CENTER FOR ENVIRONMENTAL ACCOUNTABILITY

COMMENTS OF THE CENTER FOR ENVIRONMENTAL ACCOUNTABILITY

Comments on Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA); Proposed Rule

88 Fed. Reg. 74,292 (Oct. 30, 2023)
Docket No. EPA–HQ–OPPT–2023–0496;
FRL–8529–01–OCSPP

SUBMITTED DECEMBER 14, 2023

The Center for Environmental Accountability (CEA) submits these comments on the United States Environmental Protection Agency's (EPA) proposed rule on *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, 88 Fed. Reg. 74,292 (Oct. 30, 2023) ("the Proposed Rule").

CEA is a 501(c)(3) organization devoted to educating the public and government on the importance of transparency and accountability in the areas of environmental and energy policy. CEA's work is driven by its core principles, including a commitment to the rule of law, to a clean environment, and to a healthy human environment founded on a strong economy and vibrant communities animated by people gainfully employed in all the occupations of human flourishing. CEA understands that adherence to law requires respect for the proper roles of each branch of government and for the respective roles of the federal government and of state governments. CEA recognizes that the public interest requires a balance of environmental stewardship, resource development, and energy access and security, and that environmental remediation functions best when targeted at those communities injured by unlawful pollution.

I. Introduction

"*Chemistry Is Everywhere*"

- American Chemical Society

Chemistry is all around us and always will be. And it's a good thing too, for life could not exist without it. Just as water (H_2O) and oxygen (O_2), two forms of chemistry we all know so well, exemplify how chemistry nurtures life, other less heralded chemistries create a world of possibilities for the living. Nothing, absolutely nothing, is possible without chemistry. Every product, from life-saving medicines, to protective equipment for first-responders, to our homes, vehicles, consumer appliances, and digital gadgets, all rely on chemistry. And the nearly infinite combinations of chemicals help drive endless technological innovation bounded only by those limits we impose on ourselves.

As if on cue, the Biden Administration and the U.S. Environmental Protection Agency (EPA) have taken "targeted" aim at chemistry through amendments to the procedures by which EPA evaluates chemicals under the Toxic Substances Control Act (TSCA). To be sure, evaluating chemicals so that they can be used without undue risk to people or the environment is in everyone's best interest. But instead of heeding Congress's mandate to fulfill its obligations under TSCA "in a reasonable and prudent manner," the regulatory changes that EPA has proposed are anything but.

Indeed, EPA proposes to effectively pin the red letter of "unreasonable risk" to every chemical that undergoes a risk evaluation. This is so because EPA will evaluate every chemical use, assume no one is abiding by other federal regulations, jettison robust peer review of the risk evaluations, and eliminate key science-based definitions that guide the risk evaluation process – all under the guise of adhering to Congressional intent – until the Agency finds just one use that EPA determines presents an unreasonable risk. At which point, EPA will condemn the "whole" chemical. By abandoning precise risk communication that differentiates the risk of a chemical depending on how it's used, EPA muddies the water and undermines transparency in

environmental regulation. Not only that, but EPA's amendments pay lip-service to the strict timelines that Congress imposed to complete risk evaluations.

We know where this will lead. The U.S. based chemical industry, a critical part of the U.S. manufacturing base that the Biden Administration has committed to nurture, will head off-shore to China and elsewhere. EPA got one thing right. These amendments are "targeted," but in the wrong way, and to our detriment.

II. Summary

In 2016, Congress adopted significant amendments to the Toxic Substances Control Act (TSCA), through passage of the Frank R. Lautenberg Chemical Safety Act for the 21st Century Act (Pub. L. 114-182, 130 Stat. 448) (hereinafter "TSCA Amendments"), forty years after TSCA was originally enacted in 1976. TSCA obligates EPA to regulate the manufacture, processing, distribution in commerce, use, and disposal of chemical substances.[1] The need to amend TSCA was driven in part by a long-standing recognition that TSCA did not mandate the systematic evaluation and regulation of unreasonable risks posed by existing chemicals. Indeed, EPA had added thousands of chemicals to the so-called TSCA Inventory (of existing chemicals) without having evaluated any of them for unreasonable risk.

Epitomizing this shift, when TSCA was amended, the title of section 6, which had been "Regulation of Hazardous Chemical Substances and Mixtures" was changed to "Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures." The new title reflects Congress's creation of a new paradigm for existing chemicals in which EPA must prioritize, evaluate, and, as necessary, promulgate chemical regulations. Section 6 mandates that EPA "by rule, establish a process to conduct risk evaluations."[2] But even before EPA was required to formally create a regulatory process for risk evaluation, Congress jump-started risk evaluation process by requiring EPA to "ensure that risk evaluations are being conducted on 10 chemical substances" within 6 months after the date of enactment of the TSCA Amendments.[3] To further ensure that risk evaluations were timely completed, Congress imposed "strict, enforceable deadlines for EPA action."[4] EPA was given 3 to 3.5 years to complete each risk evaluation.[5]

The culmination of every risk evaluation is a determination "whether a chemical substance presents an unreasonable risk of injury to health or the environment, without a consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the

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1 15 U.S.C. § 2601(a)(2).

2 15 U.S.C. § 2605(b)(4)(B).

3 15 U.S.C. § 2605(b)(2)(A).

4 U.S. Senate Congressional Record, S. Rep. 114-167 (June 23, 2015), at 16.

5 15 U.S.C. § 2605(b)(4)(G).

Administrator, ***under the conditions of use***."[6] TSCA also requires EPA, in cases where it finds unreasonable risk, to initiate rulemaking to eliminate that unreasonable risk "to the extent necessary."[7]

All 10 initial risk evaluations, finalized between June 2020 and January 2021, reflected the policy choices embedded in EPA's Final Rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, which was finalized on July 20, 2017 under the Trump Administration.[8] Although all but one risk evaluation missed the statutory deadline by several months, all 10 were poised to undergo risk management rulemaking by the Biden Administration, pursuant to TSCA sections 6(a) and (c), which require EPA to propose a risk management rule within one year of having finalized a risk evaluation in which an unreasonable risk determination was made.[9]

Instead of immediately initiating risk management on the initial 10 chemicals as required under TSCA, EPA reviewed all 10 risk evaluations "in accordance with the Biden-Harris Administration Executive Orders and other directives, including those on environmental justice, scientific integrity, and regulatory review."[10] Based on this review, EPA issued a June 30, 2021, announcement ("Announcement") indicating its intent to revise most of the completed risk evaluations so that they reflected different policy choices. In particular, EPA signaled that it would adopt a "whole chemical approach" to unreasonable risk determinations. Instead of each

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[6] 15 U.S.C. § 2605(b)(4)(A) (emphasis added). The statute defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

[7] 15 U.S.C. § 2605(a).

[8] *See* 82 Fed. Reg. 33726 (July 20, 2017). The regulatory timeline began in the waning days of the Obama Administration. Pursuant to TSCA section 6(b)(4)(B), EPA proposed a procedural rule on January 19, 2017, "for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment […] under the conditions of use." *See* 82 Fed. Reg. 7562 (Jan. 19, 2017). TSCA section (6)(b)(4)(D) requires EPA to identify those conditions of use it expects to consider in any given risk evaluation, which EPA interpreted in its 2017 proposed rule to mean "all conditions of use." EPA acknowledged the challenge of an "all condition of use" approach while also meeting the TSCA statutory deadline of from 3 to 3.5 years to complete a risk evaluation and subsequently promulgating regulations as necessary to eliminate any unreasonable risk. Indeed, EPA explicitly acknowledged that "Congress intended to create obligations that EPA can actually meet, and EPA intends to conduct risk evaluations in a way that is manageable given the statutory deadlines." *Id.* at 7566.

[9] 15 U.S.C. § 2605(c)(1)(A).

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

condition of use reflecting its own unreasonable risk determination, EPA would now make a *single* unreasonable risk determination for the *whole* chemical. Under this approach, EPA also telegraphed that it would "withdraw the previously issued orders for those conditions of use for which no unreasonable risk was found for all the first 10 risk evaluations."[11] The Announcement also indicated that EPA would expand the scope of risk evaluations to include all exposure routes, and would no longer assume that workers were using personal protective equipment to manage occupational exposures to chemicals, even where equipment was required by other federal regulations.[12]

On October 30, 2023, EPA moved a step closer to enshrining its policy changes in regulations at 40 CFR Part 702 by issuing a Proposed Rule on Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) ("Proposed Rule"),[13] that included not only the changes telegraphed in the Announcement, but others as well, including but not limited to:

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

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

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

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

- Assessing "cumulative risk" during the risk evaluation process, including non-chemical risks and risks posed by other chemicals.

