit EPA to impose requirements on "a particular use,"[17] a "manner or method of commercial use,"[18] or a "manner or method of disposal."[19] By presenting these options, Congress confirmed that "unreasonable risk" must be assessed by each individual application of a chemical substance or, where relevant, by

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[14] 15 C.F.R. § 2601(a)(2) (emphasis added).

[15] 15 U.S.C. § 2605(a) (emphasis added).

[16] *Id.* at §§ 2605(a)(1)-(3).

[17] *Id.* at § 2605(a)(2).

[18] *Id.* at § 2605(a)(5).

[19] *Id.* at § 2605(a)(6).

combinations of these individual applications, so that EPA may take action with respect to one or more of these uses to address the unreasonable risk. Making a determination that a chemical substance, in and of itself, poses an unreasonable risk, is not only nonsensical and unscientific, but also frustrates the Agency's ultimate task of taking action with respect to specific applications of the chemical substance.

Importantly, the language in Section 6(a) also characterizes the risk evaluation process under Section 6(b). As noted above, TSCA requires that an unreasonable risk determination be made not on the chemical itself, but on "the manufacture, processing, distribution in commerce, use, or disposal" of the chemical. Such a determination is to be made "in accordance with subsection (b)(4)(A)." Subsection (b)(4)(A), in turn, effectuates Congress's intent by tying the risk evaluation process to the "conditions of use" of a chemical substance: "The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk … under the conditions of use."[20] The statute defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[21] Thus, there is a clear link throughout the statutory text between the chemical substance, the particular applications in which it is used, the risks posed by each of those particular applications, and EPA's obligation to impose requirements "to the extent necessary" to mitigate any unreasonable risks from these applications.[22]

Beyond the plain language of the statute, Congress's intent to permit EPA to make risk determinations on a condition-of-use basis is further evidenced by the legislative history of the 2016 TSCA Amendments. The first draft of the Amendments would have required EPA to "conduct risk evaluations … to determine whether or not a chemical substance presents or will present … an unreasonable risk of injury to health or the environment."[23] The initial draft would have then required EPA to "apply requirements with respect to a chemical substance through a rule under subsection (a) only if the Administrator determines through a risk evaluation under this subsection that the chemical substance presents or will present, in the absence of such requirements, an unreasonable risk of injury to health or the environment."[24] Neither of these provisions in the initial draft would have required consideration of the "conditions of use" of the substance as part of the risk determination.

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[20] *Id.* at § 2605(b)(4)(A) (emphasis added).

[21] *Id.* at § 2602(4).

[22] *Id*. at § 2605(a).

[23] U.S. House of Representatives Report No. 114-176, at *2 (June 23, 2015).

[24] *Id.*

The text of the bill was ultimately amended to include the current language under Section 6(b)(4)(A), which requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk … under the conditions of use."[25] Congressional floor statements made on the day of passage of the 2016 TSCA Amendments underscore the reasoning for this provision, and its proper interpretation: "To be clear, every condition of use identified by the Administrator in the scope of the risk evaluation must, and will be either found to present or not present an unreasonable risk."[26]

The 2024 final rule reads Section 6(b)(4)(A) in isolation and ignores the Congressional findings and ultimate purpose of TSCA that aim to address those conditions of use of a chemical substance that pose an unreasonable risk. EPA claimed that "[t]he evaluation is on the chemical substance—not individual conditions of use—and it must be based on 'the conditions of use.'"[27] In support of its argument that there should be one determination on the chemical substance, EPA cited to various provisions of TSCA that include the terms "determination" and "chemical substance." However, EPA omitted from its discussion those other key terms that tie the determination on the chemical substance to its conditions of use. For example, Sections 6(i)(1) and 18(a)(1)(B), both examples cited by EPA that reference a "determination" on a "chemical substance," also state that such a "determination" is to be made under, or be consistent with, Section (b)(4)(A). Section (b)(4)(A) contains the important proviso, which was key to the 2016 TSCA Amendments, requiring EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk … under the conditions of use." By ignoring the clear linkages throughout the statute between the chemical substance and its conditions of use

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[25] *See, e.g.,* Exxon Corp. v. Hunt, 475 U.S. 355, 373, 106 S. Ct. 1103, 1114, 89 L. Ed. 2d 364 (1986) (Reinforcing the Court's reading of the statute by comparison with prior versions of the statute).

[26] 162 Cong. Rec. S3511-01, at *S3520 (emphasis added). In the 2023 proposed rule, EPA cherry-picked Senator Vitter's floor statement that "A Section 6(i) order, determining that a chemical substance does not present an unreasonable risk under the conditions of use, is similarly final Agency action applicable to all those conditions of use that were identified in the scope of EPA's risk evaluation on the chemical substance." The 2023 proposed rule omitted Senator Vitter's very next sentence ("To be clear…") that confirms that all conditions of use must be subject to separate risk determinations. The 2023 proposed rule's blatant omission of key language from the Congressional floor statements demonstrates the lack of support in the legislative history for the Agency's interpretation.

[27] 88 Fed. Reg. at 74301.

for the purpose of defining the proper approach to risk evaluation, EPA neglects the longstanding principle of statutory interpretation that "[s]tatutes must 'be read as a whole.'"[28]

The incongruity of EPA's approach is evident in the Agency's statement that "[a] determination that a chemical substance presents an unreasonable risk does not mean that the entirety or whole of that chemical's uses—or even a majority of uses—presents an unreasonable risk. Rather, EPA may determine that a chemical substance presents an unreasonable risk based on risk associated with even a single condition of use."[29] EPA provided no explanation of how the Agency will make an unreasonable risk determination for an entire chemical substance or how such a determination will guide the Agency's ultimate decision making under Section 6(a), which must be based on specific applications of the chemical substance as described above.

