United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
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September 15, 2026
Lyle W. Cayce
Clerk

No. 24-60227

East Fork Enterprises, Incorporated; Epic Paint Company,

Petitioners,

versus

United States Environmental Protection Agency; Lee Zeldin, *Administrator, United States Environmental Protection Agency*,

Respondents,

CONSOLIDATED WITH

No. 24-60256

East Fork Enterprises, Incorporated; Epic Paint Company; Sierra Club; American Chemistry Council,

Petitioners,

versus

United States Environmental Protection Agency; Lee Zeldin, *Administrator, United States Environmental Protection Agency*,

Respondents.

Appeal from the Environmental Protection Agency
Agency Nos. EPA-HQ-OPPT-2020-0465,
89 Fed. Reg. 39,254

Before HIGGINBOTHAM, JONES, and SOUTHWICK, *Circuit Judges*.

EDITH H. JONES, *Circuit Judge*:

Methylene chloride ("MC") is a volatile liquid chemical used widely and for decades as a solvent in consumer and commercial applications including adhesives and sealants, automotive products, and paint and coating removers. Some of its essential uses are in the furniture refinishing business and the manufacture of energy efficient air conditioner coolants and EV batteries. Methylene chloride's particular advantage as a solvent is that it removes paint or coatings without damaging underlying surfaces.

But over-exposure to methylene chloride can cause injury or even death, and it has carcinogenic properties. Acting under the Toxic Substances Control Act ("TSCA"), EPA recently determined that almost all uses of methylene chloride pose an "unreasonable risk of injury to health." 15 U.S.C. § 2605(a). The agency promulgated a rule that nearly eliminates the market for MC. *See* Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39254 (May 8, 2024) (codified at 40 C.F.R. § 751) [hereinafter MC Rule].

Finding that errors of law occurred and substantial evidence did not support EPA's decision, we GRANT the Industry Petitioners' petition for review, VACATE EPA's Rule and associated risk determination, DENY the Sierra Club's petition for review, and REMAND to EPA for proceedings consistent with this opinion.

I. BACKGROUND

A. The Toxic Substances Control Act

The Toxic Substances Control Act was enacted in 1976. Section 6(a) of the TSCA authorizes EPA to enact regulations "prohibiting or otherwise restricting" "the manufacture, processing, distribution in commerce, use, or disposal" of chemicals that EPA determines to pose "an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a). EPA may do so "to the extent necessary so that the chemical substance or mixture no longer presents such [unreasonable] risk." *Id.* Historically, EPA enacted few rules under § 6(a).[1]

Notably, in 1989, EPA published a rule that banned the use of asbestos in most products. *See* Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions; Final Rule, 54 Fed. Reg. 29460 (July 12, 1989) (codified at 40 C.F.R. § 763). This court vacated that rule for lack of substantial evidence that EPA adequately considered less burdensome regulatory options. *See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1229–30 (5th Cir. 1991). Almost a decade later, EPA published a narrower asbestos rule aimed at protecting state and local government workers. *See* Asbestos Worker Protection, 65 Fed. Reg. 69210 (Nov. 15, 2000) (codified at 40 C.F.R. § 763).

After more than a decade of regulatory silence, Congress amended the TSCA in 2016 to require EPA to begin priority risk evaluations for certain chemicals. The amendments articulated comprehensive new provisions

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[1] *See* Triethanolamine Salt of Tricarboxylic Acid, 40 C.F.R. § 747.200 (2026); Triethanolamine Salt of a Substituted Organic Acid, 40 C.F.R. § 747.195 (2026); Mixed Mono and Diamides of an Organic Acid, 40 C.F.R. § 747.115 (2026); Hexavalent Chromium-Based Water Treatment Chemicals in Cooling Systems, 40 C.F.R. § 749.68 (2026).

governing evaluations both to identify and quantify "unreasonable risk" and to regulate the chemicals' use "to the extent necessary" to eliminate such risks. The following outline describes pertinent provisions.

EPA must first determine whether each chemical "presents an unreasonable risk of injury . . . *under the conditions of use.*" 15 U.S.C. § 2605(b)(4)(A) (emphasis added). The "conditions of use," a recurring statutory phrase, is broadly defined as "the circumstances . . .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). EPA's "unreasonable risk" determination must not "consider[] costs or other nonrisk factors," but it must "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures *under the conditions of use* of the chemical substance." 15 U.S.C. § 2605(b)(4)(A), (b)(4)(F)(iv) (emphasis added). "Unreasonable risk" must also take into account "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator [of EPA], under the conditions of use," 15 U.S.C. § 2605(b)(4)(A), and it must reflect the weight of scientific evidence in identifying risks and hazards, 15 U.S.C. § 2605(b)(4)(F)(v).

Second, if a chemical poses an "unreasonable risk," EPA is to "apply one or more" mitigation measures "to the extent necessary so that the chemical substance . . . no longer presents such [unreasonable] risk." *Id.* § 2605(a).[2] Allowed mitigation measures range from modest notice and recordkeeping obligations to outright prohibitions on a chemical's manufacture or sale. *See id.* § 2605(a)(1)–(7). When choosing among these

[2] As applied to "articles" containing the chemical, any prohibitions or restrictions may be made "only to the extent necessary to" remove "unreasonable risk" from exposure to the chemical. 15 U.S.C. § 2605(c)(2)(E).

measures, EPA must "factor in, to the extent practicable," the "benefits of the chemical substance or mixture for various uses" and "the reasonably ascertainable economic consequences of the rule." *Id.* § 2605(c)(2)(A)–(B). EPA must also compare its preferred measure to an alternative. *Id.* If EPA's preferred measure would "substantially prevent[] a specific condition of use of a chemical," EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute." *Id.* § 2605(c)(2)(C).

Overarching these requirements are significant methodological parameters. Thus, "to the extent that [EPA] makes a decision based on science, [EPA] shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." 15 U.S.C. § 2625(h). EPA must consider factors bearing on the reliability of its findings. *Id.* EPA must also base its conclusions on the "weight of the scientific evidence," and it must apply "reasonably available" information bearing on the hazards of or exposure to the substance "under the conditions of use." *Id.* § 2625(i)–(k).

In a similar context, the Supreme Court interpreted a statutory provision that an agency must "use the best scientific and commercial data available," 16 U.S.C. § 1536(a)(2), as an empirical mandate to ensure that the law is not "implemented haphazardly, on the basis of speculation or surmise . . . ." *Bennett v. Spear,* 520 U.S. 154, 176–77, 117 S. Ct. 1154, 1168 (1997). Here, too, EPA's risk evaluations and rules under TSCA § 6(a) must comply with important procedural and substantive requirements "to prevent zealous[] but unintelligent pursui[t] [of] environmental objectives." *Id.* EPA has no freewheeling authority.

B. Methylene Chloride Regulation

Congress's 2016 amendments authorized EPA to bypass its new evaluation process and proceed directly to rulemaking for any risk evaluations that the agency had completed before 2016. 15 U.S.C. § 2625(l)(4). As of 2016, EPA had already completed a limited risk evaluation of MC. Accordingly, EPA published a final rule (not challenged here) in March 2019 that prohibited the manufacturing, processing, and distribution of MC solely for purposes of consumer paint and coating removal. *See* Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a), 84 Fed. Reg. 11420, 11435 (Mar. 27, 2019) (codified at 40 C.F.R. § 751); *see also Lab. Council for Latin Am. Advancement v. EPA*, 12 F.4th 234, 239 (2d Cir. 2021) (denying petition for review).

Nevertheless, many conditions of use (*i.e.*, uses in commercial or industrial settings, and consumer uses that do not involve paint and coating removal) were left unaddressed. As EPA explained in the Background to the Rule under consideration here, "[t]he total annual aggregate production volume of methylene chloride was between 100 million to 500 million pounds between 2016 and 2019," although up to about 35% of that volume was for pharmaceutical uses, which are not regulated by the TSCA. MC Rule, 89 Fed. Reg. at 39256.

As a preface to regulating more comprehensively the risks associated with MC, EPA published a final risk evaluation in June 2020 that covered fifty-three conditions of use. *See* EPA, RISK EVALUATION FOR METHYLENE CHLORIDE (2020), https://www.epa.gov/sites/default/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf [hereinafter June 2020 Final Risk Evaluation]. In the "hazard assessment" section, EPA summarized the adverse health and environmental effects that scientific

studies typically associate with MC. *Id.* at 227–313. In the "exposure assessment" section, EPA quantified the expected emissions and exposures to MC under each of fifty-three conditions of use. *Id.* at 74–226. Last, in the "risk characterization" section, EPA purported to evaluate the actual risk to human health and the environment under each condition of use. *Id.* at 33–35. More details about the agency's methodology and findings are discussed *infra* as needed. This final "risk determination" concluded that MC (1) does not pose an unreasonable risk to the environment; (2) poses an unreasonable risk to health for forty-seven conditions of use; but (3) does not pose an unreasonable risk to health for the six other conditions of use (meaning no regulation is required for those uses). *Id.* at 39–42.

