



Comments of the U.S. Chamber of Commerce

**U.S. Environmental Protection Agency,
Proposed Rule; Procedures for Chemical Risk Evaluation Under the Toxic Substances
Control Act (TSCA)
88 Fed. Reg. 74292 (Oct. 30, 2023)
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The U.S. Chamber of Commerce (Chamber) appreciates the opportunity to comment on the U.S. Environmental Protection Agency’s (EPA’s or Agency’s) proposed rule amending the procedures for chemical risk evaluations under Section 6 of the Toxic Substances Control Act (TSCA).¹ The Chamber’s members include companies across all sectors that are impacted by TSCA— chemicals, coatings, refining, petrochemicals, petroleum, forestry, wood products, batteries, electronics, energy, and electricity, among many others. These companies, which manufacture and use chemicals subject to regulations under TSCA, deliver products and innovation that are integral not only to the health and well-being of the American people, but also to the domestic economy and supply chain. Chemical technologies improve our quality of life in numerous ways by providing new solutions to problems in health, materials, transportation, agriculture, and energy usage. Protecting the health of workers and surrounding communities is a priority for our members.

EPA’s proposal to revise the procedures for chemical risk evaluations is fundamental to the entire TSCA program and will significantly change how chemicals are evaluated and regulated. As an initial matter, we note that EPA only provided a 45-day comment period despite the importance of this proposal and requests, from our members and other industry stakeholders, to provide more time for stakeholder comment. This failure to extend the comment period is inappropriate for this proposal and is inconsistent with the White House commitment² to broaden public engagement in the federal regulatory process.

The Chamber opposes EPA’s proposed rule. Many of EPA’s proposed changes are inconsistent with the statutory text of TSCA and Congressional intent, contrary to the best available science, and would create a system in which EPA would be required to conduct overly broad and complex chemical risk evaluations that cannot be completed within statutory deadlines. If finalized, the rule would cause EPA to take significantly longer than Congress intended to conduct and complete risk evaluations. Even more concerning, EPA would likely never determine that particular uses of a chemical substance *do not* present an unreasonable risk of injury to human health or the environment, not because a risk evaluation could not support such a finding, but because the proposed, unlawful “whole chemical” interpretation would not allow such an outcome. EPA’s approach to unlawfully over-regulate all substances exceeds its statutory authority, is arbitrary and capricious, and is inconsistent with the purpose of TSCA.³

¹ 88 Fed. Reg. 74292 (October 30, 2023).

² See Office of Information and Regulatory Affairs announcement “Broadening Public Engagement in the Federal Regulatory Process”: <https://www.whitehouse.gov/omb/information-regulatory-affairs/broadening-public-engagement-in-the-federal-regulatory-process/>.

³ 15 U.S.C. § 2601(b): “authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.”

The proposed rule is a reinterpretation of the approach EPA first adopted in its July 2017 procedural rule for conducting TSCA risk evaluations.⁴ However, EPA has not provided adequate explanation to support its change of position, and its policy justifications also fail to justify the expansion of its authority to conduct risk evaluations. EPA attempts to point to a challenge to the 2017 rule in the U.S. Court of Appeals for the Ninth Circuit as partial support for its expanded interpretation; however, the court in that case never reached the key question on the scope of EPA authority.⁵ There, the court considered whether TSCA requires EPA to evaluate chemical substances based on their conditions of use (“use by use” safety determinations), which was the position previously advocated by EPA, or if EPA must evaluate a substance’s uses “collectively” before determining a chemical is safe. But the court ultimately declined to rule on these issues,⁶ and the 2017 rule remained untouched as it relates to these critical interpretations of TSCA.

In June 2021, EPA abruptly changed its approach and ceased following the 2017 rule’s requirements. EPA announced,⁷ without commencing a rulemaking, that it planned to start implementing an approach to evaluating substances under TSCA known as the “whole chemical” approach rather than making safety findings for each condition of use evaluated in the risk evaluation. And without undergoing rulemaking, EPA declared it was going to modify prior-issued risk evaluations to add exposure pathways that were previously excluded from the scopes of the risk evaluations. It made other significant changes to risk evaluations, such as rejecting prior assumptions in risk evaluations that workers wear personal protective equipment, despite data to the contrary. EPA then re-issued nine of the first 10 risk determinations to incorporate these policy changes and has published one supplemental risk evaluation where it added certain exposure pathways to expand the scope of the risk evaluation, with a particular focus on environmental justice communities.⁸ EPA also proposed a screening level methodology to evaluate potential exposures for fenceline communities from air and water pathways not previously assessed.⁹ The policy changes have resulted in more

⁴ 82 Fed. Reg. 33747 (July 20, 2017).

⁵ *Safer Chemicals Healthy Families v. US EPA*, 943 F.3d 397 (9th Cir. 2019).

⁶ The Ninth Circuit found the Petitioners’ challenge regarding use-by-use determinations to be not justiciable because the rules were ambiguous and the harm to Petitioners was too speculative. And the Court found the challenge that EPA cannot exclude conditions of use from a risk evaluation to “fail on the merits” because the provisions that Petitioners took issue with did not in fact assert discretion to exclude conditions of use from evaluation. *Id.*

⁷ See EPA press release “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>.

⁸ See supplemental risk evaluation for 1,4-dioxane, released July 2023:

<https://www.epa.gov/system/files/documents/2023-07/1.%20Draft%20Supplement%20to%20the%20Risk%20Evaluation%20for%2014-Dioxane%20-%20public%20release%20-%20hero%20-%20July%202023.pdf>.

⁹ See EPA “TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities”: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-screening-level->

conservative and stringent proposals on uses of chemicals that, in some cases, were originally found by EPA to not present unreasonable risks.

Now that EPA has finally chosen to amend the 2017 rule, fundamental questions about the scope of EPA's authority under TSCA to review the risks of chemical substances have resurfaced. The Chamber provides extensive comments on the proposed statutory interpretation, legislative history, and the policy implications of EPA's proposal. The courts have acknowledged an agency's fundamental right to revisit a prior statutory interpretation or policy position, but in doing so, EPA must abide by established principles and reasoned explanations that respect statutory text and structure. The proposed rule runs afoul of those requirements.

The unlawful approach in this rule is fundamentally inconsistent with the statutory structure of TSCA. EPA's interpretation of its authority under TSCA represents a departure from TSCA's core "gap-filling" purpose to supplement and not supplant existing EPA or other federal authorities to address risks of substances:

Congress enacted TSCA in 1976 "to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. Rep. No. 94-698, at 1 (1976), as reprinted in 1976 U.S.C.C.A.N. 4491, 4491. TSCA was "designed to fill a number of regulatory gaps in premarket review, regulation of chemicals themselves (rather than regulation of discharges, emissions, ambient air, or consumer products), and information-gathering responsibility."¹⁰

By claiming that TSCA does not permit EPA to exclude any conditions of use from a TSCA risk evaluation, it undermines authority granted to the Administrator to make a determination on which conditions of use to consider and undercuts its own fundamental obligation to coordinate its own authorities to avoid duplication of regulations. Congress did not want TSCA to displace or replicate well-established environmental programs that regulate chemicals and have been in place for decades. But by claiming it lacks authority to tailor the conditions of use evaluated, EPA sidelines the "regulatory nexus" approach that it took in several of the first 10 risk evaluations. That approach properly allowed the TSCA program to defer evaluation of chemical exposure pathways to EPA sister program offices with adequate authority and expertise. The proposed approach is not reasonable because it fails to leverage EPA's own federal programs and partners and bogs down the risk evaluation process that Congress intended to be efficient and productive.

Additionally, the "whole chemical" approach would also significantly disrupt TSCA's federal preemption of state actions, which would partially be rendered ineffective and could not be

approach-assessing-ambient-air-
and#:~:text=The%20proposed%20screening%20level%20methodology,with%20such%20releases%20and%20expos
ures.

¹⁰ *Safer Chemicals, Healthy Families v. US EPA*, 943 F.3d 397, 406 (9th Cir. 2019).

used, consistent with Congressional design, to curtail a state's regulation on a use of a substance. Preemption was one of the most significantly negotiated issues and carefully tailored parts of the 2016 TSCA amendments, which Congress included to address concerns about the emerging patchwork of inconsistent state laws regulating chemicals in products. To suddenly render some of these provisions unusable is inconsistent with the Congressional goal of broadened preemption of state law to create a more unified national approach to chemical regulation.

Notably, the flawed "whole chemical" approach would also upset a carefully crafted statutory provision intended to allow chemical manufacturers to request that certain uses of their chemicals be reviewed by EPA in an efficient manner. If this rule is finalized, it would shift the burden onto industry to provide comprehensive information to support an expanded risk evaluation even in situations where a manufacturer requests the risk evaluation. Supplying data on all conditions of use of a chemical, rather than just the conditions of use of interest to the manufacturer, is contrary to the purpose of manufacturer-requested risk evaluations under TSCA. If the proposed changes are finalized, this provision is highly unlikely to ever be used again by manufacturers due to the significant burdens imposed. This is not consistent with Congressional intent for these provisions and demonstrates the poor fit between EPA's proposal and the statutory scheme.

Beyond reinterpreting fundamental TSCA provisions, EPA is also taking this opportunity to propose that risk evaluations include consideration of factors not authorized by TSCA, which would unnecessarily expand the scope of risk evaluations. These proposals, such as requiring consideration of aggregate exposures, inserting a definition of overburdened communities, and considering cumulative risk assessments and climate-related risks would give the Agency unbridled discretion that was never intended by Congress, which placed stringent timelines for completion of risk evaluations that should be focused on the conditions of use.

Finally, while claiming to follow the science, EPA proposes to remove critical scientific definitions from its rule, which creates a lack of transparency, predictability, and undermines public confidence in EPA's science-based decision-making process. EPA may want to update certain definitions but choosing to repeal basic definitions of "best available science" and "weight of the scientific evidence" does not advance scientific principles. EPA's explanations are unavailing and do not justify this attempt to give itself maximum flexibility without accountability. Likewise, EPA's proposal to cut back peer review requirements is anti-science and reduces agency accountability. In the 2016 amendments to TSCA, Congress specifically created the science advisory committee on chemicals (SACC) with a specific membership to ensure representation that is relevant to implementing TSCA and provide advice and expert consultation. Attempting to reduce the role of the SACC in reviewing certain risk evaluation materials does not advance scientific principles or good governance.

For these reasons and explained more fully below, the Chamber urges EPA to not finalize this proposed rule and to maintain and implement the 2017 risk evaluation rule.

I. EPA’s proposal to require one risk determination for a “whole chemical” rather than use-by-use risk determinations is inconsistent with TSCA’s requirements and will lead to unnecessary overregulation of chemicals.

The proposed rule is the product of a change in presidential administration where the agency has done an “about face” in interpreting its fundamental authority to assess chemical risk pursuant to the new powers Congress gave EPA in the Frank R. Lautenberg Chemical Safety for the 21st Century Act (“Lautenberg Act” or “2016 Amendments”).¹¹ As the proposed rule describes, the prior administration’s rule interpreted TSCA’s risk evaluation provisions in fundamentally different ways. It has long been settled law that an administrative agency may reconsider or revise past decisions.¹² And the Supreme Court has expressly acknowledged that agencies may change positions in response to a change in administration.¹³

However, these policy preferences must “remain[s] within the bounds established by Congress.”¹⁴ Even if the agency’s position changes, “an agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute.”¹⁵

But on the critical question of EPA’s authority on the scope and approach to risk evaluations under TSCA Section 6, the proposed rule ignores the traditional tools of statutory construction to misread plain statutory provisions. The proposed rule attempts to inject policy preferences that contravene the statute and would significantly expand agency power to make a risk determination on a “whole chemical” rather than focus on the specific uses for each chemical substance as Congress required in the 2016 Amendments. If EPA finalizes this approach, it will exceed its statutory authority and the limits on an agency’s ability to change its interpretation.

EPA states that it “no longer intends to make separate risk determinations for individual conditions of use” and instead, is proposing changes to the regulations to make a single risk

¹¹ Public Law No: 114-182.

¹² ““Regulatory agencies do not establish rules of conduct to last forever; they are supposed, within the limits of the law and of fair and prudent administration, to adapt their rules and practices to the Nation’s needs in a volatile, changing economy. They are neither required nor supposed to regulate the present and the future within the inflexible limits of yesterday.” *Am. Trucking Associations v. Atchison, T. & S. F. Ry. Co.*, 387 U.S. 397, 416 (1967).

¹³ “[A]dministrative authorities must be permitted, consistently with the obligations of due process, to adapt their rules and policies to the demands of changing circumstances.” *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968).

¹⁴ *Motor Vehicle Manufacturers Ass’n. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 59 (1983).

¹⁵ *Greater Bos. Television Corp. v. F.C.C.*, 444 F.2d 841, 852 (D.C. Cir. 1970). See also *Dep’t of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913, 207 L. Ed. 2d 353 (2020) (“When an agency changes course, as DHS did here, it must ‘be cognizant that longstanding policies may have ‘engendered serious reliance interests that must be taken into account.’” *Encino Motorcars, LLC v. Navarro*, 579 U.S. ----, ----, 136 S.Ct. 2117, 2126 (2016) (quoting *Fox Television*, 556 U.S. at 515, 129 S.Ct. 1800).”).

determination on the ‘whole chemical substance.’”¹⁶ EPA believes that “this approach is consistent with the statutory text and structure, as well as Congressional intent, and will enable the Agency’s risk determinations to better reflect the potential for combined exposures across multiple conditions of use.”¹⁷ Requiring the consideration of combined, cumulative, or aggregate exposures as part of each risk evaluation is not consistent with statutory requirements. The Chamber disagrees with EPA’s interpretation of TSCA. TSCA was structured to require use-by-use unreasonable risk determinations.

Moreover, EPA’s policy conclusion that the whole chemical approach will better reflect exposures in risk evaluations is incorrect, is inconsistent with the use-by-use approach Congress required, and would frustrate the operation of other TSCA statutory provisions that also rely on the use-by-use approach. EPA’s proposal is not a reasonable interpretation of its obligations to review existing chemicals since it will create inconsistencies with how other provisions of TSCA operate and result in misleading, overly conservative, and unscientific determinations on the safety of chemicals.

A. TSCA Section 6 requires evaluation of unreasonable risks “under the conditions of use,” and this concept is incorporated throughout TSCA.