EPA even recognized that such a scheme would be inherently confusing, acknowledging stakeholder concerns that "a singular risk determination could create confusion as to whether all uses or only certain uses of a chemical pose unreasonable risk."[30] EPA dismissed these concerns by reasoning that "these concerns are risk communication issues that the Agency can and intends to continue to improve on," in part by identifying "which conditions of use are—or are not—significant contributors to EPA's determination."[31] EPA's casual dismissal of this critical issue, with its only solution being to "improve on" these so-called "risk communication issues," does not constitute the requisite "reasoned analysis" for such a drastic change in policy.[32]

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[28] *Territory of Guam v. United States*, 141 S. Ct. 1608, 1613, 209 L. Ed. 2d 691 (2021) (quoting *United States v. Atl. Rsch. Corp.*, 551 U.S. 128, 135, 127 S. Ct. 2331, 2336, 168 L. Ed. 2d 28 (2007)); *see also Shell Oil Co. v. Iowa Dep't of Revenue*, 488 U.S. 19, 25, 109 S. Ct. 278, 281, 102 L. Ed. 2d 186 (1988) ("the meaning of words depends on their context"). As articulated by the Supreme Court in *Dubin v. United States*:

> 'a statute's meaning does not always turn solely on the broadest imaginable definitions of its component words ….' Instead, '[l]inguistic and statutory context also matter….' Even in cases where 'the literal language of the statute is neutral' in isolation, reading 'the whole phrase' can point to a more targeted reading.

599 U.S. 110, 120, 143 S. Ct. 1557, 1566, 216 L. Ed. 2d 136 (2023) (internal citations omitted).

[29] 88 Fed. Reg at 74302.

[30] *Id.*

[31] *Id.*; *see also* 40 C.F.R. § 702.39(f)(3).

[32] *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 30, 103 S. Ct. 2856, 2860, 77 L. Ed. 2d 443 (1983); *see also FCC v. Fox Television Stations,*

(continued …)

The Agency failed to recognize that the damage is done once a chemical substance, in its entirety, is branded with an unreasonable risk determination. The public rightly interprets an unreasonable risk determination for an entire chemical as meaning just that: that the chemical itself presents an unreasonable risk regardless of the particular applications in which it is manufactured, processed, distributed, used, or disposed. EPA cannot have it both ways. The agency cannot brand a chemical substance, in and of itself, as presenting unreasonable risk, and at the same time allow its continued use in ways that do not pose an unreasonable risk or contribute in any way to the unreasonable risk. Yet, this is the system that EPA has imposed. No amount of risk communication can overcome this self-contradictory approach. The best interpretation of TSCA is that separate risk determinations are required for each condition of use unless there is a scientific justification to consider certain conditions of use together. *Loper Bright* at 373, 144 S. Ct. at 2247.

2. EPA's "whole chemical" approach nullifies TSCA's preemption provisions.

EPA's approach of requiring the Agency to designate an entire chemical substance, rather than one or more conditions of use of that chemical substance, as posing an unreasonable risk conflicts with the provisions of TSCA that preempt state action on specific conditions of use of a chemical substance, rather than a substance in its entirety.[33]

In enacting the preemption provisions of TSCA, Congress contemplated specific conditions of use being deemed as presenting or not presenting an unreasonable risk.[34] Upon EPA making such a finding, TSCA provides that state action is preempted for those conditions of use that are the subject of (1) a rule under Section 6(a) applying requirements to address the unreasonable risk of the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, or (2) an order under Section 6(i) determining that a chemical substance does not pose an unreasonable risk under the conditions of use.[35] TSCA Section

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Inc., 556 U.S. 502, 515 (2009) (requiring a "reasoned explanation" for an Agency change in policy).

[33] *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 120 S. Ct. 1291, 1301, 146 L. Ed. 2d 121 (2000) (holding that courts must "interpret the statute as a symmetrical and coherent regulatory scheme and fit, if possible, all parts into an harmonious whole") (internal citations omitted).

[34] *See supra* note 25.

[35] 15 U.S.C. § 2605(i)(1). This provision makes clear that such a determination is made "under subsection (b)(4)(A)." As explained above, subsection (b)(4)(A) on its face and in the context of the statutory scheme inherently requires that unreasonable risk be evaluated on the basis of the conditions of use of the chemical substance, not simply the chemical substance itself.

18(a)(1)(B) provides that state action is preempted in either instance with regard to the manufacture, processing, or distribution in commerce or use of a chemical substance.[36]

The scope of this preemption provision is further elucidated in Section 18(c), which states that "[f]ederal preemption … applicable to specific chemical substances shall apply only to … with respect to subsection (a)(1)(B), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 2605(a) or 2605(i)(1) of this title."[37] Thus, preemption only applies to those conditions of use that are subject to restrictions under a Section 6(a) rule, or that are the subject of a no unreasonable risk determination under Section 6(i).

This scheme makes clear that Congress intended for EPA to make a determination regarding unreasonable risk with respect to particular conditions of use of a chemical substance. Those conditions of use that pose an unreasonable risk, either alone or in the aggregate, will be subject to restrictions under Section 6(a), and thus any further state action with respect to those conditions of use will be preempted. Those conditions of use that do not pose an unreasonable risk will be the subject of a Section 6(i) order, and state action with respect to those conditions of use will similarly be preempted.

