**ORAL ARGUMENT NOT YET SCHEDULED**

No. 24-1151 (consolidated with Nos. 24-1182, 24-1185, 24-1202, & 24-1237)

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS INTERNATIONAL UNION, AFL-CIO, *et al.*,
*Petitioners*,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
*Respondent*.

**On Petitions for Review of Final Agency Action of the United States Environmental Protection Agency 89 Fed. Reg. 37,028 (May 3, 2024)**

# BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS AND VACATUR

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## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with D.C. Circuit Rule 28(a)(1), *amici curiae* state as follows:

### A. Parties, Intervenors, and *Amici Curiae*

These cases involve the following parties:

**Petitioners:**

No. 24-1151: United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO.

No. 24-1182: International Association of Machinists and Aerospace Workers, AFL-CIO.

No. 24-1185: Texas Chemistry Council and American Chemistry Council.

No. 24-1202: Worksafe, Inc.

No. 24-1237: American Fuel & Petrochemical Manufacturers and American Petroleum Institute.

**Respondents:**

Respondents are the U.S. Environmental Protection Agency and Michael S. Regan, Administrator, U.S. Environmental Protection Agency (in No. 24-1185), and the U.S. Environmental Protection Agency (in Nos. 24-1151, 24-1182, 24-1202, 24-1237).

**Intervenors and *Amici Curiae*:**

Olin Corporation is Intervenor for Petitioner in No. 24-1151. Alaska Community Action on Toxics and Sierra Club are Intervenors for Respondent in No. 24-1151. *Amici curiae* are the Chamber of Commerce of the United States of America and the National Association of Manufacturers.

## B. Rulings Under Review

These consolidated cases involve final agency action of the U.S. Environmental Protection Agency titled "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)," published at 89 Fed. Reg. 37,028 (May 3, 2024).

## C. Related Cases

Five consolidated cases (Nos. 24-1151, 24-1182, 24-1185, 24-1202, 24-1237) seek review of the agency action challenged here. *Amici curiae* are unaware of any other related cases.

## CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America ("Chamber") states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

The National Association of Manufacturers ("NAM") is a non-profit, tax-exempt organization incorporated in New York. The NAM has no parent corporation, and no publicly held company has 10% or greater ownership in the NAM.

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## GLOSSARY OF TERMS

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| 2016 Amendments | Frank R. Lautenberg Chemical Safety for the 21st Century Act, P.L. No. 114-182, 130 Stat. 448, 449 (June 22, 2016) |
| APA | Administrative Procedure Act |
| Chamber | The Chamber of Commerce of the United States of America |
| CPSC | Consumer Product Safety Commission |
| EPA (or Agency) | United States Environmental Protection Agency |
| NAM | The National Association of Manufacturers |
| OSHA | Occupational Health and Safety Administration |
| PPE | Personal protective equipment |
| Rule | Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), published at 89 Fed. Reg. 37,028 (May 3, 2024) |
| TCEP | Tris(2-chloroethyl) phosphate |
| TSCA | Toxic Substances Control Act |

## INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the business community.

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs nearly 13 million men and women, contributes $2.91 trillion to the United States economy annually, has the largest economic impact of any major sector, and accounts for over half of private sector research and development in the nation. The NAM is the voice for the manufacturing community and the leading advocate for a

[1] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. *Amici* have filed an unopposed motion for leave to file this brief.

policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

*Amici* are well-positioned to aid this Court's review of the rule at issue in this case,[2] which is foundational to the Toxic Substances Control Act ("TSCA") regulatory program. Many of *amici*'s members operate in various sectors that are directly or indirectly affected by TSCA, a statute that applies to the manufacture, processing, distribution, or use of regulated substances and whose reach, in recent years, has been extended to substances in some finished articles. Sectors that will be adversely affected by the Rule include not only chemicals, but coatings, refining, petrochemicals, petroleum, forestry, wood products, batteries, electronics, energy, electricity, and defense, among many others. The Rule thus will have major impacts on the U.S. business community.

## INTRODUCTION

Under TSCA, EPA possesses limited authority to regulate certain chemical substances. 15 U.S.C. § 2601. Section 6 of TSCA, as last amended in 2016,[3] sets forth a two-step process by which EPA evaluates and regulates chemicals under their

[2] "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)," published at 89 Fed. Reg. 37,028 (May 3, 2024) ("Rule").