TSCA defines “conditions of use” as “the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”¹⁸ These circumstances determine what exposure scenarios specific to the chemical’s conditions of use the Agency should include in risk evaluations. The term was used to “describe the *context* in which EPA will apply the safety standard in safety assessments *and determinations*.”¹⁹

The term “conditions of use” was embedded in the statute for the first time throughout 2016 Amendments to drive how EPA must approach its review of existing chemicals. Congress provided a step-by-step process in which EPA evaluates and regulates existing chemicals. The steps are that EPA 1) identifies chemicals for prioritization; 2) designates substances “high” or “low” priority, with low priority designations being final agency actions that do not warrant further review and high priority substances proceeding to risk evaluation; 3) defines the scope of a risk evaluation (including which conditions of use will be evaluated); 4) conducts a risk evaluation; 5) makes risk determinations for the conditions of use evaluated; and 6) for the conditions of use that present an unreasonable risk, EPA must proceed to risk management to mitigate the risks.²⁰ This entire process contemplates evaluation and regulation of individual

¹⁶ 88 Fed. Reg. at 74301.

¹⁷ *Id.*

¹⁸ 15 U.S.C. § 2602(4).

¹⁹ Senate Report 114-67 at 7 (emphasis added).

²⁰ 15 U.S.C. § 2605; see also EPA website on “Risk Evaluation Process and Timeline”:

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

conditions of use of a substance. The statute does not ask EPA to take each of these steps or a final risk determination in an aggregated fashion that combines or aggregates all conditions of use.

1) Identification of chemicals for prioritization - TSCA Section 6(b)(1)(A) provides that the process to designate the priority of substances must include a consideration of the hazard and exposure potential of a chemical substance, the **conditions of use** or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.²¹

2) Designation of high and low priority chemicals - TSCA Section 6(b)(1)(B) requires that EPA designate as “high-priority” a substance that EPA “concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure **under the conditions of use**, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the [EPA].”²²

3) Scope of risk evaluation - TSCA Section 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, “including the hazards, exposures, **conditions of use**, and the potentially exposed or susceptible subpopulations [EPA] expects to consider.”²³

4) Risk evaluation - TSCA Section 6(b)(4)(A) requires that EPA “conduct risk evaluations...to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk 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**.”²⁴ EPA must “assess available information on hazards and exposures **for the conditions of use** of the chemical substance,” “describe whether aggregate or sentinel exposures to a chemical substance **under the conditions of use** were considered, and the basis for that consideration,” and “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures **under the conditions of use** of the chemical substance.”²⁵

5) Risk determination - EPA must then make risk determinations **for each condition of use**. The conditions of use of the substance that present an unreasonable risk proceed to risk management so that EPA can mitigate the risks to the extent necessary, while the

²¹ 15 U.S.C. § 2605(b)(1)

²² 15 U.S.C. § 2605(b)(1)(B)(i) (emphasis added).

²³ 15 U.S.C. § 2605(b)(4)(D).

²⁴ 15 U.S.C. § 2605(b)(4)(A) (emphasis added).

²⁵ 15 U.S.C. § 2605(b)(4)(F) (emphasis added).

conditions of use that are found to not present an unreasonable risk are final agency actions and the process ends.²⁶

6) Risk management - TSCA Section 6(a) requires that if EPA determines, through a risk evaluation, 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,” EPA must promulgate requirements “to the extent necessary” to mitigate the identified risks.²⁷ Here, TSCA’s risk management requirements refer to the *determination* made by EPA “in accordance with” a Section 6(b)(4)(A) risk evaluation, and a Section 6(b)(4)(A) risk evaluation is a determination of whether a substance presents an unreasonable risk “**under the conditions of use.**” EPA will propose regulations that mitigate risks of each identified condition of use.

It is evident that each step of the Section 6 process requires EPA to evaluate chemicals, make risk determinations for chemicals, and issue subsequent risk management rules for chemicals based on individual conditions of use. Congress recognized that the Agency must have this structure in place – entirely lacking prior to the 2016 Amendments – to add rigor to EPA’s process and focus the analysis on the real-world use scenarios to make the ultimate risk determination. The Agency’s change of its interpretation on this fundamental issue is based on a strained and flawed reading of the text that would take away the guardrails that Congress established and would not achieve better outcomes.

EPA argues that TSCA Section 6(a)’s risk management provisions support the whole chemical approach because the provision suggests that it is the *chemical substance* that presents the unreasonable risk, not the conditions of use.²⁸ But EPA reads statutory text out of context. Of course, it is not the condition of use standing alone that presents an unreasonable risk. TSCA defines “conditions of use” as “circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, or distributed in commerce, used, or disposed of.”²⁹ It would be odd to say that a circumstance of manufacture, processing, distribution, or use presents an unreasonable risk. Instead, it is the chemical substance *under a particular condition of use* that presents a risk. Section 6(a) makes this clear by referring to “the Administrator[’s] determin[ation] in accordance with subsection (b)(4)(A), which requires it to make “risk evaluations” of the chemical substance “under the conditions of use.”

EPA makes much of Congress’s failure to repeat the “conditions of use” language. That is a distinction without difference. Section 6(a) uses the phrase “the manufacture, processing,

²⁶ 15 U.S.C. § 2605(b)(4)(F).

²⁷ 15 U.S.C. § 2605(a).

²⁸ 88 Fed. Reg. at 74302.

²⁹ 15 U.S.C. § 2602(4).

distribution in commerce, use, or disposal of a chemical substance or mixture.”³⁰ This is virtually identical to the statutory definition of conditions of use that refers to where a chemical is “manufactured, processed, distributed in commerce, used, or disposed of.”³¹ So, the conditions of use language is directly embedded in Section 6(a). Further, in Section 6(a), Congress chose to cross-reference Section 6(b)(4)(A), and thus, incorporate the “conditions of use” language in that manner as well. That choice must be given effect as well.

Additionally, Section 6(b)(4)(A) requires EPA to conduct multiple risk evaluations for a single chemical substance by assessing whether the chemical substance presents an unreasonable risk under the conditions of use. EPA’s reading of this provision focuses on the “a chemical substance” language, but entirely ignores the remainder of the sentence, which specifies that the statute requires multiple risk evaluations for a single chemical substance and that those risk evaluations are based on the conditions of use.³²

Other examples include the TSCA provisions for critical use exemptions from risk management requirements that contemplate EPA regulating chemicals based on the conditions of use and not as a “whole chemical”: “[EPA] may, as part of a [risk management rule], or in a separate rule, grant an exemption from a requirement of a subsection (a) rule *for a specific condition of use* of a chemical substance or mixture...” if certain conditions are met to demonstrate the critical or essential use of the substance.

Other parts of TSCA also incorporate the “condition of use” concept. For example, Section 9 of TSCA provides that EPA must submit a report to other federal agencies describing risks and requesting agency action if EPA determines that the substance, *under the conditions of use*, present an unreasonable risk and such risk may be sufficiently reduced or prevented by action taken under another federal agency.³³ As other federal laws are designed to address particular types of uses and exposures, such as OSHA regulating hazardous chemicals and exposures to workers in the workplace and CPSC regulating chemicals in consumer products, this provision would not make sense if EPA only makes one determination on the whole chemical. EPA would then never defer to another agency because no agency regulates “whole chemicals” for all conditions of use in all exposure scenarios.

TSCA’s judicial review provisions also establish procedures for seeking judicial review of “no unreasonable risk” determinations from EPA under Section 6(i)(1).³⁴ This part of the statute would be superfluous if EPA no longer makes “no unreasonable risk” determinations for individual conditions of use. At bottom, EPA cannot escape that Congress directed it to focus its risk evaluation on the specific uses of a chemical, not looking at an aggregate or cumulative approach to making unreasonable risk determinations.

³⁰ 15 U.S.C. § 2605(a)

³¹ 15 U.S.C. § 2602(4)

³² 88 Fed. Reg. at 74302.

³³ 15 U.S.C. § 2608(a).

³⁴ 15 U.S.C. § 2618.

B. TSCA does not contemplate making a risk determination on the “whole chemical” or describe how that should be conducted.

In the proposed rule, EPA explains that a determination that a “whole chemical” 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.”³⁵ EPA’s explanation of the whole chemical approach appears to be a moving target. In EPA’s 2021 policy announcement, it described the whole chemical approach as making a determination of unreasonable risk for the whole chemical “when it is clear the *majority* of the conditions of use warrant one determination.”³⁶ And in EPA’s final risk determination for HBCD, it described this approach as the “chemical-specific properties cut across the conditions of use within the scope of the risk evaluation and a *substantial amount* of the conditions of use drive the unreasonable risk.”³⁷ Now, EPA is proposing that when it makes a risk determination, it “intends to identify the conditions of use that *significantly contribute* to such determination.”³⁸

These changing explanations from EPA demonstrate that the Agency has still not settled on how it will make a single determination for a whole chemical when a risk evaluation makes risk findings for dozens of individual conditions of use of a substance. EPA fails to provide a coherent explanation as to what the whole chemical approach will mean in practice, and how it will make a single risk determination for a “substantial amount” of uses or even a single use when all of the other uses for the chemical do not present an unreasonable risk. EPA’s inconsistent, vague, and patently unscientific approach implementing the “whole chemical approach” is arbitrary and capricious, fails to afford regulated entities due process or predictability as to how chemicals will be evaluated, and is inconsistent with the intent of TSCA. EPA lacks a reasoned explanation of what exactly the whole chemical approach is and how it will be implemented.³⁹ As explained further below, that is because there is no logical reason to implement the whole chemical approach as opposed to a use-by-use approach to risk determinations.

i. The whole chemical approach is arbitrary and capricious because use-by-use risk determinations are inevitably variable outcomes for each condition of use.

For the substances in which EPA has completed risk evaluations—*asbestos (part 1), trichloroethylene, methylene chloride, C.I. Pigment Violet 29, HBCD, NMP, perchloroethylene,*

³⁵ 88 Fed. Reg. at 74303.

³⁶ Emphasis added. See EPA press release, “EPA Announces Path Forward for TSCA Chemical Risk Evaluations,” June 30, 2021: <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.

³⁷ Final Unreasonable Risk Determination for HBCD (June 2022), Document ID EPA-HQ-OPPT-2019-0237-0125, Section 5.1.1.1, pp. 2-3 (emphasis added).

³⁸ 88 Fed. Reg. at 74321.

³⁹ When EPA reverses course, it must provide a reasoned explanation. See *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

1-bromopropane, 1,4-dioxane,⁴⁰ and carbon tetrachloride, each of their conditions of use have variable risk outcomes. There has not been one substance where every condition of use evaluated was found to present an unreasonable risk, or where every condition of use was found not to present an unreasonable risk. The variable risk findings for each condition of use of a chemical makes the whole chemical approach illogical in its application because EPA will essentially, at the end of the risk evaluation process, disregard many of its own scientific conclusions on individual conditions of use that do not present unreasonable risk. By ignoring some individual risk findings, and weighting others more heavily to deem the “whole chemical” to present an unreasonable risk, EPA then empowers itself to regulate uses that do not present unreasonable risk. It would then seek to reduce all risk, rather than looking at risk numbers for each condition of use and then doing a fit-for-purpose mitigation on a condition of use specific basis.

EPA has not provided an adequate explanation of how the risk determination would work in weighing the different risk outcomes from each assessment of a condition of use. Stakeholders would have no way to know ahead of a final risk determination which conditions of use EPA might select as the “drivers” of an unreasonable risk determination and which ones it will not consider in its determination for the whole chemical. This decision-making process will be made in a black box and stakeholders who participate in the rulemaking process and provide data to EPA will not know how this information on each condition of use will be ultimately used to inform a risk determination. By utilizing this approach, EPA’s proposed process is more akin to hazard evaluation for the whole chemical approach, rather than satisfying TSCA’s requirements to consider, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use and describe the weight of scientific evidence supporting the exposure description for the conditions of use, as required by Section 6. A hazard-based approach is inconsistent with the Congressional mandate to focus on hazard *and* exposures when making an unreasonable risk determination.

ii. EPA’s whole chemical approach violates Section 26(h) and (i) of TSCA, which requires a science-based approach.

EPA’s own explanations of the whole chemical approach demonstrate that the policy is arbitrary and unscientific. TSCA explicitly requires that, in carrying out the requirements of TSCA Section 6 (including risk evaluations, risk determinations and risk management), that EPA must use information and procedures in a manner consistent with the best available science and the weight of the scientific evidence.⁴¹ Making an unreasonable risk determination on a whole chemical based on one condition of use or even a “substantial” number of conditions of use is inconsistent with TSCA’s scientific standards because EPA will be communicating to the public that a “whole chemical” is unsafe, even when its own evaluations find conditions of use of the chemical that do not present an unreasonable risk. This lack of regulatory clarity is

⁴⁰ Note EPA recently released a draft supplement to the 1,4-dioxane risk evaluation.

⁴¹ 15 U.S.C. § 2625(h).

contrary to science-based principles that EPA and this administration have stated that they follow:

It is the policy of my Administration to make evidence-based decisions guided by the best available science and data.... When scientific or technological information is considered in policy decisions, it should be subjected to well-established scientific processes, including peer review where feasible and appropriate, with appropriate protections for privacy.⁴²

Science-based regulation should support risk communication to the public about the actual risk posed by a particular chemical use, not guilt by association. There are many chemicals in everyday uses that present little to no risk in the condition of use for which the public may be most familiar, and yet, in other contexts, the chemical can present a risk. For example, chemicals found in many household cleaning products and disinfectants are used by consumers safely every day. However, those same chemicals in non-household uses, like certain industrial uses, could be more dangerous due to the increased volumes, exposures, and circumstances in which the substance is handled. If an EPA risk evaluation confirms that a particular use is innocuous yet the “whole chemical” is still deemed to have unreasonable risk, it inappropriately taints the condition of use that EPA has itself deemed to be safe.

Thus, the whole chemical approach is not a reasonable approach to risk determinations because it misleads the public and is unfairly prejudicial to the company who is commercializing that innocuous use. The specific use should clearly be characterized on its own merits in the form of a risk determination and not allow the public or even litigants in other forums to unfairly described the chemical globally as having unreasonable risk.

iii. The whole chemical approach would nullify EPA’s authority under TSCA Section 6(i), which specifically contemplates EPA making findings by order that a chemical “does not present an unreasonable risk.”