EPA's current practice unlawfully eviscerates this structure. The current regulations allow EPA to adopt Section 6(a) rulemakings restricting only those conditions of use that "significantly contribute to" the unreasonable risk determination. At the same time, the whole chemical approach precludes EPA's ability to issue Section 6(i) orders for conditions of use that do not significantly contribute to the unreasonable risk or pose no risk at all. These conditions of use will be stuck in legal limbo, having not been the subject of a Section 6(a) rulemaking or a Section 6(i) order, jeopardizing the applicability of preemption to these conditions of use even though they have been evaluated by EPA and found not to pose unreasonable risk. This is contrary to both the plain language of the statute and Congressional intent. It is not a reasonable interpretation let alone a "best reading" of TSCA. *See Loper Bright* at 373, 144 S. Ct. at 2247.

Congress intended to preempt state action regarding "the manufacture, processing, or distribution in commerce or use of a chemical substance" where those activities were found not to present an unreasonable risk.[38] As noted, unreasonable risk determinations must be made on a condition-of-use basis. This intent is clearly evidenced in Congressional floor statements made on the day of passage of the 2016 TSCA Amendments supporting a condition-of-use-based approach, which the Agency curiously omitted from the preambles to its 2023 proposed rule and 2024 final rule:

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[36] 15 U.S.C. § 2617(a)(1)(B)(i).

[37] 15 U.S.C. § 2617(c)(3)

[38] 15 U.S.C. § 2617(a)(1)(B).

> Federal determinations reached after the risk evaluation process that a chemical presents no significant risk **in a particular use** should be viewed as determinative and not subject to different interpretations on a state-by-state or locality-by-locality basis. Further, under the new legislation, EPA will make decisions based on conditions of use, and must consider various conditions of use, so there could be circumstances where EPA determines that a chemical does not present an unreasonable risk in certain uses, but does in others. **Preemption for no significant risk determinations would apply as these determinations are made on a use-by-use basis.**[39] (emphasis added)

The 2024 final rule unlawfully curtails these preemption provisions, allowing states to regulate uses of chemical substances that were found by EPA not to pose a risk at all – unreasonable or otherwise – because EPA will no longer issue Section 6(i) orders for individual conditions of use. The only way EPA could make a no unreasonable risk determination under the current approach is if no condition of use contributes to unreasonable risk, a highly unlikely occurrence given how EPA in practice has interpreted unreasonable risk.[40]

Further underscoring the importance of the statute's preemption provisions,[41] Congress directed EPA, under Section 6(b)(4)(E)(iii), to give preference to manufacturer requested risk evaluations (MRREs) "on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment."[42] This ensures that, where EPA decides to evaluate a chemical substance, the exposures and conditions of use that are considered in the evaluation and ultimately determined to either pose or not pose an unreasonable risk will be protected by federal preemption from patchwork requirements imposed by states. The 2024 final rule would permit state regulation of exposures and conditions of use for chemicals evaluated by EPA and determined to be safe, because EPA may conclude that these uses do not drive unreasonable risk and therefore may not be the subject of a Section 6(a) rulemaking or a Section 6(i) order. Thus, a broad swath of conditions of use that EPA evaluates under an MRRE, regardless of their potential risks, may still be subject to state action if a single, *unrelated*

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[39] 162 Cong. Rec. S3511–01, at *3521 (June 7, 2016).

[40] *See infra* Section II.C.

[41] TSCA's preemption provisions were critical to the negotiations that led to the enactment of the 2016 amendments. Congressional floor statements recognized that "the preemption section […] was the most contentious issue of the negotiations as well as the most important linchpin in the final deal" and that preemption would "further Congress's legislative objective of achieving uniform, risk-based chemical management nationally in a manner that supports robust national commerce." 162 Cong. Rec. S3511-01, at *S3520-3521.

[42] 15 U.S.C. § 2605(b)(4)(E)(iii).

condition of use is deemed to present a risk that justifies EPA determining that the "whole" chemical presents unreasonable risk.[43]

Try as it might, the Agency cannot minimize this evisceration of TSCA's preemption provisions by casting it as a "risk communication issue[]." EPA's 2024 final rule constitutes a fundamental misreading of the law that undermines Congress's carefully crafted scheme. By assigning an unreasonable risk determination to an entire chemical substance, rather than to each of the conditions of use of that substance, EPA has rendered key statutory provisions meaningless.[44] The proposed amendments in this petition aim to restore TSCA's preemption provisions in accordance with the legislative intent and statutory text.[45]

3. EPA's "whole chemical" approach effectively eliminates the statute's provision for Manufacturer Requested Risk Evaluations.

TSCA Section 6(b)(4)(E) explicitly provides that a manufacturer of a chemical can request that EPA conduct a risk evaluation on that chemical. This section delineates minimum and maximum percentages of EPA's risk evaluations that can be conducted on manufacturer requests. To date, four manufacturer-requested risk evaluations (MRREs) have been submitted by manufacturers.[46] By submitting an MRRE, manufacturers bypass prioritization and avoid having their chemical deemed a "high priority substance." More importantly, under a condition-of-use approach (as opposed to EPA's current whole-chemical approach), manufacturers can submit an MRRE with supporting data to support a no-unreasonable-risk determination for one or more conditions of use.

Under a whole-chemical approach, however, MRREs have become a thing of the past. Although avoiding the high-priority designation may still be a motivator to file an MRRE, the likelihood that the "whole chemical" would be deemed to present an unreasonable risk is highly probable, given EPA's stated intent of assigning an unreasonable risk determination to a whole

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[43] Stripping preemption also is partly responsible for the 2024 final rule's effective nullification of TSCA's MRRE provision, as discussed below.