When a new Presidential Administration took over, it ordered a re-assessment of the June 2020 final risk evaluation. In November 2022, EPA revised its risk determination. *See* EPA, FINAL REVISED UNREASONABLE RISK DETERMINATION FOR METHYLENE CHLORIDE (2022), https://www.epa.gov/system/files/documents/2022-11/MC_Final%20Revised%20RD_10.26.22-final%20%281%29.pdf [hereinafter November 2022 Revised Risk Determination]. Although EPA did not amend any of its fundamental findings or scientific analysis, it changed the policies underlying its risk determination in two significant respects. First, instead of relying on separate risk determinations for each condition of use, EPA issued a single "whole chemical" determination that all but one of the fifty-three conditions of use posed an unreasonable risk to human health. *Id.* at 3, 25. This meant that all conditions of use must be regulated. Second, EPA assumed in the revised risk determination that employees exposed to MC do not ever wear personal protective equipment ("PPE"). *Id.* at 4, 10. The June 2020 final risk evaluation, on the other hand, had incorporated the assumption, fortified by a longstanding Occupational Safety and Health Administration ("OSHA") regulation, that employees

routinely use PPE in connection with their workplace exposure to MC. *Id.* at 3–4.

Based on the revised risk determination, EPA proposed a "risk-management rule" for MC in May 2023. *See* Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 28284 (May 3, 2023) (codified at 40 C.F.R. § 751). Thousands of comments were submitted, explaining the importance of MC and criticizing EPA's regulatory proposal. Rejecting most of the objections, EPA published its final MC Rule in May 2024. *See* Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39254 (May 8, 2024) (codified at 40 C.F.R. § 751). Under the MC Rule, forty of the fifty-three conditions of use (including products that contain MC) are prohibited, covering using, manufacturing, importing, processing, and distribution. 40 C.F.R. § 751.105–108 (2026). Thirteen commercial or industrial conditions of use are allowed, subject to rigid exposure limits. *Id.* §751.109. Those thirteen are: (1) manufacturing (domestic); (2) manufacturing (import); (3) processing: as a reactant; (4) processing: incorporation into a formulation, mixture, or reaction product; (5) processing: repackaging; (6) processing: recycling; (7) laboratory chemical; (8) paint or coating removal from certain aircraft or spacecraft components; (9) bonding agent for solvent welding; (10) processing aid; (11) plastic and rubber products manufacturing; (12) solvent that becomes part of a formulation or mixture (where the formulation or mixture will be used inside a manufacturing process and MC will be reclaimed); and (13) disposal. *Id.* § 751.109(a). The thirteen uses are subject to a Workplace Chemical Protection Program ("WCPP") that comprises exposure limits, monitoring and reporting, and respiratory and dermal protection. *Id.* § 751.109(c)–(g). For a few commercial or industrial uses, prohibition under the Rule is deferred for a

few years. *Id.* § 751.107(b)(7)–(9).[3] EPA acknowledged that the Rule would have a very severe impact on the business of antique architectural work and commercial furniture refinishing. MC Rule, 89 Fed. Reg. at 39264–67.

For the few remaining authorized conditions of use, the WCPP imposes strict exposure limits for "acute" or "short-term" and "chronic" or "existing" events. 40 C.F.R. § 751.109(c) (2026). No more than 16 parts per million ("ppm") is allowed for fifteen minutes' "acute" exposure, and for "chronic" exposure, a time-weighted average of only 2 ppm is permitted for eight hours of exposure time. *Id.* § 751.109(c)(1)–(2). These exposure limits coupled with exposure monitoring are intended to regulate a worker's MC exposure over a career of many years. *Id.* § 751.109(c)–(d). In contrast, since 1997, OSHA has enforced MC exposure limits almost ten times greater: 125 ppm for "acute" exposure and 25 ppm for "chronic" exposure. *See* Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494 (Jan. 10, 1997) (codified at 29 C.F.R. § 1910.1052(c)).

C. Procedural History

The American Chemistry Council, East Fork Enterprises, and Epic Paint Company (together, "Industry Petitioners") filed a petition for review, arguing that EPA exceeded its authority, and that EPA's conclusions are arbitrary and capricious and unsupported by substantial evidence. East Fork and Epic Paint manufacture products that contain MC. The Council's

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[3] In addition, commerce in MC is broadly stymied. "[T]o prevent products intended for industrial and commercial use under the WCPP from being purchased by consumers," the Rule prohibits all "retailers from distributing in commerce MC and all MC-containing products." MC Rule, 89 Fed. Reg. at 39282. The Rule defines "retailer" to include *any* person that "distributes" or "makes available" products to "at least one consumer." 40 C.F.R. § 751.5 (2026). "Product" is defined to include a "chemical substance" or "mixture." *Id.*

members include MC manufacturers. The Sierra Club filed a separate petition for review, arguing that EPA did not go far enough in protecting its members who live in fenceline communities (*i.e.*, communities adjacent to factories that emit MC), have cancer-favoring genetics, or live at altitudes where ozone depletion is a concern. Conferring Article III standing, a Sierra Club member lives two miles from a facility that releases MC. The petitions for review were consolidated. The Council also intervened in opposition to the Sierra Club's petition.

II. STANDARD OF REVIEW

Generally, the TSCA provides for judicial review under the framework of the Administrative Procedure Act ("APA"). 15 U.S.C. § 2618(c)(1)(B). The APA directs courts to "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The TSCA, however, modifies the APA substantial-evidence standard: EPA actions must be "supported by substantial evidence in the rulemaking record taken as a whole." *Compare* 15 U.S.C. § 2618(c)(1)(B)(i)(I), *with* 5 U.S.C. § 706(2)(E) (providing that courts shall "hold unlawful and set aside agency action . . . found to be . . . unsupported by substantial evidence."). The TSCA standard "requires (1) that the agency's decision be based upon the entire record, taking into account whatever in the record detracts from the weight of the agency's decision; and (2) that the agency's decision be what a reasonable mind might accept as adequate to support [its] conclusion." *Corrosion Proof Fittings*, 947 F.2d 1201, 1213 (5th Cir. 1991) (alteration in original) (footnote and internal quotation marks omitted). Although the two statutes' substantial evidence standards are similar textually, it is understood that the TSCA's substantial evidence standard is "fairly rigorous and more searching than the APA standard." *Vinyl Inst., Inc. v. EPA*, 106 F.4th 1118, 1124 (D.C. Cir. 2024)

(internal quotation marks omitted); *see also Corrosion Proof Fittings*, 947 F.2d at 1214 (describing the standard mandated by the TSCA as "more rigorous" than the arbitrary and capricious standard).

III. DISCUSSION

The Industry Petitioners' challenges to the MC Rule broadly critique EPA's assumptions and conclusions regarding its determination of "unreasonable risk to human health" under MC's fifty-three "conditions of use," and the agency's correlated measures to eliminate any such risk "to the extent necessary." Industry Petitioners contend the agency determinations are contrary to law, arbitrary and capricious, and without support in substantial evidence. Preliminarily, it makes sense to appraise the new legal interpretations EPA brought to bear on "unreasonable risk" when it re-assessed the June 2020 final risk evaluation. To reiterate, EPA's 2022 revised risk determination abandoned the individual analysis of "conditions of use" in favor of a "whole chemical" basis for the MC Rule, and it eliminated the assumption that workers wear PPE when exposed to MC.[4] Subsequently, we address both the legal standards and the scientific background for the agency's unreasonable risk determination and its remedial measures to eliminate unreasonable risk.

Finally, we address Sierra Club's distinct challenges to the MC Rule.

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[4] At the last minute before oral argument, EPA notified the court that it no longer defends these interpretations of the previous Presidential Administration, but the issues were fully briefed and remain at issue for the future. Moreover, these new interpretations affected the November 2022 revised risk determination and the Rule's regulations governing the few remaining non-prohibited conditions of use.

A. Industry Petitioners' Challenges

"Whole Chemical" Risk Determination

In the November 2022 revised risk determination, EPA characterized MC as posing unreasonable risk "as a whole chemical substance" regardless of the fact that not all conditions of use posed unreasonable risk according to the June 2020 final risk evaluation, and regardless of the variability of the unreasonable risk under individual conditions of use. This modification resulted in EPA's recharacterizing six uses as posing unreasonable risk that had previously been deemed not to present such risk.[5] *Compare* June 2020 Final Risk Evaluation at 517–18 (concluding that manufacture of MC does not pose unreasonable risk), *with* November 2022 Revised Risk Determination at 25 (concluding that MC poses an unreasonable risk as a whole substance). Industry Petitioners contend that a "whole chemical determination" was unlawful because the TSCA and agency procedural rules both required EPA to publish a separate risk determination for each condition of use.