[3] *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, P.L. No. 114-182, 130 Stat. 448, 449 (June 22, 2016) (the "2016 Amendments").

conditions of use. 15 U.S.C. § 2605. The first step is risk evaluation, and the second is risk management. Whether or not EPA has the power to regulate a chemical turns on a critical standard: whether the use of the chemical presents "unreasonable risk of injury to health or the environment." 15 U.S.C. § 2601(b). If EPA finds that a chemical's use poses an unreasonable risk, it then can issue risk-management rules to eliminate that risk. But if EPA finds no unreasonable risk from a chemical's use, its inquiry should be at an end and no risk management should be necessary.

The Rule challenged here sets forth new procedures that significantly change how EPA evaluates and regulates chemicals and that expand EPA's purported authority to determine and manage the risk associated with chemical use. These procedures are inconsistent with TSCA's text, are contrary to the best available science, and would create a system in which EPA would be required to conduct overly broad, duplicative, and complex chemical risk evaluations that cannot be completed within statutory deadlines. The Rule does not reflect TSCA's "single, best meaning." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024).

Although the problems with the Rule are numerous, *amici* focus on three regulatory changes in particular, which are of widespread importance for businesses operating in all aspects of the interrelated systems of manufacture, processing, distribution, and use of the many substances subject to regulation under TSCA.

*First*, in a reversal of EPA's previous practice and interpretation of TSCA, the Rule provides that EPA "will not exclude conditions of use from the scope of the risk evaluation." 40 C.F.R. § 702.37(a)(4). "Conditions of use" are the specific circumstances in which a chemical may be used. For example, a solvent's conditions of use would include its manufacture in an industrial facility, its processing by a manufacturer of adhesives, its use in an industrial manufacturing facility, its use by a consumer to remove wallpaper, and its disposal by a small commercial business.

EPA claims that it "lacks authority to exclude conditions of use from the scope of the risk evaluation." 89 Fed. Reg. at 37,031. Yet the best interpretation of TSCA is that EPA has discretion to exclude some conditions of use from the scope of a risk evaluation. EPA's contrary reading ignores the statutory text, in which Congress directed EPA to exercise discretion in prioritizing for risk evaluation those conditions of use "determined by the Administrator." 15 U.S.C. § 2602(4). Nor is EPA's interpretation practical. Refusing to exclude *any* conditions of use from the risk-evaluation process—even if the presence of the chemical is de minimis or only as an impurity, and even if another EPA statutory program is sufficient to evaluate the risk—would waste the Agency's resources at a time when it is already behind in conducting required risk evaluations and faces a backlog of thousands of chemicals.

*Second*, the Rule misreads TSCA to require EPA to "make a single determination as to whether [a] chemical substance"—as a whole, not with respect

to particular uses—"presents unreasonable risk." 40 C.F.R. § 702.37(f)(1). Under EPA's interpretation, that single determination would potentially subject all uses of the chemical to regulation under TSCA, even if all but one of the chemical's uses pose no risk whatsoever. That reading runs contrary to TSCA's risk-determination provision, 15 U.S.C. § 2605(b)(4)(A), among others, which is directed at a chemical's "conditions of use." EPA's whole-chemical approach also dramatically reduces the likelihood that it will find any chemical that does not present an unreasonable risk of injury to human health or the environment. The Rule also is incompatible with other TSCA provisions, which, by design, contemplate a use-by-use approach to risk evaluation.

*Third*, the Rule is unlawful because it instructs EPA "*not* [to] consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination." 40 C.F.R. § 702.37(f)(2) (emphasis added). This directive runs contrary to real-world data and Occupational Health and Safety Administration ("OSHA") standards dictating workers' use of personal protective equipment ("PPE"). The Rule thus *requires* risk evaluations by EPA that do not take into account reasonably available information and are contrary to the best available science.

The Rule is arbitrary and capricious, is unsupported by substantial evidence, and will result in inappropriate determinations of unreasonable risk for certain chemicals. The Court should vacate the Rule and remand it to the Agency.

## ARGUMENT

Reviewing the Rule "in accordance with" the Administrative Procedure Act ("APA"), 15 U.S.C. § 2618(c), this Court must "independently interpret the statute and effectuate the will of Congress subject to constitutional limits," *Loper Bright Enters.*, 144 S. Ct. at 2263. This Court cannot uphold EPA's interpretation of TSCA unless, after "applying all relevant interpretive tools," it determines that the Rule reflects the "single, best meaning" of the statute. *Id.* at 2266.