Section 6(i)(1) of TSCA provides that a “no unreasonable risk” determination by EPA following a risk evaluation is considered a final agency action (and, thus, subject to judicial review) that does not trigger the risk management step.⁴³ This is a statutory “off ramp” determination where conditions of use that EPA determines to be safe are final determinations and do not warrant regulation, while conditions of use that do present risks move on to the risk management stage of the process. Further Section 6(b)(4)(A) requires that EPA risk evaluations

⁴² See White House Memorandum on “Restoring Trust in Government through Scientific Integrity and Evidence-Based Policymaking.” January 27, 2021: <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/>; see also EPA Science Policy Council Handbook on Risk Characterization, EPA 100-B-00-002 (December 2000), https://www.epa.gov/sites/default/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

⁴³ 15 U.S.C. § 2605(i).

determine “whether a chemical substance presents an unreasonable risk...under the conditions of use.”⁴⁴ The use of the word “whether” indicates that Congress anticipated that EPA, because of the risk evaluation process, will make both “no unreasonable risk” and “unreasonable risk” determinations based on the inherent hazards and exposures under the conditions of use. This interpretation is confirmed in the legislative history:

A Section 6(i) order, determining that a chemical substance does not present an unreasonable risk under 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. 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.*⁴⁵

However, under the whole chemical approach, because EPA would have the authority to designate a substance as “presents an unreasonable risk” based on even one condition of use, there effectively will never be *any* “no unreasonable risk” determinations. This outcome is contrary to the intent of TSCA, which provides for procedures for chemicals that EPA determines do present an unreasonable risk and do not present an unreasonable risk. TSCA’s robust, risk-based approach to chemicals management contemplates that there will be conditions of use in which EPA finds no unreasonable risk.

EPA claims that Section 6(i) supports its reading, but that is incorrect. EPA argues that Sections 6(i)(1) and 6(i)(2) support a whole chemical approach because they speak in terms of whether the chemical substance presents an unreasonable risk and do not refer to conditions of use.⁴⁶ But that reads the language of those provisions out of context. Both provisions refer to determinations made “under subsection (b)(4)(A),” and subsection (b)(4)(A) requires the Administrator to “conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury . . . under the conditions of use.” Thus, Section 6(i) plainly incorporates the conditions of use language in subsection (b)(4)(A) and is entirely consistent with a conditions-of-use-based approach.

iv. Under the whole chemical approach, EPA can force every condition of use of a chemical to go through risk management, even ones that do not present an unreasonable risk, which is inconsistent with TSCA.

TSCA requires that, once EPA makes an “unreasonable risk” determination, it is compelled to initiate a rulemaking to mitigate the unreasonable risk “to the extent necessary”:

“[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical

⁴⁴ 15 U.S.C. § 2605(b)(4)(A).

⁴⁵ 162 Cong. Rec. S3520 (June 7, 2016) (emphasis added).

⁴⁶ 88 Fed. Reg. at 74302.

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...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....⁴⁷

At the risk management stage, EPA is compelled by TSCA to apply one or more of the following prescribed risk management requirements:

(1) A requirement (A) prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

⁴⁷ 15 U.S.C. § 2605(a).

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such determination, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.⁴⁸

These regulatory options provided in TSCA Section 6(a) do not include the choice to “take no action on the condition of use.” That is because Congress contemplated that EPA address specific conditions of use that pose an unreasonable risk through risk management. Congress did not contemplate that EPA consider risk management actions for conditions of use that do *not* pose an unreasonable risk. Those conditions of use are supposed to exit the process upon the risk determination (the final agency action under TSCA Section 6(i)(1)) and not go to risk management.

That intention is confirmed by the legislative history. The Lautenberg Amendments were not designed to change “[t]he restrictions that the Administrator is authorized to impose.” Rather, Congress contemplated that “[b]ecause a chemical substance’s intended conditions of use are important in defining the risk it presents . . . the Administrator in applying any requirements will address identified circumstances of manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance or mixture that presents or will present an unreasonable risk of injury to health or the environment that require control.”⁴⁹ Thus, Congress intended EPA to take a condition of use by condition of use approach to risk mitigation and only take action with respect to a chemical substance’s specific conditions “that present[] or will present an unreasonable risk.”⁵⁰

EPA’s reading, however, upsets this process. Because EPA will make only one risk determination for the whole chemical, including *all* conditions of use (which will likely be a “presents an unreasonable risk” determination), under TSCA Section 6(a), EPA *must* then apply “one or

⁴⁸ 15 U.S.C. § 2605(a).

⁴⁹ H. Report 114-176 at 23.

⁵⁰ *Id.*

more” of the listed requirements to the extent necessary. This compels overregulation of conditions of use that do not pose unreasonable risks to human health or the environment. As a result, EPA’s decision is arbitrary and capricious because it results in EPA regulating even conditions of use that do not pose an unreasonable risk that requires mitigation.⁵¹

EPA has stated that even with one unreasonable risk determination for a whole chemical, it will appropriately address each condition of use individually during the risk management stage. But this is a fallacy because EPA cannot choose to *not* impose any statutorily enumerated requirements on these conditions of use. Because the whole chemical, including all conditions of use, receives one unreasonable risk determination, EPA is effectively sending all of the conditions of use to risk management where it is then required to regulate them using one or more of the listed options in Section 6(a). EPA’s only other option is to not impose risk management at all, which would also violate Section 6(a). By making this concession, EPA effectively admits that its interpretation does not work in practice because it will be required to tailor its risk management to each individual condition of use in any event.

The problems with applying the “whole chemical” approach at the risk management stage further illustrate that EPA’s reading of the risk evaluation provision of Section 6(b)(4)(A) is incorrect. Once all of the conditions of use have been sent to risk management, EPA will have two options with respect to condition of use for which it has found “no unreasonable risk,” both of which violate the statute. EPA can either impose one of the regulatory options listed – and thus violate Section 6(a) by regulating well beyond “the extent necessary” to mitigate unreasonable risk because there is no unreasonable risk, or it can choose not to regulate the condition of use at all, in which case it is also violating Section 6(a) by not imposing one of the listed regulatory options. The fact that EPA’s interpretation of the risk evaluation provision requires it to violate the statute at the risk management stage should have alerted EPA to the fact that Congress did not intend for conditions of use under which the chemical does not present an unreasonable risk to move to risk management. In sum, the problem should have alerted EPA to the fact that its “whole chemical” reading is incorrect.⁵²

v. EPA’s flawed “whole chemical” approach has already caused it to inappropriately propose to regulate conditions of use that it found NOT to present an unreasonable risk.

In practice, we have already seen the consequences of the “whole chemical” approach on several of the proposed risk management rules—for methylene chloride, trichloroethylene, perchloroethylene, and carbon tetrachloride. When EPA makes a single determination for the

⁵¹ *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action is arbitrary and capricious when it “entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it cannot be ascribed to a difference in view or the product of agency expertise”).

⁵² *See Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 328 (2014) (“the need to rewrite clear provisions of the statute should have alerted EPA that it had taken a wrong interpretive turn”).

whole chemical, it makes the one “unreasonable risk” determination, then lists the conditions of use that “drive” the risk determination and ones that “do not drive” the risk determination. All of these conditions of use proceed to risk management. In each of these rulemakings, EPA has taken the position that, even if a condition of use was found not to present an unreasonable risk in the original risk determination and is still found “not to drive” the unreasonable risk determination in the revised risk determination, EPA may *still* restrict that condition of use anyway: “EPA may, for example, determine that elimination of the unreasonable risk requires regulation of the chemical’s upstream manufacture, processing or distribution in commerce—even where the upstream activity itself does not directly result in the exposures that present the unreasonable risk.”⁵³ EPA justifies this approach by explaining that it has authority to regulate certain upstream conditions of use to address risks presented by downstream conditions of use, even if the condition of use is not a “driver” of unreasonable risk.

EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.⁵⁴

This arbitrary and unscientific approach violates TSCA. EPA has not provided a reasoned explanation of what a “driver” of unreasonable risk means. By using vague and undefined terms like “drivers” of unreasonable risk, EPA attempts to shield the fact that it is justifying banning conditions of use that its own risk evaluations and own risk determinations identified as not presenting any unreasonable risk. And the regulated community is not going to be able to predict, even when a risk evaluation does not find any unreasonable risk for a condition of use, how it will be treated in risk management.

For example, for EPA’s original risk determination for TCE, EPA found consumer use in pepper spray not to present an unreasonable risk. And in the revised risk determination,⁵⁵ EPA still found that this condition of use did not “drive” the unreasonable risk determination. However, because of the whole chemical approach, all conditions of use were sent to the risk management stage, including consumer use of TCE in pepper spray. And in the proposed risk management rule, EPA chose to ban TCE in pepper spray for consumer use, while

⁵³ 88 Fed. Reg. at 74303.

⁵⁴ 87 Fed. Reg. 76481, 76486 (Dec. 14, 2022).

⁵⁵ EPA Final Revised Unreasonable Risk Determination for Trichloroethylene at 2, January 2023: https://www.epa.gov/system/files/documents/2023-01/TCE_Final%20Revised%20RD_12-21-22-FINAL-v2.pdf.

acknowledging it is proposing to do so despite not identifying risks for that condition of use.⁵⁶ This approach violates TSCA, as EPA is supposed to proceed to risk management only when it determines that a substance presents an unreasonable risk under the conditions of use. It is contrary to TSCA to regulate conditions of use that EPA finds do not pose an unreasonable risk.

C. Use-by-Use Determinations Are Supported by TSCA Section 9.

TSCA Section 9 provides that if EPA “determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance...presents an unreasonable risk of injury to health or the environment...*under the conditions of use*, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator” (emphasis added), then EPA must submit a report to the other agency identifying the risk and requesting action.⁵⁷ And EPA must coordinate “actions,” including risk evaluations and risk determinations, with actions taken under other EPA statutes. And if EPA finds that a risk could be eliminated or reduced to a sufficient extent by its other authorities, it must use such authorities.⁵⁸ If EPA makes risk determinations on a chemical “as a whole” and not use by use determinations, it would undercut any obligation or opportunity created in the statute for EPA to defer to other federal agencies or its own programs to appropriately manage that condition of use.

Consistent with the statutory purpose to supplement and not supplant other federal statutes regulating chemicals, TSCA Section 9 was intended to prevent duplicative regulation of the same uses of chemicals.⁵⁹ Therefore, if EPA finds that a certain condition of use presents an unreasonable risk, it can look to other federal authorities that can address risk. For example, if a condition of use of a chemical involves worker exposures in a manufacturing facility, and EPA identifies that the manufacture condition of use presents an unreasonable risk, EPA can look to OSHA to mitigate those risks, since OSHA standards cover worker exposures to chemicals in the workplace. And EPA can look to other statutes like the Clean Air Act that address that particular exposure scenario, like ambient air exposures. However, if EPA only provides one determination for the whole chemical, it may never defer to another agency or other EPA-administered program under TSCA Section 9(a) because no other statute empowers an agency to address *all* exposures of every single condition of use of a chemical substance. Thus again, the misreading of the statute in the proposed rule would negate the cooperative scheme that Congress created.

⁵⁶ 88 Fed. Reg. 74712, 74763 (October 31, 2023) (“Given the severity and ubiquitous nature of the risks identified in the 2020 Risk Evaluation for TCE for processing of TCE into formulation as well as for all but one consumer use (pepper spray) and, noting that those conditions of use encompass all known, intended, and reasonably foreseen consumer use, EPA proposes that prohibiting manufacture (including importing), processing, and distribution in commerce of TCE for consumer use is reasonable.”).

⁵⁷ 15 U.S.C. § 2608(a).

⁵⁸ 15 U.S.C. § 2608(b).

⁵⁹ Congress emphasized this in its discussions of Section 9: “[T]his bill reemphasizes Congress’ intent to avoid duplicative regulation through the TSCA law.” 162 Cong. Rec. H3028 (May 24, 2016).

D. EPA’s whole chemical approach would render certain Section 18 preemption provisions a nullity and deprive businesses of the benefits of preemption.

Section 18 of TSCA governs federal preemption of state actions. In reforming TSCA in 2016, Congress sought to curb the emerging patchwork of state regulations by providing EPA more authority, resources, and enforceable deadlines in which to regulate chemical substances, and at the same time, have those regulatory decisions from EPA preempt state actions. This was a high priority for the regulated community, as it faced challenges in complying with multiple state laws governing chemicals in products:

Some stakeholders have raised concern that TSCA has not fostered a robust federal chemical regulatory system, which has resulted in a number of states becoming more active on chemical regulatory matters. In their view, a proliferation of different state requirements will create confusion for the general public, and significantly increase the cost and burden of regulatory compliance for chemical manufacturers, importers and users while failing to apply any protections to more than a relatively small number of citizens.⁶⁰

Congress intended to establish a “robust, nationally uniform program for the effective regulation of chemicals....[where] prioritization, safety assessment and determination, and regulatory provisions establish a credible national program...in such a way that the need for separate state or local action may be minimized.”⁶¹ TSCA provides for federal preemption of state actions when EPA promulgates a rule, consent agreement or order that is likely to produce the same information required under TSCA Section 4 (testing), 5 (new chemicals), and 6 (existing chemicals). And preemption applies when a state takes action to prohibit the manufacture, processing, distribution, or use of a substance for which EPA has already determined it does not present an unreasonable risk following a risk evaluation, or when EPA issues a final risk management rule for a substance. TSCA also provides for “pause preemption” where a state is “paused” or prevented from restricting the manufacture, processing, distribution in commerce or use of a substance that EPA designates high priority, beginning on the date EPA defines the scope of a risk evaluation.⁶²

Preemption was a significant consideration contemplated by Congress when enacting the 2016 TSCA amendments. Congress was interested in establishing a much more robust chemicals management program that had credibility among the more modern international chemical programs (e.g., EU’s REACH) as well as states such as California and Maine, which were active in creating chemicals management programs to regulate chemicals in products over the past decade. Under the amended TSCA, preemption was part of the balance between (1) enhancing EPA’s authority and resources to address risks of chemicals and (2) not stifling innovation. This is because the benefit of such federal review and regulation of chemicals would be that EPA’s

⁶⁰ Senate Report 114-67 at 6.

⁶¹ Senate Report 114-67 at 24.

⁶² 15 U.S.C. § 2617(b)(1).

decisions would preempt certain state actions for the same substance (with respect to the same hazards, exposures, risks, and uses or conditions of use of such chemical substances). Congress contemplated that this would work on a use-by-use basis following an EPA safety determination for each use rather than a “whole chemical” basis:

If EPA has completed a safety assessment and safety determination for a chemical substance and finds the chemical substance meets the safety standard, that action preempts state restrictions on that substance *only for the uses and/or conditions of use included in the EPA review....* the section establishes clear direction that preemptive effects on state law are limited to the specified regulatory actions taken by EPA with respect to a specific chemical substance or category of substances, *and then only to the uses or conditions of use addressed by that EPA action.*⁶³

The text of the preemption provisions that Congress wrote into the statute further confirm that Congress intended a conditions-of-use-based approach, rather than a whole chemical approach, to risk determinations. Section 18(a)(1)(A) provides for preemption of statutes or administrative actions “to require the development of information about a chemical substance.” Congress also, in Section 18(a)(1)(B), provided for preemption where EPA has made a no unreasonable risk determination or where EPA has made an unreasonable risk determination and promulgates a risk management rule.⁶⁴ Subsection (b) addresses “pause preemption” with respect to high-priority substances. Then in subsection (c), Congress defined the scope of preemption with respect to those three types of preemption.