The Industry Petitioners have the edge legally. The TSCA provides that EPA must determine whether the *manufacture, processing, distribution . . . use, or disposal* of a chemical substance . . . or . . . any combination of *such activities*, presents an unreasonable risk . . . ." 15 U.S.C.

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[5] That the unreasonable risk determination was changed for several conditions of use by EPA's new legal interpretation is enough to reject EPA's position, in brief, that this change amounted to "harmless error." At least for these six affected conditions of use, the change was by no means "harmless," as EPA either prohibited or regulated stringently those conditions of use which previously had been deemed not to present "unreasonable risk." This whole chemical risk determination was all the more unreasonable insofar as EPA explicitly did not change its scientific assessment for the non-risky conditions of use. *See* November 2022 Revised Risk Determination at 4 ("EPA did not amend . . . underlying scientific analysis of the risk evaluation.").

§ 2605(a) (emphases added). Each activity in connection with a particular chemical, or combination of activities, may or may not present unreasonable risk. Grammatically, the verb "presents" connects to the activities just identified, not to the prepositional clause "of a chemical substance." Consequently, "unreasonable risk" may be "presented" by activities concerning the chemical, not simply the chemical. And as will be seen, the remainder of the TSCA makes it obvious that if such activities are individually determined to present unreasonable risk, EPA may regulate those activities while leaving unregulated other activities that are not unreasonably risky.

With this preface, § 2605(b) goes on to set criteria by which EPA will "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk . . . under the conditions of use." *Id.* § 2605(b)(4)(A). Bear in mind that "conditions of use" means "the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be . . . used." 15 U.S.C. § 2602(4). Multiple risk evaluations are required for multiple "conditions of use" of a chemical substance. Further, under § 2605(b)(4)(D), EPA must "publish the scope of the risk evaluation to be conducted, including the . . . *conditions of use* . . . [EPA] expects to consider" (emphasis added). Under § 2605(b)(4)(F), EPA's determination must "assess . . . the likely . . . exposures under the *conditions of use*" (emphasis added), and consider "aggregate or sentinel exposures . . . under the *conditions of use* . . . " (emphasis added). Section 2605, in fact, mentions "conditions of use" in no less than thirteen subsections. Summarizing Congress's instruction for the scope of EPA authority, the TSCA prescribes that EPA decisions preempt state law with respect to the "*conditions of use* . . . included in the scope of the risk evaluation . . . ." 15 U.S.C. § 2617(d)(1)(A)(iii)(II)(aa) (emphasis added). There is no getting around the conclusion that the TSCA focuses on both determining

and regulating risk according to the actual, separate "conditions of use" for a given chemical or substance. The agency lacked legal authority under the TSCA to determine that a chemical or substance poses unreasonable risk "as a whole" rather than to evaluate each of its conditions of use.

Although the statutory language is clear, this conclusion is reinforced by EPA's own consistent interpretation, even at the time that it published the revised risk determination in November 2022. At that time, EPA was still operating under the 2017 procedural rule requiring EPA to "determine whether the chemical substance presents an unreasonable risk . . . *under each condition of uses* within the scope of the risk evaluation." Procedures for Chemical Substance Risk Evaluations Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33752 (July 20, 2017) (codified at 40 C.F.R. § 702 but amended by Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 37028, 37052 (May 3, 2024) (emphasis added)); *see also id.* at 33744 (noting that "EPA will make individual risk determinations for all uses identified in the scope" and "each condition of use covered by the risk evaluation" [will receive] a risk determination" in the Rules's preamble); *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999) ("[T]he preamble to a regulation is evidence of an agency's contemporaneous understanding of its proposed rules."). Further, EPA pledged that "[a]ny [§ 6(a)] rule would apply only to the condition(s) of use that present an unreasonable risk, and those [conditions of use] that do not present an unreasonable risk will not be subject to risk management." 89 Fed. Reg. at 33744. The TSCA also provides that EPA's risk determinations must comply with EPA's operative procedural rule. *See* 15 U.S.C. § 2605(b)(4)(C) (EPA "shall conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B). . . ."); s*ee also DOJ v. Fed. Lab. Rels. Auth.*, 991 F.2d 285, 291 n.4 (5th Cir. 1993) ("[F]ederal agencies must abide by their own regulations.").

EPA's "whole chemical" interpretation in the revised risk determination contradicted its procedural rule and the TSCA's procedural requirement.

To justify abandoning a use-by-use determination, EPA construed its procedural rule as ambiguous with respect to whether a whole-chemical determination was *prohibited*. Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, 87 Fed. Reg. 67901, 67904 ("[EPA] is . . . to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." (quoting the preamble of the procedural rule at 82 Fed. Reg. 33726, 33729)). Then, EPA "interpret[ed] its risk evaluation regulation to also *allow* the Agency to issue whole-chemical risk determinations." *Id.* (emphasis added). This was wrong. Without even seeking deference for its reading of the procedural rule's preamble, EPA can hardly deny that (1) the text of the operative procedural rule is clear and unambiguous with respect to the requirement that EPA issue risk determinations for each use; and (2) EPA issued risk determinations in that manner for several years before it discovered a different interpretation of that rule.

In sum, the TSCA required EPA to issue a separate risk determination for each condition of use that it considered, and EPA's regulations followed that mandate—until EPA chose not to do so. EPA lacked authority to issue a novel "whole-chemical" revised risk determination in November 2022.

Assumption that Workers do not Wear PPE

EPA's revised risk determination also assumed that workers who work with MC do not use PPE. *See* MC Rule, 89 Fed. Reg. at 39257 (issuing a "clarification that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE"). Industry Petitioners argue that by reversing its contrary assumption in the June 2020

final risk evaluation, EPA violated the TSCA and acted without supporting evidence. We agree.

According to the TSCA, EPA must account for PPE in its risk evaluations as a "condition of use" if evidence reflects that PPE is actually used. *See* 15 U.S.C. § 2605(b)(4)(A); 15 U.S.C. § 2602(4) ("The term 'conditions of use' means the *circumstances*. . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.") (emphasis added). The use of PPE is plainly a critical "condition" or "circumstance" regarding the use of MC. PPE dramatically reduces workers' exposure through respirators that protect the respiratory tract; gloves and apparel that prevent skin contact; and protective glasses that ward off eye contact with MC. The June 2020 final risk evaluation, which complied with TSCA's definition of "conditions of use," reflected much lower workplace exposures with the assumed use of PPE.

EPA's only statutory rationale for abandoning its previous consideration of PPE as a condition of use is that it decided to factor PPE use instead as a limit on the intensity of the exposure in the "risk management" phase of regulation (*i.e.,* after determining unreasonable risk by assuming no use of PPE). November 2022 Revised Risk Determination at 3–4. That is contrary not only to the definition of "conditions of use," but also to EPA's duty to formulate its unreasonable risk determination by considering the "intensity . . . of exposures under the conditions of use." 15 U.S.C. § 2605(b)(4)(F)(iv).

EPA fares no better in supporting its new assumption factually. To begin, the agency speculated in the revised risk determination that some subpopulations of workers may not be covered by OSHA standards, or their employers failed to comply with OSHA requirements. November 2022

Revised Risk Determination at 4. Contrary to this speculation, EPA found in the 2020 final risk evaluation that PPE use is a "condition of use" for commercial and industrial applications. The agency then explained:

> EPA used reasonably available information, including public comments, indicating that some employers, particularly in the industrial setting, are providing appropriate engineering or administrative controls or PPE to their employees consistent with OSHA requirements. While EPA does not have similar information to support this assumption for each condition of use, EPA does not believe that the Agency must presume, in the absence of such information, a lack of compliance with existing regulatory programs and practices. Rather, EPA assumes there is compliance with worker protection standards unless case-specific facts indicate otherwise . . . EPA believes this is a reasonable and appropriate approach that reflects real-world scenarios, accounts for reasonably available information related to worker protection practices, and addresses uncertainties regarding availability and use of PPE.

June 2020 Final Risk Evaluation at 27.

Two noteworthy points emerge from this statement in the June 2020 final risk evaluation. First, as it was required to do in evaluating unreasonable risk, EPA took account of "reasonably available information" about the exposure under the "case-specific" "conditions of use." 15 U.S.C. § 2625(k). In so doing, EPA accepted information from the users of MC. Additionally, EPA found that PPE usage was reasonably foreseeable because EPA had no basis for assuming that employers were not complying with OSHA requirements. 29 C.F.R. § 1910.1052 (2026) (OSHA requirements for covered employers to control occupational exposure to MC). "Conditions of use," after all, include "reasonably foreseen" circumstances such as compliance with other federal, state, and local mandates. 15 U.S.C. § 2602(4).