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

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

[13] 88 Fed. Reg. 74292 (October 30, 2023).

If finalized as proposed, the procedural changes unquestionably will fundamentally alter the manner in which EPA conducts risk evaluations of chemicals that it has identified as "high priority" and of chemicals voluntarily submitted by manufacturers to EPA for risk evaluation. As discussed throughout these comments, the Proposed Rule is untethered to TSCA's statutory text, structure, and Congressional intent, despite what EPA asserts in the Proposed Rule. Moreover, EPA will have created and implemented a risk evaluation process hopelessly mired in a massively burdensome and inefficient quagmire, dashing any hopes of meeting statutory deadlines, and further frustrating not only the many chemical industry stakeholders who have relied on the current procedural regulations for years, but the public at large.

The Proposed Rule would reverse many of the commonsense policies in EPA's 2017 Final Rule that encourage a more efficient regulatory review process and properly inure to the benefit of chemical manufacturers.[14] At every turn, EPA has taken an unlawfully expansive view of its authority. In proposing to reverse many of the key policies underlying the previous administration's risk evaluation approach, EPA runs afoul of several bedrock principles of rulemaking and administrative law. Specifically, the Agency has failed to provide the requisite "reasoned explanation" mandated when an Agency reverses course, whether based on TSCA's plain language and structure, the statute's legislative history, or guiding principles underlying effective risk evaluations. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). EPA may alter its policies over time, but it must engage in reasoned decision-making and ground such changes in the statute's provisions and overall purposes.

Moreover, EPA has failed to address the factual underpinnings that supported the 2017 Final Rule, as well as the significant disruption to the chemical industry's substantial reliance interests engendered by the 2017 Final Rule, contravening the Supreme Court's holding in *Department of Homeland Security v. Regents of the University of California*. *See* 140 S. Ct. 1891 (2020).

Given the significant legal and policy deficiencies of the Proposed Rule, EPA should promptly withdraw it. EPA has failed to justify, either factually or legally, why the current procedural regulations should be so drastically revised. Instead, EPA should recommit itself to implementing TSCA as Congress intended it to be carried out: "in a reasonable and prudent manner."[15]

III. EPA's proposal to require a single risk determination for a whole chemical substance conflicts with the plain language and purpose of TSCA and will dismantle the statutory scheme.

The Proposed Rule would eliminate EPA's ability to make determinations regarding the risks posed by the conditions of use of a chemical substance, instead requiring a single risk determination for a chemical substance as a whole, regardless of the contribution to the risk of

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[14] *See* 82 Fed. Reg. 33726 (July 20, 2017).

[15] 15 U.S.C. § 2601(c).

each condition of use.[16] Such a scheme is contrary to the plain language and intent of the statute and will create profound confusion within the Agency and among the states, regulated entities, and the general population regarding the risks posed by the chemical substance under its conditions of use. In addition, EPA's proposed approach will render key sections of TSCA meaningless, including provisions relating to preemption and manufacturer-requested risk evaluations.

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

TSCA explicitly states in its introductory "findings" section that "among the many chemical substances and mixtures which are constantly being developed and produced, there are some ***whose manufacture, processing, distribution in commerce, use, or disposal*** may present an unreasonable risk of injury to health or the environment."[17] Thus, Congress's initial finding in 1976, which was maintained in the 2016 TSCA Amendments, was *not* that chemical substances *themselves* may pose an unreasonable risk, but that *particular applications* of chemical substances had the potential to pose unreasonable risk. Congress recognized, for example, that the disposal of a chemical alone may pose an unreasonable risk, while its manufacture, processing, or distribution in commerce may not.

To effectuate Congress's intent of addressing the actual uses of chemical substances that pose an unreasonable risk, Congress gave EPA the authority to impose requirements on *particular applications* of chemical substances under Section 6. Section 6(a) states in relevant part:[18]

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

The regulatory options available to EPA that follow ("the following requirements") incorporate the language from subsection (a) above, tying a chemical substance to its manufacture, processing, distribution in commerce, use, or disposal, rather than only referencing the chemical itself.[19] Certain options even permit EPA to impose requirements on "a particular

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[16] 88 Fed. Reg. at 74301.

[17] 15 C.F.R. § 2601(a)(2) (emphasis added).

[18] 15 U.S.C. § 2605(a) (emphasis added).

[19] *Id.* at §§ 2605(a)(1)-(3).

use,"[20] a "manner or method of commercial use,"[21] or a "manner or method of disposal."[22] By presenting these options, Congress confirmed that "unreasonable risk" may be assessed by each individual application of a chemical substance or, where relevant, by combinations of these individual applications, so that EPA may take action with respect to one or more of these uses to address the unreasonable risk. Making a determination that a chemical substance, in and of itself, poses an unreasonable risk, is not only nonsensical and unscientific, but also patently unhelpful to the Agency's ultimate task of taking action with respect to specific applications of the chemical substance.

Importantly, the language in Section 6(a) also characterizes the risk evaluation process under Section 6(b). As noted above, TSCA requires that an unreasonable risk determination be made not on the chemical itself, but on "the manufacture, processing, distribution in commerce, use, or disposal" of the chemical. Such a determination is to be made "in accordance with subsection (b)(4)(A)." Subsection (b)(4)(A), in turn, effectuates Congress's intent by tying the risk evaluation process to the "conditions of use" of a chemical substance: "The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk … ***under the conditions of use***."[23] The statute defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be ***manufactured, processed, distributed in commerce, used, or disposed of***."[24] Thus, there is a clear link throughout the statutory text between the chemical substance, the particular applications in which it is used, the risks posed by each of those particular applications, and EPA's obligation to impose requirements "to the extent necessary" to mitigate any unreasonable risks from these applications.[25]

Beyond the plain language of the statute, Congress's intent to permit EPA to make risk determinations on a condition-of-use basis is further evidenced by the legislative history of the 2016 TSCA Amendments. The first draft of the Amendments would have required EPA to "conduct risk evaluations … to determine whether or not a chemical substance presents or will present … an unreasonable risk of injury to health or the environment."[26] The initial draft would have then required EPA to "apply requirements with respect to a chemical substance through a rule under subsection (a) only if the Administrator determines through a risk evaluation under this subsection that the chemical substance presents or will present, in the absence of such

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[20] *Id.* at § 2605(a)(2).

[21] *Id.* at § 2605(a)(5).

[22] *Id.* at § 2605(a)(6).

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

[24] *Id.* at § 2602(4).

[25] *Id*. at § 2605(a).

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

requirements, an unreasonable risk of injury to health or the environment."[27] Neither of these provisions in the initial draft would have required consideration of the "conditions of use" of the substance as part of the risk determination.

The text of the bill was ultimately amended to include the current language under Section 6(b)(4)(A), which requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk … ***under the conditions of use.***" Congressional floor statements made on the day of passage of the 2016 TSCA Amendments underscore the reasoning for this provision, and its proper interpretation: "To be clear, every condition of use identified by the Administrator in the scope of the risk evaluation must, and will be either found to present or not present an unreasonable risk."[28]

In the Proposed Rule, EPA reads Section 6(b)(4)(A) in isolation and ignores the Congressional findings and ultimate purpose of TSCA that aim to address those conditions of use of a chemical substance that pose an unreasonable risk. EPA claims that "[t]he evaluation is on the chemical substance—not individual conditions of use—and it must be based on 'the conditions of use.'"[29] In support of its argument that there should be one determination on the chemical substance, EPA cites to various provisions of TSCA that include the terms "determination" and "chemical substance." However, EPA omits from its discussion those other key terms that tie the determination on the chemical substance to its conditions of use. For example, Sections 6(i)(1) and 18(a)(1)(B), both examples cited by EPA that reference a "determination" on a "chemical substance," also state that such a "determination" is to be made under, or be consistent with, Section (b)(4)(A). Section (b)(4)(A) contains the important proviso, which was key to the 2016 TSCA Amendments, requiring EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk … ***under the conditions of use.***" By ignoring the clear linkages throughout the statute between the chemical substance and its conditions of use, EPA neglects the longstanding principle of statutory interpretation that "[s]tatutes must 'be read as a whole.'"[30]

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[27] *Id.*

[28] 162 Cong. Rec. S3511-01, at *S3520. In the Proposed Rule, EPA omits this language from Senator Vitter's floor statement, but cherry-picks the preceding sentence to support its assertion that TSCA does not permit EPA to make separate risk determinations for each condition of use evaluated in the risk evaluation. EPA's blatant omission of key language from the Congressional floor statements demonstrates the Proposed Rule's lack of support in the legislative history.