For either an unreasonable risk determination or a risk management rule, Congress took a condition of use approach, providing that “federal preemption . . . shall apply to . . . the hazards, exposures, risks, and uses or *conditions of use* of such chemical substances included in any action” taken.⁶⁵ Thus, Congress chose to target its preemption provision to the specific conditions of use that were found either to present an unreasonable risk or not to present an unreasonable risk. That approach to preemption would not make sense under EPA’s whole chemical approach because there would be only one risk determination for the chemical and so there would be no reason to specify that the scope of preemption applies to the conditions of use included in the action taken.

The conditions of use approach fits with the scope of the other types of preemption. Regarding preemption under subsection (b), which relates to preemption for high priority chemicals, the scope of preemption includes “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).”⁶⁶ That makes sense because at that stage EPA has only determined the conditions of use it expects to evaluate, not those that actually pose an unreasonable risk, but it

⁶³ Senate Report 114-67 at 25 (emphasis added).

⁶⁴ 15 U.S.C. § 2617(a)(1)(B)(i), (ii).

⁶⁵ 15 U.S.C. § 2617(c)(3).

⁶⁶ 15 U.S.C. § 2617(c)(2).

still takes a conditions of use approach. But in the scope of preemption with respect to Subsection (a)(1)(A) regarding information development, Congress took a different approach—a chemical by chemical approach. There, Congress provided that the scope of preemption is “the chemical substances or category of chemical substances subject to a rule, order, or consent agreement.”⁶⁷ This contrasts with how Congress approached preemption with respect to risk evaluations and shows that Congress knew how to provide for a whole chemical approach when it wanted to do so. But it chose not to do so with respect to risk evaluations. And “[w]hen Congress includes particular language in one section of a statute but omits it in another[,] . . . [the reader] presumes that Congress intended a difference in meaning.”⁶⁸

EPA’s attempt to use Section 18 to bolster its interpretation of Section 6 fails. EPA argues that Congress’ use of “the determination” in Subsection 18(a)(1)(B) indicates that EPA must make only one determination for each chemical substance.⁶⁹ But EPA reads those words in isolation rather than in the context of the provision as a whole. The provision states that a state statute or other action to prohibit or restrict a chemical substance for which “the determination described in section 2605(i)(1) of this title is made” is preempted.⁷⁰ So here, Congress is referring to the particular type of determination that is described in Section 2605(i)(1)—a no unreasonable risk finding. Having identified the type of determination to which preemption applies, Congress then explains in subsection (c) that the scope of preemption is to reflect the specific conditions of use for which the risk determination was made. Also, the sentence in Section 18(a)(1)(B) says “the determination...consistent with the scope of the risk evaluation under section 2605(b)(4)(D),” which, in referencing Section 6(b)(4)(D), refers to the scope of the risk evaluation, which includes consideration of the individual conditions of use.

In addition to being wrong on the text of Section 18, EPA’s interpretation also effectively reads the preemption provision for findings of no unreasonable risk out of the statute. The whole chemical approach creates a scheme where EPA will be unlikely to ever make a determination that a chemical substance presents no unreasonable risk. EPA’s reading thus renders the preemption provision superfluous and seriously limits the benefits of preemption that Congress unambiguously intended to provide when it amended TSCA.

i. The whole chemical approach is also incompatible with how states regulate chemicals.

In the Lautenberg Amendments, Congress specifically sought to address the issue of state law restrictions that pose challenges for interstate commerce in products containing chemicals. The programs of primary concern were California’s Safer Consumer Products Program, Vermont’s chemical disclosure program for children’s products, Washington’s Safe Products Act,

⁶⁷ 15 U.S.C. § 2617(c)(1).

⁶⁸ *Digital Realty Trust, Inc. v. Somers*, 583 U.S. 149, 161 (2018) (quoting *Loughrin v. United States*, 573 U.S. 351, 358 (2014)).

⁶⁹ 88 Fed. Reg. at 74302.

⁷⁰ 15 U.S.C. § 2617(a)(B)(i).

Minnesota’s Toxic Free Kids Act, Maine’s Toxic Chemicals in Children’s Products Program, and Oregon’s Toxic Free Kids Act. These state laws each provide programs in which the relevant state agencies decide to prioritize chemicals of high concern, create reporting or disclosure programs for manufacturers who make and sell products containing these chemicals in the state, and in some cases ban the products.

In the context of restrictions or bans, all of these programs are structured to focus on the use of chemicals in certain products. California’s Safer Consumer Products Program, for example, creates a program in which the state Department of Toxic Substances Control designates candidate chemicals with properties of concern, defines product categories to evaluate, and identifies “priority products,” which are specific product-chemical combinations with exposures of concern, requiring manufacturers of priority products to submit notifications and conduct alternatives analyses, and issue a regulatory response. Similarly, Washington state also creates a process in which priority chemicals are designated, priority consumer products are designated (products containing these chemicals that cause exposures of concerns), and determinations of appropriate regulatory restrictions are made for these products.

While these state programs have lists of chemicals of concern, they do not make decisions on “whole chemicals.” Rather, states review and regulate chemicals based on the individual conditions of use of the chemical—primarily uses in certain consumer products. Therefore, if EPA takes the approach of making single risk determinations for a “whole chemical,” even if it is a “no unreasonable risk determination,” it is unclear how such a determination would be applied to state actions which are for specific chemicals in products. For example, if EPA finds Chemical A “as a whole” to NOT present an unreasonable risk, but a state wants to ban the use of Chemical A in children’s products, the question becomes to what extent does EPA’s decision about the whole chemical preempt a state action on just a specific condition of use of that same chemical. This question is further complicated when state regulation of chemicals, despite TSCA reform, continues to be on the rise. For example, 12 states have enacted reporting or disclosure requirement or bans on various consumer products containing per-and-polyfluoroalkyl substances (PFAS), and over 200 legislative proposals were introduced in state legislatures in 2023 alone to address PFAS.⁷¹ States are also continuing to address chemicals such as flame retardants, phthalates, lead, and cadmium in certain consumer products. For example, Minnesota passed a law this year that restricts lead and cadmium content in certain consumer products.

⁷¹ See Safer States “PFAS” page: <https://www.saferstates.com/toxic-chemicals/pfas/>.

E. EPA’s whole chemical approach will create uncertainty for the regulated community and the public regarding the risks of chemical substances, contrary to TSCA’s mandate to “consider the environmental, economic, and social impact of any action.”

Congress was clear that, in implementing TSCA, EPA must “consider the environmental, economic, and social impact of any action the Administrator takes or proposes.”⁷² EPA’s whole chemical approach fails to consider the serious market and social impacts that misleading messaging from the Agency about the safety of a chemical substance will have on the economy and consumer perception. The whole chemical approach will result in EPA over-designating substances as having unreasonable risk and create significant uncertainty for the regulated community as to the outcome of chemicals undergoing risk evaluation and risk management.

By considering the risks of the individual conditions of use “collectively,” stakeholders will not be able to anticipate or understand when certain conditions of use will be subject to regulation or not. For some chemicals, EPA could base an unreasonable risk determination for a whole chemical on a majority of the conditions of use, or certain conditions of use it chooses, or even one condition of use. The potential for inconsistent application of the whole chemical approach and uncertainty for industry will have an adverse economic impact as many businesses have to make decisions on what types of chemistries and products in which to invest. Even if information provided in the risk evaluation itself suggests that a particular use does not present risk, it will not be enough to address these concerns.

Confusion about EPA’s risk determinations for a whole chemical could also mislead, state legislators, consumers, and the general public. States could forge ahead and propose regulations imposing broad restrictions on a chemical substance. The public is unlikely to pay attention to the nuances of the TSCA risk evaluation and risk determination process to understand that even if a chemical “presents an unreasonable risk,” that does not mean EPA necessarily found risk with every condition of use. By labeling a substance as presenting an unreasonable risk, EPA is essentially signaling to the public that the chemical is unsafe for manufacture, processing, distribution, use or disposal, in any application, regardless of exposure.

EPA dismisses these concerns as purely “risk communication issues that the Agency can and intends to continue to improve.”⁷³ But EPA has not demonstrated any interest in doing so thus far following the re-issuance of 9 of the 10 risk determinations for the “first ten” chemicals. EPA’s commitment to improve risk communications provides absolutely no assurance that consumers will not seek to avoid products or exposure scenarios, even ones that are safe, that involve the chemical EPA found to present an unreasonable risk. Nor does it prevent private businesses, such as retailers, from voluntarily deselecting chemicals and imposing requirements

⁷² 15 U.S.C. § 2601(c).

⁷³ 88 Fed. Reg. at 74303.

upon their suppliers to only supply products and materials that do not contain the chemical. EPA must consider the implications of communicating to the public that a chemical substance, as a whole, “presents an unreasonable risk” and must be regulated. EPA also fails to consider the market impacts of its rule, which could be significant and result in consumers turning away from products that are safe.

EPA’s failure to consider these issues and brushing them off as simply “risk communication issues” that it intends to improve without any indication as to how it intends to do so is arbitrary and capricious. Agency rules are arbitrary and capricious, among other things, when the agency “entirely failed to consider an important aspect of the problem.”⁷⁴ In TSCA, Congress instructed EPA to “consider the environmental, economic, and social impact of any action the Administrator takes or proposes” under the Act.⁷⁵ That means that EPA must consider the social and economic impact of labeling chemicals, that are in fact safe, as unsafe under certain conditions of use.

II. The proposed rule’s claim that TSCA prohibits the exclusion of conditions of use from the scope of risk evaluations misapprehends EPA’s authority under Sections 6 and unlawfully restricts the Administrator’s authority under Section 9 and Section 18.

The proposed rule would codify EPA’s change of position regarding whether it is permitted by statute to exclude any condition of use from the scope of a TSCA risk evaluation under Section 6. The proposed rule acknowledges that it previously gave effect to the language in the statutory definition of conditions of use, “as determined by the Administrator,” which allowed the agency to exclude certain conditions.⁷⁶ However, it claims that allowing the Administrator to exclude certain conditions of use under that authority “conflicted with the plain language of the law to evaluate chemical substances under the known, intended or reasonably foreseen circumstances associated with the full lifecycle of the chemical substance.”⁷⁷

However, the Agency provides no explanation why, notwithstanding the statutory requirement to look at the foreseeable uses, it lacks discretion to exclude conditions of use from a risk evaluation. It simply asserts that the “‘expects to consider’ in TSCA section 6(b)(4)(D) simply refer[s] to the Agency’s role in determining what the conditions of use are for a particular substance....”⁷⁸ The Agency does not claim administrative deference to its new interpretation, but simply asserts that the better reading of the statute is that the agency lacks this authority. To support this “better reading,” EPA reiterates its position that the purpose of the TSCA risk evaluation process is to obtain a comprehensive assessment of a chemical’s risk which is incompatible with excluding any uses, even *de minimis* uses or uses assessed under another EPA-administered statute.

⁷⁴ *State Farm*, 463 U.S. at 43.

⁷⁵ 15 U.S.C. § 2601(c).

⁷⁶ 15 U.S.C. § 2602(4).

⁷⁷ 88 Fed. Reg. at 74294.

⁷⁸ *Id.* at 74297.

EPA's statutory construction does not support limiting the Agency's discretion. EPA must explain clearly whether it believes this interpretation is compelled by the statute. EPA's policy rationale also does foreclose important statutorily supported reasons, discussed below, why a TSCA risk evaluation should exclude certain conditions. Moreover, EPA's reliance on the Ninth Circuit's decision in *Safer Chemicals, Healthy Families v. EPA* is misplaced, because the court never reached the question of whether the Agency had this authority generally.⁷⁹ Therefore, if EPA believes that it cannot exclude conditions of use under the statute, but it has not said so plainly and merely implies that that it believes that is a better interpretation, it has misapprehended its authority. The statutory language is more than sufficient to support EPA's authority to exclude conditions of use on a case-by-case basis if the Agency has a non-arbitrary basis to do so that is consistent with the statute's purpose.

A primary reason why Congress would not have foreclosed EPA's ability to exclude certain conditions – which was not at issue in *Safer Chemicals, Healthy Families v. EPA* – is that TSCA contemplates deference to other programs within EPA that have already or have the appropriate expertise to analyze a particular condition of use or exposure pathway. TSCA Section 9 provides for coordination with, and, in some cases, deference to other authorities to regulate chemicals for certain exposure pathways. Indeed, TSCA Section 9 references Section 6(b) risk evaluations, which require review of the substance “under the conditions of use.”⁸⁰

As recognized by *Safer Chemicals, Healthy Families v. EPA*, when Congress enacted TSCA in 1976, and again when it revised TSCA through the Lautenberg Amendments in 2016, EPA was not authorized to go beyond TSCA's “gap-filling” purpose:

Congress enacted TSCA in 1976 “to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances.” S. Rep. No. 94-698, at 1 (1976), as reprinted in 1976 U.S.C.C.A.N. 4491, 4491. TSCA was “designed to fill a number of regulatory gaps in premarket review, regulation of chemicals themselves (rather than regulation of discharges, emissions, ambient air, or consumer products), and information-gathering responsibility.”⁸¹

And Congress reiterated in 2016 that the purpose of the TSCA amendments was to “reinforce TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals.”⁸²

Congress intended Section 9 of TSCA to *require* that EPA coordinate with its other offices (and other federal agencies) to avoid confusion, complication, unnecessary, and duplicative

⁷⁹ *Safer Chemicals, Healthy Families v. US EPA*, 943 F.3d 397, 405 (9th Cir. 2019).

⁸⁰ 15 U.S.C. § 2608(a)(1) (“If the Administrator determines in accordance with subsection (b)(4)(A).”).

⁸¹ *Safer Chemicals, Healthy Families v. US EPA*, 943 F.3d 397, 406 (9th Cir. 2019).

⁸² H. Rep. No. 114-176 at 28.

regulation of the same conditions of use of chemicals and to maintain TSCA's gap-filling purpose.⁸³ In fact, any reading to the contrary makes no sense. Legislating against the known backdrop of all EPA's extensive authority, it makes no sense that Congress would want the agency to assess all risks under a newly created TSCA program and ignore the expertise and regulatory judgments that EPA has made for decades under statutes such as the Clean Air Act regarding the same chemicals.