[44] *See Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 217–18, 122 S. Ct. 708, 717, 151 L. Ed. 2d 635 (2002) (reasoning that it is the duty of the courts "to avoid rendering what Congress has plainly done devoid of reason and effect").

[45] *See Brown & Williamson*, *supra* note 32.

[46] *See* List of Manufacturer-Requested Risk Evaluations under TSCA Section 6 (EPA last updated Apr. 11, 2023), *available at* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-manufacturer-requested-risk-evaluations-under-tsca.

chemical based on a single condition of use.[47] A single manufacturer is also unlikely to have knowledge regarding all conditions of use of a particular chemical (beyond those that the manufacturer intends for its specific product) and would risk provoking an unreasonable risk determination for its product, based on a condition of use of which it is not aware (and which has no relevance to the manufacturer's operations) but that EPA considers to be relevant under the "whole chemical" approach.

As noted above, manufacturers would also be stripped of the benefits of preemption, even if the manufacturer's intended, known, or reasonably foreseen uses of the chemical substance do not pose an unreasonable risk, following an unreasonable risk determination based on a single, unrelated condition of use that is unknown to the manufacturer. Under EPA's approach, the Agency has removed the incentive, made plain by the statutory text of TSCA, for any manufacturer to file an MRRE, as the likely result will be a determination by EPA that the whole chemical presents unreasonable risk. In doing so, EPA has rendered meaningless the provisions of TSCA permitting MRREs and requiring the Agency to give preference to MRREs on chemicals for which restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

Further limiting any prospects for future MRREs, EPA has also burdened the would-be submitter of an MRRE with providing all of "the information necessary to carry out the risk evaluation"[48] Invoking "TSCA's statutory text and structure," EPA stated in its 2023 proposed rule that this provision is intended to convey that MRRE requests "should attempt to identify all intended, known and reasonably foreseen circumstances of the chemicals manufacture, processing, distribution in commerce, use and disposal, and provide all available information regarding the chemical's hazards and exposures – not just information of relevance to the submitter's interest."[49] It is unreasonable for EPA to expect a single manufacturer will make itself aware of conditions of use beyond those that are intended, known, or reasonably foreseen by the manufacturer with respect to the manufacturer's own operations and intended activities with respect to a chemical substance. Imposing this open-ended, overwhelming task on manufacturers renders MRREs virtually impossible to apply for, let alone to obtain. We readily acknowledge that TSCA authorizes EPA to establish the "form and manner" for MRRE submissions, but that authority cannot be abused to effectively eviscerate the MRRE provisions

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[47] EPA procedures for manufacturer requests for risk evaluations are described in 40 CFR §702.37. If the whole chemical approach is to be applied to EPA initiated risk evaluations, including the initial 10 risk evaluations, then under the regulations, EPA must apply the same approach to MRREs: "EPA will conduct these assessments and make proposed determinations **based on the same considerations applied in the same manner** as it would for a risk evaluation for a high-priority substance." *Id.* (emphasis added)

[48] 40 C.F.R. 702.45(a)(2); *see also* 89 Fed. Reg. at 37046.

[49] 88 Fed. Reg. at 74313.

from TSCA. EPA's action in this regard is contrary to law, unreasoned, and arbitrary and capricious.[50]

B. EPA's practice of automatically including all exposures and conditions of use within the scope of a risk evaluation is contrary to the plain language of TSCA and Congressional intent.

The 2024 final rule requires EPA to consider all potential exposures and conditions of use of a chemical substance, however *de minimis*, during the risk evaluation process.[51] This blanket requirement unlawfully limits the discretion that Congress expressly granted to EPA to include within the scope of the risk evaluation only those exposures and conditions of use that EPA "expects to consider."[52] In addition, the 2024 final rule *eliminated* EPA's ability to consider relevant statutory factors that the Agency is *required* to take into account when determining the scope of the risk evaluation and the conditions of use it expects to consider, such as the impact of existing regulations in mitigating the risks posed by chemical substances.

EPA's 2024 final rule placed additional burdens on a process that is already strained to fulfill statutorily imposed deadlines. No reasonable explanation is provided for how EPA will properly scope its risk evaluations such that EPA will carry them out "in a reasonable and prudent manner," as required by TSCA.[53]

The proposed amendments in this petition would focus EPA's resources on the conditions of use that are relevant to the risk evaluation and the Agency's determination of unreasonable risk. The proposed amendments would clarify that "conditions of use" do not include intentional misuse of chemical substances or accidents and spills that are not part of routine operations and are addressed by other environmental regulations. The proposed amendments would also clarify the factors that EPA will consider in determining the conditions of use it expects to consider in the risk evaluation, including (1) the extent to which the condition of use presents greater opportunity for risk reduction as opposed to those that are deemed negligible or are already well-controlled, (2) whether the substance is present at only *de minimis* levels or otherwise presents insignificant risk under the condition of use, (3) the extent to which the potential risks posed by a

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[50] *See Williams v. Taylor*, 529 U.S. 362, 404, 120 S. Ct. 1495, 1519, 146 L. Ed. 2d 389 (2000) ("It is, however, a cardinal principle of statutory construction that we must 'give effect, if possible, to every clause and word of a statute.'") (quoting *United States v. Menasche*, 348 U.S. 528, 538–539, 75 S.Ct. 513, 99 L.Ed. 615 (1955) (internal quotations omitted)).