The APA requires courts to "set aside agency action[s]" that are, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). But TSCA imposes another standard that is even "more searching" than the APA's arbitrary-and-capricious standard and is "particularly demanding" for the agency to meet. *Chem. Mfrs. Ass'n v. EPA*, 859 F.2d 977, 992 (D.C. Cir. 1988) (internal quotations omitted). A court must "hold unlawful and set aside [a] rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i).

In each respect below, the Rule fails both standards.

## I. The Rule is arbitrary and capricious, and is not supported by substantial evidence, because it reads out of TSCA EPA's discretion to exclude certain of a chemical substance's conditions of use from risk evaluation.

### A. TSCA section 6 provides EPA discretion to exclude some conditions of use from risk evaluation.

In its July 2017 procedural rule for conducting TSCA risk evaluations, EPA confirmed its "discretion to determine the conditions of use that the Agency will address in its evaluation of [a] priority chemical, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk." 82 Fed. Reg. 33,439, 33,728 (July 20, 2017). EPA now "believes" the opposite—"that the better reading of TSCA's statutory text and structure is that EPA lacks authority to exclude conditions of use from the scope of the risk evaluation." 89 Fed. Reg. at 37,031; *see also* 40 C.F.R. § 702.37(a)(4) (codifying EPA's decision "not [to] exclude conditions of use from the scope of risk evaluation"). EPA's new approach is mistaken.

Under TSCA, EPA must conduct "risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Thus, EPA must evaluate a chemical's risk in terms of a particular condition of use, and not in the abstract. But that does not mean that EPA lacks discretion to decide the scope of uses a risk evaluation will address. Rather, the statutory definition and usage of the phrase "conditions of use" reflects that Congress accorded some

discretion to EPA, in evaluating a chemical's risk, to focus on certain conditions of a chemical's use, such as those posing a higher risk. "The term 'conditions of use' means 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." 15 U.S.C. § 2602(4) (emphasis added).

Reading these provisions "in their context and with a view to their place in the overall statutory scheme," *Util. Air Regul. Grp. v. E.P.A.*, 573 U.S. 302, 320 (2014), shows Congress's intention that EPA exercise discretion to determine 1) whether a particular circumstance qualifies as a condition of use and 2) whether it warrants consideration in the evaluation of the chemical's risk. That is, as EPA previously recognized, "EPA may, on a case-by-case basis, *exclude* certain activities . . . in order to focus its analytical efforts on those exposures that are likely to present the greatest concern." 82 Fed. Reg. at 33,729 (emphasis added).

EPA now reads § 2605(b)(4)(A) differently, positing that "consideration of *all* conditions of use in TSCA risk evaluations is . . . necessary." 89 Fed. Reg. at 37,032 (emphasis added). "A sufficient answer to this argument is that Congress did not use the words on which [EPA] relies." *Columbia Nat. Bank of Wash. v. D.C.*, 195 F.2d 942, 943 (D.C. Cir. 1952). TSCA does not require EPA to evaluate "all" conditions of use, despite repeatedly using that qualifier elsewhere in section 6.

"[W]hen Congress includes particular language in one section of a statute but omits it in another," courts "presume that Congress intended a difference in meaning." *Loughrin v. United States*, 573 U.S. 351, 358 (2014); *see also Pub. Citizen, Inc. v. Rubber Mfrs. Ass'n*, 533 F.3d 810, 816–17 (D.C. Cir. 2008) (declining to "add[] words that are not in the statute that the legislature enacted").

EPA's construction also is impermissible because it reads TSCA's scoping provision out of the statute. That provision requires EPA to "publish the scope of the risk evaluation to be conducted, including the . . . conditions of use" that EPA "expects to consider." 15 U.S.C. § 2605(b)(4)(D). This language necessarily implies that EPA has discretion to exclude some conditions of use from a risk evaluation, necessitating an announcement of the conditions of use that EPA *will* include. EPA's new interpretation renders this provision superfluous, by requiring EPA to consider *all* conditions of use (and thereby negating the need to specify which). EPA's construction of TSCA violates the "cardinal principle of statutory construction" of construing a statute so that "no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001).

The Rule fails to "give effect to all [TSCA's] provisions" and ensure that "no part will be inoperative or superfluous," *Genus Med. Techs. LLC v. U.S. Food & Drug Admin.*, 994 F.3d 631, 638 (D.C. Cir. 2021), and it should be vacated.