TSCA Section 9(b)(1) directs EPA to coordinate actions, including risk evaluations, taken under TSCA with actions taken under other federal laws administered in whole or in part by EPA. If EPA determines that a risk to health or the environment associated with a substance *could be* "eliminated or reduced to a sufficient extent" by actions taken under the authorities contained in the other federal laws, then EPA must use those authorities to protect against risks (unless EPA determines it is in the public interest to act under TSCA).⁸⁴ Congress provided the example that, if EPA "determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, [EPA] should use those authorities to protect against the risk."⁸⁵ And if EPA "finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, [EPA] should ensure that the relevant office of the EPA receives that information."⁸⁶ Therefore, coordination of intra-agency action on risks under TSCA Section 9 involves both an identification of risk and a referral of any risk that could be eliminated or reduced to a sufficient extent under other EPA-administered laws to the EPA offices responsible for implementing those laws.⁸⁷

In prior risk evaluations, EPA has recognized TSCA Section 9 supports coordination with and referral of action to other EPA offices, "especially when statutes and associated regulatory programs administered by those offices could address exposure pathways or risks associated with conditions of use, hazards, and/or exposure pathways that may otherwise be within the scope of TSCA risk evaluations."⁸⁸ EPA acknowledged that exercising TSCA Section 9 authority to coordinate on tailoring TSCA risk evaluations is consistent with Congressional intent.⁸⁹

⁸³ The purpose of TSCA Section 9 is further clarified in the colloquies that took place on the House floor during consideration of TSCA reform legislation from Rep. Pittenger: "These amendments reemphasize and strengthen Congress' intent that TSCA serve as an authority of last resort for the regulation of a chemical when another authority under EPA's jurisdiction, or another Federal agency, already regulates the chemical and the risk identified by EPA....[I]n light of yet another regulatory overreach in the rulemaking at EPA, the new amendments to section 9 of TSCA are a welcome reform with the intent that it will help restrain the agency's unnecessary activities." 162 Cong. Rec. H3028 (May 24, 2016).

⁸⁴ 15 U.S.C. § 2608(b)(1).

⁸⁵ H. Rep. No. 114-176 at 28.

⁸⁶ S. Rep. No. 114-67 at 21.

⁸⁷ EPA Final Risk Evaluation for 1,4-Dioxane at 49 (December 2020): https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_14-dioxane_casrn_123-91-1.pdf.

⁸⁸ EPA Final Risk Evaluation for 1,4-Dioxane at 50.

⁸⁹ *Id.*

In risk evaluations conducted on the first ten chemicals, EPA did, consistent with TSCA Section 9, appropriately coordinate with other EPA agencies and explained why it chose to tailor the risk evaluation to exclude environmental exposure pathways that were covered by other EPA statutes, which has been referred to as the “regulatory nexus” approach (see, for example, the risk evaluation for 1,4-dioxane):

EPA found that exposures to the general population may occur from the conditions of use due to releases to air, water or land. During the course of the risk evaluation process for 1,4-dioxane, OPPT worked closely with the offices within EPA that administer and implement regulatory programs under the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and the Resource Conservation and Recovery Act (RCRA). Through this intra-agency coordinat[ion], EPA determined that 1,4-dioxane exposures to the general population via drinking water, ambient air and sediment pathways fall under the jurisdiction of other environmental statutes administered by EPA, i.e., CAA, SDWA, CERCLA, and RCRA. As explained in more detail in section 1.4.2, EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with the statutory text and legislative history, particularly as they pertain to TSCA’s function as a “gap-filling” statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadlines for completing risk evaluations. EPA has therefore tailored the scope of the risk evaluations for 1,4-dioxane using authorities in TSCA Sections 6(b) and 9(b)(1). EPA did not evaluate hazards or exposures to the general population from ambient air, drinking water, and sediment pathways for any of the conditions of use in this risk evaluation, and as such the unreasonable risk determinations for relevant conditions of use do not account for exposures to the general population from ambient air, drinking water, and sediment pathways.⁹⁰

There, EPA correctly explained that a risk evaluation pursuant to TSCA 6(b)(4)(D) is not required to consider all conditions of use⁹¹ because it should exclude conditions of use that fall under the jurisdiction of other EPA-administered statutes. Through intra-agency coordination, EPA

⁹⁰ EPA Final Risk Evaluation for 1,4-Dioxane at 34.

⁹¹ 15 U.S.C. § 2605(b)(4)(D): “The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority substance....”

provided a detailed analysis in the final risk evaluation that concluded that specific exposure pathways such as ambient air, drinking water, onsite release to land, ambient water, and disposal pathways are already well-regulated by other EPA statutes⁹² and, therefore, were excluded from the scope of the TSCA risk evaluation.

However, EPA through this rulemaking is reversing course and seeking to require that all potential exposure pathways, even those that are regulated or can be regulated adequately by other EPA authorities, in the scope of risk evaluations. Perhaps more concerning, EPA in current practice reversed course in applying the regulatory nexus approach in risk management rules without completing the amendment to the framework rule.⁹³ This approach is contrary to the statutory text and the intent of TSCA. As discussed, TSCA Section 6(b) provides that EPA may define in the scope of the risk evaluation the conditions of use the Agency “expects to consider,”⁹⁴ meaning the conditions of use and exposures it expects to review as opposed to the conditions of use it will exclude. And EPA’s evaluation of a substance under the “conditions of use” means “the circumstances, *as determined by [EPA]*, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”⁹⁵ The word “determine” means discretion from EPA. EPA has discretion to decide which the conditions of use will undergo evaluation. And the statute does not say that “all” conditions of use must be evaluated.

Critically, Section 9 requires such coordination and appropriate deference to other EPA programs to fulfill TSCA’s requirements that risk be addressed without unnecessarily creating duplicative regulation. Neglecting to coordinate with other EPA offices and failing to consider other EPA authorities that can best address these exposure pathways is contrary to EPA’s obligations under Section 9 of TSCA and TSCA’s “gap-filling” role. This attempt by EPA to avoid an in-depth analysis of other EPA statutes is inconsistent not only with TSCA, but also with its intent to avoid unnecessary duplication of regulatory burden.

EPA’s proposal to prohibit the exclusion of any condition of use of a substance from the scope of a risk evaluation will also be impractical and lead to more delays and challenges in the Agency’s ability to complete risk evaluations. This prohibition on excluding conditions of use would not only bring in conditions of use that can be more appropriately regulated by other EPA authorities and agencies, but it would also bring in conditions of use that are largely irrelevant or uninformative about a chemical’s risk to human health or the environment. For

⁹² EPA indicates that OPPT worked closely with the offices within EPA that administer and implement regulatory programs under the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and the Resource Conservation and Recovery Act (RCRA). EPA Final Risk Evaluation for 1,4-Dioxane at 51.

⁹³ EPA proposed a Draft Supplement to the 1,4-dioxane risk evaluation to add additional exposure pathways that were previously excluded: EPA *Draft Supplement to the Risk Evaluation for 1,4-Dioxane, CASRN 123-91-1*, Office of Chemical Safety and Pollution Prevention, 2023, available at: <https://downloads.regulations.gov/EPA-HQ-OPPT-2016-0723-0103/content.pdf>.

⁹⁴ 15 U.S.C. § 2605(b)(4)(D).

⁹⁵ 15 U.S.C. § 2602(4) (emphasis added).

example, it could include uses of a chemical where the presence of the chemical is only *de minimis* or even present as an impurity. EPA should have the discretion to exclude such conditions of use that will only waste the Agency's resources and not meaningfully contribute to a risk evaluation. At the very least, EPA should incorporate a *de minimis* level into the scoping process to weed out unnecessary conditions of use from the scope of EPA's review.

When Congress discussed this issue, Senator Vitter clarified that it is not the intent of TSCA to force EPA to devote its resources to reviewing every condition of use, and EPA can choose which conditions of use to evaluate based on its priorities:

The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical. This assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's strict deadlines. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency's job would be more difficult.⁹⁶

Finally, the TSCA preemption provisions also contemplate that not all conditions of use are evaluated by EPA. TSCA clarifies under the "scope of preemption" provisions that federal preemption applies "only to"... "the hazards, exposures, risks, and uses or conditions of use of such chemical substances are included in the scope of the risk evaluation" (for "pause" preemption) and any final action EPA takes for risk management.⁹⁷ By limiting preemption to "only" those "conditions of use" that EPA addresses in its risk evaluation, this means that TSCA allows EPA to exclude certain conditions of use from the scope of its risk evaluations. The legislative history also demonstrates that Congress intended for EPA to have discretion to choose which conditions of use to evaluate by making reference to risk determinations under the conditions and the application of preemption to the uses considered by EPA in the risk evaluation:

[Section 18(a)(2)(B)] provides that if the Administrator makes a final determination under Section 6(b) that a chemical substance will not present an unreasonable risk of injury to health or the environment *under the intended conditions of use*, no state or political subdivision of a state may, after the date the determination is published, establish or continue in effect any requirement that applies to such chemical substance *under the conditions of use* and is designed to protect against exposure to such chemical substance under the intended conditions of use *considered by the Administrator in the chemical's risk evaluation* under Section 6(b).⁹⁸

⁹⁶ 162 Cong. Rec. S3519 (June 7, 2016).

⁹⁷ 15 U.S.C. § 2617(c).

⁹⁸ House Report 114-176 at 30 (emphasis added).

III. EPA’s proposed approach to no longer assume use of personal protective equipment (PPE) in making risk determinations for chemicals is arbitrary and capricious.

EPA proposes to “clarify” that, in making risk determinations, it “will not consider...exposure reduction based on assumed use of [personal protective equipment (PPE)], by workers.”⁹⁹ EPA proposes to delay consideration of evidence supporting PPE use from the risk evaluation exposure assessment until the risk management stage. EPA’s rationale is that a “blanket occupational exposure assumption” of PPE does not reflect the “known or reasonably foreseen” chemical exposures that impact workers due to concerns about potential non-compliance with OSHA standards, PPE not being sufficient to address a risk, or PPE not functioning properly.¹⁰⁰ EPA has been implementing this policy change since its 2021 announcement.

It appears that EPA is addressing its concerns about “assumptions” of PPE use by merely substituting these assumptions with its own assumptions about the *lack* of proper use of PPE. EPA does not proffer any evidence to demonstrate that this assumption is any more accurate than the assumption that workers do comply with PPE requirements. And EPA’s blanket assumption is not based on any data provided for the specified condition of use in the risk evaluation. This approach to making risk determinations is arbitrary, capricious, and inconsistent with TSCA as it violates the statute’s scientific standards.

EPA should not implement this general assumption in making a risk determination for chemicals because it will result in overly conservative unreasonable risk determinations, and it is contrary to OSHA standards and current industrial hygiene practices for an employer to not provide exposed employees with appropriate workplace protection or implement workplace controls. EPA should view compliance with workplace protections as the standard and not the exception. EPA’s approach to not assuming PPE use is contrary to known practice, and would add an unnecessary layer of regulation on top of existing OSHA standards and workplace practices that already sufficiently mitigate risks.

A. Assuming no PPE use is inconsistent with TSCA Section 26 requirements and the use of the best available science based on the weight of the scientific evidence.

Section 26 of TSCA requires EPA to make decisions in making risk determinations based on the best available science and describe the weight of the scientific evidence for the identified hazard and exposure.¹⁰¹ As part of the TSCA Section 6 risk evaluation process, the risk determination must be a reflection of the findings of the risk evaluation. Here, EPA proposes to disregard real-world data provided in its own risk evaluations about the PPE and worker controls used to mitigate exposures to chemicals in the workplace. EPA also disregards the

⁹⁹ 88 Fed. Reg. at 74305.

¹⁰⁰ *Id.*

¹⁰¹ 15 U.S.C. § 2625(h).

important role OSHA plays in regulating and enforcing workplace exposures to hazardous chemicals by assuming, for every condition of use of every chemical, that OSHA standards are not followed, or they are ineffective. EPA cannot disregard science in favor of unsupported, overly conservative assumptions about how in real life workers are exposed to chemicals in the workplace. EPA does not use the best available science in ignoring the impact that PPE and OSHA standards have on reducing exposures in the workplace. EPA's "no assumption of PPE" approach is overly precautionary, inconsistent with real world activity, and without any evidence supporting why this approach would be justified for every condition of use for every chemical evaluated in the future.

Long before the TSCA amendments were passed in 2016, OSHA has been regulating the workplace since 1970 with standards for specific chemical hazards and physical hazards. OSHA has detailed requirements for hazardous materials,¹⁰² PPE (including head, foot, hand, eye, face, and respiratory protection),¹⁰³ hazard communication,¹⁰⁴ and chemical exposure limits.¹⁰⁵ OSHA policy also utilizes the hierarchy of controls for employers to identify and rank safeguards to protect workers from hazards (elimination, substitution, engineering controls, administration controls, and PPE). Each standard has requirements for worker training and re-training, recordkeeping, and protections for workers. For PPE, OSHA has a step by step process in which an employer assesses employee exposures, determines the appropriate PPE, tests it to ensure efficacy, and medically evaluate employees.¹⁰⁶ OSHA not only can and does enforce these rules, but OSHA can enforce against employers who do not protect their employees from serious hazards (that are not regulated by an existing standard) that cause or are likely to cause death or serious physical harm.¹⁰⁷ It is arbitrary and capricious for EPA to completely ignore existing OSHA requirements that reduce worker exposures to chemicals, as this is a critical component for a chemical's condition of use. EPA even acknowledges that it received many public comments from industry about occupational safety practices of their facilities and compliance with OSHA and voluntary industry guidelines.¹⁰⁸

This policy, which ignores requirements in OSHA regulated facilities, does not reflect the best available science, or any science at all. EPA is seeking to codify an assumption that will, for conditions of use involving worker exposures, guarantee an "unreasonable risk" finding and subject the use to risk management. EPA should, consistent with TSCA science requirements, seek to rely on the best available science by consulting with OSHA and industrial hygiene (IH) experts to better understand how workplace risks are appropriately mitigated through compliance with OSHA and other IH practices, rather than making broad, erroneous assumptions of misuse or ineffectiveness of such programs.

¹⁰² 29 C.F.R. § 1910 Subpart H.

¹⁰³ *Id.* at Subpart I.

¹⁰⁴ 29 C.F.R. § 1910.1200.

¹⁰⁵ 29 C.F.R. § 1910 Subpart Z.

¹⁰⁶ 29 C.F.R. § 1910 Subpart I.