[51] 40 C.F.R. § 702.37(a)(4)

[52] 15 U.S.C. § 2605(b)(4)(D).

[53] 15 U.S.C. § 2601(c). *See Stand Up for California! v. United States Dep't of the Interior*, 994 F.3d 616, 627 (D.C. Cir. 2021) (using introductory "findings" section in statutory interpretation).

chemical impurity can be addressed in a risk evaluation for the separate chemical substance that bears the impurity, and (4) whether there is actual or reasonable potential for exposure to humans or the environment from the chemical substance.

Below, we identify in greater detail the aspects of the 2024 final rule that would be corrected through this petition.

1. The 2024 final rule unlawfully eliminates EPA's discretion to determine those exposures and conditions of use that fall within the scope of a risk evaluation.

TSCA Section 6(b)(4)(D) requires EPA to publish the scope of its risk evaluation, "including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider."[54] This provision plainly provides EPA with discretion to exclude any hazards, exposures, conditions of use, or potentially exposed or susceptible subpopulations that the Agency deems irrelevant to the risk evaluation. To read it otherwise would render Congress's use of the phrase "expects to consider" entirely meaningless. Despite this plain language mandating that EPA exercise its discretion to properly scope the risk evaluation, EPA now contends that the Agency does not have "discretionary scoping authority."[55] This direct contradiction of the statutory text and Congressional intent is a fatal flaw to this aspect of the 2024 final rule.

EPA also failed to take into account other provisions of TSCA that clearly indicate an intent to afford EPA with discretion to exclude irrelevant conditions of use from the scope of a risk evaluation. For example, as discussed above, Section 18(a)(1)(B) preempts state action with respect to the manufacture, processing, or distribution in commerce or use of a chemical substance (1) for which a no unreasonable risk determination is made under Section 6(i), or (2) for which a final rule is promulgated under Section 6(a). The scope of this preemption is limited "only to…the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes…,"[56] which confirms that there may be *other* conditions of use that were not considered by EPA in its risk evaluation and for which no final Agency action has been rendered.

Similarly, Section 18(b) preempts any new state action with respect to the manufacture, processing, distribution in commerce, or use of any chemical substance designated as "high-priority," between the period when the scope of the risk evaluation is published and when the

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54 *Id.* at § 2605(b)(4)(D).

55 89 Fed. Reg. 37032.

56 15 U.S.C. §2617(c).

risk evaluation ends.[57] Section 18(c)(4) limits the scope of this preemption "only to … the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 2605(b)(4)(D) of this title."[58] Congress recognized that there may be conditions of use for a chemical substance that would not be included within the scope of a risk evaluation, and that States would be free to enact new laws regulating these conditions of use while the risk evaluation process was ongoing.[59] EPA's assertion that a risk evaluation must include every conceivable condition of use of a chemical substance would render these preemption scoping provisions in Section 18(c)(4) utterly meaningless, counter to "one of the most basic interpretive canons, that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant."[60]

2. The 2024 final rule requires EPA to overreach into the jurisdiction of other Federal statutes and Agencies.

The 2024 final rule unlawfully sought to eliminate EPA's express statutory authority to exclude from the scope of the risk evaluation those conditions of use for which the risk is already addressed by another Federal statute. When TSCA was originally enacted in 1976, Congress believed that the legislation "would close a number of major regulatory gaps, for while certain statutes, including the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act, may be used to protect health and the environment from chemical substances, none of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances."[61]

To effectuate this purpose, Section 9(b)(1) explicitly directs EPA to consider the impacts of other Federal laws administered in whole or in part by EPA. If the risks posed by the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance can be addressed by actions taken under such other Federal laws, EPA must use such other authority, unless the Agency determines that it is in the public interest to use its authority under TSCA. Thus, Congress explicitly granted EPA with the discretion to consider the impact of other

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[57] *Id.* at § 2617(b)(1).

[58] *Id.* at § 2617(c)(4).

[59] *See* 162 Cong. Reg. H2989-02 (May 24, 2016) (Rep. Pallone's statement in support of the TSCA Amendments that "we clarified the scope of preemption in order to make clear that States are only preempted from regulating the uses that the EPA has studied or regulated").

[60] *Corley v. United States*, 556 U.S. 303, 314, 129 S. Ct. 1558, 1566, 173 L. Ed. 2d 443 (2009) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101, 124 S.Ct. 2276, 159 L.Ed.2d 172 (2004)).

[61] S. REP. 94-698, S. Rep. No. 698, 94TH Cong., 2ND Sess. 1976 (Mar. 26, 1976).

Federal statutes in addressing the risks posed in its evaluations of chemical substances, as follows:

> The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.[62]

This provision makes clear that intra-agency coordination applies to any agency "actions," not just "final agency actions," such as risk management rulemakings, that are referenced elsewhere in Section 6 of TSCA.[63] Congress's use of the term "actions" in Section 9(b)(1) confirms that EPA must consider the impacts of other Federal laws at all stages of the risk evaluation process, including in determining the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency expects to consider in it scoping document.

Section (9)(d) further requires that EPA "shall consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."[64]

Importantly, the 2016 TSCA Amendments did not alter these provisions. To the contrary, Congress believed that the Amendments would "reinforce[] TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals."[65]

Despite the plain language in these provisions and the legislative history underpinning this statutory text, EPA's 2023 proposed rule contended that the Agency "no longer interprets the

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62 15 U.S.C. § 2608(b)(1) (emphasis added).

63 *See*, *e.g.*, 15 U.S.C. §2605(d)(3) and (i)(1)-(2).

64 15 U.S.C. § 2608(d).