### B. Eliminating EPA's authority to exclude certain conditions of use from a risk evaluation is contrary to EPA's obligations under section 9 and TSCA's gap-filling purpose.

EPA's interpretation is also belied by the gap-filling nature of TSCA. While TSCA was "designed to fill a number of regulatory gaps," *Safer Chems., Healthy Fams. v. U.S. Envtl. Prot. Agency*, 943 F.3d 397, 406 (9th Cir. 2019) (internal quotation omitted), it also was anticipated that regulation under "other authorities," such as the Occupational Safety and Health Act, would "in many cases be sufficient to adequately protect health and the environment," S. Rep. No. 94-698 at 1–2 (1976).

Consistent with TSCA's gap-filling purpose, Congress inserted a requirement that EPA defer to other programs within EPA that have already evaluated, or have appropriate expertise to evaluate, a specific condition of use. In particular, section 9 requires EPA to "coordinate [its] actions"—including risk evaluations—with actions taken under other federal laws administered by EPA. 15 U.S.C. § 2608(b)(1). Thus, EPA must limit the scope of risk evaluations, under certain circumstances, to exclude conditions of use that can be addressed under other laws. TSCA requires robust coordination with other agencies and EPA's other programs to fulfill TSCA's goal of "imposing the least burdens of duplicative requirements on those subject to the chapter." *Id.* § 2608(d).

Until now, that is how EPA has operated. For example, in the risk evaluation for 1,4-dioxane, EPA determined that "exposures to the general population via

drinking water, ambient air and sediment pathways fall under the jurisdiction of other environmental statutes administered by EPA," including the Clean Air Act and the Safe Drinking Water Act.[4] Accordingly, EPA "tailored the scope of [its] risk evaluation" and "did not evaluate hazards or exposures to the general population from ambient air, drinking water, and sediment pathways." *Id.*

EPA's current reading of the statute forges a different and unlawful path. By ignoring EPA's section 9 obligation, the Rule fails to "give effect to all [TSCA's] provisions." *Genus Med. Techs. LLC*, 994 F.3d at 638.

### C. Requiring consideration of all conditions of use in a risk evaluation is impractical and will only extend the existing delays in completing risk evaluations.

EPA's construction of TSCA is also unrealistic, given EPA's inability to satisfy the statutory deadline for completing risk evaluations even before EPA imposed the new requirement to consider *all* conditions of a chemical's use in the process. That mandate sweeps in not only conditions that are or can be regulated under other EPA authorities, but also uses where the presence of the chemical is de minimis or the chemical presents only as an impurity. *See* 89 Fed. Reg. at 37,035. Assessing every condition of use, however insignificant, will waste the Agency's resources and further hinder its progress in evaluating chemical substances.

[4] EPA Final Risk Evaluation for 1,4-Dioxane at 34 (Dec. 2020), https://nepis.epa.gov/Exe/ZyPDF.cgi/P1010RWQ.PDF?Dockey=P1010RWQ.PDF.

TSCA requires that EPA "complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates the risk evaluation." 15 U.S.C. § 2605(b)(4)(G). The Rule pays lip service to EPA's obligation of "completing its actions within statutory deadlines." 89 Fed. Reg. at 37,032. But EPA itself previously questioned its ability "to meet the statutory risk evaluation deadlines if all intended known and reasonably foreseen activities must be considered conditions of use." 82 Fed. Reg. at 33,728. After struggling to complete the initial 10 risk evaluations within the statutory timeframe, EPA adopts this change at a time when it remains *years* behind in evaluating the first "20 high-priority substances" required by the 2016 Amendments. 15 U.S.C. § 2605(b)(2). EPA has released a final risk evaluation for only *one* priority substance, Tris(2-chloroethyl) phosphate ("TCEP"), which was completed only last month—long past EPA's three-year deadline. And that is despite TCEP's having just 21 conditions of use, far fewer than other chemicals on the list.

Thus, the Rule is not just incorrect, it is wasteful and will result in further delaying EPA's completion of risk evaluations. The Rule will produce "absurd results," and its interpretation should "be avoided" because a better "alternative interpretation[] consistent with the legislative purpose [of TSCA is] available." *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982).

## II. TSCA requires EPA to make individual risk determinations for a chemical's particular conditions of use, not a single risk determination for the chemical as a whole.