¹⁰⁷ Also known as the General Duty Clause, 29 U.S.C. 654(a)(1).

¹⁰⁸ 88 Fed. Reg. at 74304.

Already, we have seen that in some of the risk determinations for the “first ten” chemicals, EPA has changed its risk findings for certain conditions of use due to its “no PPE” assumption:

Chemical	Conditions of use that were found to pose “no unreasonable risk” in original risk determination but were changed to be “drivers of unreasonable risk” in revised risk determination due to removal of PPE assumption	Proposed risk management requirements for the condition of use
Methylene chloride	Manufacture (domestic manufacture) ^{109,110}	Subject to workplace chemical protection program ¹¹¹
	Processing as a reactant	Subject to workplace chemical protection program
	Processing: recycling	Subject to workplace chemical protection program
	Industrial and commercial use as laboratory chemical	Subject to workplace chemical protection program
	Disposal	Subject to workplace chemical protection program
Perchloroethylene	Industrial and commercial use as a solvent for penetrating lubricants and cutting tool coolants ^{112,113}	Prohibition ¹¹⁴

These arbitrary changes in designation have resulted in more regulation of these conditions of use without any recognition of existing OSHA requirements and industrial hygiene practices. Instead, EPA disregards these exposure controls in the risk determination and is then forced to

¹⁰⁹ EPA Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) at 517, June 2020: https://www.epa.gov/sites/default/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf.

¹¹⁰ EPA Final Revised Risk Determination for Methylene Chloride at 1-2, November 2022: https://www.epa.gov/system/files/documents/2022-11/MC_Final%20Revised%20RD_10.26.22-final%20%281%29.pdf.

¹¹¹ 88 Fed. Reg. 28284 (May 3, 2023).

¹¹² EPA Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-) at 562, December 2020: https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_perchloroethylene_pce_casrn_127-18-4_0.pdf.

¹¹³ EPA Final Revised Unreasonable Risk Determination for Perchloroethylene at 3, December 2022: https://www.epa.gov/system/files/documents/2022-12/PCE_Final%20Revised%20RD_12-5-22.pdf.

¹¹⁴ 88 Fed. Reg. at 39690.

address the issue in risk management, where it promulgates rules that are duplicative, costly, overlapping, or worse, inconsistent or more stringent than the applicable OSHA requirements. Such an approach is contrary to the best available science provisions of TSCA as well as TSCA Section 9, which is intended to reduce duplicative regulation of substances.

B. EPA’s rationale that the no-PPE assumption policy is to address “reasonably foreseen circumstances ... including circumstances that result or could result in exposures to workers” does not appropriately apply TSCA’s requirement.

EPA explains in the proposal that TSCA requires that risk evaluations consider reasonably foreseen circumstances that result or could result in worker exposures; therefore, EPA believes that circumstances that result in occupational exposures to chemicals are “reasonable to foresee” and oftentimes known.

TSCA requires that EPA determine whether a chemical presents an unreasonable risk “under the conditions of use,” which includes the circumstances under which a chemical is reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. Therefore, if for a given condition of use, EPA has data in the risk evaluation that demonstrates that worker exposures are reduced with the use of PPE and other workplace controls, it must consider this information as part of the “foreseen” circumstances in which the substance is manufactured, processed, distributed, used, or disposed of. EPA must also “take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use.”¹¹⁵ Here, EPA is opting to forego a risk-based approach as designed by TSCA and ignores exposure altogether.

IV. EPA’s proposal to shift the burden to manufacturers to supply data on all conditions of use for manufacturer-requested risk evaluations is extremely burdensome and contrary to Section 6 of TSCA.

TSCA provides that it is not only EPA that can initiate risk evaluations; manufacturers can also request risk evaluations (manufacturer-requested risk evaluations or MRREs).¹¹⁶ Under the current risk evaluation procedural regulations, a manufacturer may request a risk evaluation for particular conditions of use of a chemical, and EPA will identify the remaining conditions of use for the chemical and gather the necessary data on those conditions of use to do an evaluation. EPA states in the proposed rule that this process for MRREs has been “unrealistic” and a “heavy burden” for the Agency because it lacks “fulsome” information in the manufacturer requests.¹¹⁷

Therefore, EPA proposes to address this issue by completely shifting the “unrealistic” and “heavily burdensome” requirements entirely onto the manufacturer requesting an MRRE. EPA proposes to significantly upend its procedural requirements for MRREs by requiring that a

¹¹⁵ 15 U.S.C. § 2605(b)(4)(F)(iv).

¹¹⁶ 15 U.S.C. § 2605(b)(4)(C)(ii).

¹¹⁷ 88 Fed. Reg. at 74312.

manufacturer who wishes to take advantage of this option not only provide data on the conditions of use of interest to the manufacturer but identify and provide data for *all* conditions of use for the substance, to the extent it is known to or reasonably ascertainable by the submitter. Manufacturers will be in the position of not only paying the required fee to defray the entire cost of the risk evaluation, but also doing EPA's job by devoting time, personnel, effort, and resources to gathering data for EPA to support an expansive risk evaluation that, in many cases, will be mostly irrelevant to the manufacturers own uses.

EPA's decision to pass the buck entirely onto the manufacturer requesting a risk evaluation to provide data on all known, intended, and reasonably foreseen condition of use is impractical, unreasonable, and inconsistent with Section 6 of TSCA. This approach will render MRREs so burdensome and costly that they will never be used by manufacturers.

A. Congress's creation of Manufacturer-Requested Risk Evaluations (MRREs) under TSCA Section 6(b)(4)(C)(ii) confirms that it did not intend all risk evaluations to include every condition of use.

TSCA does not require that manufacturers assume the role of EPA and take on the cost and effort to evaluate all conditions of use identified by EPA for a substance. As discussed, under Section 6 of TSCA, EPA has discretion to exclude conditions of use from the scope of a risk evaluation: "EPA shall...publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations [EPA] *expects to consider*."¹¹⁸ This same requirement for risk evaluations also applies to risk evaluations that EPA conducts in response to a manufacturer request.

Other parts of the MRRE provisions of TSCA indicate that Congress intended that manufacturers have the option of requesting risk evaluations for selected conditions of use and not necessarily every condition of use of a substance. For example, TSCA Section 6(b)(4)(E)(iii) provides that "[i]n deciding whether to grant [manufacturer-requested risk evaluations, EPA] shall give preference to requests for risk evaluations on chemical substances for which the [EPA] determines that restrictions imposed by one or more states have the potential to have a significant impact on interstate commerce or health or the environment." As discussed, states typically evaluate substances as they are used in particular products or exposure scenarios, not as "whole chemicals." In passing this provision, Congress contemplated that EPA must consider an MRRE when there is a state law already in existence that has the potential for significant impacts on interstate commerce for the same chemical under the same conditions of use. The purpose of the MRRE is so that manufacturers can request EPA make determinations on specific conditions of use of a chemical so that EPA's final decision can preempt a state's

¹¹⁸ 15 U.S.C. § 2605(b)(4)(D)

action.¹¹⁹ Any regulatory initiative that deprives manufacturers of the option of requesting a risk evaluation for a specific condition of use therefore undermines the intent of Congress.

B. EPA’s proposal will cause MRREs to be so burdensome on manufacturers that it will not be a viable option and will never be used, thwarting Congress’s intent.

Congress would not have included a pathway for manufacturers to initiate risk evaluations if it did not expect the provision to ever be used in practice. EPA’s proposal would result in the MRRE never being utilized, because a manufacturer cannot practically expend such significant resources to identify all of the conditions of use for a substance, even conditions of use it has no experience with and that are completely unrelated to its business and provide all data to support a risk evaluation. It would render the MRRE process ineffective because the bar to entry would be so high it would be impractical and undesirable for manufacturers to do so.

By EPA’s own estimates, it costs *at least* \$3 million to perform an MRRE for a chemical for all conditions of use.¹²⁰ Manufacturers will have to provide data on all of the “circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”¹²¹ EPA believes that “requesting manufacturers should be making a *reasonable amount of effort* to gather all available information on the chemical—whether that information is available to the general public, or otherwise available to the manufacturer—and compile it for the Agency’s review as part of an MRRE.”¹²² So, EPA expects manufacturers to undertake the effort of compiling *publicly available* information and information available to them. This would impose the burden on companies to have their scientific staff, or any relevant personnel, conduct public literature reviews and research on any available information in the public domain on potentially dozens of conditions of use of a chemical. EPA clearly expects manufacturers to, “at a minimum, involve a thorough search and collection of publicly available information on the chemical’s hazards, exposures and conditions of use.”¹²³ Unless a manufacturer makes a chemical for every condition of use, much of this work would require significant resources and expertise.

¹¹⁹ Representative John Shimkus confirmed this statutory purpose: “Now, why would a manufacturer invite EPA scrutiny of its product? There are several reasons. First, some interest or even a retailer may be raising concerns about a product, and the manufacturer wants to put those concerns to rest. Or one or two States may be thinking about regulating the chemical. The State-by-State approach can spell disaster for someone trying to capture economies of scale in a national market. What better way to put these concerns to rest than to have EPA, with the scientific standards that we require, perform an objective risk evaluation? Then the EPA decision on that chemical will apply in all the States, and consumers and the public can have the confidence that the chemical is safe for its intended uses.” 161 Cong. Rec. H4556 (June 23, 2015).

¹²⁰ 87 Fed. Reg. 68647 (November 16, 2022). EPA proposes that the fee for manufacturer-initiated risk evaluations be approximately \$3 million (two payments of \$1,497,000) and then a final payment of an unknown amount to cover 100% of the actual costs of the risk evaluation.

¹²¹ 15 U.S.C. § 2602(4).

¹²² 88 Fed. Reg. at 74313 (emphasis added).

¹²³ 88 Fed. Reg. at 74313.

The standard of diligence required by a manufacturer—information that is “known to or reasonably ascertainable by” the manufacturer—is complex and burdensome in and of itself. The standard requires that a manufacturer review “all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.”¹²⁴ Information is in a company’s “possession or control” if it is information that any person in the company (including subsidiaries and partnerships) has in their own files, commercially available databases that the company has purchased access to, and maintained in the files of agents. The standard also may require inquiries outside of the organization to fill in gaps in knowledge.¹²⁵ Even conducting such diligence within a company is extremely difficult, particularly for companies with multiple facilities, hundreds or thousands of employees, multiple product lines, and extensive records about numerous products and chemicals.

If a manufacturer submits an MRRE after conducting such due diligence and research, and the information turns out to be misleading, inaccurate, or incomplete, EPA proposes that the consequence would be potentially “significant criminal penalties...including the possibility of fine and imprisonment.”¹²⁶ Manufacturers should not be subject to potentially severe, criminal penalties for trying to comply with an unreasonably broad and burdensome requirement just to be able to use an MRRE. Most manufacturers would not want to assume such a risk and would, instead, opt not to request an MRRE. EPA’s proposal therefore defeats the purpose of the MREE provisions.

V. EPA Proposes to Unlawfully Amend the Definition of Potentially Exposed or Susceptible Subpopulations to Include Overburdened Communities.

EPA is required to make a determination on whether the new substance “presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation [PESS] identified as relevant by the Administrator under the conditions of use.”¹²⁷ TSCA defines PESS as “a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.”¹²⁸ Notably, Congress did not include any other group in this list. In defining PESS, Congress

¹²⁴ 40 C.F.R. § 704.3 (definition of “known to or reasonably ascertainable by”).

¹²⁵ 88 Fed. Reg. at 74313. EPA explains “For example, such activities might include inquiries to upstream suppliers or downstream users or employees or other agents of the manufacturer, including persons involved in the research and development, import or production, or marketing for information pertinent to the criteria listed in the proposed rule.”

¹²⁶ 88 Fed. Reg. at 74324.

¹²⁷ 15 U.S.C. § 2604(a)(3)(A).

¹²⁸ 15 U.S.C. § 2602(12).

emphasized that the intention was “that [EPA] be clear about who is being identified and the basis for such a decision when invoking provisions involving subpopulations.”¹²⁹

EPA proposes to modify this statutory definition of PESS in the proposed rule, adding “overburdened communities” into the definition of PESS so that they will need to be specifically evaluated by EPA when assessing the unreasonable risks of a chemical under the conditions of use. However, EPA provides no definition for what is meant by “overburdened communities” and provides no justification for why it is necessary to change the statutory definition of PESS.

When construing the scope of its authority under Section 3(12), i.e., what types of exposed or susceptible subpopulations may be given additional consideration in a risk evaluation, EPA is limited to PESS that are within the same category as the illustrative list created by Congress: “infants, children, pregnant women, workers, or the elderly.” The *eiusdem generis* canon¹³⁰ requires that EPA’s discretion to add to the Congressional list be limited to the same kind or class that has already been listed. “Overburdened communities” fails this test, as it is not consistent with the characteristics that make up this list, either a life stage of a human being or an occupation. EPA already has sufficient authority to look at data on exposure to a chemical; in addition to being outside the kind or class that Congress created, adding “overburdened communities” also introduces a vague term that will cause confusion and unlawfully expand EPA’s authority into areas not intended by TSCA. This amorphous proposed addition does not give the public or regulated community adequate notice to fully understand how the Agency would expand risk evaluations.

EPA’s allegedly “procedural” revision to the definition of PESS would presumably expand the scope of existing chemicals reviews and require review of exposures to potentially thousands of communities and individuals throughout the country. There is no way of fully understanding this due to the vague nature of the proposal. This revision would likely have the unintended consequence of delaying and complicating the chemical risk evaluations even more. To the extent this is incorporating environmental justice concerns, the statute itself does not provide that as a consideration. Regulations mandating EPA’s review of undefined “overburdened communities” for every chemical undergoing risk evaluation therefore exceed the scope of Agency authority.

¹²⁹ House Report 114-176 at 22.

¹³⁰ “[E]iusdem generis[] counsels: ‘where general words follow specific words in a statutory enumeration, the general words are [usually] construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words.’” *Yates v. United States*, 574 U.S. 528, 545 (2015) (quoting *Washington State Dept. of Social & Health Servs. v. Guardianship Estate of Keffeler*, 537 U.S. 371, 384 (2008)).

VI. EPA’s Removal of the Definitions of Best Available Science and Weight of the Scientific Evidence from the Rule’s Definitions Create a Lack of Transparency and Undermine Public Confidence.

TSCA Section 26(h) requires that EPA, in carrying out risk evaluations and risk determinations, use “scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.”¹³¹ TSCA requires that EPA consider as applicable—

- (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
- (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
- (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.¹³²

TSCA also requires EPA to make decisions on risk evaluations and risk determinations based on the weight of scientific evidence.¹³³ However, TSCA does not provide definitions for best available science or the weight of the scientific evidence.