65 HR Rep. 114-176, at 28 (June 23, 2015).

law to authorize exclusion of exposure pathways from the scope of TSCA risk evaluations because other EPA offices have already or could in the future regulate those chemicals."[66] EPA argued that Congress's mandate to coordinate with other statutes and other Federal agencies "cannot be read to displace the more specific requirements under TSCA section 6(b)(4)(F)."[67] However, EPA's interpretation under the 2024 final rule ignores the explicit grant of discretion afforded to the Agency to rely on other statutory authority when the risks "could be eliminated or reduced to a sufficient extent."[68] The 2024 final rule also disregards the balance that Congress intended to strike both in originally enacting TSCA and in amending it in 2016, to achieve maximum enforcement while avoiding duplicative requirements through other Federal statutes. EPA cannot allow its authorities under TSCA to overtake the authority granted under other Federal statutes in light of the coordination requirements under TSCA Section 9.

3. The 2024 final rule eliminated EPA's ability to exclude from the scope of the risk evaluation conditions of use presenting *de minimis* exposures.

The 2024 final rule expanded even further an already unwieldy risk evaluation process by eliminating EPA's ability to exclude conditions of use that result in only *de minimis* exposures

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66 88 Fed. Reg. at 74299

67 *Id*. TSCA Section 6(b)(4)(F) states the following:

> In conducting a risk evaluation under this subsection, the Administrator shall—
>
> (i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;
>
> (ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;
>
> (iii) not consider costs or other nonrisk factors;
>
> (iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and
>
> (v) describe the weight of the scientific evidence for the identified hazard and exposure.

68 15 U.S.C. § 2608(b)(1).

(*i.e.*, where the level of exposure is so low so as to present no risk at all).[69] EPA reasoned that such individual uses may contribute to unreasonable risk when considered in the aggregate, and that the Agency may decide to use "more tailored or qualitative analyses" for these uses.[70]

The proposed modifications presented in this petition would restore EPA's ability to exclude conditions of use presenting only *de minimis* exposures to chemical substances, consistent with EPA's express statutory authority to limit the scope of the risk evaluation only to those conditions of use it "expects to consider."[71]

C. Definition of "unreasonable risk"

The most important term in all of TSCA, arguably, is the term "unreasonable risk of injury to health or the environment" (or simply "unreasonable risk"). Under Section 6 of TSCA, EPA evaluates the risk of chemicals to determine whether uses present "unreasonable risk." A determination of unreasonable risk triggers risk management regulations to ensure, "to the extent necessary," that the chemical no longer presents unreasonable risk.[72] Thus, knowing what is and isn't unreasonable risk is critical to effectively eliminating that risk. Although TSCA does not define unreasonable risk, legislative history makes clear that "'unreasonable risk does not mean no risk; it means that EPA must determine, on a case-by-case basis, whether the risks posed by a specific high priority substance are reasonable in the circumstances of exposure and use."[73]

This petition's proposed amendments define unreasonable risk as actual or reasonable potential for significant, irreversible adverse acute or chronic human health effects from known exposure to a chemical substance. With respect to the environment, the proposed amendments in this petition define unreasonable risk as actual or reasonable potential for significant, irreversible adverse changes in the diversity, productivity, or stability of an ecological community from known exposure to the chemical substance undergoing risk evaluation. The term would not include risks that are speculative, transient, insubstantial, or similar to risk levels attributed to normal human metabolism or natural exogeneous sources of the chemical substance. The definition would further specify that, in assessing unreasonable risk, EPA will consider human health and environmental benefits attributed to the chemical substance under evaluation.

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69 89 Fed. Reg. at 37033.

70 *Id.*

71 15 U.S.C. § 2605(b)(4)(D).

72 *Id.* at § 2605(a).

73 *See* 162 Cong. Rec. S3511-01, at *3522.

D. Definitions for scientific terms

EPA's 2024 final rule eliminated key scientific definitions that brought clarity, focus, and transparency to the risk evaluation process, including definitions for "best available science" and "weight of scientific evidence."[74]

TSCA Section 26(h) requires that "in carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner ***consistent with the best available science***" and that such decisions must be "based on the ***weight of the scientific evidence***."[75]

The 2017 final rule adopted a detailed definition of "best available science" that listed factors EPA would consider in its scientific decision-making, including peer review, relevance, clarity and completeness of data, and uncertainty/variability in the data, among other criteria.[76] The 2017 final rule further defined "weight of scientific evidence" as "a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."[77] These definitions ensured that scientific decision making would be carried out consistently and responsibly during the risk evaluation process, while still providing the Agency with the flexibility to adapt to evolving scientific developments.

In eliminating these definitions, the 2024 final rule made broad, conclusory statements that defining these terms is "unnecessary and inhibits the Agency's flexibility to quickly adapt to and implement changing science."[78] However, the Agency failed to explain *how* the specific language in EPA's then-existing definitions would hinder the Agency's flexibility or prevent the Agency from adapting to evolving scientific developments. In fact, the elimination of these definitions opens the door to EPA minimizing or ignoring scientific information that it deems inconvenient. The 2024 final rule also failed to address how the recission of these definitions would disrupt industry and the public's reliance on these definitions for the past seven years and cast significant uncertainty on the information that EPA considers relevant to the risk evaluation

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[74] 89 Fed. Reg. at 37030-31.

[75] 15 U.S.C. § 2625(h) ("Scientific standards") (emphasis added).