[29] 88 Fed. Reg. at 74301.

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

(continued …)

The incongruity of the approach outlined in the Proposed Rule is made plain by EPA's statement on the very next page that "[a] determination that a chemical substance presents an unreasonable risk does not mean that the entirety or whole of that chemical's uses—or even a majority of uses—presents an unreasonable risk. Rather, EPA may determine that a chemical substance presents an unreasonable risk based on risk associated with even a single condition of use."[31] EPA provides no explanation of how the Agency will make an unreasonable risk determination for an entire chemical substance or how such a determination will guide the Agency's ultimate decision making under Section 6(a), which must be based on specific applications of the chemical substance as described above.

EPA even recognizes that such a scheme will be inherently confusing, acknowledging stakeholder concerns that "a singular risk determination could create confusion as to whether all uses or only certain uses of a chemical pose unreasonable risk."[32] EPA dismisses these concerns by reasoning that "EPA believes these concerns are risk communication issues that the Agency can and intends to continue to improve on," in part by identifying "which conditions of use are—or are not—significant contributors to EPA's determination."[33] EPA's casual dismissal of this critical issue, with its only solution being to "improve on" these so-called "risk communication issues," does not constitute the requisite "reasoned analysis" for such a drastic change in policy.[34]

The Agency fails to recognize that the damage will be done once a chemical substance, in its entirety, is branded with an unreasonable risk determination. The public will rightly interpret an unreasonable risk determination for an entire chemical as meaning just that: that *the chemical itself*, regardless of the particular applications in which it is manufactured, processed, distributed, used, or disposed of, presents an unreasonable risk. EPA cannot have it both ways. A chemical substance cannot, in itself, present an unreasonable risk, and at the same time be used in ways

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As articulated by the Supreme Court in *Dubin v. United States*:

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

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

[31] *Id.* at 74302.

[32] *Id.*

[33] *Id.*

[34] *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 30, 103 S. Ct. 2856, 2860, 77 L. Ed. 2d 443 (1983); *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (requiring a "reasoned explanation" for an Agency change in policy).

that do not pose an unreasonable risk or contribute in any way to the unreasonable risk. Yet, this is the system that EPA intends to impose. No amount of risk communication can overcome this self-contradictory approach.

B. EPA's "whole chemical" approach would nullify TSCA's preemption provisions.

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

In enacting the preemption provisions of TSCA, Congress contemplated specific conditions of use being deemed as presenting or not presenting an unreasonable risk. Upon EPA making such a finding, TSCA provides that state action is preempted for those conditions of use that are the subject of (1) a rule under Section 6(a) applying requirements to address the unreasonable risk of the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, or (2) an order under Section 6(i) determining that a chemical substance does not pose an unreasonable risk under the conditions of use.[35] TSCA Section 18(a)(1)(B) provides that state action is preempted in either instance with regard to the manufacture, processing, or distribution in commerce or use of a chemical substance.[36]

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

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

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

[36] 15 U.S.C. § 2617(a)(1)(B)(i).

[37] 15 U.S.C. § 2617(c)(3)

The Proposed Rule would eviscerate this structure. EPA readily admits its belief that the Agency "may determine that a chemical substance presents an unreasonable risk based on risk associated with even a single condition of use."[38] To correct for the overbreadth of deeming a chemical substance, in and of itself, as presenting an unreasonable risk, EPA argues that it will use its discretion to only address those conditions of use that contribute to the unreasonable risk in its Section 6(a) rulemaking.[39] However, EPA will also refuse to issue an order under Section 6(i) explaining that those conditions of use that do not contribute to the unreasonable risk do not pose an unreasonable risk. Thus, preemption will not apply to these conditions of use even if the Agency has found they pose little if any risk, let alone unreasonable risk. This is contrary to both the plain language of the statute and Congressional intent.

Because the preemption provisions apply only to those conditions of use that are the subject of a Section 6(a) rulemaking or a Section 6(i) no-unreasonable-risk determination, the conditions of use that do not contribute to risk in any way (*i.e.*, those that do not pose an unreasonable risk), will effectively be stripped of the benefits of preemption when the *whole* chemical substance is deemed to present an unreasonable risk. Congress intended for state action to be preempted with regard to "the manufacture, processing, or distribution in commerce or use of a chemical substance" where those activities were found not to present an unreasonable risk.[40] This determination *must be made* on a condition-of-use basis. This intent is clearly evidenced in Congressional floor statements made on the day of passage of the 2016 TSCA Amendments supporting a condition-of-use-based approach, which the Agency curiously omits in the Proposed Rule:

> Federal determinations reached after the risk evaluation process that a chemical presents no significant risk ***in a particular use*** should be viewed as determinative and not subject to different interpretations on a state-by-state or locality-by-locality basis. Further, under the new legislation, ***EPA will make decisions based on conditions of use, and must consider various conditions of use, so there could be circumstances where EPA determines that a chemical does not present an unreasonable risk in certain uses, but does in others. Preemption for no significant risk determinations would apply as these determinations are made on a use-by-use basis.***[41]

EPA's proposed approach would unlawfully curtail these preemption provisions, allowing states to regulate uses of chemical substances that were found by EPA *not to pose a risk at all* – unreasonable or otherwise – because EPA will no longer issue Section 6(i) orders for individual conditions of use when an unrelated condition of use for that chemical is found to pose an unreasonable risk.

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[38] 88 Fed. Reg. at 74302.

[39] *Id.* at 74303.

[40] 15 U.S.C. § 2617(a)(1)(B).

[41] 162 Cong. Rec. S3511–01, at *3521 (June 7, 2016).

Further underscoring the importance of these provisions,[42] Congress even directed EPA, under Section 6(b)(4)(E)(iii), to give preference to manufacturer requested risk evaluations (MRREs) "on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment."[43] This ensures that, where EPA decides to evaluate a chemical substance, the exposures and conditions of use that are considered in the evaluation and ultimately determined to either pose or not pose an unreasonable risk will be protected by federal preemption from patchwork requirements imposed by states. EPA's proposed approach would permit state regulation of exposures and conditions of use for chemicals evaluated by EPA and determined to be safe, because EPA may conclude that these uses do not drive unreasonable risk and therefore may not be the subject of a Section 6(a) rulemaking or a Section 6(i) order. Thus, a broad swath of conditions of use that EPA evaluates under an MRRE, regardless of their potential risks, may still be subject to state action if a single, *unrelated* condition of use is deemed to present a risk that justifies EPA determining that the *chemical* (due to *other* conditions of use) presents unreasonable risk.[44]

These issues are not just "risk communication issues" as the Agency contends. EPA's proposal constitutes a fundamental misreading of the law. By assigning an unreasonable risk determination to an entire chemical substance, rather than the conditions of use of that substance, EPA will have upended the statutory scheme mandated by Congress and rendered key provisions of TSCA meaningless.

C. EPA's "whole chemical" approach will effectively eliminate the statute's provision for Manufacturer Requested Risk Evaluations.

TSCA Section 6(b)(4)(E) explicitly provides that a manufacturer of a chemical can request that EPA conduct a risk evaluation on that chemical. This section delineates minimum and maximum percentages of EPA's risk evaluations that can be conducted on manufacturer request. To date, four manufacturer-requested risk evaluations (MRREs) have been submitted by manufacturers, and all are currently undergoing risk evaluation.[45] By submitting an MRRE,

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

[43] 15 U.S.C. § 2605(b)(4)(E)(iii).

[44] Stripping preemption also is partly responsible for the Proposed Rule's effective nullification of TSCA's MRRE provision, as discussed below.

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

manufacturers bypass prioritization and avoid having their chemical deemed a "high priority substance." More importantly, under a condition-of-use approach (as opposed to EPA's proposed whole-chemical approach), manufacturers can submit an MRRE with supporting data to support a no-unreasonable-risk determination for one or more conditions of use.