EPA provided these definitions when it issued the 2017 risk evaluation regulation. The regulations provide a definition of “best available science” that largely adopts the statutory criteria for scientific standards. However, the regulation has several important additions. The regulation explains that “best available science” means 1) science that is “reliable and unbiased,” and that use of best available science involves 2) using studies conducted in accordance with sound and objective science practices, including 3) peer reviewed science and supporting studies, and 4) data collected by acceptable methods or best available methods.¹³⁴ This language provides necessary guidelines for EPA and clarifications for stakeholders seeking to determine if a given EPA decision is based on the best available science.

¹³¹ 15 U.S.C. § 2625(h).

¹³² *Id.*

¹³³ 15 U.S.C. § 2625(i).

¹³⁴ 40 C.F.R. § 702.33.

The 2017 risk evaluation regulation provides a detailed explanation of what it means to have science that is based on the “weight of the scientific evidence”: “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.”¹³⁵ It is imperative that EPA provide specific criteria which would allow for consistency and transparency in the Agency’s use of science in risk evaluations.

EPA is now proposing to eliminate the definitions in the risk evaluation regulations for “best available science” and “weight of the scientific evidence” based on an unfounded belief that such definitions are “unnecessary and inhibit[] the Agency’s flexibility to quickly adapt to and implement changing science.”¹³⁶ However, EPA provides no justification or explanation for why the definitions are “unnecessary” or limit its flexibility and mandate to incorporate the best available science into risk evaluations. Rather, this appears to be an attempt by EPA to remove parameters on its use of science and give it more “flexibility” to rely on the data it wants to without a clear standard to follow. This increase in the Agency’s discretion to avoid any identifiable standard would undermine public confidence and predictability.

A. Codifying definitions and approaches to risk evaluation promotes transparency into EPA’s process, predictability, and creates confidence.

If EPA were to remove these definitions, it would deprive stakeholders the clarity they need to evaluate EPA decisions on substances undergoing risk evaluation. Without clear scientific standards for risk evaluation, the application of these principles will be inconsistent and not transparent. Not every impacted business, nor the public generally, will have the requisite scientific background to understand the application of these terms. Even if they did, these definitions could vary across scientific disciplines as to what precisely they require, and it would not be clear or predictable which definition EPA plans to follow. Nor is referring people to Section 26(h) of TSCA sufficient, as the statute only provides criteria EPA must *consider* in risk evaluations, but no definitions for the terms “best available science” and “weight of the scientific evidence.”

The regulatory definitions provide much needed clarity and predictability as to how EPA is going to apply these scientific principles to its decisions on chemical risk evaluations. If EPA has concerns that the definitions do not provide them with enough “flexibility to quickly adapt to changing science,” they should seek to clarify the definitions rather than remove them which will cause more confusion. Regardless, EPA’s justification for removing scientific clarity in its procedures for risk evaluation falls flat. The definitions, as they exist, account for the need to

¹³⁵ *Id.*

¹³⁶ 88 Fed. Reg. at 74296.

adopt to changing science. The “best available science” is defined to include “reliable” data, “sound and objective” data, “peer reviewed science,” and “data collected by...best available methods.”¹³⁷ Nothing in this definition limits EPA and, in fact, it mandates EPA to use the most up to date and reliable data.

Moreover, EPA did not explain its change of position on the need for codified definitions of best available science and weight of the scientific evidence. EPA has not explained why the current definitions are not adequate, what science has changed that would require an update in the definitions, why guidance documents still being used by the Agency are not appropriately incorporated in regulatory text, and why the science of risk evaluation is changing so rapidly that it could not be subject to further minor rulemakings to update these definitions in the future.

B. The example guidance documents cited by EPA are older and do not reflect evidence integration practices that are informed by systematic review. These guidance documents are not representative of best available methods.

While EPA recognizes the importance of systematic review, stating that it is “critical to meet the scientific standards in TSCA section 26(h),¹³⁸ by allowing itself flexibility, EPA’s removal of the definition of “weight of the scientific” evidence, removes EPA’s commitment to use systematic review to inform evidence integration. EPA’s proposal removes its commitment to integrate evidence based on the strengths, limitations, and relevance of the information. Without such a commitment, EPA would be able to pick any endpoint of its choosing even if it is inconsistent with the best available science. For instance, in EPA’s proposed regulation for TCE, instead of using the value that represents the best available science from the final TCE risk evaluation, EPA instead chose the most sensitive endpoint.¹³⁹ This is not consistent with best available science and without a requirement to integrate studies based on the findings from a systematic review, EPA’s risk evaluations may no longer represent best available science. EPA’s proposal is a step backwards for ensuring transparency, consistency, and best available scientific reviews. Instead, EPA discusses that it will instead use other EPA guidance documents,¹⁴⁰ including EPA’s Guidelines for Carcinogen Risk Assessment, which were developed in 2005, well before advancements in systematic review approaches. EPA also cites to the ORD IRIS handbook as well as guidance from EPA’s endocrine disruptor screening program.¹⁴¹ However, none of the documents cited by EPA were developed to be consistent with the TSCA scientific standards in Section 26, nor are they consistent with best available scientific approaches for integrating evidence.

¹³⁷ 40 C.F.R. § 702.33.

¹³⁸ 88 Fed. Reg. at 74310.

¹³⁹ 88 Fed. Reg. at 74712.

¹⁴⁰ *Id.* at 74311.

¹⁴¹ *Id.*

VII. EPA’s proposal to look at “aggregate exposures” and “cumulative risk” is beyond the scope of statutory authority.

Section 6(b)(4)(F)(ii) of TSCA and the current risk evaluation regulations only require EPA to “describe whether aggregate and sentinel exposures under the conditions of use were considered and the basis for their consideration.”¹⁴² Aggregate exposures are combined exposures to an individual from the same chemical across multiple routes and multiple pathways.¹⁴³ EPA proposes to require, rather than leave to its discretion, the consideration of aggregate exposures to a substance in conducting the exposure assessment portion of a risk evaluation. EPA is also taking comment on whether to incorporate cumulative risk assessments, or assessments on combined risk from multiple chemical stressors, in TSCA risk evaluations.¹⁴⁴

A. EPA’s proposal to require that risk evaluations consider aggregate exposures is inconsistent with TSCA Section 6 and an expansion of EPA authority.

Within the list of requirements for risk evaluations under TSCA Section 6(4)(F), the statute only mandates that EPA “describe whether” aggregate exposures to a chemical under the conditions of use were considered.¹⁴⁵ This same section clearly requires that EPA consider “likely duration, intensity, frequency, and number of exposures under the conditions of use,”¹⁴⁶ but it did not list aggregate exposures. There is no requirement in TSCA that EPA consider or perform aggregate exposure assessments. Because EPA is required only to *explain whether* it considered aggregate exposures, the language suggests that Congress contemplated that EPA could choose whether or not to review aggregate exposures; and, there will be instances in which consideration of aggregate exposure is not appropriate for a given risk evaluation, in which case, EPA would explain that it did not consider such exposures. It is contrary to TSCA Section 6(4)(F) to handcuff EPA into considering aggregate exposure and aggregate exposure assessments for every condition of use in every risk evaluation.

Further, TSCA requires that for risk evaluations, EPA determine whether a chemical substance presents an unreasonable risk of injury to health or the environment...under the conditions of use.” EPA cannot review exposures, including aggregate or “combined” exposures from a chemical “across multiple pathways,” that are outside the specified conditions of use defined in the scope of the risk evaluation. EPA even goes so far as to claim that it may be appropriate, in an aggregate exposure assessment, to consider potential background exposures from non-TSCA uses that are not within the scope of the risk evaluation.”¹⁴⁷ It is not appropriate or lawful for EPA to consider exposures from non-TSCA uses of a substance in a risk evaluation, as these uses

¹⁴² 40 C.F.R. § 702.43(a)(2).

¹⁴³ 40 C.F.R. § 702.33.

¹⁴⁴ 88 Fed. Reg. at 74305.

¹⁴⁵ 15 U.S.C. § 2605(b)(4)(F)(ii).

¹⁴⁶ 15 U.S.C. § 2605(b)(4)(F)(iv).

¹⁴⁷ 88 Fed. Reg. at 74306.

are statutorily excluded from TSCA jurisdiction and the definition of a “chemical substance.”¹⁴⁸ The outcome of a risk evaluation, which informs a risk determination and risk management decisions from EPA, cannot not be determined by uses of a substance that are regulated by other federal authorities and uses exempt from TSCA. EPA’s proposal attempts to expand its statutory authority to include more uses and exposures it does not have authority to evaluate or regulate.

B. Cumulative risk assessment is not provided for in TSCA and would unlawfully expand EPA’s authority to base an unreasonable risk determination on factors other than the unreasonable risks presented by the chemical substance under the conditions of use.

Cumulative risk assessments can be performed on categories of chemicals or combined risk from multiple chemicals.¹⁴⁹ Cumulative risk assessments involve review of many “non-chemical agents” and/or stressors other than the specific chemical under consideration in the risk evaluation. EPA seeks comment on how it could incorporate provisions for cumulative risk assessment into risk evaluation procedures. The Agency believes that in some cases, the best approach for risk evaluation may be to look at “combined risk” from multiple chemicals or a category of chemicals, as well as the totality of exposures to combinations of chemical and non-chemical stressors.¹⁵⁰

Cumulative risk assessments are not authorized anywhere in TSCA, and the proposed rule has not explained the legal basis for its authority to conduct cumulative risk assessments under TSCA. EPA should not incorporate cumulative risk assessments in the procedures for chemical risk evaluations as it would significantly expand the scope of risk evaluations because they would include review of multiple chemical exposures and non-chemical stressors. Further, TSCA risk evaluations must be evaluations of a chemical substance under its conditions of use.¹⁵¹ TSCA does not permit risk evaluations and risk determinations based on factors other than *the substance* that is the subject of the risk evaluation, and under its identified conditions of use *of the substance*, not conditions of use separate from the substance being evaluated. While EPA does have authority to designate categories of substances as high priority and subject to risk evaluation, it cannot simply take a single substance that is already undergoing risk evaluation and add other, different chemicals or other information to the evaluation.

While EPA’s incorporation of cumulative risk assessment would be unlawful, the definition of cumulative risk even by EPA’s own standards is also flawed. EPA proposes that it use the definition of cumulative risk from its “Framework for Cumulative Risk Assessment” document which defines the term to mean “an analysis, characterization, and possible quantification of

¹⁴⁸ 15 U.S.C. § 2602(2)(B).

¹⁴⁹ 88 Fed. Reg. at 74306.

¹⁵⁰ *Id.*

¹⁵¹ 15 U.S.C. § 2605(b)(4)(A).

the combined risks to health and/or the environment from multiple agents *and/or* stressors.”¹⁵² The use of “or” in this definition allows EPA to narrowly focus on one aspect of similarity (multiple agents OR stressors) without considering whether there is a common mode of action, which is the standard approach for cumulative risk. Consistent with best practices in EPA’s office of pesticide programs, EPA would have to ensure, at a minimum, that cumulative risk evaluations focus on chemicals that have a common mode of action.

In addition, as EPA has noted in its Draft Cumulative Risk Assessment Guidelines, methods for evaluating non-chemical stressors is complicated.¹⁵³ The appropriate methods and approaches for assessing and quantifying the impacts of non-chemical stressors have not even been developed, let alone could they incorporated into TSCA risk evaluations. Even consideration of non-chemical stressors in a qualitative manner is inappropriate due to the large uncertainties that exist due to the current poor understanding of how these stressors interact with other well-defined stressors.

For legal and practical reasons, the proposed rule’s introduction of cumulative risk assessment into TSCA risk evaluations is not appropriate and should not be finalized.

VIII. EPA Should Not Require Consideration of “Climate-Related Risks” in All Risk Evaluations.

In addition, EPA seeks comment on whether TSCA risk evaluations should address climate-related risks.¹⁵⁴ EPA proposes that if “information reasonably available to the Agency indicated that factors such as rising sea levels or extreme temperatures made worse by climate change were leading to regular and predictable changes in exposures associated with a given condition of use of a chemical substance, EPA would expect to consider those exposures within the scope of the risk evaluation.”¹⁵⁵

EPA should not finalize the proposal to require consideration of climate-related risks in TSCA risk evaluations. This issue was never raised when the legislature considered revisions to Section 6 of TSCA. EPA’s charge under the statute is to consider “the likely duration, intensity, frequency, and number of exposures under *the conditions of use of the chemical substance*.”¹⁵⁶ Similarly, with climate-related weather events, these are not the conditions in which a chemical is *intended, known, or reasonably foreseen* to be manufactured, etc. It is outside of TSCA’s risk evaluation requirements to incorporate exposures from climate change.

¹⁵² U.S. EPA. Framework for Cumulative Risk Assessment. EPA/630/P-02/001F. Risk Assessment Forum. Washington, DC. May 2003. https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (emphasis added).

¹⁵³ EPA, Risk Assessment Forum, *Draft Guidelines for Cumulative Risk Assessment Planning and Problem Formulation*, May 2023, available at: <https://www.regulations.gov/document/EPA-HQ-ORD-2013-0292-0169>.

¹⁵⁴ 88 Fed. Reg. at 74316.

¹⁵⁵ 88 Fed. Reg. at 74298.

¹⁵⁶ 15 U.S.C. § 2605(b)(4)(F) (emphasis added).

EPA does not define this term or clarify any parameters for what constitutes a climate-related risk. This proposed requirement will make it less predictable to stakeholders what EPA is going to consider in the scope of a risk evaluation and exponentially expand and complicate the scope of a risk evaluation to the point that it would be impractical for EPA to complete such an evaluation. Accordingly, EPA should focus on authorities other than TSCA, where there is a clear nexus with climate change concerns, to address such concerns.

IX. Collectively, EPA’s proposed re-interpretations of key aspects of risk evaluations are unreasonable because all of these proposed changes would significantly expand and complicate risk evaluations and serve as a barrier for timely completion of risk evaluations, which is contrary to TSCA.

If the proposed rule is finalized, EPA would not be permitted to exclude any condition of use from the scope of a risk evaluation; must disregard worker protections when determining risks of chemicals to workers (resulting in overestimates of risk); make a single “unreasonable risk” determination for the “whole chemical” in order to send every condition of use of the chemical to risk management for potential restrictions; incorporate aggregate exposures and cumulative exposures in risk evaluations; add an entire category of vaguely defined populations, “overburdened communities,” to the scope of PESS that must be considered; add “climate related risks” to the scope of risk evaluations; and reduce transparency and accountability on the use of science in risk evaluations by removing key scientific definitions.