Later, even while reversing the assumption of widespread PPE use, EPA insisted that its revised approach "should not be viewed as an indication that EPA believes . . . there is widespread noncompliance with applicable OSHA standards." November 2022 Revised Risk Determination at 4. And contrary to its supposition that many workers are not covered by OSHA standards, the final MC Rule acknowledges that "[b]ecause of its adverse health effects, methylene chloride is subject to numerous State, Federal, and international regulations . . . ." MC Rule, 89 Fed. Reg. at 39256. If one also considers EPA's decision not to alter the exposure assessments when it revised its risk determination, these "explanations" for assuming non-use of PPE are remarkably self-contradictory.

In sum, EPA's turnabout on the use of PPE not only refused to consider a significant "condition of use," but the agency also pivoted without "reasoned explanation . . . for disregarding facts and circumstances that underlay . . . [the] prior policy." *BNSF Ry. Co. v. Fed. R.R. Admin.*, 105 F.4th 691, 700 (5th Cir. 2024) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16, 129 S. Ct. 1800, 1811 (2009)). Further, its speculation that workers may not be using PPE lacked evidence, contrary to the TSCA's "particularly demanding" standard of substantial evidence. *See* 15 U.S.C. § 2618(c)(1)(B)(i); *Corrosion Proof Fittings v. EPA,* 947 F.2d 1201, 1213–14 (5th Cir. 1991); *Chem. Mfrs. Ass'n,* 859 F.2d 977, 991–92; *Ausimont U.S.A., Inc. v. EPA,* 838 F.2d 93, 96 (3d Cir. 1988). This new assumption was contrary to law, arbitrary and capricious, and lacked substantial evidence.

EPA's Legal Approach to "Unreasonable Risk"

Industry Petitioners also submit that EPA's approach to evaluating risk did not square with its statutory mandate to identify only "unreasonable" risks and to regulate to "to the extent necessary" to eliminate "such [unreasonable] risks." According to the Petitioners, EPA

essentially treated *any* risk as unreasonable and regulated far beyond what removing "unreasonable risk" entails. At least, we conclude, EPA's approach to "unreasonable risk" was far more conservative than the statutory term connotes.

Explaining the term "unreasonable risk," the *Corrosion Proof Fittings* court aptly stated that "Congress did not enact TSCA as a zero-risk statute." 947 F.2d at 1215. As will be seen, EPA's approach seems to mirror its risk assessments under statutes that require the agency to remove virtually all risks. In *Natural Resources Defense Council v. EPA*, *Nat. Res. Def. Council v. EPA*, EPA had authority *not* to eliminate any "unreasonable risk," but to determine pesticide exposure level at which "there is a reasonable certainty that no harm will result." 658 F.3d 200, 203 (2d Cir. 2011) ("EPA applies at least two separate 10X [uncertainty] factors . . . The traditional 10X [uncertainty] factors [] account for differences between animals and humans . . . and differences among humans. . . ." (third alteration in original)). The similarity raises a real question whether EPA properly distinguished between "unreasonable risk" in regulating under the TSCA and the precautionary principle adopted by other statutes. "Unreasonable risk" does not incorporate any precautionary principle. Congress has spoken clearly when it instructed administrative agencies to adhere to the precautionary principle. *See* Clean Air Act, 42 U.S.C. § 7409(b)(1) (requiring an "adequate margin of safety" when EPA sets air quality standards); *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 115–55 (D.C. Cir. 1980) (observing that the "precautionary nature" of the Clean Air Act requires EPA to "err on the side of caution").

As the D.C. Circuit held, courts must not infer a precautionary principle from unclear statutory text. *Me. Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.,* 70 F.4th 582, 599 (D.C. Cir. 2023). "The precautionary principle, taken seriously, can multiply an agency's power over the economy. It allows an agency to regulate or veto activities even if it cannot be shown

that those activities are likely to produce significant harms." *Id.* (internal quotation marks omitted). Similarly to this case, the Endangered Species Act, interpreted in *Maine Loberstermen's*, required federal agencies to ensure that government actions are "not likely to jeopardize the continued existence of" a protected species. 16 U.S.C. § 1536(a)(2). The court explained that this plain language required the agency to "avoid acts that will more likely than not jeopardize a species. No more, no less." *Maine Lobstermen's*, 70 F.4th at 595.

The TSCA's text does not authorize anything like a precautionary or lowest possible risk principle. The word "unreasonable" means something that "exceed[s] the bounds of reason, appropriateness, or moderation." *Unreasonable*, MERRIAM-WEBSTER DICTIONARY, https://www.merriam-webster.com/dictionary/unreasonable (last visited Aug. 8, 2026). Webster's Third New International Dictionary defines "unreasonable" as "exceeding the bounds of reason or moderation: inordinate, unconscionable;" for illustration, this definition quotes the Fourth Amendment's proscription of "unreasonable searches and seizures." *Unreasonable*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (2002 ed.) "Unreasonable risk" must allow for some risk experienced by users of MC or those in contact with it: No More, No Less, as the D.C. Circuit stated. The relevant question is how much risk is "unreasonable."

EPA contends that "Congress explicitly gave EPA authority to make the technical determination what constitutes an 'unreasonable risk,'" while providing methodological guardrails. EPA defends its methodology because

it applied conventionally approved techniques of appraising toxic risks;[6] it sought the "best available science" and applied the weight of scientific evidence to evaluate risk; and in any event, courts must generally defer to agency fact findings based on agencies' technical expertise. *Loper Bright Enters. v. Raimondo,* 603 U.S. 369, 392, 144 S. Ct. 2244, 2261 (2024); *Corrosion Proof Fittings*, 947 F.2d at 1214.

But the agency confuses substantial evidence with statutory interpretation. "Unreasonable risk" is not a factual finding but a prudential baseline set by the statute. Here, Congress insisted that the baseline be determined in light of numerous additional statutory provisions that expressly counsel EPA, *inter alia*, how to apply the science, how to gauge reliability of findings, and how to maintain transparency of agency decisionmaking. *See* 15 U.S.C. § 2625. "Unreasonable risk" summarizes the legal conclusion that must be drawn from those parameters; it is not a cover for whatever numerical estimates EPA generates using the parameters.

After *Loper Bright,* of course, courts are the "independent" interpreters of statutory language. *Loper Bright,* 603 U.S. at 406, 144 S. Ct. at 2269. In that capacity, the Supreme Court had no trouble construing the statutory term "undue hardship" in Title VII. *Groff v. DeJoy*, 600 U.S. 447, 468, 143 S. Ct. 2279, 2294 (2023). Likewise, this court recently interpreted "unclassifiable" in the Clean Air Act, and we vacated and remanded a regulation because of the agency's problematic scientific analysis. *Texas v. EPA,* 137 F.4th 353, 367 (5th Cir. 2024). Prudential terms like "undue," "unclassifiable," or "unreasonable" are simply not immune from judicial review because an agency applied its views of their meaning to particular

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[6] *See generally* 2 Federal Judicial Center, Reference Manual of Scientific Evidence 1049–68 (4th ed. 2025), https://www.fjc.gov/sites/default/files/materials/15/Reference%20Manual_Vol_II_March_2026.pdf.

facts. Consequently, this court must carefully review whether the facts found by EPA support its "unreasonable risk" determinations, and whether the risk-avoidance measures operate "to the extent necessary" to eliminate unreasonable risks. 15 U.S.C. § 2605(a).

EPA's Methodological Approach to "Unreasonable Risk"

The Industry Petitioners also take aim at the agency's assumptions and findings in the final risk determination and the menu of regulatory measures required to eliminate "unreasonable risk" "to the extent necessary." *Id.* For these issues, the question is whether EPA's decisions are arbitrary and capricious under the APA and supported by substantial evidence on the record as a whole under the TSCA.

As has been noted, EPA followed its standard methodology for regulation of toxic substances in estimating whether MC poses an unreasonable risk to human health. *See* 15 U.S.C. § 2605(b)(4); 40 C.F.R. 702.39(a) (2026). It undertook a four-part study, including a "[h]azard [a]ssessment," an "[e]xposure [a]ssessment," a "[r]isk [c]haracterization" and a "[r]isk [d]etermination." 40 C.F.R. 702.39(a) (2026).

Oversimplifying a description of the methodology for present purposes, the MC's health hazards identified ranged from death by inhaling MC in extreme concentrations to temporary neurotoxicity and potential effects on the liver and heart.[7] June 2020 Final Risk Evaluation at 227–313. The "exposure assessment" estimated, for each condition of use, the amount of MC to which workers and "occupational non-users" (including men and women of reproductive age, and adolescents) may be exposed in

[7] Although MC is recognized as a potential carcinogen, that feature of the chemical played little role in EPA's final risk determination and no role in the Industry Petitioners' briefing. Sierra Club's arguments, *infra*, discuss carcinogenic exposure.