[76] 82 Fed. Reg. at 33748. This definition stems in part from the definition adopted under the Safe Drinking Water Act (SDWA), 42 U.S.C. 300f *et seq.*

[77] *Id.*

[78] 88 Fed. Reg. at 74295.

process. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 212, 136 S. Ct. 2117, 2120, 195 L. Ed. 2d 382 (2016); *see Loper Bright* at 375, 144 S. Ct. at 2247. EPA's analysis in the 2024 final rule lacked the requisite "thoroughness" in its considerations and "validity" in its reasoning that would give such interpretations persuasive effect. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S. Ct. 161, 164, 89 L. Ed. 124 (1944).

This petition would reinstate the regulatory definitions for "best available science" and "weight of scientific evidence," returning needed clarity to how the Agency considers scientific information that is central to the risk evaluation process.

E. Bolstering intra- and interagency collaboration

TSCA Section 9(d) requires EPA to "consult and coordinate with" other Federal agencies "for the purpose of achieving the maximum enforcement of this chapter while imposing the least burdens of duplicative requirements on those subject to the chapter and for other purposes."[79] In explaining the purpose of Section 9, the House Committee on Energy and Commerce explained that these provisions were intended "to encourage decisions that avoid confusion, complication, and duplication."[80] The Committee further explained that EPA "should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety. ***Specifically, the Committee does not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls.***"[81] But this is precisely what EPA did in the 2024 final rule.

The 2024 final rule introduced a new, default assumption that standards imposed by OSHA are either not enforced or not sufficiently protective of workers. Specifically, EPA now assumes in its risk evaluations that workers do not use personal protective equipment (PPE) because "their employers are out of compliance with OSHA standards, the PPE is not sufficient to address the risk from the chemical, or their PPE does not fit or function properly," unless EPA is presented with evidence to the contrary.[82] EPA provided no explanation or factual basis for this newfound blanket assumption, which would put the burden on manufacturers to prove to EPA, an Agency that has no expertise in worker safety, that they are in compliance with requirements under the OSH Act, a statute administered by an entirely different Agency.[83] EPA

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79 15 U.S.C. § 2608(d).

80 HR Rep. 114-176 (June 23, 2015), at 28.

81 *Id.* at 29 (emphasis added).

82 89 Fed. Reg. at 37037.

83 EPA stated in the 2023 proposed rule that the Agency "is not suggesting that there is widespread non-compliance with applicable OSHA standards." 88 Fed. Reg. at 74304.

(continued …)

stated that in certain narrow circumstances, it may conclude that workplace protection is used, such as in "particularly advanced manufacturing facilities (e.g., those involved in the aerospace and defense industrial base industrial sectors" or when EPA has received "information demonstrating that performance of a condition of use is impossible in the absence of PPE."[84] Again, EPA provided no evidence of widespread non-compliance with applicable OSHA standards, and even acknowledges this fact,[85] and yet forged ahead with its expectation that most workplaces are not in compliance with OSHA standards, jeopardizing the accuracy of the exposures calculated during the risk evaluation process for workers.

Another basis for EPA's disregard of worker protections is the Agency's unfounded belief that OSHA standards are inherently inadequate because "[m]any of OSHA's chemical-specific permissible exposure limits were adopted in the 1970s and have not been updated since they were established"[86] Thus, EPA is assuming, automatically (and without evidence), that safety standards imposed by OSHA are not protective of workers, despite the OSH Act's mandate that such standards attain "the highest degree of health and safety protection for the employee."[87]

EPA argues that it may disregard these protections because "TSCA risk evaluations are subject to statutory science standards, an explicit requirement to consider risks to potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk factors when determining whether a chemical presents an unreasonable risk that warrants regulatory actions—all requirements that do not apply to development of OSHA regulations."[88] This statement is patently false and demonstrates the danger posed by EPA overtaking the authority of OSHA in regulating workplace safety. The OSH Act requires the Agency to promulgate standards for toxic materials and harmful physical agents "on the basis of the best

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However, in the paragraphs immediately preceding this statement, EPA made the contradictory statement that it will ignore OSHA standards because of the possibility that "employers are out of compliance with OSHA standards." *Id.* EPA's change in policy "rests upon factual findings that contradict those which underlay its prior policy," yet the Agency has not provided "a more detailed justification than what would suffice for a new policy created on a blank slate." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, at 515. Accordingly, EPA's interpretation under the 2024 final rule is arbitrary and capricious.

[84] 89 Fed. Reg. at 37037.

[85] *See id.* (claiming that "EPA is not asserting there is widespread noncompliance with OSHA requirements").

[86] *Id.* at 37037.

[87] 29 U.S.C. § 655(b)(5).

[88] 89 Fed. Reg. at 37037.

available evidence" and to consider "the latest available scientific data in the field."[89] The OSH Act is also specifically designed to address workplace exposures, and thus inherently involves consideration of a subpopulation that is more susceptible to exposure than the general population. Ultimately, OSHA standards must ensure "that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."[90]

Under the approach mandated by the 2024 final rule, and as discussed above, EPA automatically assumes that OSHA standards are unenforced or otherwise inadequate, leading to unrealistically inflated exposure assessments that have resulted in worker requirements that conflict with existing OSHA standards. Instead of consultation and coordination with other Agencies, EPA now assumes that OSHA regulations are ineffective and require EPA to implement duplicative standards, notwithstanding any existing OSHA requirements for workplace exposure. EPA's regulations now require the Agency to disregard the potential for exposure reduction due to the use of personal protective equipment, even when such protections are required by OSHA.[91] Where Congress directed EPA to conduct its TSCA work in deference to OSHA's role, EPA's regulations now do the opposite. This is a fatal flaw in this aspect of EPA's regulations.