Under a whole-chemical approach to unreasonable risk determinations, however, MRREs will be a thing of the past. Although avoiding the high-priority designation may still be a motivator to file an MRRE, the likelihood that the "whole chemical" would be deemed not to present an unreasonable risk is highly improbable, given EPA's stated intent of assigning an unreasonable risk determination to a whole chemical based on a single condition of use.[46] A single manufacturer is also unlikely to have knowledge regarding *all* conditions of use of a particular chemical (beyond those that the manufacturer intends for its specific product) and would risk provoking an unreasonable risk determination for its product, based on a condition of use of which it is not aware (and which has no relevance to the manufacturer's operations) but that EPA considers to be relevant under the "whole chemical" approach.

As noted above, manufacturers would also be stripped of the benefits of preemption, even if the manufacturer's intended, known, or reasonably foreseen uses of the chemical substance do not pose an unreasonable risk, following an unreasonable risk determination based on a single, unrelated condition of use that is unknown to the manufacturer. Under EPA's proposed approach, the Agency will have removed the incentive, made plain by the statutory text of TSCA, for any manufacturer to file an MRRE, as the likely result will be a determination by EPA that the whole chemical presents unreasonable risk. In doing so, EPA will have rendered meaningless the provisions of TSCA permitting MRREs and requiring the Agency to give preference to MRREs on chemicals for which restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.[47]

Further limiting any prospects for future MRREs, EPA now proposes to burden the would-be submitter of an MRRE with "providing EPA [] all information necessary to conduct a risk evaluation on the chemical substance."[48] Invoking "TSCA's statutory text and structure," the Proposed Rule states that MRRE requests "should attempt to identify all intended, known and reasonably foreseen circumstances of the chemicals manufacture, processing, distribution in commerce, use and disposal, and provide all available information regarding the chemical's

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

[47] *See, e.g., infra* fn 62.

[48] 88 Fed. Reg. at 74313.

hazards and exposures – not just information of relevance to the submitter's interest."[49] It is unreasonable for EPA to assume that a single manufacturer is aware of conditions of use beyond those that are intended, known, or reasonably foreseen by the manufacturer with respect to the manufacturer's own operations and intended activities with respect to a chemical substance. Imposing this open-ended, overwhelming task on manufacturers would render MRREs virtually impossible to apply for, let alone to obtain. We readily acknowledge that TSCA authorizes EPA to establish the "form and manner" for MRRE submissions, but that authority cannot rationally be viewed as enabling EPA to effectively eviscerate the MRRE provisions from TSCA. The fact that EPA's proposed approach would effectively nullify this provision of the statute is another reason why that approach is contrary to law, unreasoned, and arbitrary and capricious.[50]

Moreover, without MRRE submissions each year, a significant revenue stream entirely evaporates, further exacerbating the resource constraints underscored in Assistant Administrator Freedhoff's written testimony before the Committee on Energy and Commerce.[51] EPA admits that it is reliant on MRREs to operate its programs and assumes that it will be working on at least 3 MRREs at any given time.[52] How does EPA anticipate making up this shortfall? Neither the Proposed Rule nor any other public document we are aware of addresses this question.

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[49] *Id.*

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

[51] *See* Testimony of Michal Ilana Freedhoff, Ph.D., Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, Before the Committee on Energy and Commerce, United States Congress, October 27, 2021, *available at* https://www.epa.gov/system/files/documents/2022-06/EPA%20Test.Final_.HEC%20hearing%20on%20TSCA.10.27.21.pdf. "The Office of Pollution Prevention and Toxics or OPPT has been – and remains – incredibly underfunded." *Id.* at 3. The fees generated through MRRE submissions represent a significant source of revenue for EPA's Office of Pollution Prevention and Toxics. In EPA's proposed fees rule, for example, EPA anticipates that EPA's workforce will be involved in at least 3 MRREs at all times, generating millions of dollars in revenue to support TSCA implementation. *See* 87 Fed. Reg. 68647, 68654 (Nov. 16, 2022).

[52] *See id.*; EPA has elsewhere relied on an assumption that it will receive MRREs at a relatively high rate. *See, e.g.*, 82 Fed. Reg. 7562, 7563 (Jan. 19, 2017) ("Assuming EPA receives requests in excess of [the statutory minimum of 25 percent] threshold…").

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

The Proposed Rule would require EPA to consider all exposures and conditions of use of a chemical substance, however *de minimis* the potential exposures may be, for a given chemical during the risk evaluation process.[53] This blanket requirement unlawfully limits EPA's discretion, explicitly provided to the Agency by Congress, to include within the scope of the risk evaluation only those exposures and conditions of use that EPA "expects to consider."[54] The Proposed Rule would *eliminate* EPA's ability to consider relevant factors that the Agency is *required* to take into account when determining the scope of the risk evaluation, such as the impact of existing regulations on the risks posed by chemical substances.

EPA's proposed system will be overly burdensome on a process that is already strained to fulfill statutorily imposed deadlines, and no reasonable explanation is provided for how EPA will properly scope its risk evaluations to continue them out "in a reasonable and prudent manner," as required by TSCA.[55]

A. The Proposed Rule unlawfully eliminates EPA's discretion to determine those exposures and conditions of use that fall within the scope of a risk evaluation.

TSCA Section 6(b)(4)(D) requires EPA to publish the scope of its risk evaluation, "including the hazards, ***exposures***, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator ***expects to consider***."[56] This provision plainly provides EPA with discretion to exclude any hazards, exposures, conditions of use, or potentially exposed or susceptible subpopulations that the Agency deems irrelevant to the risk evaluation. Despite this plain language *mandating* that EPA exercise its discretion to properly scope the risk evaluation, EPA now contends that the Agency "does not have discretionary scoping authority."[57] This direct contradiction of the statutory text and Congressional intent is a fatal flaw to this aspect of the Proposed Rule.

EPA also fails to take into account other provisions of TSCA that clearly indicate an intent to afford EPA with discretion to exclude irrelevant conditions of use from the scope of a risk evaluation. For example, as discussed above, Section 18(a)(1)(B) preempts state action with respect to the manufacture, processing, or distribution in commerce or use of a chemical substance (1) for which a no unreasonable risk determination is made under Section 6(i), or (2)

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[53] 88 Fed. Reg. at 74297.

[54] 15 U.S.C. § 2605(b)(4)(D).

[55] 15 U.S.C. § 2601(c).

[56] *Id.* at § 2605(b)(4)(D).

[57] 88 Fed. Reg. at 74297.

for which a final rule is promulgated under Section 6(a). The scope of this preemption is limited "***only to***…the hazards, exposures, risks, and uses or ***conditions of use*** of such chemical substances ***included in any final action*** the Administrator takes…."[58]

Similarly, Section 18(b) preempts any new state action with respect to the manufacture, processing, distribution in commerce, or use of any chemical substance designated as "high-priority," between the period when the scope of the risk evaluation is published and when the risk evaluation ends.[59] Section 18(c)(4) limits the scope of this preemption "***only to*** … the hazards, exposures, risks, and uses or ***conditions of use*** of such chemical substances ***included in the scope of the risk evaluation*** pursuant to section 2605(b)(4)(D) of this title."[60] The inclusion of this provision established that Congress recognized that there may be conditions of use for a chemical substance that would not be included within the scope of a risk evaluation, and that states would be free to enact new laws regulating these conditions of use while the risk evaluation process was ongoing.[61] EPA's assertion that a risk evaluation must include every conceivable condition of use of a chemical substance would render these preemption scoping provisions in Section 18(c)(4) utterly meaningless, counter to "one of the most basic interpretive canons, that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant."[62]

B. The Proposed Rule would require EPA to overreach into the jurisdiction of other Federal statutes and Agencies.

The Proposed Rule would unlawfully eliminate EPA's express statutory authority to exclude from the scope of the risk evaluation those conditions of use for which the risk is already addressed by another Federal statute. When TSCA was originally enacted in 1976, Congress believed that the legislation "would close a number of major regulatory gaps, for while certain statutes, including the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act, may be used to protect health and the environment from chemical substances, none of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances."[63]

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[58] 15 U.S.C. §2617(c).

[59] *Id.* at § 2617(b)(1).

[60] *Id.* at § 2617(c)(4).

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

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

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

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

> The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture ***could be eliminated or reduced to a sufficient extent*** by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection ***shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws***.[64]

Section (9)(d) further requires that EPA "shall consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act ***while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes***."[65]

Importantly, the 2016 TSCA Amendments did not alter these provisions, as Congress believed that the Amendments would "reinforce[] TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals."[66]

Despite the plain language in these provisions and the legislative history underpinning this statutory text, EPA now contends in the Proposed Rule that the Agency "no longer interprets the law to authorize exclusion of exposure pathways from the scope of TSCA risk evaluations because other EPA offices have already or could in the future regulate those chemicals." EPA argues that Congress' mandate to coordinate with other statutes and other Federal agencies "cannot be read to displace the more specific requirements under TSCA section 6(b)(4)(F)."[67]

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[64] 15 U.S.C. § 2608(b)(1) (emphasis added).