These changes to the risk evaluation procedures, if adopted in a final rule, would, collectively, result in significantly more expansive and complex risk evaluations that Congress did not intend. Congress intended for EPA to complete the prioritization, risk evaluation, risk determination, and risk management process efficiently by instituting statutory deadlines for each step. Congress sought to hold EPA accountable to completing timely reviews of existing chemicals and address public concerns about the glacial pace of EPA chemical reviews, which resulted in a lack of public confidence in the TSCA program and increased state activity:

In the nearly four decades since its enactment and particularly during the last decade, there have been persistent concerns about the pace of EPA’s work under TSCA.... A variety of factors, including EPA’s slow pace in regulating chemicals already on the market, has led to several new state chemical control statutes—ranging from specific chemical restrictions to general chemical control programs—and retailer-based systems to identify and promote products that were considered safer for consumers. Ultimately, public confusion about chemical-specific claims, a perceived lack of expeditious action by EPA, and a domestic and foreign marketplace that has become increasingly uneven, unpredictable, and incompatible with economic and regulatory realities led Congress to examine TSCA and how it can operate more effectively in the 21st century.¹⁵⁷

¹⁵⁷ House Report 114-176 at 13.

Under TSCA, EPA must complete the following actions within the specified timeframes:

- Within 180 days of enactment of the TSCA Amendments, EPA must ensure that risk evaluations are being conducted on 10 substances from the 2014 TSCA Work Plan.¹⁵⁸
- Within three and a half years of enactment of the TSCA Amendments, EPA must be conducting risk evaluation on at least 20 high priority chemicals and at least 20 chemicals that are low priority.¹⁵⁹
- Once a chemical is being considered for prioritization, EPA must make a designation of “high” or “low” priority within 9-12 months.¹⁶⁰
- After that, when a risk evaluation is initiated for a high priority chemical, EPA has six months to publish the scope of the risk evaluation.¹⁶¹
- The risk evaluation must be completed within three years with the option to extend this deadline by up to six months.¹⁶²
- If EPA determines that a substance presents unreasonable risk, EPA must propose a risk management rule within one year of the final risk evaluation.¹⁶³ The final risk evaluation rule must be published within two years of the final risk evaluation. These deadlines can only be extended by up to two years, subject to the condition that the aggregate length of extensions does not exceed two years.¹⁶⁴

However, as already demonstrated by the “first ten” chemicals, EPA is already struggling to meet its statutory deadlines under TSCA Section 6. EPA missed its deadlines for completion of all of the risk evaluations for the first ten chemicals (which were required to be completed by December 2019) and their risk management rules (which were required to be completed by December 2021). Eight of the ten chemicals are still proposed risk management rules (or forthcoming proposals), one (asbestos) is expected to have a final risk management rule in the near future, and one (1,4-dioxane) has gone backwards to the risk evaluation stage because EPA supplemented the risk evaluation to expand the scope to include previously excluded exposure pathways.

¹⁵⁸ 15 U.S.C. § 2605(b)(2)(A).

¹⁵⁹ 15 U.S.C. § 2605(b)(2)(B).

¹⁶⁰ 15 U.S.C. § 2605(b)(1)(C).

¹⁶¹ 15 U.S.C. § 2605(b)(4)(D).

¹⁶² 15 U.S.C. § 2605(b)(4)(G).

¹⁶³ 15 U.S.C. § 2605(c)(1).

¹⁶⁴ *Id.*

Recently, environmental groups brought suit against EPA for missing its statutory deadlines to complete risk evaluations for 22 chemicals.¹⁶⁵ EPA could continue receiving similar lawsuits for failing to meet its statutory obligations for timely existing chemical reviews. EPA leadership in this Administration have also repeatedly stressed the Agency's severe lack of resources to conduct the work required under TSCA by the statutory deadlines.¹⁶⁶ EPA will only exacerbate its own resource constraints and cause further significant delays in existing chemical reviews if it adds more requirements to risk evaluations that go beyond what is allowed by TSCA, go beyond what is necessary, and make the statutory timelines unachievable. Further administrations would also be faced with the same challenge of completing unwieldy, highly conservative and expansive risk evaluations that will clog up the existing chemicals program for years to come.

Finally, EPA states that it will use a fit-for-purpose approach to conduct risk evaluations. EPA is merely seeking to allow maximum flexibility, which may result in TSCA risk evaluations incorporating unnecessary elements, without being sufficiently robust to inform potentially significant regulations. Thus fit-for-purpose reviews will likely lower the quality of risk evaluations and potentially lead to additional litigation on risk management rules that are supported by scientific evaluations that do not meet the required TSCA standards.

X. EPA Should Not Weaken the Peer Review Requirements

A. Risk evaluations, not just "portions," must undergo robust peer review.

As EPA acknowledges, peer review is important for ensuring that decisions are consistent with best available science and weight of the scientific evidence.¹⁶⁷ EPA also recognizes that peer review has been "extremely instructive," has resulted in "more robust and scientifically defensible product," and has improved EPA's methods.¹⁶⁸ The importance of peer review is not controversial and is well-accepted. Yet, EPA is proposing to decrease its commitment to peer review and proposes that, instead of conducting peer review on risk evaluations, it only *expects*

¹⁶⁵ See Earthjustice press release: "Health and Environmental Justice Advocates Sue EPA to Force Action on Overdue Toxic Chemical Reviews," September 18, 2023: <https://earthjustice.org/press/2023/health-and-environmental-justice-advocates-sue-epa-to-force-action-on-overdue-toxic-chemical-reviews>.

¹⁶⁶ See Congressional Testimony of Michal Ilana Freedhoff, Assistant Administrator for the Office of Chemical Safety and Pollution Prevent before the Senate Committee on Environment and Public Works, June 22, 2022: <https://www.epa.gov/system/files/documents/2022-06/EPA-Freedhoff%20testimony-%20SEP%20TSCA%20Hearing%206.22.2022.pdf>. Dr. Freedhoff testified extensively discussed the TSCA program's challenges in fulfilling its obligations under TSCA due to resource constraints: "[W]e will continue to fall short...without additional resources to support the program.... Despite the best efforts of EPA's dedicated staff, in most circumstances, the Agency is missing statutory deadlines to review and ensure protections for new and existing chemicals.... To implement the 2016 TSCA amendments, EPA needs the additional resources provided in the fiscal year 2022 and 2023 budgets.... The statutory deadline for risk management actions under TSCA means that all of EPA's rules underway are due to be finalized before the end of this year. The Agency will not be able to meet a single one of those deadlines."

¹⁶⁷ 88 Fed. Reg. at 74307.

¹⁶⁸ *Id.*

to conduct peer review on “portions thereof,”¹⁶⁹ and states that, when it uses peer-reviewed products from another EPA office or another authoritative body, peer review under TSCA may not be required.¹⁷⁰ EPA specifically seeks comment on these modifications to make peer review discretionary and asks if these changes are consistent with OMB and Agency guidance. EPA’s proposed changes are not consistent with OMB and Agency guidance, and they are not consistent with the requirements of TSCA. The flaws in EPA’s proposed peer review modifications are described below.

First, documents developed by another EPA office do not necessarily meet the statutory standards for best available science and weight of the scientific evidence as required under TSCA and may not be fit for purpose, despite having undergone peer review previously. For instance, when hazard assessments are reviewed under the EPA IRIS program, for which there are no statutory requirements or mandated scientific standards, they are not reviewed with an eye towards meeting the best available science and weight of the scientific evidence standards required by TSCA. In addition, TSCA requires that the science advisory committee on chemicals (SACC) have a very specific membership to ensure representation that is relevant to implementing TSCA and directs the SACC to provide the advice and expert consultation necessary to implement TSCA. TSCA Section 26(o) is very specific in requiring the formation of the SACC to conduct reviews under TSCA.¹⁷¹ When TSCA was updated in 2016, Congress was well aware of the multitude of existing EPA peer review mechanisms, including the existing EPA FACA committees,¹⁷² yet Congress determined that a new committee, that included a broad range of expertise and interests, including public health and industry, was required.¹⁷³ If EPA were to rely on other review committees, in addition to the reviews not being fit for purpose, EPA would be skirting the requirements of TSCA.

Second, EPA’s proposed regulatory text does not firmly commit the Agency to conduct peer review. Instead, it only states that EPA “expects” to conduct peer review.¹⁷⁴ This language must be strengthened, and, regardless of whether or not peer review has been conducted by other EPA offices or other authoritative bodies, scientific and technical documents that will inform TSCA risk management actions, not just portions thereof, must undergo SACC review. As described earlier in these comments, EPA seeks to broaden the scope of risk evaluations, which will take significant time and agency resources, yet the statutory timelines for completing this work do not account for this broadening of scope. EPA should not cut corners and sacrifice robust peer review to help meet timelines that are unworkable due to EPA’s discretionary approach of expanding the scope of risk evaluations. EPA states that the proposed changes to peer review will increase EPA’s flexibility and conserve agency resources.¹⁷⁵ If EPA were to stick

¹⁶⁹ 88 Fed. Reg. at 74323.

¹⁷⁰ 88 Fed. Reg. at 74308.

¹⁷¹ 15 U.S.C. § 2625(o).

¹⁷² <https://www.epa.gov/faca/all-federal-advisory-committees-epa>.

¹⁷³ Senate Report 114-76 at 10: <https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf>.

¹⁷⁴ 88 Fed. Reg. at 74323.

¹⁷⁵ 88 Fed. Reg. at 74308.

to the requirements of TSCA, consistent with the legislators' intent that TSCA be a gap-filler, EPA would not need to cut corners on peer review to compensate for expending unnecessary time and resources when conducting risk evaluations.

B. Because these evaluations will support economically significant regulations, consistent with EPA's peer review handbook and OMB guidance, peer reviews appropriate for highly influential scientific assessments (HISAs) are required.

EPA proposes that reviews will be consistent with EPA peer review policies, procedures, guidance documents, and OMB guidance.¹⁷⁶ However, EPA also notes that the EPA Peer Review Handbook does not necessitate additional peer review if the work product was previously reviewed consistent with the OMB Bulletin or EPA's Peer Review Handbook.¹⁷⁷ As described above, if EPA were to skirt SACC review, this would be inconsistent with TSCA. Peer reviews by the SACC would not be redundant because they will have the TSCA required expertise and representation, and charge questions would be appropriately framed to incorporate the scientific standards required by TSCA. Peer reviews by other EPA program offices or other authoritative bodies, unless designed to be consistent with the requirements of TSCA Section 26(h), 26 (i) and 26(o), do not meet the standards required by TSCA and are not fit for purpose.

Risk evaluations conducted under TSCA should be treated as "highly influential scientific assessments" (HISAs) consistent with the OMB Bulletin and EPA's Peer Review Handbook. Because they will support risk management rules that will impact how and where chemicals are used, as we have seen with EPA's proposed risk management rules, these proposed actions are economically significant. EPA's Peer Review Handbook recognizes that for HISAs, a panel review is a preferable approach.¹⁷⁸ While other types of reviews, including letter reviews, may be appropriate in some cases, the Peer Review Handbook notes that letter review is appropriate when a work product is "not controversial."¹⁷⁹ EPA should expect, based on the proposed risk management rules thus far, that taking action to modify how and where chemicals are used in the workplace, including potentially prohibiting uses that may impact thousands of businesses and users, will typically be controversial and economically significant. EPA should ensure the highest level of peer review for all underlying scientific documents.

XI. If EPA is to continue to rely on ECELS, their derivations should be part of the risk evaluation and must undergo peer review.

In all of EPA's recent risk management proposed rule, EPA proposes to require compliance with existing chemical exposure limits, or ECELS, to control exposures in the workplace. However, ECELS have only been introduced in the risk management stage and have not been part of the

¹⁷⁶ 88 Fed. Reg at 74323.

¹⁷⁷ 88 Fed. Reg. at 74308.

¹⁷⁸ U.S. EPA, Peer Review Handbook, 4th edition, 2015, at pages 55-57, available at: https://www.epa.gov/sites/default/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf.

¹⁷⁹ *Id.*

risk evaluations or peer review process. This is a critical flaw with the ECEL approach to risk management—EPA draws the line for “unreasonable risk,” for worker exposures at compliance with an ECEL. Therefore, if EPA continues to use ECEls to address unreasonable risks from substances under the conditions of use, the ECEL should be part of the risk evaluation process, developed transparently, commented on, and undergo peer review.

XII. EPA cannot combine prioritization and scoping steps because doing so would violate Section 6 of TSCA and would deprive the public of opportunities to participate in the risk evaluation process.

EPA proposes to add “efficiencies” to its risk evaluation process by combining the prioritization and risk evaluation “scoping” steps. EPA believes that either during prioritization or before, EPA should make preliminary efforts to scope the potential risk evaluation. Therefore, EPA is proposing a process in which it would publish and take comment during prioritization on preliminary information to inform the scope of the potential risk evaluation, which may result in the publication of the “draft scope” *before the initiation* of the risk evaluation.¹⁸⁰

This proposal is contrary to the scoping provisions of TSCA, where EPA must complete the scope of a risk evaluation “not later than 6 months *after the initiation* of a risk evaluation.”¹⁸¹ The progression of the prioritization, scoping, risk evaluation, risk determination, and risk management process is a step-by-step process in which stakeholders are given the opportunity, by statute, to comment and participate in the process. For example, EPA must provide a public comment period during the prioritization process before it designates a chemical high priority. Then, there is another comment period once EPA publishes a draft scope of the risk evaluation. If EPA combines the prioritization and scoping steps, this would unjustly deprive the public of an opportunity to provide input into the process. EPA must keep these steps separate, distinct, and inclusive of all public participation requirements of TSCA and not short-circuit the process for the sake of claimed efficiency.

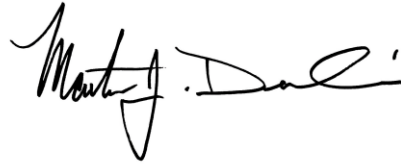
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¹⁸⁰ 88 Fed. Reg. at 74300.

¹⁸¹ 15 U.S.C. § 2605(b)(4)(D).

Thank you for the opportunity to provide these comments. The Chamber welcomes further discussion with EPA on this important proposal. Please contact Preston Beard, Director of Policy, at pbeard@uschamber.com with any questions regarding these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Martin J. Durbin". The signature is fluid and cursive, with the first name "Martin" and last name "Durbin" clearly legible.

Martin J. Durbin
President, Global Energy Institute
Senior Vice President, Policy
U.S. Chamber of Commerce