"acute" circumstances lasting 15 minutes, or in "chronic" conditions over an 8-hour working day. *Id.* at 74–226, 453. These exposures were compared with points of departure ("PODs"), the estimates of the exposure that would yield a lowest-observed-adverse-effect level ("LOAEL") in humans or a no-observed-adverse-effect-level ("NOAEL") in humans.[8] *Id.* at 294–313, 453. The result of that comparison was deemed the "margin of exposure," and it estimated exposure to parts per million of MC in the air inhaled by workers. *Id.* at 455–56.

The "margin of exposure" comparison, in turn, was divided by an estimated "benchmark margin of exposure." This is a fudge factor. The benchmark MOE constituted a "composite uncertainty factor" reducing the estimated "points of departure." The benchmark margin of error was the product of multiplying a series of numbers designed to account for various scientific uncertainties ranging from potential shortcomings in the data and intraspecies and interspecies variations in sensitivity, as well as "the uncertainty in extrapolating from a [LOAEL] rather than from a NOAEL."[9] November 2022 Revised Risk Determination at 7. In practical effect, the benchmark margin of error, whatever its size, reduced the "points of departure" by multiples. *Id.*

EPA applied this comparative process, *inter alia*, to characterize the human health risks associated with specific exposure scenarios, principally

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[8] Technically, EPA calculated a "margin of exposure" by dividing the "point of departure" for MC (reflected in scientific studies as the LOAEL or NOAEL) by the actual exposure level ordinarily experienced by a person under each condition of use. A higher margin of error means that adverse health effects are less likely to occur under a condition of use.

[9] As EPA explained, a lower benchmark margin of error means that EPA has "greater certainty in the data" underlying its analysis and is willing to tolerate a less-protective ratio between actual exposures and the point of departure.

acute and chronic inhalation of MC. A table contained in the June 2020 final risk evaluation summarized the "Risk Estimates for Inhalation and Dermal Exposures to Workers by Condition of Use." Invariably, EPA deemed a risk "unreasonable" when the margin of exposure was less than the benchmark margin of exposure.[10]

How this methodology, rife with estimates and uncertainties, applied in practice to MC, and the Industry Petitioners' challenges, must be discussed separately for acute and chronic levels of exposure.

Acute Exposure Limit

When EPA issued the MC Rule, it fixed a fifteen-minute acute exposure limit at 16 ppm for the few conditions of use that it continued to allow. OSHA's comparable limit, as noted, is 125 ppm. How did EPA arrive at this low figure?

EPA began with a fifteen-minute point of departure at 478 ppm. This figure was based on a double-blind study of twelve humans (the "Putz study") who suffered temporary modest impairment (around 7% reduction) to their peripheral vision about ninety minutes after they were exposed to 195 ppm MC. EPA used an equation to convert 195 ppm over ninety minutes to a comparable fifteen-minute amount. The Putz study's points of departure, and the anticipated exposure levels under each condition of use, were used to calculate the margins of error for acute inhalation.

For the benchmark margin of error for acute inhalation, EPA chose an uncertainty factor of ten to account for variability among humans (*i.e.*,

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[10] EPA insists that comparing these two figures is not always dispositive in determining unreasonable risk. However, the "whole chemical approach" renders that statement nugatory, and in any event, EPA never identified what other factors contributed to its final risk determination.

variability between susceptible subpopulations like infants, children, pregnant women, elderly, smokers, etc.) that would make it difficult to predict the actual exposure levels at which adverse effects might occur. EPA also chose an additional uncertainty factor of three to account for existing studies producing an LOAEL, which EPA considers to be less accurate than an NOAEL.[11] EPA multiplied these individual uncertainty factors to arrive at a composite uncertainty factor (and thus benchmark margin of error) of thirty.

In the June 2020 final risk evaluation, these numbers yielded "unreasonable risk" conclusions whenever the margin of exposure for any condition of use was less than 30, which was true for 47 conditions of use. Further, based on these numbers, EPA crafted a fifteen-minute acute exposure limit at 16 ppm (*i.e.*, 478/30 rounded up) for the few conditions of use that it allowed to continue.

As the Industry Petitioners explain, extrapolating its acute exposure limit from the Putz study involved three critical assumptions that dramatically affected the overall risk assessment. First, Putz's study found minimal impairments to its participants—a temporary 7% decrease in peripheral vision—after four hours' exposure to 195 ppm MC. Far from being an "unreasonably risky" exposure, the adverse health effects observed in the study were small to begin with, as the EPA acknowledges. Second, in adjusting the 15-minute exposure by a benchmark margin of error, the agency decreased it by a factor of 3 based on the difference between the LOAEL result in the Putz study and the EPA's favored NOAEL method. In other

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[11] EPA says its "default" LOAEL-to-NOAEL uncertainty factor is ten. EPA picked a lower uncertainty factor to characterize risk from acute inhalation because it considered a seven-percent decrease in peripheral vision to constitute a relatively minor adverse health effect.

words, the agency significantly reduced potential exposure to ensure that individuals would encounter "NO" adverse effects from exposure. Third, it again decreased the 15-minute exposure by a benchmark factor of 10 to account for "interspecies variability," that is, the possibility that extremely sensitive individuals like smokers or people with heart disease might experience the temporary limit in peripheral vision at much lower MC concentrations. On their face, it is hard to reconcile these downward extrapolations with this court's reminder that "[r]educing risk to zero . . . was not the task that Congress set for the EPA in enacting TSCA." *Corrosion Proof Fittings,* 947 F.2d at 1217.

EPA's acute exposure conclusion runs afoul of the TSCA's more stringent substantial evidence standard. Recall that the standard, reflecting the parameters placed on the agency to determine "unreasonable risk of injury to health," 15 U.S.C. § 2605(b)(4)(A), requires the agency decision to be "based upon the entire record, taking into account whatever in the record detracts from the weight of the agency's decision." *Corrosion Proof Fittings,* 947 F.2d at 1213. Yet EPA relied exclusively on the Putz study, which observed twelve humans who were exposed to 195 ppm MC for four hours. EPA maintains that vision impairments observed in the Putz study indicate nervous-system depression, which is a "precursor" to incapacitation and death. In plain language, a "precursor" is not in itself an "adverse health effect." Moreover, EPA even admitted this was a "small magnitude" effect and never explained how that risk could be unreasonable.

In addition, EPA discounted another relevant study, the "Winneke study," which observed minimal adverse health effects in individuals who were exposed to 500 ppm MC for 3.8 hours. EPA criticizes the Winneke study on various grounds and emphasizes other results from the Putz study that it interprets as evidence of risks to human health: after four hours of exposure, the participants exhibited a thirty-six-percent reduction in hand-

eye coordination, seventeen-percent reduction in peripheral vision, and seventeen-percent reduction in auditory vigilance.

EPA's response does not alleviate concerns that its analysis overlooked important information undermining its conclusions. This is not to say that the Putz study should not have factored into EPA's risk determination or other conclusions. The problem is that EPA placed *exclusive* reliance on a study of twelve people just because it deemed that study the "best." Yet EPA has not shown that the Winneke study was so worthless as to be properly excluded. Indeed, Winneke's participants were exposed to as much as 800 ppm MC without experiencing severe health effects. Common sense suggests that as researchers, neither Putz nor Winneke would have knowingly subjected humans to MC concentrations of 195 or 500 ppm for several hours if they had expected serious health effects. Another study by Soden involved workers who were subject to 475 ppm for 8 hours daily over at least ten years. Soden reported no deaths or adverse health effects. Ignoring all these commonsense indicators of exposures amounting to less than "unreasonable risk," EPA concluded that a mere 16 ppm is the maximum exposure allowed for 15 minutes.

A few workers have perished when exposed to MC in much higher concentrations. EPA's final risk evaluation listed about a dozen fatalities in situations involving exposure to concentrations of at least 1711 ppm, near the 2,300 ppm concentration level rated "immediately dangerous to life or health." And OSHA has had a standard in place for a quarter century setting a maximum MC exposure of 125 ppm for acute exposure. Indeed, OSHA ratified this limit after reconsidering it in 2010. EPA paid no attention to the OSHA standard in selecting its own acute exposure limit at nearly one-tenth of the OSHA standard.

The differences among exposures in studies, the OSHA standard, and the actual "immediately dangerous" standard compel the conclusion that EPA's ratcheting the maximum acute exposure down to 16 ppm was substantially below the base for an "unreasonable risk" to human health. Because EPA's methodological assumptions were excessively conservative, and it failed to sufficiently account for contradictory evidence, we hold that its fifteen-minute exposure limit is not supported by substantial evidence.

Chronic Exposure Limit

Based on one rat study, and discounting several studies of humans exposed to MC in the workplace, EPA arrived at a maximum chronic exposure limit of 2 ppm/8-hour working day. OSHA's comparable limit has been 25 ppm—over ten times higher—for over a quarter century. Characterizing the risks from chronic inhalation of MC proved less straightforward and even more attenuated than its process to determine the acute exposure limit.