The Rule violates TSCA in a second major respect. The Rule now requires that EPA make a single risk determination for a chemical substance, rather than for each individual use of a chemical. *See* 40 C.F.R. § 702.37(f)(1). Despite taking the opposite tack in the 2017 rule, *see* 82 Fed. Reg. at 33,744, EPA claims its new approach is compelled by TSCA, *see* 89 Fed. Reg. at 37,035.[5]

EPA is wrong. The best meaning of the statute is that EPA must make risk determinations for a chemical substance's individual conditions of use, rather than a single risk determination for the "whole chemical." The Rule is arbitrary and capricious, is not supported by substantial evidence, and should be vacated.

### A. The chemical regulation process under section 6 of TSCA contemplates risk determinations for individual conditions of use.

EPA's whole-chemical approach is incompatible not only with TSCA's plain language, as shown below, but with TSCA's structural emphasis on individual "conditions of use."

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[5] EPA unveiled this change in position in a 2021 statement, which was not preceded by any notice-and-comment process. *See* Press Release: EPA Announces Path Forward for TSCA Risk Evaluations (June 30, 2021) ("announc[ing] important policy changes surrounding [TSCA] risk evaluations"), https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

When Congress significantly amended TSCA in 2016, it embedded the phrase "conditions of use" throughout the statute to emphasize that the regulation of chemical substances is to be accomplished on a use-by-use basis. *See, e.g.*, 130 Stat. at 449 (inserting "conditions of use" in 15 U.S.C. § 2602, TSCA's "Definitions"). Notably, the 2016 Amendments injected the "conditions of use" concept at each step of the process for evaluating and regulating chemicals, with that new phrase appearing 30 individual times.

- *First*, EPA must identify chemicals for prioritization, taking into account "the conditions of use or significant changes in the conditions of use of the chemical substance." *Id.* § 2605(b)(1).
- *Second*, EPA must designate a substance as "high-priority" based on "a potential hazard and a potential route of exposure under the conditions of use." *Id.* § 2605(b)(1)(B)(i).
- *Third*, EPA must determine the scope of the risk evaluation to be conducted, "including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations." *Id.* § 2605(b)(4)(D).
- *Fourth*, EPA must "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or environment . . . under the conditions of use." *Id.* § 2605(b)(4)(A).
- *Fifth*, EPA must make risk determinations based on whether the individual conditions of use present unreasonable risk. *Id.* § 2605(b)(4)(F).
- *Finally*, if EPA makes a finding of unreasonable risk, TSCA section 6(a) requires EPA to regulate a chemical substance's conditions of use "to the extent necessary" so that the use "no longer presents" an unreasonable risk. *Id.* § 2605(a).

At each step, EPA is to focus on the particular circumstances under which a chemical substance may be manufactured or used.

EPA's single-risk-determination approach conflicts with TSCA's text and structure. Congress expressly provided that risk evaluations and risk determinations turn on the conditions of use: "The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." *Id.* § 2605(b)(4)(A). The critical import of the concluding language "under the conditions of use" is unmistakable: that phrase modifies what precedes it. It does violence to the statute to strip "chemical substance" from its context, as if EPA could evaluate the substance's risk in isolation—it cannot. A risk evaluation is impossible without examining a particular condition of the chemical's use. *Id.* § 2605(b)(4)(F).

EPA claims it will comply with section 6(b)(4) by "consider[ing] exposures associated with each condition of use." 89 Fed. Reg. at 37,035. But even if that language could be read to require multiple risk *evaluations* but only one risk *determination*, EPA's reading cannot be the best because, as discussed above, requiring evaluation of every condition's risk is inconsistent with the discretion the Administrator must exercise under TSCA. And, as shown below, a whole-chemical risk determination also is inconsistent with the rest of TSCA. *See Territory of Guam*

*v. United States*, 593 U.S. 310, 316 (2021) ("Statutes must be read as a whole[.]") (cleaned up).

Read as a whole, section 6 reflects TSCA's instruction that EPA make use-specific risk determinations, so that conditions of use found to pose no risk do not proceed to the risk-management stage. It provides that a no-unreasonable-risk finding by EPA is final agency action subject to judicial review upon issuance. 15 U.S.C. § 2605(i)(1). That provision thus gives an off-ramp, pursuant to which specific conditions of use that EPA determines to be safe can avoid unnecessary regulation. But that off-ramp is accessible only if EPA has made a no-unreasonable-risk determination "under subsection (b)(4)(A)," which asks "whether a chemical substance presents an unreasonable risk . . . *under the conditions of use*." *Id.* § 2605(b)(4)(A) (emphasis added).