[65] 15 U.S.C. § 2608(d) (emphasis added).

[66] HR Rep. 114-176, at 28 (June 23, 2015).

[67] 88 Fed. Reg. at 74299. TSCA Section 6(b)(4)(F) states the following:

(continued …)

However, EPA's new interpretation ignores the explicit grant of discretion afforded to the Agency to rely on other statutory authority when the risks "could be eliminated or reduced to a sufficient extent."[68] The Proposed Rule also disregards the balance that Congress intended to strike both in originally enacting TSCA and in amending it in 2016, to achieve maximum enforcement while avoiding duplicative requirements through other Federal statutes. EPA cannot allow its authorities under TSCA to overtake the authority granted under other Federal statutes in light of the coordination requirements under TSCA Section 9.

1. The Proposed Rule unlawfully disregards the worker-risk-mitigating effect of standards issued by the Occupational Health and Safety Administration.

Perhaps the most egregious overreach of EPA's authority in the Proposed Rule is the Agency's new, default assumption that standards imposed by the Occupational Safety and Health Administration (OSHA) are either not enforced or not sufficiently protective of workers.

Specifically, the Proposed Rule states that EPA will now *assume* in its risk evaluations that workers do *not* use personal protective equipment (PPE) because "their employers are out of compliance with OSHA standards, or because the PPE is not sufficient to address the risk or their PPE does not fit or function properly," unless EPA is presented with evidence to the contrary.[69] EPA provides no explanation or factual basis for this newfound blanket assumption, which would put the burden on manufacturers to prove to EPA, an Agency that has no expertise in worker safety, that they are in compliance with requirements under the OSH Act, a statute

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

[68] 15 U.S.C. § 2608(b)(1).

[69] 88 Fed. Reg. at 74304.

administered by an entirely different Agency.[70] EPA states that in certain narrow circumstances, it may conclude that workplace protection is used, such as in "particularly advanced manufacturing facilities (*e.g.*, those involved in the aerospace and defense industrial base industrial sectors" or when EPA has received "information demonstrating that performance of a condition of use is impossible in the absence of PPE."[71] Again, EPA provides no evidence of widespread non-compliance with applicable OSHA standards, and even acknowledges this fact,[72] and yet plans to forge ahead with its expectation that most workplaces are not in compliance with OSHA standards, jeopardizing the accuracy of the exposures calculated during the risk evaluation process for workers.

Another basis for EPA's disregard of worker protections is the Agency's unfounded belief that OSHA standards are inherently inadequate because "many of OSHA's chemical-specific permissible exposure limits were largely adopted in the 1970s and have not been updated since they were established."[73] Thus, EPA is assuming, automatically (and without evidence), that safety standards imposed by OSHA are not protective of workers, despite the OSH Act's mandate that such standards attain "the highest degree of health and safety protection for the employee."[74]

EPA argues that it may disregard these protections because "TSCA risk evaluations are subject to statutory science standards, an explicit requirement to consider risks to potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk factors when determining whether a chemical presents an unreasonable risk that warrants regulatory actions—all requirements that do not apply to development of OSHA regulations."[75] *This statement is patently false* and demonstrates the danger posed by EPA overtaking the authority of OSHA in regulating workplace safety. The OSH Act requires the Agency to promulgate standards for toxic materials and harmful physical agents "on the basis of the best

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[70] EPA states that the Agency "is not suggesting that there is widespread non-compliance with applicable OSHA standards." 88 Fed. Reg. at 74304. However, in the paragraphs immediately preceding this statement, EPA makes the contradictory statement that it will ignore OSHA standards because of the possibility that "employers are out of compliance with OSHA standards." *Id.* EPA's change in policy "rests upon factual findings that contradict those which underlay its prior policy," yet the Agency has not provided "a more detailed justification than what would suffice for a new policy created on a blank slate." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, at 515. Accordingly, EPA's new interpretation is arbitrary and capricious.

[71] 88 Fed. Reg. at 74304.

[72] *See id.* (claiming that "EPA is not suggesting that there is widespread non-compliance with applicable OSHA standards").

[73] *Id.*

[74] 29 U.S.C. § 655(b)(5).

[75] 88 Fed. Reg. at 74304.

available evidence" and to consider "the latest available scientific data in the field."[76] The OSH Act is also specifically designed to address workplace exposures, and thus inherently involves consideration of a subpopulation that is more susceptible to exposure than the general population. Ultimately, OSHA standards must ensure "that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."[77]

EPA will now assume that OSHA is not meeting its own statutory standards and that OSHA-regulated entities are otherwise not in compliance with such standards. In place of OSHA standards, EPA intends to implement its own workplace exposure standards, which it believes are more protective, to effectively usurp the authority granted by Congress to OSHA. This outcome is one that Congress explicitly sought to avoid.

TSCA Section 9(d) requires EPA to "consult and coordinate with" other Federal agencies "for the purpose of achieving the maximum enforcement of this chapter while imposing the least burdens of duplicative requirements on those subject to the chapter and for other purposes."[78] In explaining the purpose of Section 9, the House Committee on Energy and Commerce explained that these provisions were intended "to encourage decisions that avoid confusion, complication, and duplication."[79] The Committee further explained that EPA "should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety. ***Specifically, the Committee does not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls.***"[80] But this is precisely what EPA will do if the Proposed Rule is finalized. Under the scheme contemplated in the Proposed Rule, EPA will automatically assume that OSHA standards are unenforced or otherwise inadequate, leading to unrealistically inflated exposure assessments that will result in worker protections that conflict with existing OSHA standards. Instead of consultation and coordination with other Agencies, the Proposed Rule would have EPA assume that OSHA regulations are ineffective and require EPA to implement duplicative standards, notwithstanding any existing OSHA requirements for workplace exposure. Where Congress directed EPA to conduct its TSCA work in deference to OSHA's role, the Proposed Rule would do the opposite. This is a fatal flaw in this aspect of the Proposed Rule.

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[76] 29 U.S.C. § 655(b)(5).

[77] *Id.*

[78] 15 U.S.C. § 2608(d).

[79] HR Rep. 114-176 (June 23, 2015), at 28.

[80] *Id.* at 29.

C. EPA provides inadequate explanation for how the risk evaluation process will be able to properly function, given the expansive scope envisioned in the Proposed Rule.

The Proposed Rule eliminates any possibility of EPA meeting its statutory deadlines for risk evaluation. The Proposed Rule significantly expands the exposures and conditions of use that EPA is required to consider, beyond what is mandated and permitted by the statute. EPA acknowledges that the new considerations in the Proposed Rule "could all lead to future TSCA risk evaluations that are more comprehensive in scope" and that the Agency "recognizes the enormity of the challenge to complete these responsibilities within the timeframes set forth by Congress."[81] This challenge is particularly daunting, given that EPA has already failed to meet the statutory deadlines under the more efficient approach outlined in the 2017 final rule,[82] which properly interprets TSCA to give EPA discretion to exclude from the scope of the risk evaluation any irrelevant conditions of use or exposures that are *de minimis* or are already addressed through other statutes.

EPA's strategies to make up for the additional time that it will take to consider this new information include (1) relying on a "fit-for-purpose" approach and (2) altering the procedural steps required of the Agency under TSCA. As described below, both strategies are either inadequate or unlawful.

1. EPA's reliance on "fit-for-purpose" is inadequate to ensure that EPA meets its statutory deadlines for risk evaluation.

EPA first contends that a "fit-for-purpose" approach will allow the Agency to meet the applicable deadlines. However, the "fit-for-purpose" concept is already in place. Specifically, in its 2017 final rule, EPA explained:

> [A]ll conditions of use evaluated will not warrant the same level of evaluation, and that EPA expects, that in some cases, it may be able to reach conclusions without extensive or quantitative evaluations of risk. For example, a lower-volume or less dispersive (those uses that do not spread as far in the environment, either indoors or outdoors as compared to a different use) condition of use might require a less quantitative, data-driven evaluations to credibly characterize the risks than uses with more extensive or complicated exposure patterns. Consistent with EPA's current practice in conducting risk assessments, technically sound risk determinations can be made, consistent with the best available science, through a combination of different types of information and methods approaches.[83]

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[81] 88 Fed. Reg. at 74300.