The proposed amendments in this petition would bolster intra- and interagency coordination in several ways. Requirements for the consideration of other Federal regulations would be incorporated into the definitions for "conditions of use" and "reasonably available information." More specific requirements for intra- and interagency coordination would also be delineated in Section 702.37(a) ("Considerations"), such as the mandate that EPA incorporate, at all stages of the risk evaluation, the requirements of existing regulations administered by EPA and other Federal agencies in its baseline assessment. In publishing the scope of the risk evaluation, EPA would be required to explain its intra- and interagency coordination efforts and the impacts of existing regulations. In conducting its exposure assessment, EPA would also be required to consider the impacts of existing regulations on the estimated exposures to a chemical substance under each condition of use included within the scope of the risk evaluation. Section 702.47 would be amended to require intra-agency coordination in addition to consultation with other Federal agencies. Finally, Section 702.49 ("Publicly available information") would require EPA to maintain in the public docket documentation of all intra- and interagency coordination efforts.

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89 29 U.S.C. § 655(b)(5).

90 *Id.*

91 *See* 40 C.F.R. § 702.39(f)(2) ("EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination.")

F. Reasonable derivation of assumptions, uncertainty factors, models, and/or screening approaches.

Under the framework of the 2024 final rule, one of the emerging trends plaguing risk evaluations has been the use of assumptions, uncertainty factors, models, and screening approaches that are completely untethered to any reasonably anticipated use of a chemical substance. For example, one of the key assumptions underlying EPA's unreasonable risk determination for n-methylpyrrolidone (NMP) was that that each worker would have both hands emersed in 100% liquid NMP for 8 hours each and every working day each week (5 days/week).[92] Similarly, in reaching its unreasonable risk determination for formaldehyde, EPA used models that assumed that worker activities involving spray applications were equivalent to immersive exposures to formaldehyde.[93] These are just two examples, among many others, that led EPA to brand entire chemicals as presenting unreasonable risk, when in fact the Agency had utterly failed to assess the realistic uses of these substances during the risk evaluation process.

The proposed amendments in this petition would require EPA to ensure that any assumptions, uncertainty factors, models, and/or screening approaches are informed by the conditions of use of the chemical substance in practice. EPA would also be required to use its authorities under TSCA to gather information necessary to appropriately determine the conditions of use, rather than proceeding with a risk evaluation based on speculative assumptions. Finally, to further bolster EPA's ability to gather information relevant to the risk evaluation process, the proposed amendments in this petition would extend the comment period on draft risk evaluations to 90 days, with opportunities for extension as appropriate.

G. Peer review

EPA's recent risk evaluations have ignored criticisms from the Science Advisory Committee on Chemicals (SACC) and other reviewing bodies, often opting to rely on flawed studies and assumptions. EPA has also unlawfully excluded key portions of risk evaluations from SACC peer review.

The proposed amendments in this petition would mandate robust peer review on the risk evaluation in its entirety, and would require the publication of peer review charge questions for public comment. In addition, peer review participants would be required to reflect a balance of

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[92] EPA, *Summary of External Peer Review and Public Comments and Disposition for n-Methylpyrrolidone (NMP)*, at 126–27 (Dec. 2020), available at https://www.epa.gov/sites/default/files/2020-12/documents/2_summary_of_external_peer_review_and_public_comments_and_disposition_for_n-methylpyrrolidone_response_to_support_risk_evaluation_for_nmp.pdf.

[93] EPA, *Occupational Exposure Assessment for Formaldehyde*, at 117 (Dec. 2024), available at https://www.epa.gov/system/files/documents/2025-01/14.-formaldehyde-.-occupational-exposure-assessment-.-public-release-.-hero-.-dec-2024.pdf.

representatives, of such science, government, public health, public interest, industry, and other groups, with scientific expertise and experience relevant to reviewing all components of draft risk evaluations.

H. Development and Submission of Draft Risk Evaluations by Interested Persons

Section 26(l)(5) of TSCA requires EPA to develop guidance "to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator," which must, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations.[94] The Agency's current guidance, published pursuant to this statutory requirement, recommends that external parties adhere to the same scientific standards and other substantive requirements that apply to EPA in the course of implementing TSCA section 6(b) and preparing risk evaluations. However, there is currently no clear regulatory process for submitting draft risk evaluations, even though these external draft risk evaluations are expressly contemplated under TSCA.

The proposed amendments would create a regulatory pathway for manufacturers to submit draft risk evaluations concurrently with an MRRE. The proposed amendments would require manufacturer-derived draft risk evaluations to be consistent with the Agency's guidance, including the scientific standards, content, and peer review considerations. The proposed amendments would further allow requesting manufacturers to submit draft risk determinations concurrently with their draft risk evaluations for those conditions of use included within the scope of the manufacturer's draft risk evaluation. Consistent with the proposed changes to the requirements for EPA's risk determinations, manufacturer-developed draft risk determinations would be required to be submitted on the basis of each condition of use.

The proposed amendments would extend the ability to submit a draft risk evaluation to any interested person. Thus, an MRRE is not a prerequisite to submitting a draft risk evaluation, *e.g.*, in response to EPA's prioritization of a chemical substance. The same considerations and content requirements would apply to draft risk evaluations submitted by interested persons as those submitted by requesting manufacturers, in accordance with EPA's guidance.

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[94] 15 U.S.C. 2605(l)(5). EPA published this guidance on June 22, 2017. *See* https://www.regulations.gov/docket/EPA-HQ-OPPT-2017-0341.