Congress's use of the word "whether" in § 2605(b)(4)(A) shows that it intended that EPA would make *both* unreasonable-risk and no-unreasonable risk determinations. EPA's whole-chemical approach disregards that important feature of the statutory scheme. If EPA makes a single risk determination for a chemical, covering all conditions of use, it is unlikely ever to make a no-unreasonable-risk finding. That is because EPA is unlikely to prioritize a chemical for risk evaluation unless at least one condition of use poses unreasonable risk. And the Rule states that "[w]here one or more conditions of use for the chemical present an unreasonable

risk, the chemical substance itself necessarily presents an unreasonable risk." 89 Fed. Reg. at 37,035. That is so whether the chemical's other conditions of use number 10 or 1000, and even if those other uses present no risk. Thus, EPA's reading effectively nullifies Congress's choice to provide an off-ramp from regulation for conditions of use that do *not* present unreasonable risk.

EPA claims that, in making a single unreasonable-risk determination for the entire chemical, nonetheless it "will identify the conditions of use that significantly contribute to such determination." 40 C.F.R. § 702.39(f)(3). But EPA itself admits this is "not necessarily a perfect indicator of how EPA will ultimately regulate to address unreasonable risk." 89 Fed. Reg. at 37,035. EPA's interpretation also lacks any statutory basis. TSCA makes no provision for identifying which conditions of use "significantly contribute" to unreasonable risk. Nor does it define what it means for a condition of use to "significantly contribute" to unreasonable risk. The only similar language in section 6 relates to an exemption for replacement parts for complex durable goods and complex consumer goods, *see* 15 U.S.C. § 2605(c)(2)(D)(i); its use in that context, but not in the risk-evaluations context, underscores the lack of support for EPA's reading. *See Loughrin*, 573 U.S. at 358.

### B. Other sections of TSCA further demonstrate that risk determinations are to be made on a use-by-use basis.

The Rule also undermines the intended operation and interplay of multiple provisions of TSCA.

*First*, EPA's approach would nullify the consultation provisions of TSCA section 9. That section provides that, if EPA determines that a substance presents an unreasonable risk under the conditions of use, and that risk can be prevented or sufficiently reduced by another federal agency's action under a different law, EPA must submit a report to that other federal agency requesting action. 15 U.S.C. § 2608(a)(1). This system avoids imposing "burdens of duplicative requirements on those subject to the chapter." *Id.* § 2608(d).

A single-risk-determination approach would undercut EPA's obligation under this section. EPA's approach assumes that it has singular authority to address *all* uses of a chemical, and so it need not consult with other federal agencies. But that ignores the reality that other agencies—to which EPA must defer under § 2608(a)(1)—manage particular uses of chemicals in certain settings, such as OSHA in the workplace and the Consumer Product Safety Commission ("CPSC") in the area of consumer products. Thus, if a chemical's condition of use involves worker exposures at a private manufacturing facility, for instance, EPA should look to OSHA to mitigate those risks, to avoid duplicative regulation. But under EPA's new, mistaken construction of TSCA, if EPA makes a risk determination for an entire chemical, it might never defer to OSHA, the CPSC, or any other federal agency, because no other agency regulates chemicals in all their applications.

*Second*, as noted above, EPA's whole-chemical approach virtually eliminates the possibility that EPA will ever make "a determination . . . that a chemical substance does not present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(i)(1). EPA's approach thus obviates any meaningful role for TSCA's judicial-review provision, 15 U.S.C. § 2618, which provides for review of no-unreasonable-risk orders issued under § 2605(i)(1). That provision would become effectively superfluous under EPA's interpretation.

*Third*, EPA's approach also would eliminate opportunities for preemption in TSCA section 18, which Congress enacted to promote a uniform national chemicals policy. In the 2016 Amendments, Congress sought to curtail state regulations of chemical substances by providing that EPA's regulatory decisions preempt state actions. Congress provided for preemption where EPA has made a no-unreasonable-risk determination, *id.* § 2617(a)(1)(B)(i), or where EPA has made an unreasonable-risk determination and promulgated a risk-management rule, *id.* § 2617(a)(1)(B)(ii). Subsection (c) explains that preemption "shall apply only to . . . the hazards, exposures, risks, and uses or *conditions of use of [the] chemical substance[]* included in any final action the Administrator takes pursuant to section 6(a) or section 6(i)(1)." *Id.* § 2617(c) (emphasis added). Thus, only state actions targeting specific conditions of use are preempted. If EPA's single-risk-determination approach were correct, there would be no specific conditions of use that receive the

benefit of preemption. Nor would as many chemical substances be eligible for preemption, given the unlikelihood of unreasonable-risk-determinations. Thus, the Rule will significantly limit the benefits of preemption that Congress provided.