[82] *See* U.S. EPA, *Ongoing and Completed Chemical Risk Evaluations under TSCA* (last updated Dec. 14, 2023), *available at* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under.

[83] 82 Fed. Reg. at 33734.

The 2017 final rule updated the regulations to provide that "[t]he extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment," to give EPA the flexibility to conduct risk evaluations in a manner consistent with a fit-for-purpose approach.[84]

EPA now contends in the Proposed Rule that the fit-for-purpose approach will compensate for the extraordinarily broad set of exposures and conditions of use it must now consider during a risk evaluation. The Proposed Rule states that "[i]n order for TSCA implementation efforts to be sustainable, risk evaluations must be fit-for-purpose such that the Agency meets both the substantive statutory and regulatory requirements for conducting risk evaluations, while completing those evaluations within the statutory deadlines."[85]

However, EPA does not acknowledge that the fit-for-purpose approach is already used by the Agency, and that prior risk evaluations have still not met the applicable statutory deadlines for risk evaluation. EPA provides no explanation for how it will modify the existing fit-for-purpose approach to achieve its goals. By expanding the type and quantity of information that must be considered in a risk evaluation, without explaining the additional efficiencies of the fit-for-purpose approach, risk evaluations will necessarily take more time. Thus, EPA is conceding that it will not meet its statutory deadlines, in conflict with TSCA's requirements that the Agency "conduct risk evaluations … at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G)."[86] A proposal that the Agency admits will prevent it from complying with statutory timelines is both *ultra vires* and irrational.

2. EPA's proposal to begin the risk evaluation before the completion of the prioritization phase is unlawful.

EPA's final strategy for meeting the statutory deadlines for risk evaluation is to begin the risk evaluation process *during or before the prioritization process*, in conflict with the procedures set forth in TSCA.

TSCA Section 6(b)(1) provides that, prior to the initiation of a risk evaluation, chemical substances must first be *prioritized* and *designated* as either high- or low- priority.[87] TSCA Section 6(b)(3)(A) then states that, "[u]pon designating a chemical substance as a high-priority

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84 *Id.* at 33751.

85 88 Fed. Reg. at 74300.

86 15 U.S.C. § 2605(b)(2)(C).

87 *Id.* at § 2605(b)(1).

substance, the Administrator shall initiate a risk evaluation on the substance."[88] Thus, only after a substance has been designated as high priority may EPA initiate a risk evaluation.

The Proposed Rule would depart from this requirement by allowing EPA to initiate the risk evaluation process and publish a draft scope of the risk evaluation "either during prioritization or before."[89] EPA states its intention to front-run the risk evaluation process in this manner "when early indications suggest the chemical is likely to meet the criteria for a high-priority designation."[90] Thus, EPA will essentially pre-prioritize substances to provide itself with additional time to complete the risk evaluation process. But TSCA does not permit EPA to make such early designations of the priority of a chemical substance. A high-priority designation requires: (1) a 90-day public comment period to receive information relevant to the prioritization; and (2) publication of the proposed designation with an explanation of the information, analysis, and basis for the used to make the proposed designation; and (3) an additional 90-day public comment period on the proposed prioritization.[91] Once this process is complete, EPA may then designate a substance as high-priority. Only once a high-priority designation is made may EPA begin the risk evaluation, the first step of which is developing the scope of the risk evaluation.[92]

EPA's strained proposal of consolidating the risk evaluation procedures, which TSCA explicitly requires to be performed in a stepwise manner, demonstrates EPA's acknowledgment that it cannot meet TSCA's statutory deadlines under the approaches outlined in the Proposed Rule without unlawfully changing TSCA's procedural requirements through the rulemaking process. EPA's predicament is further evidence that the expansive considerations that the Proposed Rule places on the Agency are beyond those permitted by TSCA.

V. Cumulative Risk

The preamble to the Proposed Rule states EPA's intent to consider "cumulative risk" during the TSCA risk evaluation process, which includes risks posed by non-chemical agents and/or stressors other than the specific chemical under consideration in the risk evaluation.[93] Attempting to justify this expansion of the risk evaluation process, EPA states that "a risk evaluation on a single chemical may not accurately provide a complete understanding of the risks to an exposed population, given simultaneous exposure to multiple chemicals."[94] The Agency's

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88 *Id.* at § 2605(b)(3)(A).

89 88 Fed. Reg. at 74300.

90 *Id.* at 74300-74301.

91 15 U.S.C. § 2605(b)(1)(C).

92 *Id.* at § 2605(b)(4)(D).

93 *See* 88 Fed. Reg. at 74305-74306.

94 *Id.* at 74306.

commentary ignores Congress's mandate in adopting Section 6 to identify, prioritize, and evaluate the risks posed by discrete chemical substances.

Under the new approach described in the Proposed Rule, EPA intends to incorporate other chemicals into the risk evaluation process based on toxicological similarity and co-exposure to the specific chemical that is the subject of the risk evaluation.[95]

The preamble to the Proposed Rule argues that EPA's authority to perform a cumulative-risk assessment of multiple chemical substances stems from provisions of TSCA that permit consideration of "categories of chemical substances." Under TSCA Section 26(c)(2)(A), "category of chemical substances" is defined as:

> *a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.*

EPA's reliance on the provisions in TSCA relating to categories of chemical substances is wholly misplaced. These provisions do not give EPA discretion to assess unrelated chemicals once a risk evaluation for a specific chemical is initiated. EPA may only consider a "category of chemical substances" in the following circumstances:

- EPA can require *testing for categories* of chemical substances under Section 4(b)(4);
- EPA can *group* substances together in efforts to *reduce testing on vertebrates* under Section 4(h)(1)(B)(ii);
- EPA can consider *categories* of chemical substances when *designating* a chemical substance as high- or -low priority under Section 6(b)(A);
- EPA may list *categories* of chemical substances, in lieu of listing single chemical substances, on its published *inventory* under Section 8(b)(2).

Of these provisions, only one relates to the risk evaluation process under Section 6(b), which provides that a "category of chemical substances" must be identified at the very beginning (*i.e.*, during the prioritization phase) of a risk evaluation and that this category will carry through the rest of the risk evaluation process.[96] This provision does not give EPA the authority to

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[95] *Id.*

[96] 15 U.S.C. § 2605(b)(1)(A).

consider new categories of chemical substances once a discrete chemical has already been identified as high- or low- priority and the substantive risk evaluation is underway.

EPA's misapplication of this language relating to a "category of chemical substances" is also evident in reviewing the overall statutory scheme. Once a category of chemical substances has been identified by EPA for the testing, prioritization, and listing purposes identified above, Section 26(c)(1) then requires that any action taken by EPA with respect to *one* chemical substance in the category be applicable to *each* chemical substance within the category.[97] Thus, it is critical that the category of chemical substances be well-defined and identified early in the prioritization process, as any restrictions imposed on one substance within the group is statutorily deemed to apply to all other substances within the category.

Under EPA's proposed approach, the Agency may begin to consider other chemical substances during the risk evaluation phase, long after a discrete chemical substance has been identified and prioritized. Any requirements that are imposed on the discrete chemical would then necessarily apply to all other substances considered as part of the "cumulative risk" evaluation, insofar as the Agency considers its cumulative risk evaluation to apply to a category of chemical substances. This would place the Agency in the untenable position of imposing requirements on chemical substances that have not undergone the prioritization processes described in TSCA Section 6(b)(1).

EPA's reliance on those TSCA provisions relating to "categories of chemical substances" as justification for its "cumulative risk" approach is clearly misplaced, unworkable, and contrary to the intent of the statute. The proposed expansion of the risk evaluation process is yet another example of the Agency's desire to reach beyond its statutory authority and would again exacerbate the Agency's inability to meet the applicable deadlines.

VI. Potentially Exposed or Susceptible Subpopulations

EPA's proposed rule unlawfully expands the definition of "potentially exposed or susceptible subpopulation" to include any "overburdened communities," reflecting the Agency's desire to incorporate environmental justice concerns into the TSCA risk evaluation process. Under TSCA Section 6(b)(3)(A), identification and consideration of "potentially exposed or susceptible subpopulations" is an integral part of the risk evaluation process. "Potentially exposed or susceptible subpopulation" is defined under TSCA Section 3(12) as follows:[98]

> *[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*

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[97] Section 26(c)(1) specifically states "[w]henever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category."