For acute exposures, EPA extrapolated the point of departure from a study of 180 female rats (the "Nitschke study") that exhibited liver irregularities, such as lesions, after being exposed to 500 ppm MC for six hours a day for two years. They experienced no such irregularities, however, when exposure was capped at 200 ppm. To fix the point of departure, EPA started with the Nitschke study, estimating the amount of MC that might generate a ten-percent risk of liver irregularities in rats. Then, EPA applied a "physiological-based pharmacokinetic model" to its most conservative estimate (*i.e.*, the first percentile) to calculate a "human-equivalent concentration" of MC that might produce similar liver irregularities in humans over a working lifetime of exposure.

Next, EPA calculated a margin of error by dividing the human-equivalent concentration by the estimated actual exposure to MC over a

working lifetime under each condition of use. The benchmark margin of error was calculated by multiplying individual uncertainty factors. EPA chose two uncertainty factors of three to account for both intraspecies (between rats and humans) and interspecies variability.[12] There was no reason to apply an LOAEL-to-NOAEL uncertainty factor for chronic inhalation because the Nitschke study produced an NOAEL. The ultimate result was a composite uncertainty factor (or benchmark margin of error) of ten (*i.e.*, 3 x 3 rounded up). Had EPA fixed the maximum exposure limit in the conventional way, by dividing the point of departure by the benchmark margin of error, it would have yielded an impossible limit of less than 0.5 ppm. Instead, the agency increased the exposure limit to 2 ppm.[13]

The Industry Petitioners contend that EPA's reliance on a single flawed rat study was arbitrary and capricious. They point to three different epidemiological studies of humans that evaluated possible liver toxicity from sustained MC exposure. These studies, submitted during the notice and comment phase of proceedings, observed workers who were exposed to MC on a regular basis. In two of the studies, the median exposures were as high as 475 ppm, which is 240 times the level of EPA's newly minted eight-hour exposure limit. EPA rated all three studies "medium quality" and described them as "acceptable." This is not surprising, because EPA's eight-hour exposure limit was also based on a study that EPA rated medium quality. One public commenter retained Dr. Jonathon Borak, Clinical Professor of Medicine at Yale University and a faculty member of the Yale Occupational

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[12] EPA rated these factors "low" because it determined that the extraordinarily conservative human-equivalent concentration already accounted to some extent for interspecies and intraspecies variability.

[13] Coincidentally, the Putz study correlated closely with this result, as Putz found an 8-hour point of departure at 80 ppm, applied to each condition of use, to which EPA applied its benchmark margin of exposure of 30: 80/30 adjusted down is nearly 2 ppm.

and Environmental Medicine Program, to review the three epidemiological studies and evaluate whether they support a conclusion that chronic exposure to MC causes liver toxicity in workers. Dr. Borak concluded from his review that "the three studies . . . provide no evidence of hepatic effects, even at exposures for longer than 10 years at levels nearly 20-fold greater than the current OSHA [eight-hour exposure limit] of 25 ppm. They also contain no evidence of dose-related hepatic effects of exposures."

EPA's response to the human epidemiological studies is inadequate. It contends that two of the studies showed increased bilirubin in blood, and that such increases are a biological concern that *could* indicate the potential for liver disease in humans. But increased bilirubin is not a necessary or sufficient marker for adverse liver conditions, and it has many possible causes. Increased bilirubin therefore does not signal unreasonable risk to human health. EPA also argues that it need not factor any of the human epidemiological studies into its exposure limits because it found "these data don't provide clear evidence of adverse liver effects." But isn't that a finding worthy of note? It was irrational for EPA to ignore evidence contrary to its presuppositions. Third, and closely related to this non-finding that it chose to ignore, EPA did not respond to (much less wrestle with) Dr. Borak's analysis. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96, 135 S. Ct. 1199, 1203 (2015) ("An agency must consider and respond to significant comments received during the period for public comment").

Instead, EPA relied exclusively on the Nitschke study involving rats, but the Nitschke study was far from perfect. In addition, the rats suffered no adverse effect (NOAEL) when exposed to 200 ppm, far in excess of what EPA purports to permit for humans. And just as elevated bilirubin has little bearing on unreasonable risk, likewise the "liver vacuolation" that Nitschke observed—at 500 ppm exposure in a small rodent rather than a smaller dose in a human—was considered by EPA only a "precursor of toxicity." These

are serious deficiencies in extrapolating to human health risks. But even an ideal rat study could hardly justify EPA in entirely discarding three "acceptable" human epidemiological studies.

We have encountered this sort of issue before. *See Gulf S. Insulation v. U.S. Consumer Prod. Safety Comm'n*, 701 F.2d 1137 (5th Cir. 1983). There, the Consumer Product Safety Commission ("CPSC"), charged with addressing "unreasonable risk of injury," 15 U.S.C. § 2058(f)(3)(A), promulgated a prohibition on urea-formaldehyde foam insulation based on a determination that the material posed unreasonable risk of irritation and cancer. *Gulf S. Insulation*, 701 F.2d at 1139. "While the [CPSC] correctly note[d] that the epidemiologic evidence [was] not conclusive, its *exclusive reliance* on the Chemical Institute study [of 240 rats] . . . [was] equally unsupportable." *Id.* at 1146 (emphasis added). That is because "in a study as small as [that] one the margin of error is inherently large." *Id.* Thus, we said that even an accurate rat study could "not authenticate the use of the study's results, and only those results." *Id.* Especially relevant here, it made no difference that "the epidemiologic studies cited by the industry [did] not demonstrate conclusively that formaldehyde poses no cancer risk to man" because "it is not good science to rely on a single experiment." *Id.* For these reasons, the court vacated CPSC's prohibition on urea-formaldehyde foam insulation as unsupported by substantial evidence; the CPSC substantial-evidence standard was identical to the TSCA substantial-evidence standard. *Id.* at 1150. Industry Petitioners discussed this circuit precedent in their brief. EPA did not respond.

EPA's eight-hour exposure limit is unsupported by substantial evidence and arbitrary and capricious for several reasons. First, EPA made the same mistake as the CPSC. *See also Johnson v. Arkema, Inc.*, 685 F.3d 452, 463 (5th Cir. 2012) (recognizing "the 'very limited usefulness of animal studies when confronted with questions of toxicity . . . for human beings.'"

(quoting *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996))); *Am. Tunabout Ass'n v. Baldrige*, 738 F.2d 1013, 1016 (9th Cir. 1984) (agency decision was arbitrary and capricious because it "ignore[d] a comprehensive data base that is the product of many years' effort by trained research personnel"). Further, although there may have been limitations to the human epidemiological studies, our case law has made clear that the substantial evidence standard did not allow EPA to completely exclude those results when it developed its exposure limits. *See also Ctr. for Biological Diversity v. Zinke,* 900 F.3d 1053, 1068 (9th Cir. 2018) (invalidating an endangered species listing because the agency "failed to account for" a particular study). Significantly, the studies undermine EPA's decision because the observed workers, who were chronically exposed to MC, showed, at most, potential, inconclusive hepatic effects without any serious complications and without any signs of impaired liver function compared to other employees. *See* KENNETH R. FOSTER, ET AL., PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 12 (1993) ("[H]igh-dose animal studies are only one part of the toxicologic puzzle and their relevance to low environmental exposures is indirect at best and possibly nil."). EPA failed in its duty to respond to "significant comments received during the period for public comment." *Perez*, 575 U.S. at 96, 135 S. Ct. at 1203; *Chamber of Comm. of U.S. v. SEC,* 85 F.4th 760, 774 (5th Cir. 2023). And EPA failed to heed the TSCA's "more stringent" test for substantial evidence when it failed to discuss conflicting evidence on the record.

EPA's Conclusion on Unreasonable Risk

EPA's risk analysis yielded extraordinarily small limits for both acute and chronic exposures to MC. As the above discussion indicates, the agency's results lack epidemiological support, reflect selective use of data and failures to consider alternative acceptable data, and were based on unrealistic benchmark margins of error. In sum, the risk analysis did not

accord with the best available science as the TSCA requires, and the results more closely approximate the precautionary principle than the statute's "unreasonable risk" standard. In sum, this analysis was arbitrary and capricious, lacking substantial evidence, and contrary to law.

Regulating "To the Extent Necessary" to Remove Unreasonable Risk

Although it would be sufficient to vacate the MC Rule and remand to EPA because of the Rule's many shortcomings, we must also address the agency's aggressive decision to largely prohibit MC's uses, rather than approve or modestly revise the OSHA standards. The Industry Petitioners do not assert that MC presents no "unreasonable risk." Once legally compliant standards of unreasonable risk are determined, EPA must follow the menu of permissible regulations under the TSCA. The Industry Petitioners properly raised issues concerning the limits of the agency's authority.