*Finally*, EPA's approach also nearly eliminates the opportunity for risk evaluations requested by manufacturers under 15 U.S.C. § 2605(b)(4)(C)(ii). In deciding whether to grant a manufacturer's request for a risk evaluation, EPA "shall give preference to requests for risk evaluations on chemical substances 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." *Id.* § 2605(b)(4)(E)(iii). And because states typically evaluate substances as they are used in particular products or scenarios,[6] Congress contemplated that EPA will consider a manufacturer's request when there is a state law or regulation that responds to the same chemical under the same conditions of use. Given EPA's single-risk-determination approach, manufacturers will be exceedingly unlikely to submit a risk-evaluation request, because they will not obtain the benefit of state-law-preemption for specific conditions of use.

[6] *See, e.g.*, Conn. Gen. Stat. § 21a-12d (2023) (prohibiting manufacture or sale of "children's jewelry that contains cadmium at more than .0075 per cent by weight").

## III. EPA's decision to no longer assume use of personal protective equipment is arbitrary and capricious and is not supported by substantial evidence.

The Rule explains that EPA will no longer assume that workers are provided and use PPE in a manner that achieves respiratory protection. 89 Fed. Reg. at 37,055. EPA believes that assuming use of PPE could underestimate risk because workers may not be covered by relevant OSHA standards, their employers may be out of compliance, or their PPE may not fit or function properly. *Id.* It is arbitrary and capricious, and not supported by substantial evidence, for EPA to ignore existing legal requirements and industry practices that reduce worker exposures through PPE.

Section 26 of TSCA requires EPA to make risk determinations based on the "best available science" and the "weight of scientific evidence." 15 U.S.C. § 2625(h). And EPA must consider "reasonably available information" when carrying out TSCA sections 4, 5, and 6. *See* 15 U.S.C. § 2625(k). EPA's assumption that employers do not provide exposed employees with appropriate workplace protection or implement workplace controls is contrary to "reasonably available information" because it conflicts with known practice.

But EPA likewise fails those standards when it ignores real-world data demonstrating PPE's impact and the important role of OSHA standards in reducing exposures. OSHA has long regulated the workplace and has detailed requirements for PPE's use (including head, foot, eye, face, and respiratory protection). 29 C.F.R. § 1910 Subpart I. OSHA has a step-by-step process by which employers are

required to assess employee exposures, determine the appropriate PPE, test PPE to ensure efficacy, and medically evaluate employees. 29 C.F.R. § 1910 Subpart I. OSHA can and does enforce these requirements. 29 U.S.C. § 654(a)(1). EPA provides no evidence that OSHA standards are not followed, despite suggesting widespread violations.

Given that PPE is designed to, and does, mitigate risk, ignoring its use will result in EPA's overestimating risk—and potentially lead to unsupported unreasonable-risk determinations—in nearly every case involving worker exposures. Accordingly, EPA will be overregulating conditions of use where the risk is already mitigated by PPE and applicable OSHA standards.

Because its assumptions about the non-use of PPE are arbitrary and capricious and "not supported by substantial evidence," 15 U.S.C. § 2618(c)(1)(B)(i), the Rule should be set aside.

## CONCLUSION

The Petitions should be granted and the Rule vacated.

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Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

The undersigned counsel states that this document complies with Federal Rules of Appellate Procedure 29(a)(5) and this Court's briefing order dated September 9, 2024, because it contains 5103 words, as counted by Microsoft Word, excluding the parts excluded by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1).

This document also complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (6) because it has been prepared in a proportionally spaced typeface in 14-point Times New Roman font.

/s/ *Trevor S. Cox*

**CERTIFICATE OF SERVICE**

I hereby certify that on this 17th day of October 2024, I caused a true and correct copy of the foregoing to be electronically filed with the Clerk of the Court of the United States Court of Appeals for the District of Columbia Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ *Trevor S. Cox*