[98] 15 U.S.C. § 2602(12).

exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

The Proposed Rule would expand this definition to add "overburdened communities" to the list of example subpopulations.[99] EPA justifies this addition by relying on the lack of statutory definitions for "greater susceptibility" or "greater exposure."[100] The Agency takes a broad approach to these terms, interpreting them as including circumstances with no relationship to the particular chemical risk evaluation, such as pre-existing conditions including "immune-compromised conditions, lifestyle factors such as smoking status or alcohol abuse, age, ethnicity, or sex."[101] The Proposed Rule would allow EPA to consider these factors in identifying overburdened communities, which the Agency defines as "communities that may be disproportionately exposed ***or impacted*** by environmental harms." (emphasis added). The preamble to the Proposed Rule goes on to explain:[102]

> *The disproportionality can be as a result of greater vulnerability to environmental hazards, lack of opportunity for public participation, or other factors. Increased vulnerability may be attributable to an accumulation of negative or lack of positive environmental, health, economic, or social conditions within these populations or places. The term describes situations where multiple factors, including both environmental and socio-economic stressors, may act cumulatively to impact health and the environment and contribute to persistent environmental health disparities. These situations may apply to communities with environmental justice concerns.*

EPA's proposed inclusion of "overburdened communities" within the subpopulations definition is plainly outside the scope and purpose of this provision under TSCA, which is necessarily tied to *the specific chemical* under consideration in the risk evaluation. This intent is evident from the plain language of the statutory definition of "potentially exposed or susceptible subpopulation," which requires that the "greater risk" of a subpopulation be presented "from exposure to a chemical substance or mixture."[103]

The conflict between EPA's proposed definition and the intent of Congress is also made clear through the legislative history of TSCA. When the amendments relating to subpopulations were initially introduced in 2015 and under consideration by the House Committee on Energy and Commerce, the proposed statutory definition did not include any of the example

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99 *See* 88 Fed. Reg. at 74320.

100 *See* 88 Fed. Reg. at 74306.

101 *Id.*

102 *Id.*

103 15 U.S.C. § 2602(12).

subpopulations that were ultimately incorporated into the adopted legislation.[104] As underscored in its favorable Report on the amendments, "it is the Committee's intention that the Administrator be clear about who is being identified and the basis for such a decision when invoking provisions involving subpopulations."[105]

To confirm this intent and to provide additional guidance on the types of subpopulations that Congress intended for EPA to consider, infants, children, pregnant women, workers, and the elderly were subsequently incorporated into the statutory text as specific examples of potentially exposed or susceptible subpopulations.[106] The choice to insert these examples in the statutory definition demonstrates that Congress did not intend to provide EPA with discretion to consider any potential subpopulation that could be grouped according to any set of criteria unrelated to chemical risk. Rather, Congress intended for distinct and easily identifiable subpopulations to be considered on the basis of greater risk of exposure to the chemical being evaluated.

The expansive list of factors that EPA has proposed to consider in identifying "overburdened communities" is unworkable and involves subject matter far outside the scope of EPA's expertise and unrelated to chemical risk under TSCA. EPA is unqualified and unauthorized to evaluate all of the social and economic stressors that impact communities throughout the United States and has provided no explanation of the criteria it will use to identify these stressors. The Agency has also provided no explanation of how these factors would be incorporated into the risk evaluation process, *i.e.*, how (and how much) weight may be afforded to these non-chemical factors in the context of a chemical risk evaluation for a particular substance.

Moreover, the vague and expansive scope of these new, non-chemical factors that the Agency intends to consider when identifying potentially exposed or susceptible subpopulations will only exacerbate EPA's inability to meet its statutory deadlines.

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[104] Early versions of the 2016 TSCA amendments defined "potentially exposed subpopulation" as "a group of individuals within the general population who, due to either greater susceptibility or greater potential exposure, are likely to be at greater risk than the general population of adverse health effects from exposure to a chemical substance" and did not include the examples of infants, children, pregnant women, workers, or the elderly.

[105] *See* HR 114-176 (June 23, 2015), at 22.

[106] U.S. Senate Congressional Record, 162 Cong. Rec. S3511-01, at *S3513 (including a statement from Senator Udall that "[v]ery soon, it will be enshrined in the law that the EPA must protect the most vulnerable people - pregnant women, infants, the elderly, and chemical workers.").

VII. The Proposed Rule would erode the scientific standards that are central to meaningful implementation of TSCA.

A. The Proposed Rule would revoke key scientific definitions without providing adequate justification for doing so, particularly in light of the central role the underlying terms play in the Agency's functions under TSCA.

The proposed rule would eliminate key definitions that were adopted as part of the 2017 final rule, including "best available science" and "weight of scientific evidence."

TSCA Section 26(h) requires that "in carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner ***consistent with the best available science***" and that such decisions must be "based on the ***weight of the scientific evidence***."[107]

The 2017 final rule adopted a detailed definition of "best available science" that listed factors EPA would consider in its scientific decision-making, including peer review, relevance, clarity and completeness of data, and uncertainty/variability in the data, among other criteria.[108] The 2017 Final Rule further defined "weight of scientific evidence" as "a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." [109]

In proposing to eliminate these definitions, EPA makes broad, conclusory statements that defining these terms is "unnecessary and inhibits the Agency's flexibility to quickly adapt to and implement changing science."[110] However, the Agency provides no *explanation* of *how* the specific language in EPA's current definitions would hinder the Agency's flexibility or prevent the Agency from adapting to evolving scientific developments. Rather, the elimination of these definitions could facilitate EPA minimizing or ignoring scientific information that the Agency may deem inconvenient. EPA also fails to address how the recission of these definitions would disrupt industry and the public's reliance on these definitions for the past 7 years and cast significant uncertainty on the information that EPA considers relevant to the risk evaluation process.

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[107] 15 U.S.C. § 2625(h) ("Scientific standards") (emphasis added).

[108] 82 Fed. Reg. at 33748. This definition stems in part from the definition adopted under the Safe Drinking Water Act (SDWA), 42 U.S.C. 300f *et seq.*

[109] *Id.*

[110] 88 Fed. Reg. at 74295.

EPA should maintain the regulatory definitions for "best available science" and "weight of scientific evidence," which provide needed clarity regarding scientific information that is central to the risk evaluation process.

B. The Proposed Rule would reduce the requirements for peer review, inconsistent with TSCA's scientific standards.

TSCA Section 6(h) requires that, when EPA makes a decision based on science during the risk evaluation, it must do so in a manner consistent with the best available science and in consideration of "the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models."[111] This provision was not originally included in TSCA, but was added as part of the 2016 TSCA Amendments. Thus, Congress found it critical to specifically reference peer review as an important factor in the risk evaluation process.

The current regulations make unequivocally clear that all risk evaluations conducted pursuant to TSCA section 6 will be peer reviewed.[112] EPA now proposes to abandon that commitment in an effort "to conserve Agency resources and avoid redundant peer review."[113] Specifically, under the revised provision, "EPA *expects* that peer review activities on risk evaluations […] *or portions thereof*, will be consistent with peer review policies […]."[114] The Proposed Rule would effectively remove any mandate for peer review from the regulations. EPA claims that this change will allow EPA to focus peer review efforts "on only portions or sections that constitute unreviewed influential information."[115] However, the language in the Proposed Rule would more likely permit the Agency to avoid peer review of the final risk evaluation based on an assertion that the underlying methods and procedures have already been peer reviewed.

EPA's Peer Review Handbook defines "peer review" as "a documented process for enhancing a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis."[116] EPA's Peer Review Handbook further defines "scientific and technical work product" as scientific information that is "used to support a research agenda, regulatory program, policy position, or other EPA position or

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111 15 U.S.C. § 2605(h).

112 82 Fed. Reg. at 33752 ("Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).")

113 88 Fed. Reg. at 74308.

114 *Id*. at 74233 (emphasis added).

115 *Id.* at 74308.

116 U.S. EPA. Peer Review Handbook (4th Edition). EPA/100/B–15/001. Science and Technology Policy Council. (Oct. 2015), at 20.

action."[117] Such work product includes "***risk assessments***, technical studies and guidance, analytical methods, scientific database designs, technical models, technical protocols, statistical surveys/studies, technical background materials, technical guidance (except for guidance providing policy decisions), research plans and research strategies."[118] Thus, EPA's Peer Review Handbook considers that peer review not only involves an analysis of underlying methods and procedures, but also the actual risk assessment.