The TSCA outlines the limits of EPA authority after it has made an unreasonable risk determination for a chemical in the conditions of use. EPA "shall . . . apply" one or more of seven itemized measures "*to the extent necessary* so that the chemical substance or mixture no longer presents [unreasonable] risk . . . ." 15 U.S.C. § 2605(a) (emphasis added). Those measures range from recordkeeping and notification duties to regulation of the chemical or even outright prohibition. *Id.* § 2605(a)(1)-(7). Further, in promulgating the requisite rule, EPA "shall consider" and "shall factor in, to the extent practicable," in addition to the chemical's health and environmental effects, the chemical's "benefits" and the "reasonably ascertainable economic consequences" of its rule. *Id.* § 2605(c)(2)(A), (B). The statute twice states the necessity of considering one or more primary alternatives to the regulated chemical as well as "technically and economically feasible" and "reasonably available" substitute alternatives

when prohibition or restrictions are prescribed. *Id.* § 2605(c)(2)(A)(iv), (C). Thus, although the unreasonable risk determination itself must be undertaken without considering costs or other nonrisk factors, 15 U.S.C. § 2605(b)(4), EPA's available menu of options following that determination reflects significant cost-benefit considerations. As the D.C. Circuit emphasized in *Maine Lobstermen's*, "[n]o more, no less" regulation is authorized than "to the extent necessary" to relieve unreasonable risk. 70 F.4th at 595.

EPA misconceived its ameliorative role in two ways. First, EPA's stated basis for declaring a near-complete prohibition of MC, as opposed to any more modest exposure limit, was unauthorized. Even if its unreasonable risk determinations had not been unsound, EPA justified extraordinary restriction of MC because its exposure limits "are significantly lower than the [existing] OSHA [exposure limits], [and] there is a high degree of uncertainty as to whether most industrial and commercial users will be able to comply with such a level and thus whether the unreasonable risk would be addressed." EPA also expressed concern that without a ban, MC users would continue trying unsuccessfully to satisfy the agency's dramatically reduced exposure limits, thereby risking harm to workers, and it regretted "the potential for use of MC to increase in a sector that has already moved away from it." All of these speculative rationales misconstrue EPA's statutory authority. EPA cannot simply ban a chemical substance whenever it is "*uncertain*" whether a risk will *remain reasonable*. Instead, EPA is authorized to regulate "to the extent necessary" to eliminate actual, identified "unreasonable risk." 15 U.S.C. § 2605(a). *See also Corrosion Proof Fittings*, 947 F.2d at 1227 ("Musings and conjecture are 'not the stuff of which substantial evidence is made.'" (quoting *Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n*, 569 F.2d 831, 843 (5th Cir. 1978))).

To be sure, EPA offered companies a chance to comment and show that they could meet its newly promulgated exposure limits, and many regulated parties did not comment. But allowing an absence of comments to support EPA's prohibition improperly shifted the burden to the regulated entities to prove that they could comply. The TSCA, however, plainly requires EPA itself to bear the burden of showing a risk is *unreasonable* or a remedial measure "to the extent necessary" eliminates *unreasonable risk*. 15 U.S.C. § 2605(a). An absence of comments is also not particularly probative given EPA's admission that "there may be some . . . facilities that could . . . ensure that exposures remain below the [exposure limits]." The agency similarly falters in relying on OSHA's issuance of forty-four citations between October 2022 and September 2023 for violations of OSHA's MC exposure limits. The citations, EPA avers, show that "high" non-compliance rates with the new exposure limits would fail to eliminate unreasonable risk. But bare proof of citations demonstrates nothing because EPA failed to discuss their nature (*e.g.*, degree, willfulness, failure to keep records, etc.).

Second, when EPA "decid[es] whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance," the TSCA requires it to "consider, to the extent practicable, whether technically and economically feasible alternatives . . . will be reasonably available as a substitute." *Id.* § 2605(c)(2)(C). Industry Petitioners contend, and the record corroborates, that when considering alternatives, EPA tended to focus exclusively on whether a chemical or process performs the same or similar function as MC. More generally, EPA admitted that it "did not find it practicable to consider alternative processes that may be reasonably available as a substitute for methylene chloride when the proposed prohibitions or restrictions would take effect." But it was "practicable" for EPA to take seriously numerous specific comments

explaining that there are no feasible alternatives to MC for many conditions of use. Moreover, the agency repeatedly ignored tackling the economic feasibility of alternative chemicals or processes. EPA did not account for much higher costs and lower productivity, in addition to adverse environmental consequences, associated with the adoption of alternatives to MC. In this context, the "practicability" of alternatives bears on exactly what remedial regulation EPA should formulate, given the wide range permitted by the TSCA and the severe consequences of its draconian limits on MC's uses.

B. Sierra Club's Challenges

The Sierra Club challenges the MC Rule from a different angle. It argues that the MC Rule does not go far enough to eliminate unreasonable risks because EPA's risk analysis failed to adequately address risks to (1) fenceline communities, (2) people whose genes make them more susceptible to cancer, and (3) people who live at high elevation and are subjected to ozone depletion. The agency's principal response to these challenges is that the MC Rule adequately protects vulnerable subpopulations. Our vacating and remanding the MC Rule vitiates EPA's response to Sierra Club's issues. We assess the group's issues differently but conclude that Sierra Club's petition lacks merit.

1.

The Sierra Club argues that EPA violated the TSCA by failing to "determine and eliminate unreasonable risks to fenceline communities," which might be exposed to MC through the water and air surrounding a facility that emits MC. Some background is necessary. The TSCA requires EPA, when developing the scope of a risk evaluation, to identify the hazards, exposures, conditions of use, and potentially exposed subpopulations it "*expects* to consider." 15 U.S.C. § 2605(b)(4)(D) (emphasis added). The

preamble to EPA's operative procedural rule provides that "EPA may . . . exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern." 82 Fed. Reg. at 33729; *see also* 15 U.S.C. § 2605(b)(4)(B); 40 C.F.R. § 702 (2026). Accordingly, EPA excluded air and drinking-water exposures from the scope of its initial risk evaluation.

In July 2020, the Sierra Club and other organizations filed suit to challenge EPA's initial determination that six of MC's conditions of use pose no unreasonable risk. *Neighbors for Env't Just v. EPA,* No. 20-72091 (9th Cir.). A year later, under the new Administration, EPA agreed to a remand for the agency to reconsider its risk determination. EPA then followed a June 2021 policy document criticizing the risk evaluation for "failing to consistently and comprehensively address potential exposures to potentially exposed or susceptible subpopulations, including fenceline communities."

Despite having previously excluded air and water exposure pathways from the scope of its risk evaluation, EPA tried to allay Sierra Club's and others' concerns by conducting a "screening-level" assessment to consider whether MC *might* "present unreasonable risks to these communities." First, EPA prepared a Fenceline Assessment Methodology ("FAM") to govern its analysis of those potential risks. The FAM "uses reasonably available data, information, and models to quantify environmental releases, evaluate exposures to fenceline communities and characterize risks." Then, applying the FAM, EPA compared its fenceline risk estimates with tentative benchmark levels to characterize fenceline risk. This research ultimately demonstrated that most risk was adequately addressed by the MC Rule and other statutes like the Clean Air Act, which regulates MC emissions.

EPA did not, however, amend the scope of its TSCA risk evaluation to directly address whether such risks (including risk from "aggregate

exposure")[14] might be unreasonable because the agency was "continuing to develop the science" for sufficiently rigorous assessment of those risks and preferred to focus its evaluation on areas where it expected the most risk to occur. *See* 15 U.S.C. § 2605(b)(4)(F)(ii) (requiring EPA to "describe *whether* aggregate . . . exposures to a chemical substance . . . were considered" (emphasis added)). When finalizing the MC Rule, EPA reiterated that the FAM "was not developed for th[e] purpose" of making a TSCA unreasonable-risk determination. MC Rule, 89 Fed. Reg. at 39284.

The Sierra Club argues that this truncated analysis is inadequate. According to the Sierra Club, EPA cannot exclude an actual exposure pathway from the risk evaluation because the TSCA requires EPA to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury . . . to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Responding to one of EPA's arguments, the Sierra Club contends that EPA need only state what it "*expects* to consider" in a risk evaluation because it might not be possible for EPA to account for every condition of use at the outset—not because EPA can exclude exposure pathways whenever it chooses. *See id.* § 2605(b)(4)(D) (emphasis added). The Sierra Club relies on *Safer Chems., Healthy Fams. v. EPA*, 943 F.3d 397, 419 (9th Cir. 2019), in which the court held that language like "plans to consider" in EPA's procedural rule, no different from language like "expects to consider" in the TSCA, "simply refers to the Agency's role in determining what the

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[14] Sierra Club's position that EPA was required to evaluate "aggregate exposure pathways" is inconsistent with the statute, which grants the agency discretion on this point. *See* 15 U.S.C. § 2605(b)(4)(F)(ii) (EPA shall "describe whether aggregate . . . exposures . . . were considered, and the basis for that consideration.")

conditions of use are for a particular substance" and does "not grant EPA discretion to exclude conditions of use."

The Ninth Circuit's decision is inapposite.[15] First, that decision involved a challenge to EPA's procedural rule, not a challenge to a specific TSCA risk evaluation. *Id.* at 405. Also, "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *West Virginia v. EPA*, 597 U.S. 697, 721, 142 S. Ct. 2587, 2607 (2022) (internal quotation marks). For present purposes, EPA was required to conclude its risk evaluation based on "reasonably available information." 15 U.S.C. § 2625(k). Other TSCA provisions require EPA to carry out its responsibilities using "scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." *Id.* § 2625(h). EPA must consider, *inter alia*, the extent to which its methodologies are "reasonable for and consistent with the intended use of the information," whether information is "relevant" for EPA's decision, and the extent to which "variability and uncertainty" are "evaluated and characterized." *Id.*

The TSCA gave EPA a statutory deadline to conduct the risk evaluation, and the Risk Evaluation Rule did not allow EPA to stop the clock to gather more data. We cannot say that EPA is prohibited from excluding exposure pathways and exposure types that it does not have a methodology to accurately assess. EPA explained significant uncertainties inherent in the

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[15] This is not to say whether we agree with the Ninth Circuit's reading of the statute. While the TSCA directs EPA to publish the scope of its unreasonable risk determination in terms of "potentially exposed or vulnerable subpopulations the Administrator *expects to consider* . . . ," 15 U.S.C. § 2605(b)(4)(B), the more general statutory directives refer to such a group "*identified as relevant* . . . by the Administrator under the conditions of use." *See, e.g.,* 15 U.S.C. § 2605(b)(4)(A). We leave this debate for another day.

FAM. For example, the dataset that EPA used for the analysis lacked release point locations and number of release days, and EPA made other assumptions that it acknowledged "likely overestimate[] actual air emissions." A fair reading of the TSCA leaves ample latitude for EPA to exclude certain exposure pathways when the science or methodology is not developed.

The Sierra Club's other arguments concerning fenceline communities likewise fail. First, the Sierra Club claims that EPA violated the TSCA by "fail[ing] to eliminate the elevated risks it identified in its fenceline assessment." But EPA is not authorized to address "elevated" risk, only "unreasonable" risk. 15 U.S.C. § 2605(b)(4)(A). This court's case law is clear that "unreasonable" risk is not "no risk" because Congress "did not enact TSCA as a zero-risk statute." *Corrosion Proof Fittings*, 947 F.2d at 1215. Second, the Sierra Club argues that EPA arbitrarily retreated from "past positions and current guidance" on evaluating fenceline risk, because EPA identified some risk, but it did not pursue one of five proposed options for following up on potential risks outlined in the FAM. But the FAM is not a "settled policy" for which EPA must give a "reasoned explanation" before departing from it. *See Noranda Alumina, L.L.C. v. Perez*, 841 F.3d 661, 665 (5th Cir. 2016) (internal quotation marks). The FAM is marked "Public Comment Draft — Do Not Cite or Quote," and EPA has not finalized a "proposed methodology."

2.

The Sierra Club argues that EPA failed to consider whether MC poses an unreasonable risk to people whose genetics make them more susceptible to cancer from MC exposure. This issue fails. EPA acknowledged that roughly one-third of the U.S. population is similarly genetically susceptible to cancer. To account for that vulnerable subpopulation, EPA "rel[ied] on a conservative [cancer risk] estimate for the general population" by basing its

risk assumptions on the 95th percentile of the population. According to EPA, "it is reasonable to expect that risk to the subpopulation is reflected within the risks to the general population." The Sierra Club offers no significant response other than to resist EPA's characterization of its estimate as "conservative." To the extent that Sierra Club argues EPA should have been bound by the cancer risk quantification specified in the Clean Air Act (a 1 in 1-million risk), 42 U.S.C. § 7412(f)(2), it is wrong. The TSCA contains no such directive. Moreover, the Clean Air Act's rigid precautionary standard is far afield of addressing no more than "unreasonable risk." That said, we do not opine on what level of carcinogenic risk coincides with an "unreasonable risk."

3.

The Sierra Club argues that EPA violated its obligations under the TSCA to evaluate MC's risks to health and the environment, 15 U.S.C. § 2605(b)(4)(A), and to "integrate and assess available information on hazards and exposures," *id.* § 2605(b)(4)(F)(i), because it did not evaluate MC's depletion of the ozone layer. Sierra Club lacks standing to challenge EPA's conclusions with respect to this alleged risk.

"Under Article III, federal courts do not adjudicate hypothetical or abstract disputes." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423, 141 S. Ct. 2190, 2203 (2021). To establish standing to sue, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *Id.* In particular, we have noted that "[i]ncreased-risk [of harm] claims . . . often cannot satisfy the 'actual or imminent' requirement" of standing." *Shrimpers & Fishermen of RGV v. Tex. Comm'n on Env't Quality*, 968 F.3d 419, 424 (5th Cir. 2020).

That is the problem for the Sierra Club's claim. At bottom, the Sierra Club argues that EPA's allegedly inadequate regulation might lead to an insufficient decrease in emissions of MC, which might survive long enough in the atmosphere to break down atmospheric ozone, which might increase the amount of ultraviolet radiation to which Sierra Club's members are exposed over a lifetime, which in turn might increase those members' risk of developing cancer. Each step in that causal chain is conjectural and even unlikely because EPA already regulates MC emissions as a hazardous air pollutant. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410, 133 S. Ct. 1138, 1148 (2013) ("highly attenuated chain of possibilities" is not enough for standing) (citations omitted). In short, the Sierra Club has failed to show that there is a "substantial probability" that any of its members might be injured. *Nat. Res. Def. Council v. EPA*, 464 F.3d 1, 6 (D.C. Cir. 2006).

The Sierra Club argues that its members have suffered a procedural injury. "Procedural injury occurs when a plaintiff is deprived of a procedural right to protect its concrete interests." *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 497 (5th Cir. 2024). But even then, a litigant only "has standing if there is 'some possibility' that enforcing the procedural right 'will prompt the [defendant] to reconsider the decision.'" *Id.* at 503 (quoting *Massachusetts v. E.P.A.*, 549 U.S. 497, 518, 127 S. Ct. 1438, 1453 (2007)). *See also Summers v. Earth Island Inst.*, 555 U.S. 488, 496, 129 S. Ct 1142, 1151 (2009) ("[D]eprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing."). Here, the Sierra Club cannot show that "the procedural step was connected to the substantive result" because EPA has consistently found that MC is not an ozone-depleting substance. *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 94–95 (D.C. Cir. 2002). EPA first made such a finding in 1994 when it listed MC as an acceptable alternative to ozone depleting substances. *See* Protection of

Stratospheric Ozone, 59 Fed. Reg. 13044, 13082–84 (Mar. 18, 1994). EPA has reiterated that finding in several subsequent rulemakings (including in recent TSCA rulemakings). *See* Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7469 (Jan. 19, 2017) ("[MC] is not an ozone-depleting substance."). EPA noted in 2016 when regulating under a different authority that "[r]ecent research indicates that emissions of MC from multiple industrial sources have been increasing and could have a detectible impact on the ozone layer, despite the historical assumption of negligible [ozone depletion potential]." But that statement was the exception, and EPA maintains that it determined here, consistent with previous findings, that its regulation adequately addresses any potential *unreasonable* risk of ozone depletion. The Sierra Club does not explain how its preferred evaluation procedure would have resulted in a more restrictive rule, so it does not have standing.

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At every juncture of its scientific analysis, EPA has gone with the most extreme position: (1) it discounted relevant human studies despite decades of MC's use without significant adverse epidemiological findings; (2) it assumed (contrary to law) no PPE use by workers, the most "at risk" subpopulation, despite OSHA requirements; (3) it relied on a rat study with extreme exposures, questionable results, and gross extrapolation; and (4) it used the smallest temporary impacts on humans' peripheral vision or bilirubin for its point of departure. Then the agency applied inflated benchmark exposure measures. In addition to finding exaggerated unreasonable risk for the conditions of use, the agency applied the (legally unauthorized) "whole chemical" risk determination to regulate every use of MC and ignored widespread PPE use. The results are unsurprising. EPA's ultimate exposure limits are approximately ten times smaller than those that

OSHA has enforced for twenty-five years. What is more, EPA (impermissibly) shifted the burden on regulated entities to prove they could comply with the MC Rule, and it failed to adequately consider profound economic consequences of its regulation or the limited availability of alternatives that are economically and technically feasible. EPA cannot justify the MC Rule in light of the TSCA's requirements, the more demanding substantial-evidence standard that the TSCA requires, and the arbitrary and capricious standard.

For the foregoing reasons, we GRANT the Industry's Petitioners' petition for review, VACATE the challenged rule and associated risk determination, DENY the Sierra Club's petition for review, and REMAND to EPA for proceedings consistent with this opinion.