According to EPA, the new language in the Proposed Rule "add[s] clarity around what will be peer reviewed."[119] Not only is this language anything but clear, but it appears to be a veiled attempt by EPA to shorten the timeline for finalizing risk evaluations at the expense of peer review and fully meeting the scientific standards of best available science and weight of scientific evidence.

EPA should maintain the current language in the regulations, which *requires* peer review for risk evaluations, rather than adopting an equivocal provision that only references an expectation of peer review for unspecified portions of a risk evaluation.

VIII. EPA ignores the impact of the Proposed Rule on stakeholder interests created by reliance on the current regulations.

EPA has failed to address the significant disruption to regulated industry's substantial reliance interests engendered by the 2017 final rule, contravening the Supreme Court's holding in *Department of Homeland Security v. Regents of the University of California*.[120] In the Proposed Rule, EPA dismisses with a wave of the hand any notion that chemical manufacturers reasonably relied on and adjusted their conduct accordingly based on the 2017 version of the risk evaluation rule, and that the proposed changes to the regulations will disrupt the considerable efforts made by regulated entities to conform to those requirements. Indeed, EPA makes no effort in the Proposed Rule to either acknowledge those reliance interests or take steps to alleviate any harm to chemical manufacturers due to changed policies, despite the changes to the regulations that will lead to the virtual elimination of MRREs and the preemption benefits afforded to manufacturers under TSCA, discussed in greater detail above.

Since the initial risk evaluation procedural rules were finalized in 2017, the chemical industry, from manufacturers to down-stream users and throughout the supply chain, have relied on those rules. Of particular importance was the process by which EPA determined unreasonable risk. Because risk can only arise from the *particular use* of a chemical, EPA's practice of rendering an unreasonable risk or no unreasonable risk determination for each condition of use within a risk evaluation comported not only with TSCA, but with the science

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117 *Id.* at 40-41.

118 *Id.* at 41.

119 *Id.*

120 *See* 140 S. Ct. 1891 (2020)

underlying risk evaluations. This approach statutorily dovetailed with other key provisions of TSCA, including the MRREs and preemption.

With regard to the MRREs, at least four are still undergoing risk evaluation. Importantly, all four submissions relied upon the current risk evaluation procedural rule, which codifies the condition of use approach to unreasonable risk determinations.[121] The manufacturers who submitted those requests did so with an understanding that EPA had the authority, if scientifically supported, to ultimately determine that one or more of their conditions of use did not present unreasonable risk. It makes no sense, of course, for a manufacturer to voluntarily expend resources compiling and submitting an MRRE if the regulations no longer permitted EPA to make no unreasonable risk determinations for individual COUs, through issuance of an order under TSCA Section 6(i).

But if EPA finalizes the rule as proposed, EPA will have effectively changed the rules of the game and extinguished any possibility of a condition of use-based approach to unreasonable risk determination and thus any possibility that any condition of use would be deemed not to present unreasonable risk. And gone too, would be the ability to rely on TSCA section 18 to preempt state regulations based on a no unreasonable risk determination.

Companies whose chemicals were either the subject of an MRRE or an EPA-initiated risk evaluation also relied on other key aspects of the current risk evaluation procedural regulations, in particular, definitions of best available science and weight of scientific evidence,[122] and the unequivocal assurance that every risk evaluation would undergo peer-review.[123]

Although TSCA requires EPA to ensure that its scientific decisions are grounded in the best available science and weight of the scientific evidence, TSCA does not define either term. EPA, however, defined both terms in its 2017 Final Rule, codified in the current regulations. Stakeholders and peer reviewers alike have relied on those definitions to inform their public comments and peer review comments, respectively, for each of the initial 10 chemicals that underwent risk evaluation. Without those definitions, not only is EPA free to pick and choose which studies it deems fit its view of best available science, but EPA can then "weigh" those studies with equal impunity. And if EPA relegates peer review to only an "expectation," stakeholders will no longer be able to rely on peer review to provide a robust check and balance on risk evaluations.

EPA's cursory dismissal of these reliance interests reads as follows:

> EPA believes that there are either no reliance interests on those past statutory interpretations, or that any such interests are minor. The current rule and proposed changes largely pertain to internal Agency procedures that guide the Agency's risk evaluation activities under TSCA and mostly do not directly impact external

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121 *See* 40 C.F.R. § 702.47.

122 *See* 40 C.F.R. § 702.33.

123 *See id.* at § 702.45.

> parties, with one exception being modified procedural requirements for voluntary requests for risk evaluation submitted by manufacturers. However, to the extent there were any reliance interests on the prior interpretations, or the risk evaluations that were developed based on the previous procedural requirements, nothing in the proposed rule is intended to apply retroactively. EPA does not believe stakeholders have reliance interests pertaining to the process for future, yet-to-be-completed risk evaluations that will be carried out in accordance with this proposed rule.[124]

This is not the only section of the Proposed Rule in which EPA asserts that it does not intend to retroactively impose any of the proposed changes. EPA states in its initial explanation of the applicability of the updated procedures that the Agency "does not expect to apply these procedures retroactively to risk evaluations already completed."[125] Most importantly, the new proposed Section 702.31(c) of the regulations also explicitly states that "[t]hese requirements shall not apply retroactively to risk evaluations already finalized."[126]

None of these statements are true. On June 30, 2021, over 2 years before the Proposed Rule was published, EPA announced that it would (1) change most of the 10 finalized risk evaluations (all of which were issued as final during the previous administration) to expand consideration of exposure pathways (including exposures to so-called "fenceline communities"), (2) abandon the assumption that PPE is always used in occupational settings when making risk determinations for a chemicals, and (3) convert unreasonable risk determination for conditions of use into a single unreasonable risk determination for the whole chemical.[127] Indeed, EPA has already implemented these policy changes in its risk evaluation for 1,4-Dioxane, which was finalized in December 2020, but reopened following EPA's Announcement so the agency could consider additional exposure pathways and conditions of use beyond those included in the "final" risk evaluation.[128]

When EPA issued the Proposed Rule, it was fully aware of its earlier announcement, and the Proposed Rule repeatedly cites to it.[129] We are at a loss to understand how or why the

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[124] 88 Fed. Reg. at 74316.

[125] *Id*. at 74295.

[126] *Id.* at 74320.

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

[128] *See* U.S. EPA, *EPA Releases Meeting Minutes and Final Report from Science Advisory Committee on Chemicals 1,4-Dioxane Review* (released Nov. 17, 2023), *available at* https://www.epa.gov/chemicals-under-tsca/epa-releases-meeting-minutes-and-final-report-science-advisory-committee.

[129] *See* 88 Fed. Reg. at 74294.

Proposed Rule is riddled with inaccurate statements, and we question how the Proposed Rule can possibly comport with the Administrative Procedure Act's requirement for EPA to provide a meaningful opportunity to comment, if EPA has already implemented several of the "proposed" procedural changes.[130]

IX. Conclusion

The Proposed Rule represents a sharp departure from the Agency's prior policies that have defined existing chemical risk evaluations since the adoption of the 2016 TSCA Amendments. The Proposed Rule lacks a reasoned explanation for such drastic changes, and suffers from glaring deficiencies in EPA's analysis of the plain language and structure of TSCA, of Congressional intent in adopting the statute, and of how the factual underpinnings of the prior policies can be squared with the new approaches espoused in the Proposed Rule. These deficiencies run afoul of settled principles of statutory interpretation and administrative law. EPA's proposal and the inadequate explanation provided will admittedly lead to significant, unlawful delays, as well as widespread confusion regarding the presence of unreasonable risk. The proposal's turn away from peer-reviewed science will only compound matters. The result will be a renewed crisis of confidence in chemical risk evaluations, the very problem that led Congress to amend TSCA in the first place. Accordingly, EPA should abandon the policy changes discussed in these comments, and recommit itself to the path charted by Congress and the 2017 Rule by retaining the commonsense approaches included in the existing regulations pertaining to chemical risk evaluations under TSCA Section 6.

/s/ Marc Marie

President

Center for Environmental Accountability

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130 *See, e.g., Shands Jacksonville Med. Ctr., Inc. v. Azar*, 366 F. Supp. 3d 32, 58 (D.D.C. 2018), aff'd, 959 F.3d 1113 (D.C. Cir. 2020) (holding that courts must assess whether the agency acted in "observance" of the procedures "required by law" pursuant to 5 U.S.C. § 706(2)(D), "including by providing a meaningful opportunity for interested parties to submit comments").